



DOSE PATIENT RADIATION DOSE MONITORING SOFTWARE

USER MANUAL V24

KINGDOM OF SAUDI ARABIA

QAELUM NV

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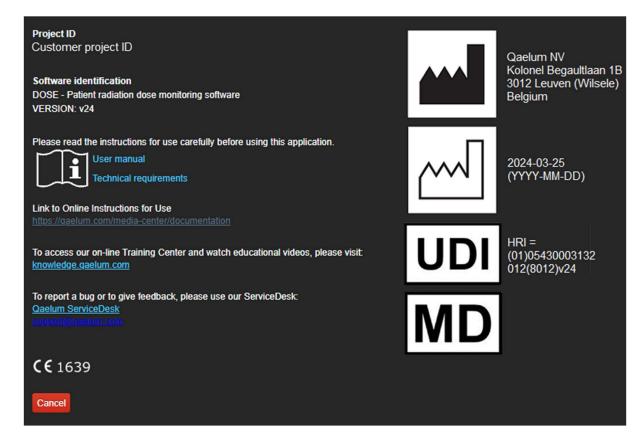
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SOFTWARE IDENTIFICATION



USER MANUAL

DOSE v24

DOCUMENT NAME	DOCUMENT DESCRIPTION	DOCUMENT REVISION NUMBER
Qaelum - DOSE V24 - User	User manual v24 –	Version 1
Manual – EN - KSA	English version - KSA	

GENERAL INFO		
Target regulatory jurisdiction:	KINGDOM OF SAUDI ARABIA	
Notice to the user and/or patient:	Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the Saudi Food and Drug Authority	

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Date of issue: 25MAR2024 (initial version)

	WHO	Application date
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1. First access to the system

1.1. Login

The application can only be accessed by users who are logged in. The user is asked to input his/her login credentials on the start page. New accounts can be created by clicking on *Create account* below the blue 'Log in' button. The user can select the preferred language from a list of languages as defined in the relevant regulations by clicking on the language button in the top right corner of the page. The background of the login page can be customized if the user provides Qaelum with the desired image.

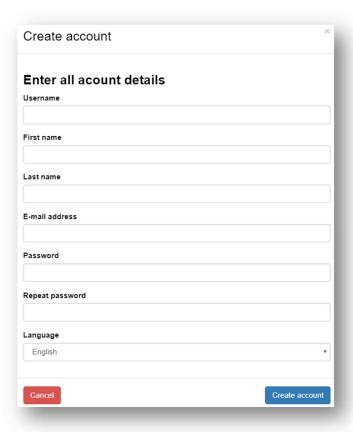


Login page

1.2. Create an account

A user can create an account by clicking on the *Create account* button. A guest account will be created, and the administrator (this can be Qaelum or a user with the appropriate role) can assign new users the right team, role and permissions. The user can select the desired language.



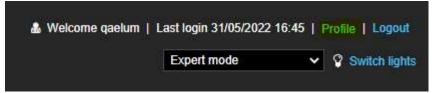


Create account

Administrators can also create new user accounts inside the DOSE application by clicking on *Actions->Register Account* in *Settings/User Management*.

1.3. Edit account information

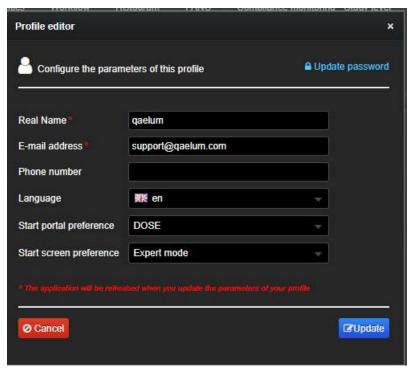
After logging in to the application, a user can change the account information and password by clicking on the *Profile* button, situated at the top right corner of the page.



Profile button

The user can select the default Start Portal setting and choose between DOSE and COACH (if available). Additionally, the start screen preference 'Quick overview', 'Expert mode', 'Live Dashboard', or 'Live Dashboard Modality' can be selected here.





Edit profile

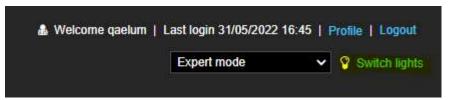
We strongly recommend users to change passwords immediately in cases when the credentials are created by an Administrator. For safety and privacy reasons it is vital to choose a strong password and to change it frequently.



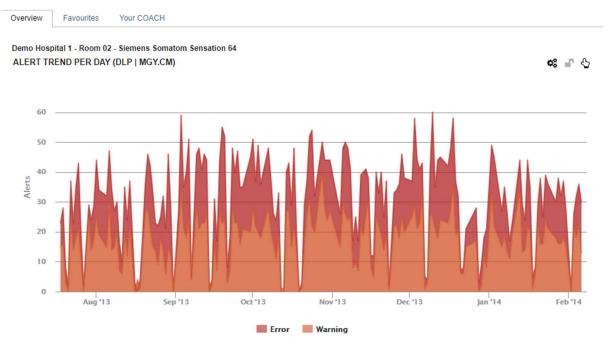
Change password

It is also possible to change the color of the background. By clicking on **Switch Lights**, the background will change from dark to light. The dark background is the default setting, and is more user friendly.





Switch lights



The light color version of DOSE

2. User management

2.1. Introduction

It is possible to manage access to specific sites and devices by using **Teams** and it is possible to manage the functionalities the user can access by using **Roles**. This chapter will explain how to manage teams and roles within DOSE.

From v24, there is a new interface for user management called "User management v2" that will coexist with the previous "User management" for some releases, but it will eventually replace it. For new users we recommend using directly "User management v2".

2.2. User management v2

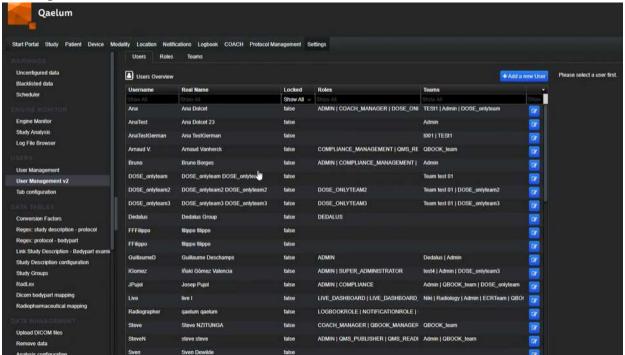
In the **Settings** of DOSE, a section called **User Management** can be found by any user with "User management" rights. Upon clicking on it, 3 tabs can be accessed: Users, Roles and Teams.

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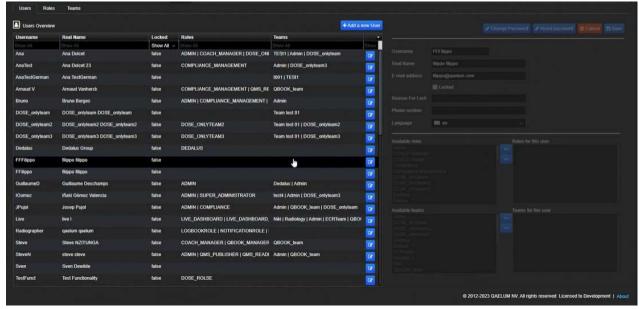


2.2.1. Users tab

On the first tab, the user has the possibility to create new users or to manage the existing ones.

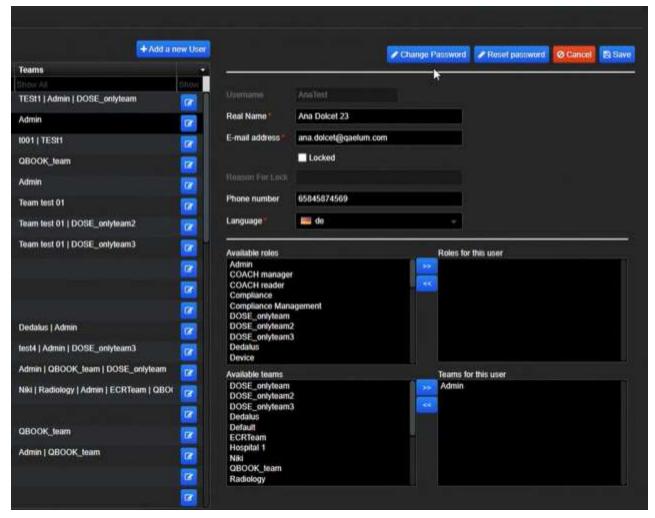


By clicking on a single user in the table, all details of the user are shown. The details are greyed up as this is a read-only function.



By clicking on the user edit button (the blue button on the right end of the table), the details become editable.





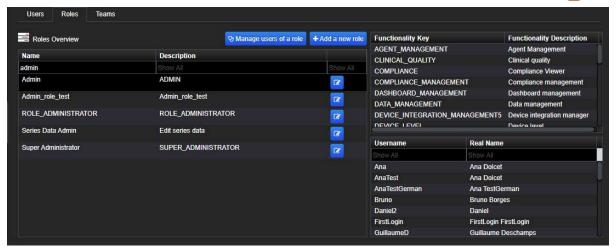
In edit mode, it is possible to edit the user details as well as assign the user to teams and roles.

In the current version, it is not possible to edit multiple users at the same time in the user tab, however, it is possible to assign multiple users to a role/team in the following tabs.

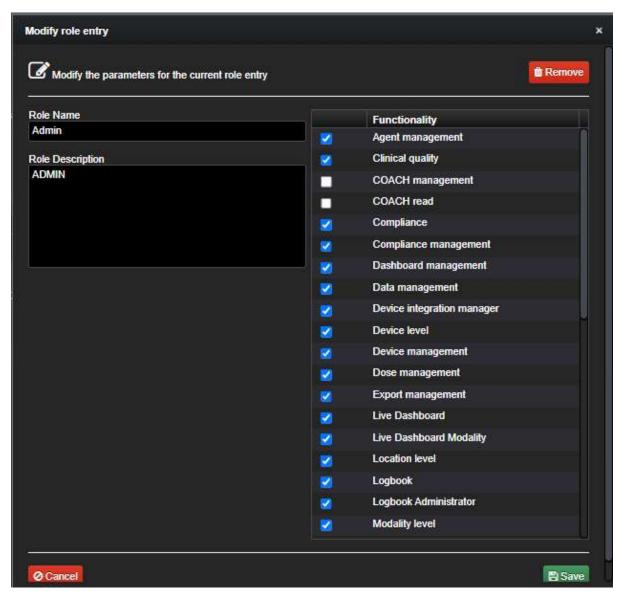
2.2.2. Roles tab

The interface of the Roles tab is coherent with the interface of the Users tab. By clicking on a single role in the table, all details of the role are shown. It is possible to search for a user belonging to the role in this read-only mode.





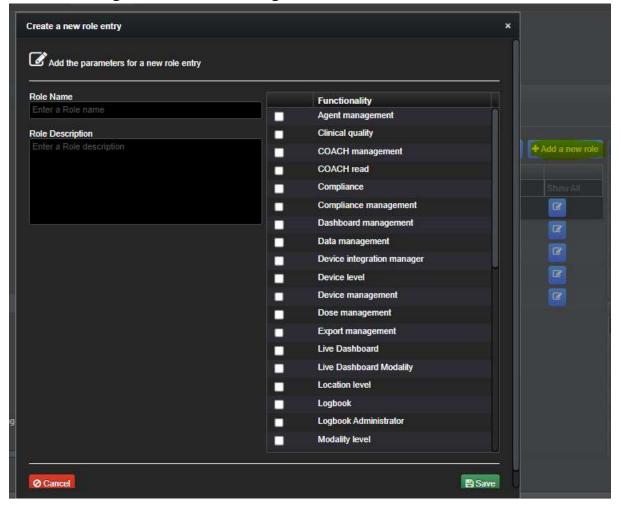
By clicking on the role edit button (the blue button on the right end of the table), a dialog is shown to allow editing the name of the role, its description and the list of functionalities assigned to it.



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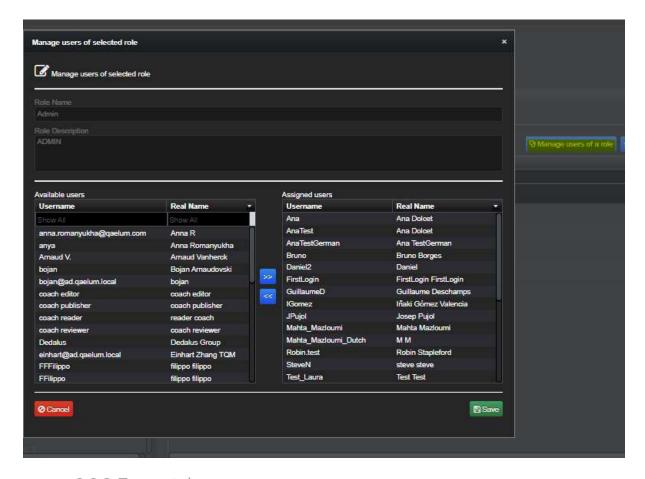


The same dialog is shown when clicking on the Add a new role button.



Users can be assigned to the role on the User tab, editing each user. As an alternative, the button *Manage users of a role* of selected role allows assigning several users at a time to a role.





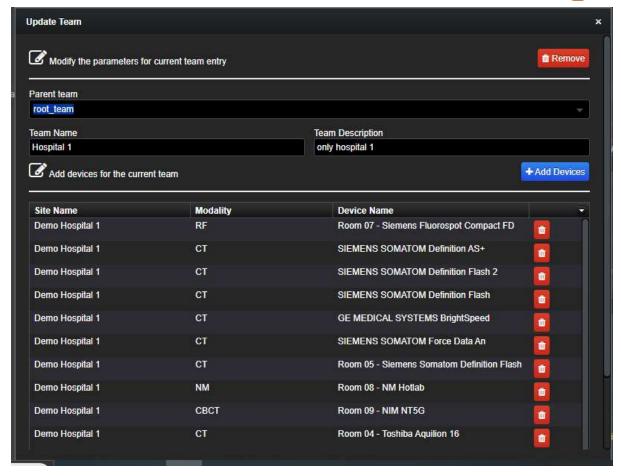
2.2.3. Teams tab

The interface of the Roles tab is coherent with the other tabs. By clicking on a single team in the table, all details of the team are shown. In this read-only mode it is possible to search for a device or a user belonging to the team.



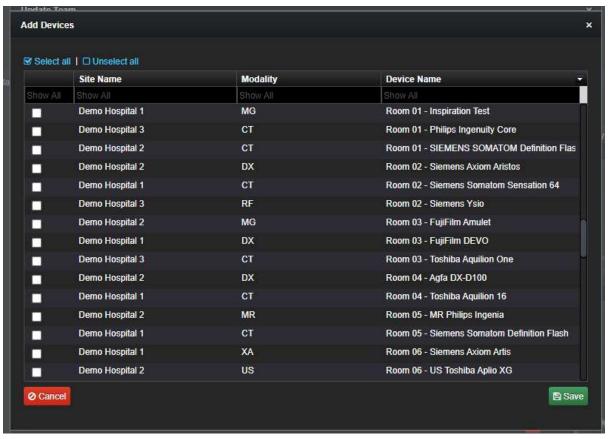
By clicking on the team edit button (the blue button on the right end of the table), a dialog is shown to allow editing the name of the team, its description, the parent team and the list of devices belonging to it.





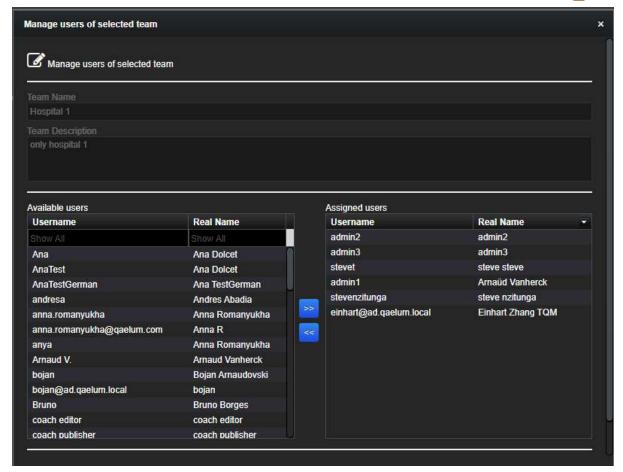
The red button on the right of each row in the table allows removing the devices, while clicking on Add devices allows selecting devices to add to the team.





Users can be assigned to the team on the User tab, editing each user. As an alternative, the button *Manage users of a team* of selected team allows assigning several users at a time to a team.





2.3. User management [deprecated]

In the **Settings** of DOSE, a section called **User Management** can be found. Upon clicking on it, 4 tabs can be accessed:

- User Overview: an overview of all users, possibility to create, edit, or lock a user
- Team Management: used to create/edit/view the teams
- User-Team: to assign and check user teams
- User-Role: to assign and check user roles

2.4. User overview

User Overview contains a table displaying an overview of all registered users. Users can be created or edited by using the "Actions" button in the bottom left corner.



User overview tab

It is possible to activate or disactivate the "Toggle Filter Bar", allowing to filter by the Username, E-mail address, Real Name, Locked/Unlocked status and Language. With the



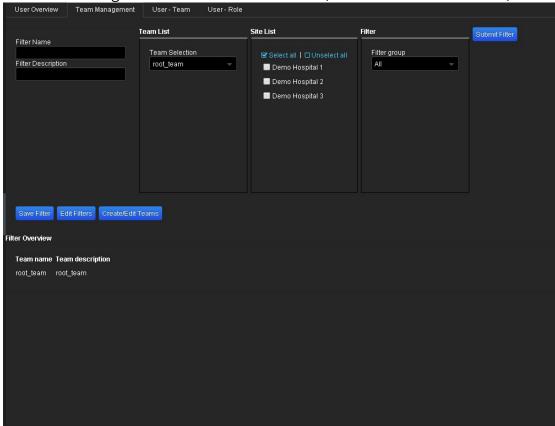
dropdown arrow additional columns can be shown (e.g. Registration date, Reason For Lock, etc.). The toggle bar is deactivated by default.



Toggle filter bar

2.5. Team management

Teams are used to allow access to specific sites and devices. The **Team Management** tab is used to manage the teams and team's filters (see Team Structure below).



Team management tab

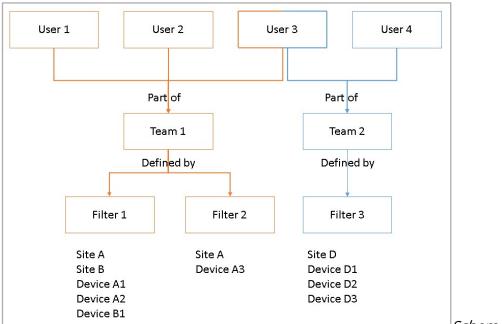
2.6. Team structure

A team is defined by one or more filters that contain a list of specific sites and devices. A single or multiple teams can be assigned to a user. In order to explain how it is managed, the scheme "Team and filter structure" will be used. In this example, User1 and User2 are part of the Team1. Because Team1 is defined by Filter1 and Filter2, User1 and User2 will only have access to the specific sites and devices contained in Filter1 and Filter2. User4 is part of Team2 and will have access to the sites and devices specified in Filter3. User3 is part of both Team1 and Team2 and will have access to all sites and devices specified in Filter1, Filter2 and Filter3.

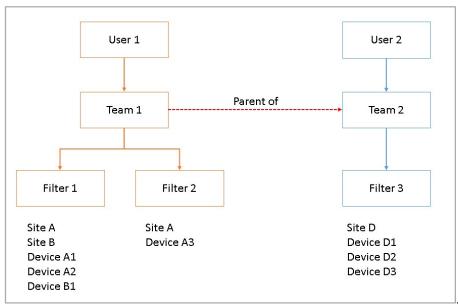
It is also possible to give access to a site but not to its devices. In this case, the user will be able to see all the information about the site in DOSE, but will not have access to any devices of this site.



In order to have a certain hierarchy in the user management, every team has a parent team, as shown in the scheme "Team relationship". In this example, User1 is part of Team1, which is the parent of Team2. In this case, User2 will only have access to the sites and devices defined for Team2, but User1 will have access to all sites and devices from Team1 and Team2, even if Team2 is not directly assigned to him.



Scheme users filter_1



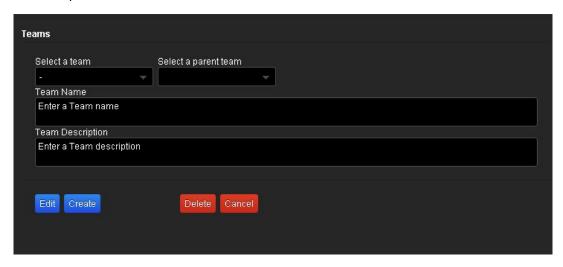
Scheme users_2



2.7. Create / Edit a team

To create or edit a team, click on Create/Edit Teams.

Select a *Parent team* that can be an existing team or standalone (*root_team*), enter a name and a description for the new team, and click on the **Create** button. All users from the selected parent team will have access to the new team.



To edit a team:

- select the team to be edited
- modify the parent team, if necessary
- edit the team name and/or the description, if necessary
- save changes by clicking on the **Edit** button

It is also possible to delete a team. To do so, select the desired team and click on the **Delete** button.

!!WARNING!!

If you delete a team, all sub-teams (children) of this team will also be deleted. This means that specific access to the site/devices that was linked to the team will not be possible anymore by users of the deleted team.

Create/Edit team

2.8. Create a filter

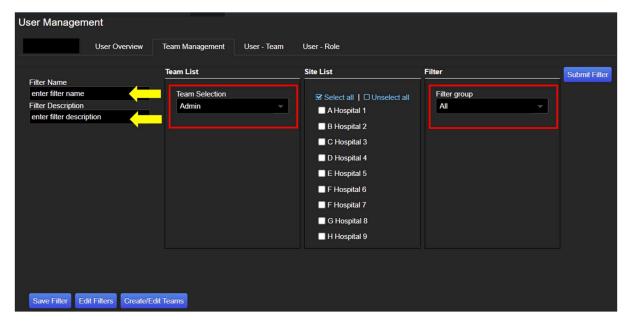
Creation of a new filter is performed using the Create/Edit Teams window

- Enter a name and description of the new filter
- Select the team that needs to be filtered (Team List)
- Select the sites to be added to the new filter (Site List)
- Devices can be filtered by *Modality, Vendor, Model*, and *Dose information* in the **Filter** section
- Click on Submit Filter to get the list of devices

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- Select the devices to be added to the new filter by ticking the checkbox next to the devices
- Click on Save Filter



When a team is selected, all the filters associated with this team are shown at the bottom of the window.

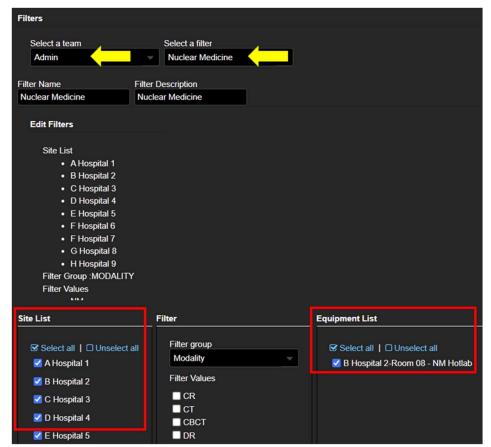
For more information, refer to the video *How to create a new team and customize user access* in our online training center.

2.8.1. Edit a filter

To edit a filter:

- Click on the blue Edit Filters button at the bottom left
- Select the team that the filter is attached to
- Select the filter
- Once the filter is selected, the list of sites and devices within the filter are displayed
- The name/description, Site List, and Equipment List within the filter can be modified by selecting/unselecting the desired sites and devices
- Click on the **Edit** button to save the changes





Filters can also be deleted by selecting the filter and clicking on the **Delete** button.

For more information, refer to the video *How to modify an existing team* in our online training center.

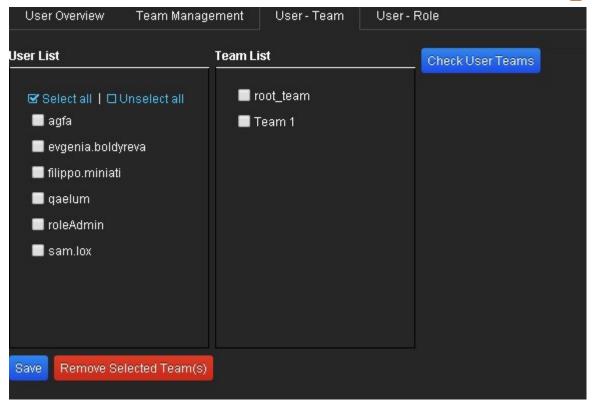
2.9. User-Team

When a team is created, it is possible to assign this team to users within the **User - Team** tab. To check the current team(s) that users belong to, select the user(s) and click on the blue button **Check User Teams**. To assign a new team to a user:

- Select the user
- Select the team(s)
- Click on the blue Save button

It is also possible to remove a user from a team by selecting the user and the team, and clicking on the red **Remove Selected Team(s)** button.





User team tab

2.10. Role Management

Roles are used to grant specific permissions to users. A dedicated customized list of functionalities can be assigned to each role. Each functionality allows access to certain features of DOSE. This means that every user can be easily assigned a suitable function according to her/his tasks in the hospital. The **User – Role** tab is used to manage the roles. The User List and Role List are displayed, along with an overview of all existing roles and associated functionalities below. From this window it is possible to:

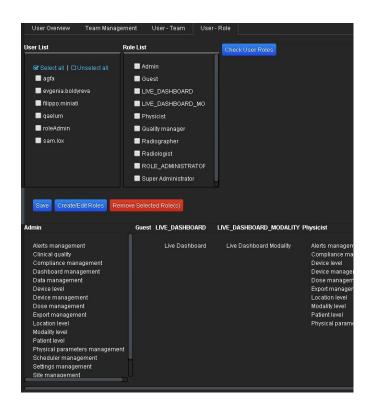
- Check user roles by selecting users and clicking on the blue *Check User Role* button
- Assign a role to a user
- Remove a role from a user
- Create or edit a role

2.10.1. Assigning and removing user roles

To assign a role to a user, select the user and the desired role and click on the blue **Save** button.

To remove a role from a user, select the user and the role to be removed and click on the red *Remove Selected Role(s)* button.





For more information, refer to the video *How to create a new user and assign teams and roles* in our online training center.

To create or edit a role, click on the blue Create/Edit Roles button.

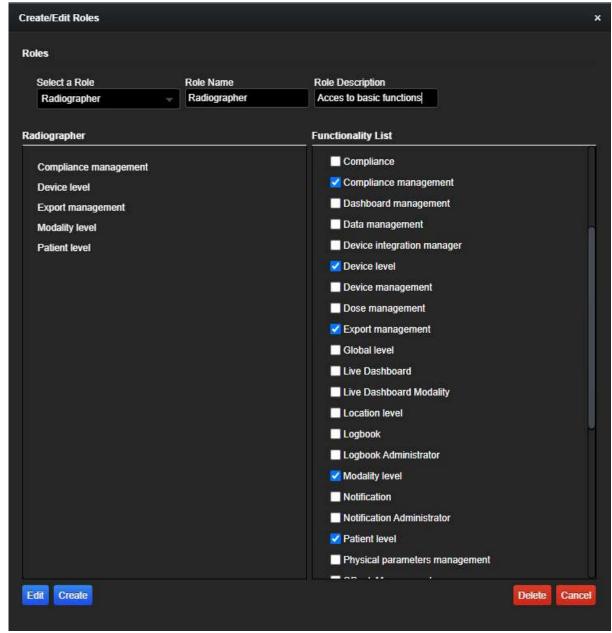
To create a new role:

- Enter a name and a description
- Check all desired functionalities for this role
- Click on the blue "Create" button

To edit a role:

- Select the role to be edited
- In the left panel, all functionalities that are already set for the selected role will be displayed
- In the right panel, all the functionalities assigned to this role are shown as checked
- The name and/or the description can be edited
- The desired functionalities can be checked to add and/or unchecked to remove
- Click on the "Edit" button to save all changes





Create/Edit roles window

For more information, refer to the video *How to modify an existing role* in our online training center.

2.11. Restrictions

In order to avoid potential mistakes in using the User Management tool, some restrictions are in place. A list of all restrictions can be found below.

General restrictions

 Only the SuperAdministrator, RoleManager and users with the "User Management" functionality can access User Management in Settings.



Team management restrictions

- The SuperAdministrator and RoleManager can see everything, including all existing teams, sites and devices.
- The SuperAdministrator and the RoleManager only can delete a team.
- Users with the "User management" permission can only access teams they belong to.
- Users with the "User management" permission can only see the sites and devices they have been assigned access to, depending on the teams that they are part of. If a user is part of a team that can only see site A, she/he will only be able to create or edit teams within site A.

User - Team

- SuperAdministrator can see all users and all teams.
- RoleManager can see all users and all teams except the "root_team".
- Other users with the "User management" permission can see all users but can only see the teams they are part of.

User - Role

- SuperAdministrator can see all users and all roles.
- RoleManager can see all users and all roles except the roles "Role_administrator" and "Super Administrator".
- SuperAdministrator and RoleManager only can delete a role.
- Other users with the "User management" permission can only create or edit roles that have been assigned to them.
- Users with the "User management" permission can only assign the roles they hold to other users.



2.12. Default roles and their functionalities

2.12.1. Admin

Access to:

- Agent Management
- Clinical Quality
- Compliance Management
- Dashboard Management
- Data Management
- Device Level
- Device Management
- Dose Management
- Export Management
- Location Level
- Logbook Administrator
- Modality Level
- Notification Administrator
- Patient Level
- Physical parameters Management
- Scheduler Management
- Settings Management
- Site Management
- Study management
- User Management

2.12.2. Radiologist

Access to:

- Clinical Quality
- Compliance
- Device Level
- Export management
- Logbook Administrator
- Modality Level
- Notification
- Patient Level

2.12.3. Radiographer

Access to:

- Compliance
- Device Level
- Export Management

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- Logbook
- Modality Level
- Notification
- Patient Level

2.12.4. Physicist

Access to:

- Compliance Management
- Device Level
- Device Management
- Dose Management
- Export Management
- Location Level
- Logbook Administrator
- Modality Level
- Notification Administrator
- Patient Level
- Physical parameters management

2.12.5. Quality Manager

Access to:

- Clinical Quality
- Data Management
- Device Level
- Export Management
- Location Level
- Logbook Administrator
- Modality Level
- Notification Administrator
- Patient Level
- Scheduler Management

For more information about these permissions or functionalities, please consult the *Description of Roles* document.



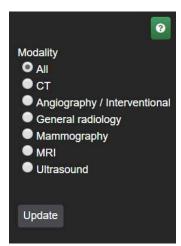
3. Quick overview

This start page gives users an 'easy landing' page that shows a simple KPI analysis of the department. When users log in to the system, 'Quick Overview' will be the first page that will be shown. There is a possibility to change to 'Expert mode' via the drop-down menu in the upper right corner.



Quick overview

The question mark button in the right corner explains all the components of the Quick overview.



Users have the possibility to choose the KPI overview for all modalities or only for one modality by selecting and clicking on "Update"

Choice of modality for KPI overview

Refer to the figure below showing each numbered field from the Quick overview.

- 1. From this menu the extended version of DOSE can be accessed.
- 2. Percetage of studies in the 'achievable' range.
- 3. Number of studies performed.
- 4. The red bars show the average value of the previous four weeks for each weekday.
- 5. Number of patients examined.
- 6. The color of the arrow shows whether the trend is an improvement.
- 7. Average study duration (from the moment the study was started to the moment the study was closed).
- 8. The percentage shows the difference between the current value and the average of the four comparison points.
- 9. The current weekday, up until the current time, is compared against the same weekday, up until the current time, of the previous four weeks.
- 10. Percentage of studies in the acceptable range.
- 11. The blue line is the average of the four other bars.
- 12. Percentage of studies outside the acceptable range.



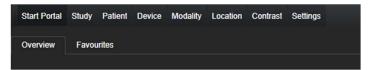


Quick overview



4. Start portal

After the login to DOSE, the user arrives in the Start Portal: this is a personal page that every user can customize with charts and tabs the user needs the most.



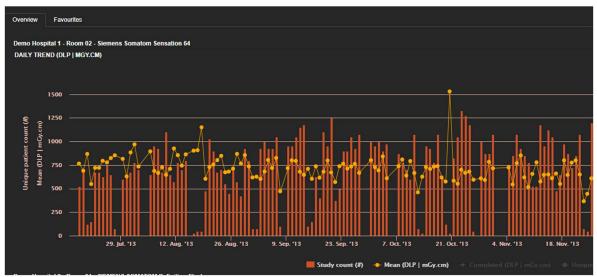
Start portal

The Start portal tab is divided into 2 tabs: the 'Overview', with the favorite graphs, and 'Favourites', where the user can manage the previously starred graphs. In Favourites, the user can remove a component from the Overview page. Preferably, a maximum of 5 components should be added to the Overview page.



Favourites

Please refer to the specific section on how to mark (star) charts and tabs as favorites and how to set them as part of the user's personal Start Portal.

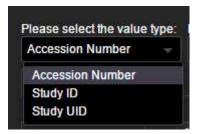


Start Portal - overview



5. Study level

On **Study** level users have the possibility to look up studies based on search values (i.e. Accession Number, Study ID or Study UID).

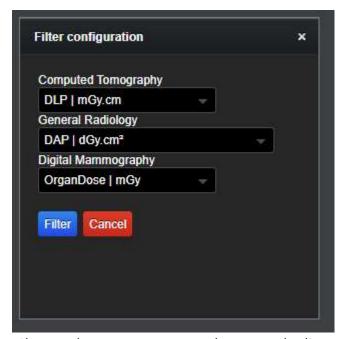


Search values



Study level filtered by accession number

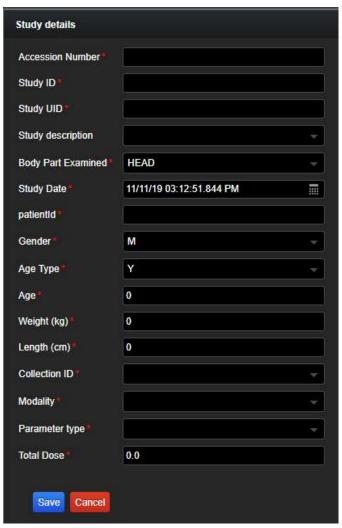
The *Parameter Type* shown in the list can be changed by clicking on the **Filter** button in the upper-right corner.



Change the parameter type shown on the list

A study can be created manually by clicking on the *Actions* button in the lower-right corner and selecting *Add study*. The study details can be entered here.





Manual addition of a study

When weight and height are entered, the body mass index will be calculated automatically.

For interventional procedures and NM examinations, it is possible to create studies manually with specific templates (see <u>Manual entry of an XA study</u> and <u>Study Overview</u> <u>section in the NM chapter</u>).

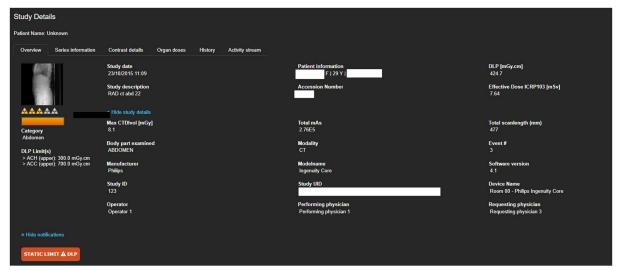


5.1. Study details page

This page opens when a study is selected (by double clicking).

5.1.1. General study information (Overview)

Here all general information about the study and the patient can be found. If weight and height are collected, the BMI is automatically calculated and displayed.



Study details overview

If a certain study/series is linked to a study group with static limits, it is possible to proactively see whether this study is compliant to the limits.

ACH = Achievable level

ACC= Acceptable level

The compliance bar color shown below the thumbnail follows this logic:



• Default – gray (not linked to a study group)





• Below ACH level - green

Between ACH and ACC level – orange

Above ACC level – red

This compliance color bar will always show the color of the highest compliance notification. For example, if a CT study has an orange DLP notification and a red CTDI notification, the resulting compliance bar will be red.

An exception to this behavior in DOSE is the Compliance Monitoring table, in which case the compliance bar will be the color corresponding to the selected parameter (DLP, CTDI, etc.) for optimization purposes.

If the series contained in a study are linked to a study group limit, their compliance color will be shown in Series Details and the compliance bar at study level will show the color of the series with the highest color.

The compliance bar does not take into account other notifications that are not directly generated by the study group configuration (i.e. Notification Center rules, dynamic alerts and manually created notifications).

To see the study groups that a study/series is linked to, the user can click on *Show study groups* below the thumbnail.





Study groups linked to a study



Radiation triangles

The radiation triangles that are shown next to/below the thumbnail show a relative representation of the effective dose (according to American College of Radiology (ACR) Appropriateness Criteria). Please note that the effective dose is based on the BodyPart, and thus if it is missing, the triangles are empty. Below you can find the explanation of the Relative Radiation Level.

Table 1. Relative radiation level designations along with common example examinations for each classification

Relative Radiation Effective Dose Estimate Range O 0 mSv		Pediatric Effective Dose Estimate Range	Example Examinations	
		0 mSv	Ultrasound; MRI	
₩	<0.1 mSv	<0.03 mSv Chest radiographs; Hand radiographs		
**	0.1-1 mSv	0.03-0.3 mSv Pelvis radiographs; Mammography		
€€€ 1-10 mSv 0.3-3 mSv Abdomen CT, Nuclear medicine bone		Abdomen CT, Nuclear medicine bone scan		
***	Abdomen CT without and with contrast; Wh PET Abdomen CT without and with contrast; Wh		Abdomen CT without and with contrast; Whole body PET	
ॐॐॐॐ 30-100 mSv		10-30 mSv	CTA chest abdomen and pelvis with contrast; Transjugular intrahepatic portosystemic shunt placement	

^{*}The RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, the region of the body exposed to ionizing radiation, the imaging guidance that is used, etc.). The RRLs for these examinations are designated as "Varies."

Please note that dose is shown in scientific notation when its value exceeds 1000 or is inferior to 0.01. The point is used to separate units from decimals.



Dose notation

5.1.1.1. NOTIFICATIONS

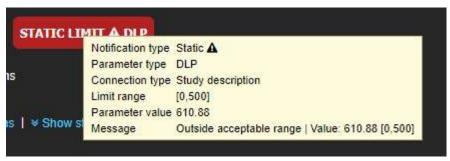
Alerts are created when study/series dose parameters are outside acceptable or achievable limits. All study alerts are shown in the *Notifications* tab. Notifications can be for the dynamic or static limits (according to the study group and limit configuration) or for a Notification Center rule.





Visual limits

Hovering over these alerts will display alert details and double-clicking will open the *Notifications* tab.

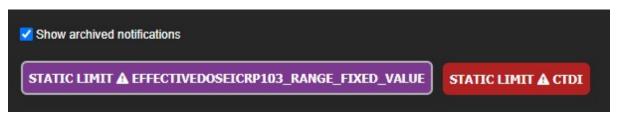


Notification tooltip



Notifications tab

If archived notifications are present (i.e. notifications that were saved after a recalculation), they can be visualized by selecting the *Show archived notifications* checkbox.



Archived notifications

For more information about notifications, please refer to the **Notifications** section in this User Manual.



5.1.1.2. CLINICAL QUALITY EVALUATION

Clinical quality evaluations (CIQs) make it possible to perform a subjective scoring of the clinical image quality. This is possible from every *Actions* menu in the Study Details and from the *Live dashboard*. On the CIQ evaluation page the user (with the appropriate role assigned in User Management) can score the image contrast, image sharpness and patient positioning. Additional comments can also be entered.

This feature is mostly used as PACS integration (Webservice). For more information see the *Clinical Quality Evaluation* section of *Webservice integration*.

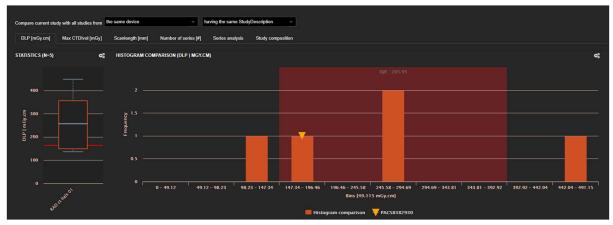


Clinical quality evaluation scores

If no evaluations are found, the overview is collapsed by default. If data is present, the evaluations are visible.

5.1.1.3. STUDY COMPARISONS

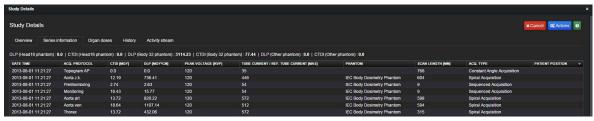
The current study can be compared to all studies from the same device or modality, or to studies with the same study description, examined body part, study composition, protocol name. A histogram is available for DLP, CTDI, scanlength, number of series, series analysis and study composition. Every histogram can be expanded to full window, exported, saved and printed. The histogram data can also be exported.



Study comparison



5.1.2. Series information



Series information tab

This tab contains all the information about the series/instances that comprise the selected study.

By selecting the spiral/axial CT acquisition protocols, Advanced CT Analysis (if applicable/available) can be accessed.

Weighted CTDIvol is a weighting factor of the acquisitions (excluding localizers) taking into account the scan length of the acquisition. This length is calculated using the ratio of DLP/CTDIvol instead of the DICOM scan length, as it is more consistent between different scanner vendors. This ratio is shown as a column in the series information.

Bodypart	Effective Dose ICRP 103	DLP / CTDIvol [mm]
HEAD	0	N/A
HEAD	0.1	175.16

Ratio DLP/CTDIvol for calculation of Weighted CTDIvol

$$Weighted CTDIvol = \frac{Total DLP}{Total Scanlength}$$

where

$$TotalDLP = \sum_{i}^{n} DLP_{i}$$

$$Total scanlength = \sum_{i}^{n} \frac{\textit{DLP}_{i}}{\textit{CTDIvol}_{i}}$$

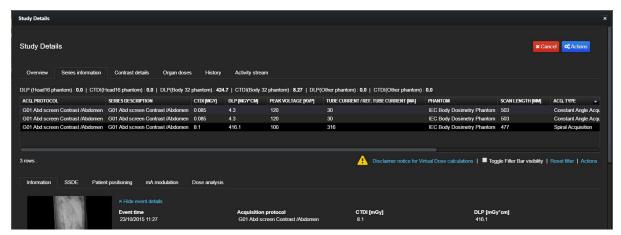
Where *i* is each series (excluding topograms) and *n* the total number of series for that study.

Weighted CTDIvol is included as a parameter for the DRL configurations in *Settings/Study groups* and as a parameter for the automatic notifications. For more information see *Compliance Configuration* and *Notification Center*.



5.1.2.2. SIZE-SPECIFIC DOSE ESTIMATES (SSDE)

Size specific dose estimate (SSDE) analysis for CT studies can be found in the study details by navigating to the *Series information* tab and selecting the desired acquisition protocol.



Series information tab with subcategories

The SSDE analysis also takes patient positioning into account. The real dimensions and positioning of the patient are measured and compared to the dimensions of a reference phantom to obtain a dose that depends on the morphology and positioning of the patient. The conversion factor and the blind scan can be seen next to the topogram(s). In the image the white lines are the geometric dimensions of the patient that are used to calculate the effective diameter. The red line represents the mA modulation and the blue line represents the pixel density. If they are following each other, the tube current modulation is working well.



AP and LAT topogram

DOSE uses scout images for segmentation and slice information to define the actual scan range. The scan range is shown on the scout. The center of the scan range is defined as the reference (marked by the white line). The software segments the patient on the scout images and measures the segmented diameter of the reference slice. This



procedure is done both for AP and LAT (if available) topograms. The effective diameter is calculated either using both AP and LAT or one of them, if both are not available.

The calculated effective diameter is matched to the corresponding conversion factor according to AAPM Report No 204. The SSDE is calculated using the CTDIvol of the examination corrected by the specific conversion factor.

The SSDE_{WED} is then calculated taking into account the patient attenuation (Water Equivalent Diameter, AAPM Rpt 220).

The calculation method of effective diameter and water equivalent diameter can be found in the information table in the SSDE tab (*SSDE calculation method*). The *calculation mode* indicates whether SSDE values are calculated using axial images, truncated axial images, or localizer (AP, LAT or both). The truncation percentage of the received axial images is also calculated, and when it exceeds 20%, the user is notified of the possibility of inaccurate calculations.



SSDE and SSDE_{WED}

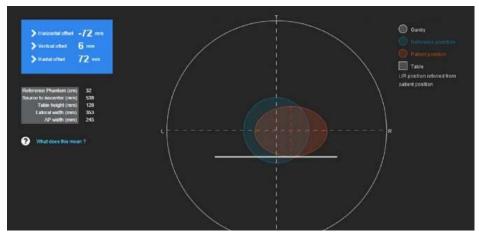
5.1.2.3. PATIENT POSITIONING

In the graphical representation of the patient positioning tab, the blue circle shows the expected centering of the CTDI phantom and the orange ellipse represents the patient, based on the calculated effective diameter. The large white circle represents the gantry, the central point of the two axes is the isocenter, x-axis is the left-right direction, y-axis is the top-bottom direction.

The ellipse representing the patient dimensions (AP and lateral) is generated using the SSDE calculation according to the effective diameter. The horizontal, vertical and radial offsets are calculated and displayed in the blue box.

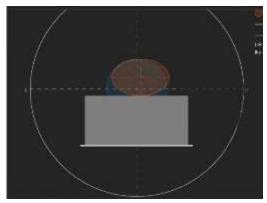
The source to isocentre distance and table height are extracted from the header, and the lateral positioning is calculated using image data. The difference between the gantry isocentre and the patient's isocentre is used to calculate the vertical, horizontal and radial patient offsets.





Patient positioning

As the primary option for the calculation is the axial images, it does not always correspond to a calculation using the table height. The gap between the estimated patient position and the tabletop is covered by an assumed pad.



Assumed pad

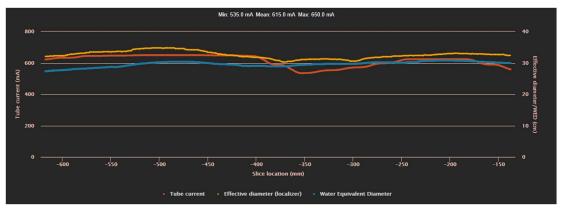
5.1.2.4. TUBE CURRENT MODULATION

Tube current modulation should adapt the tube current to the attenuation of the body region using the water equivalent diameter as reference, as follows:

- o increase tube current for higher attenuating area
- o decrease tube current for lower attenuating area

The overall goal is to reduce dose while maintaining image quality. All plotted data (tube current and three effective diameters) can be clicked to see the exact slice location on the localizer, represented by the red line. The data can also be hidden by clicking on the plotted value name(s) below the chart.



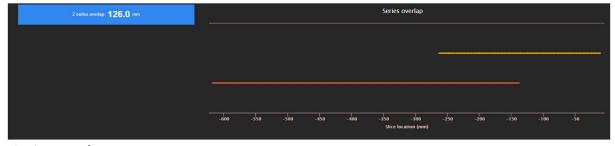


mA modulation

The chart can be exported using the options of the gear button in the upper right corner of the chart. The exported file includes all chart information (slice location, tube current, effective diameter from localizer, effective diameter from axial images, WED from axial images).

5.1.2.5. SERIES OVERLAP

When a study is composed of more than one series, overlap between scanned areas is calculated, and the overlap length is displayed in mm.



Series overlap

5.1.3. Peak Skin Dose (PSD)

This tool is designed to help users estimate the patient's skin dose after an interventional procedure. As the skin dose is directly linked to deterministic effects / tissue reactions, this tool allows for faster and improved follow-up strategy. The peak skin dose analysis can be found under the *Peak Skin Dose* tab, located within the **Study details** interventional procedures. Peak skin dose calculation is based on the parameters extracted from the Radiation Dose Structured Report (RDSR) of the particular interventional procedure. Correctness of calculated values depends on the correctness of the collected parameters. Additionally, several assumptions are taken into consideration in the calculation that could lead to a relatively different result compared to other calculation methods (e.g. table and pad attenuation can differ from system to system). For other limitations and assumptions please refer to the "DOSE Technical Information" document that you can find in the "About" button.



Peak Skin Dose is calculated for head and trunk examinations of adult and pediatric patients. Extremities are currently not supported.

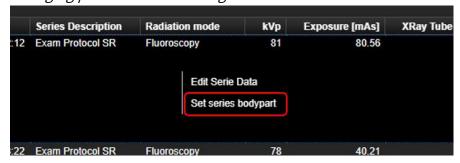
The RDSR provides geometry (tube angles, table movement) and dose data (dose area product, air kerma at reference point) for every exposure event. The collimator shape is not available in the RDSR, and thus is predefined for the calculations. If the collimated irradiated area for each event is available, it is taken into consideration. If the area changes during the irradiation, then only the value mentioned in the RDSR for this event is used. The backscatter radiation factors are based on the thickness, field size and beam quality as described in literature (Benmakhlouf et al 2011 and 2013) for each irradiation event. A standard attenuation from the table and table pad is considered. The factor corresponds to a specific type of table and table pad (total thickness of 8 cm).

Besides the adult phantom, five pediatric phantoms are included in the calculations (15 year-old, 10 year-old, 5 year-old, 1 year-old and newborn). The dimensions of the standard phantoms are defined as the corresponding head and body sections of the MIRD phantoms.

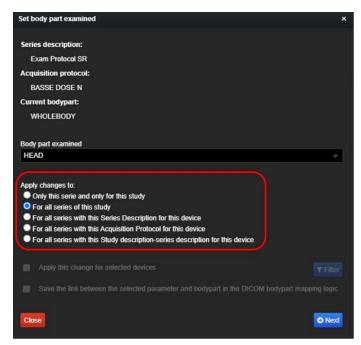
The phantom is initially selected based on the age of the patient. If the dimensions of the patient are filled in (weight and height), the phantom is scaled to match the actual patient size. The calculation is performed on the corresponding head or body phantom, based on the bodypart of the first irradiation event. All phantoms are considered headfirst and supine due to the lack of exact position and orientation on the table. If the information for patient age, patient size or the target region ('bodypart') as indicated in the data source are not correct, then this information can be corrected directly within DOSE, and peak skin dose map recalculated. Patient age and size can be edited by selecting *Edit study* in Actions (top right corner of the Study overview), while the body part can be edited within the *Series information* tab, by right clicking and selecting *Set series bodypart* (for all series of this study). This may happen in protocols not assigned to the correct body part by default.



Changing patient size and/or age







Changing the body part for the study

Spatial distribution of the skin dose is shown as a map of 1x1 cm² pixels on the phantom surface. Each pixel value corresponds to the calculated dose. The map is recalculated with every dose event to add the associated dose value. This allows to follow the evolution of the skin dose distribution during the intervention. Peak skin dose is determined as the maximum dose value on the map.

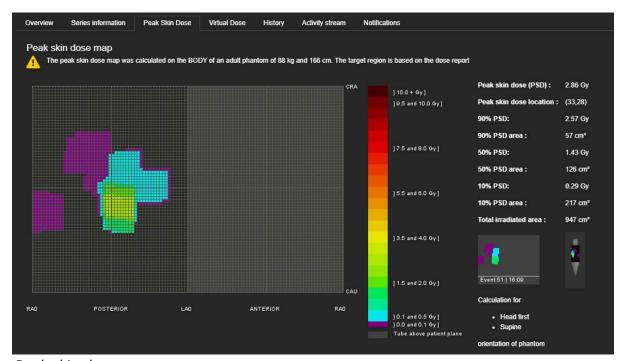
As there no information indicating the exact positioning of the patient on the table is available, the displayed dose distribution map is shown centrally located on the patient. The exact location can differ, e.g. it can be closer to the head or closer to the feet than displayed. The physician should be aware of the center of irradiation, depending on the type of procedure.

Peak Skin Dose

Peak skin dose map. The surface of the reference patient is represented in pixels of 1 cm². The x-axis is the transverse perimeter of the patient, while the y-axis corresponds to the length of the trunk (head-feet direction). The map represents the dose distribution on the surface of the patient, as if the surface is unfolded at the right part of the patient. To distinguish between back and front side of the patient, the front side is represented by grey pixels. The user must keep in mind that for the PSD calculations, the patient is considered supine and head first. For other types of positioning, the map must be interpreted accordingly. An additional note for the user is that the exact location of the dose distribution on the skin can differ from what is displayed on the map, as there is no information concerning the exact positioning of the patient on the table. The physician should interpret that, depending on the type of procedure. The pixels that have been



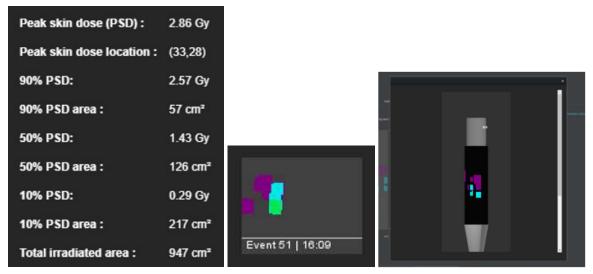
irradiated are represented by a color corresponding to the dose delivered there. The color-dose correspondence is shown in the legend. A sentence above the skin dose map shows the phantom (head or body), the patient age and size considered for the calculations. If no patient size information is available, then the standard dimensions of the phantom are considered and the phantom is selected only by age.



Peak skin dose map

At the side of the colored legend, the user can see interesting information about the skin dose and the area irradiated. In particular besides the peak skin dose value and the total irradiated area, the area that received 10%, 50% and 90% of the peak skin dose are calculated based on the colored pixels in the map. The user can also follow the evolution of dose distribution throughout the intervention (animated gif passing through events). In order to understand the 2D map easier, a 3D representation is introduced. The user can see it next to the animated gif and can also enlarge it by clicking it. The enlarged 3D phantom can be manually rotated by holding and moving the left button of the mouse.





Information about peak skin dose and irradiated area, animated gif and 3D phantom

At the right part, there is a menu where the user can select to see the impact on the map from each of the planes in case of a biplane system, or a combination of them.



Impact on skin dose map by different planes can be visualized.

Near this menu, there is an exclamation mark, where the user can click on the PSD calculation method to get extra information about the methodology used, as well as about the dimensions of the standard phantoms. By clicking Potential radiation-induced skin reactions & advice to patient, the user is guided to a table that provides information about radiation-induced skin injuries (with the corresponding references). One of the table rows is highlighted (colors according to the severity, with green less severe) to show in which category the particular PSD belongs.



PSD calculation method and potential skin reactions.



PSD Radiation r	isks						
			Approximate Time of Onset of Effect	s			
Band	Single-Site Acute Skin-Dose Range (Gy)	NCI Skin Reaction Grade	Prompt (< 2 wk)	Early (2-8 wk)	Midterm (6-52 wk)	Longterm (>40 wk)	Advice to Patient
		NA	No observable effects expected	No observable effects expected	No observable effects expected	No observable effects expected	No need to inform patient, because there should be no visible effects; if patient reports skin changes, then treat in response to the signs and symptoms
			Transient erythema	Epitation		No observable effects expected	Advise patient that erythema may be observed but should fade with time; Advise patient to call you if skin changes cause physical discomfort.
	5-10		Transieri erythema	Erythema, epilation	Recovery, at higher doses, prolonged erythema, permanent partial epilation	Recovery, at higher doses, dermal alrophy or industrion	Advise patient to perform self-examination or ask a partner to examine for ask effects iron about 2 to 10 vector and procedure, the patient where shall effects when the stay occur is shall represent any therefore the stay occur patient should call advolgent of one, shall reach one of the stay occur patient should call advolgent to one, shall reach one of the stay occur patient should call patient patient to be examined by demandicagid or other bending physician and to indem bending physician that along may be due to adduce and to indem bending physician that along may be due to adduce and to indem bending physician that along may be due to adduce and where the actualism enable of the disks on a thing to cour or allow the stay of where the actualism enable of the disks on a thing to cour or taken to a stay of the stay of th
	10 - 15		Transient erythema	Erythema, epilation; possible dry or moist desquamation; recovery from desquamation	Prolonged crythema, permanent epilation	Telangiectasia; dermal atrophy or induration; skin likely to be weak	Medical follow-up is appropriate, advice is same as that for band ibut also advise dermatologist or other treating physician that skin effects may be prolonged due to realization does and hard prophylactic treatment for infection and monitoring of wound progression and be required, pain could become a concern if doses were in the higher range of this band
			Transient erythema; after very high doses, edema and acute ubcrafion; long-term surgical intervention likely to be required	Erythema, epilation; moist desquamation	Dermal alrophy, secondary ulceration due to failure of moist designamation to heat, surgical intervention likely to be required; at higher doses, dermal necrosis, surgical intervention likely to be required	Telangiectasia, dermal atrophy or induration; possible late skin beautdown, wound might be persident and progress into a deeper lesion; surgical intervention likely to be required	Medical follow-up is essential, nature and frequency of which depending on estimated radiation dose, advice is same as that for band C, but advice treating physician that the wound could progress to ulcoration or necrosis
weeks; Advice Skin do NCI = N	long term, . 40 weeks. is applicable to normal range se refers to actual skin dose lational Cancer Institute.	of patient radiosensitivities (including backscatter). This	ee of miligaling or aggravaling physical or clinical facto in the absence of miligaling or aggravaling physical or quantify is not the reference point air kerma describe aled with area of initial moist desquamation or healing	clinical factors. d by Food and Drug Administration (21 CFR § 1020			increases. Prompt is , 2 weeks, early, 2-8 weeks, midferm, 6-52 ale than 6 50%. NA – not applicable.
Citations:							
			al, J Vasc Interv Radiol 2009 Radiation Effects on Patients' Skin and Hair'. Balter e	t al. Radiology 2010			

Table for potential skin reactions for each peak skin dose range.

Angular dependency analysis

The graph indicates the primary and secondary angles that were used in the procedure. The colors show the frequency that each angle combination is used, with dark red being the most frequent. The signs of the angles are defined as in DICOM standards. The grey-colored pixels indicate the primary angles for which the tube is above the table. The x-axis corresponds to tube primary angle (left-right movement) and y-axis corresponds to tube secondary angle (craniocaudal movement).



Usage of primary and secondary angle during the procedure



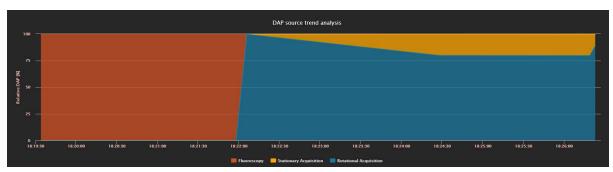


Select a plane (or All planes) then select a parameter and Analyse

For the angular analysis, the user can select to see the angles used for a particular plane or for all planes. Next to that, there is a menu where the user can select the parameter for which the graph will provide the angular dependency and then analyse. For example, by selecting DAP, the graph will color the angles according to the distribution of DAP as coming from each angle combination (primary and secondary).

DAP trend analysis

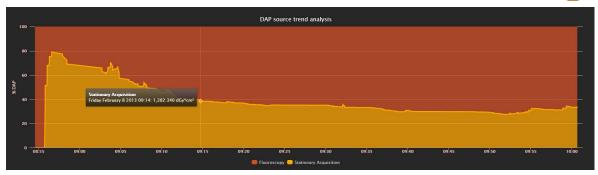
The graph differentiates the origin of the delivered DAP. The user can see the percentage of DAP that is delivered by fluoroscopy, stationary acquisition, rotational acquisition, etc. throughout the procedure. This is a relative chart, which means that the total DAP given by each moment in the procedure is considered 100% and the percentage of each irradiation type can be seen in the y-axis for the corresponding color.



Contribution to DAP by different irradiation modes

By passing the mouse above each line, the user sees the exact value of DAP delivered for each of the irradiation type until that moment. For example, the point shown in the figure below, corresponds to stationary acquisition DAP of 1382 dGy*cm² which is the 40% of the total DAP until that moment.





DAP source trend analysis

Charts for dose analysis and angle / position

In all four charts, the x-axis is the real-time of the intervention. By passing the mouse above each line, the user can see the date and time of the procedure and the exact value of the represented parameter at this moment.



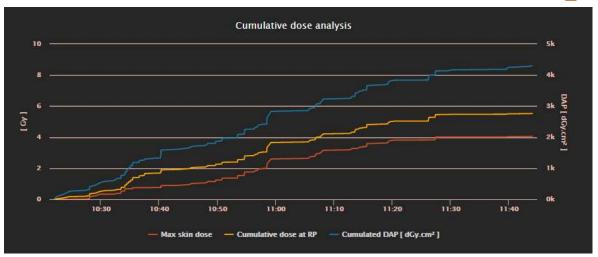
Changes in dosimetric and geometric parameters throughout the procedure

Cumulative dose analysis

The graph follows the increase of maximum skin dose (peak skin dose) and cumulative dose at Reference Point (RP) during the intervention.

If the operators change the irradiation parameters (tube angle, table position, etc), this will be depicted in the graph, as the maximum skin dose will stop increasing, even though irradiation continues.



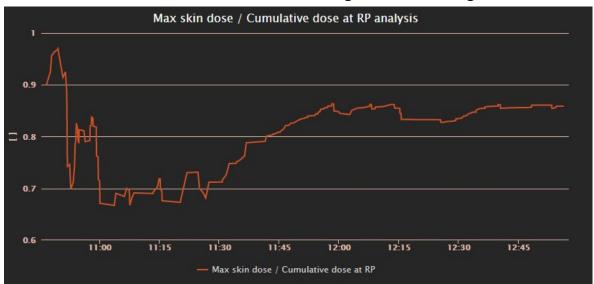


Cumulative dose analysis

Max skin dose / Cumulative dose at RP analysis

This graph shows the ratio of Maximum skin dose and Cumulative dose at RP throughout the procedure and it is, as expected, a unitless number. From this graph, the user can see the changes in the technique used.

For example, when the ratio is shown to decrease, it means that even though the cumulative dose at RP increases, the maximum skin dose has stopped increasing or increases with lower rate. This can be due to changes in the tube angles, irradiation field



or table positioning.

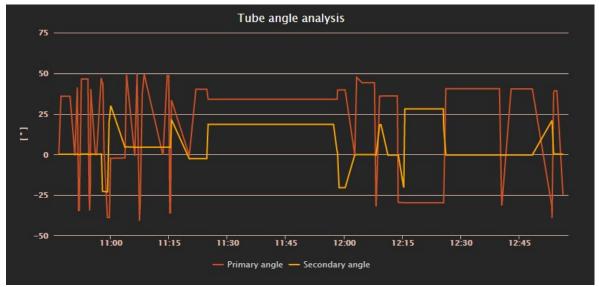
Analysis of max skin dose to cumulative dose at RP

In order to track the changes in the technique, the user is also able to see the tube angles and table position analysis.



• Tube angle analysis

This graph enables the user to follow the changes of primary and secondary angles throughout the procedure. By passing the mouse above each line, the exact angle value at this moment is shown.



Tube angle analysis

• Table position analysis

The user is able to see the table position in all axes (longitudinal, lateral and height) throughout the procedure.



Table position analysis

For a general overview, refer to the video *How to use Peak Skin Dose* in our online training center.



5.1.4. Organ doses

This tab allows users to check the dose received by every single organ, replacing the effective dose tool. From an optimization/justification/follow-up point of view, this empowers users and can help raise their awareness.



Organ dose comparison

The user can compare the organ dose of the current examination with the 25th/75th percentile and a median organ dose. The comparison can be made with all the studies from the same device/modality and with the same BodyPart/Study description.

The calculation is done for each series and then added to show the total organ doses of the study. If one series has a body part not included in the following list, this acquisition will not be considered in the calculated organ doses.

ABDOMEN
ABDOMENPELVIS
CHEST
CHESTABDOMEN
CHESTABDPELVIS
HEAD
HEADNECK
MAXILLA
NECK
PELVIS
WHOLEBODY

List of suitable body parts for organ dose calculation

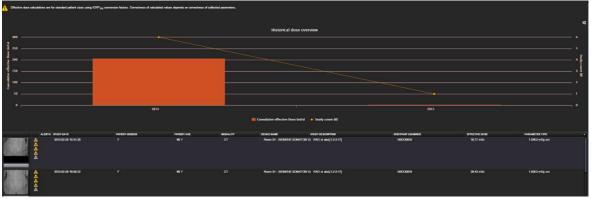


! Please note that the organ dose values are indicative, they consider standard settings and standard scanlength for all irradiation events based on the body part and they should be assessed by an expert.

5.1.5. History

History tab shows the dosimetry history of patient. Here the cumulative dose trend for one single patient is shown. The bars represent the annual cumulative effective dose, while the yellow dots represent the number of studies. By clicking on a year, the monthly contribution opens. In order to go back, click the gear and reset the chart. There is a possibility to export the patient dose history in XLS, PDF or CSV (click on the gear in the right corner).

Note: There is a possible security check if you belong to another Team (see <u>user</u> <u>management</u>), the user is not able to click further on the study details that is performed in another site.



Historical dose overview

5.1.6. Activity stream

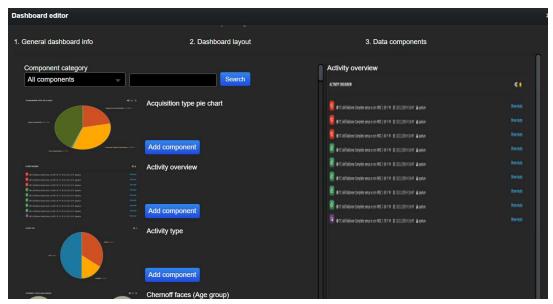
In the *Activity stream* users can manually enter the *cause/action/justification* to explain any outliers and share best practices.



Activity stream

The activity stream for studies within the same device can be evaluated using the *Activity Overview* chart on **Device** level.





Dashboard editor

On **Notifications** level, the *cause/action/justification* are displayed for studies corresponding to the search criteria.

When a comment is present for a study, it will be visible in several places inside the application within the following icon:



Study comment icon

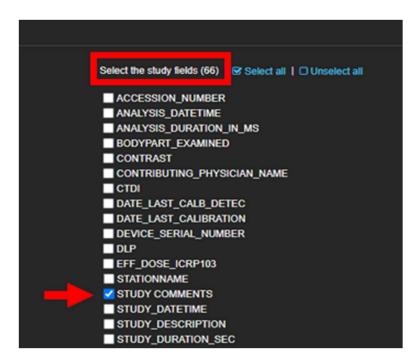
Hovering over the icon will display comment text.

Cause	Action	Justification
Update protocol		
Obese patient		
Wrong protocol		

Tooltip showing the study comment

Comments can also be exported on Device level in Actions/Export data.





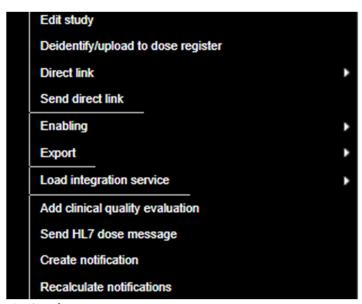
Export study comments from Device Level

For more information please refer to the section **Export**.

5.1.7. Actions

Various options are available within the *Actions* button in Study Details, situated at the top right corner:

- Edit study
- Open in clinical viewer (if configured)
- Deidentify/upload to dose register (only superadmin)
- Create and share a link to the study
- Enabling (to ignore studies)
- Export study and / or series information as a csv, xls or pdf file



Action button

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- Load the PACS integration service (when available)
- Add clinical quality evaluation
- Send HL7 dose message (under licence)
- Create notification
- Recalculate notifications

The user will see only aspects that he/she is allowed see (depending on <u>user</u> <u>management</u>).

6. Patient level

On Patient level users have the possibility to see the patient radiation dose passport and the study overview / patient history. It is possible to search for patients by Patient ID and/or Patient Name. It is also possible to search by patient name, however, due to the possible breach of privacy, the activation of the patient name search is not done automatically and must be requested.

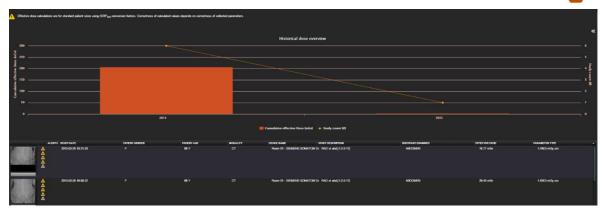
6.1. Patient radiation dose passport

The cumulated effective dose is shown, together with a timeline of all the patient's studies across different modalities, including the interval time between studies. The bars for each year/month are clickable and exportable (via gear button).



Patient Radiation Dose Passport - general information





Patient Radiation Dose Passport - more details on study level

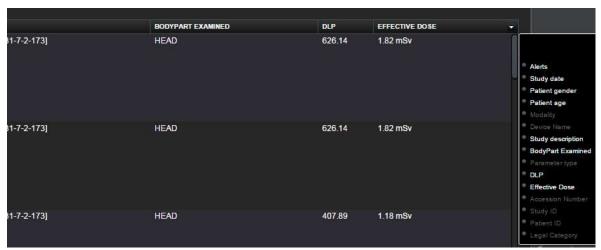
6.2. Study overview

The Study overview shows the studies that apply to the chosen filter value. Each row represents a study: study details are shown when the user double clicks on the row.



Study overview

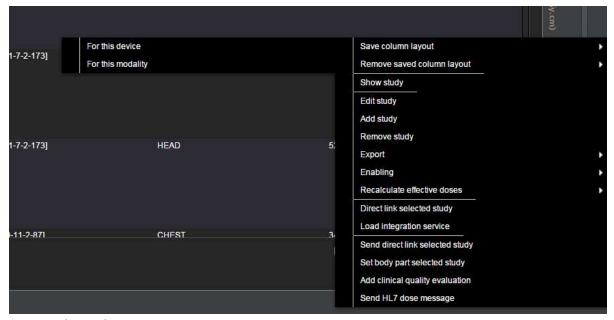
The user can activate and deactivate the visible parameters in the study overview as in the study overview (series analysis tab) by clicking on the little arrow on the right side.



Choose your filters

There is possibility to save the choice of visible columns for the device of the same modality, as a user setting via an "Action" button in the right corner below.





Save column layout

6.2.1. Color coding of studies

Color coding of the text is used to mark studies with different conditions.

Study description RAD ct thorax 00,[10-11-2-146]	A study is colored white when all parameters are filled in, effective dose is calculated and the body part is available.		
Study description RAD ct thorax 00,[10-11-2-146]	A study is colored orange if study effective dose is 0, no dose value is present and/or if the body part examined is missing/not recognized.		
Study description RAD ct thorax 00,[10-11-2-146]	A study is colored red if the study is ignored (ignored studies are visible when Show ignored studies option is enabled).		



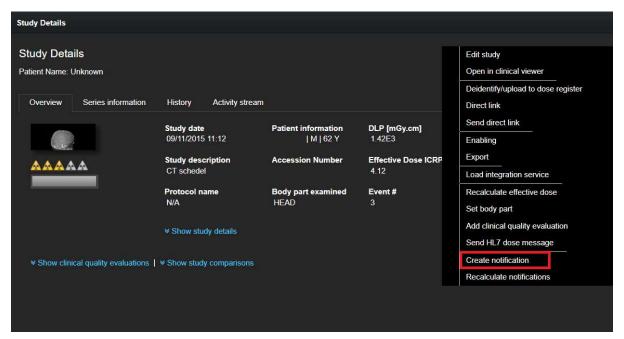
7. Notifications

The purpose of notifications within DOSE is to allow users to manage the vast amounts of data collected by the software, facilitating alert management and handling. Notifications can be generated automatically based on the **study group**, **Notification center** and **dynamic limit** configurations. Users can also create manual notifications, which go with their daily practices. It is possible to trigger a manual notification from Live Dashboard and from Study Details. This notification can be found and handled on Site Level, Device Level or on the Notifications Tab.

7.1. Notifications from Study Details

To create a notification from a specific study, the user must search a study, open the Study Details and then click on **Actions** \rightarrow **Create Notification**.

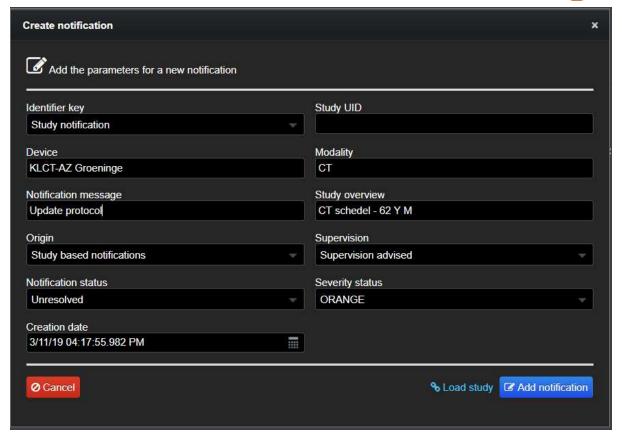
NOTE: Automatic notifications can also be recalculated from here, by clicking on "Recalculate notifications". See <u>Compliance Configuration</u> for more details.



Study Details

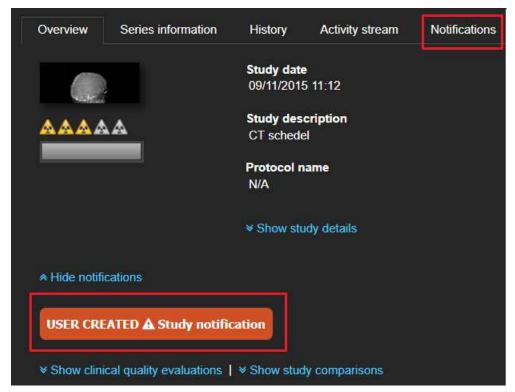
A window will open to enter the details of the notification, the user should choose a notification key and write down the Notification Message, for example, "update protocol".





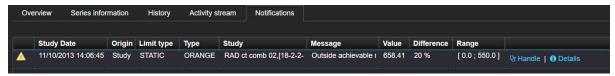
Create Notification

Then, after Adding the notification and refreshing, an alert will appear, and the details can be consulted in the Notification tab inside Study Details.



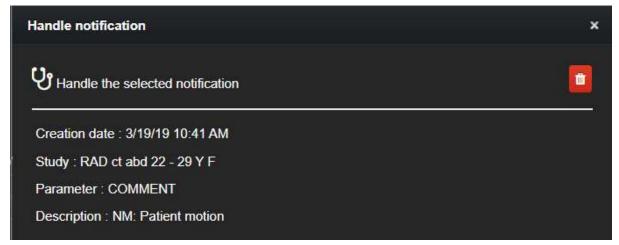
Orange sign for the created notification





Notifications tab in Study Details

The notification can be handled directly from this Notification tab or, if the user has the proper rights (Notification Administrator) and it is a manually created notification, deleted.

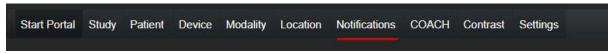


Handle notification with delete icon

For more information, refer to the video *How to create notifications from a study* in our online training center.

7.2. Notifications Module

This is where users can manage notifications at institution level. It is an extra tab next to the Location Level.



Notifications Tab

The user can select the devices they want to see, the parameter, the type of notification and its status. The numbers above change according to the filter they select.

The procedure would be as follows: select Study based notifications \rightarrow select a site (If you want you can select them all, starting from the first one and clicking the mouse until the last one or selecting one and pressing CTRL+A) \rightarrow select modalities \rightarrow select devices \rightarrow select a key \rightarrow select a status \rightarrow select severity type \rightarrow click on REFRESH.

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All the selected notifications will appear below. You can also see statistics of these notifications in the upper bar.

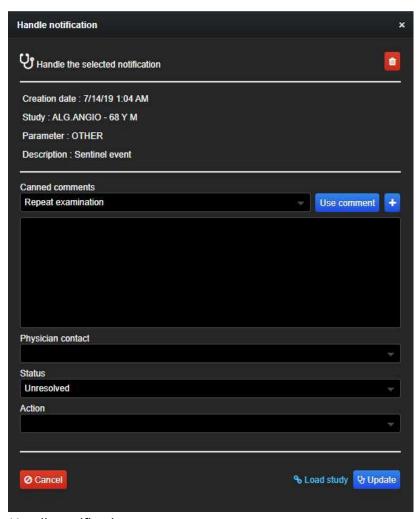


Notifications tab

The user doesn't have to do all the steps of the selection, but the more they select, the better the findings will be.

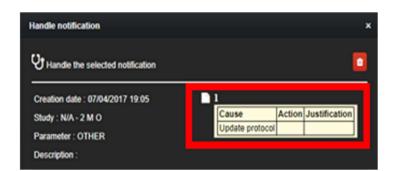
After the user has reviewed a notification by opening the study clicking on "Details", they can resolve them by clicking on "Handle", where they can add comments, declare if the physician has been contacted, update its status (resolved/under investigation, etc) and stablish needed actions. The notification can also be deleted from here by the Notification Administrator.



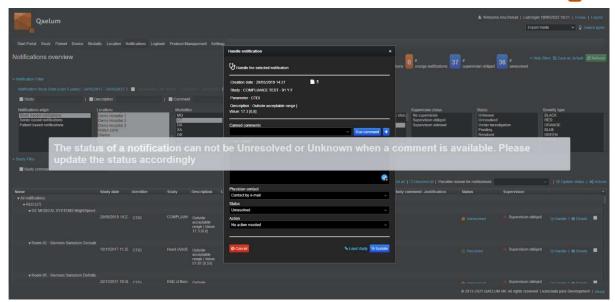


Handle notification

If the study that generated this notification had a comment, it will appear as a comment icon, which the user can hover over to see its content.







NOTE: If a comment is entered, the status must be changed from "Unresolved" or "Unknown" to another status, e.g. "Under investigation", "Pending", etc. A pop-up message will remind the user to change the notification status.

If a comment is added to this notification, the following icon will be displayed for the study:



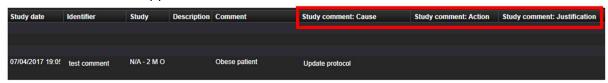
Notification comment icon

The user can filter by "Unresolved" notifications to see studies with notifications that have not yet been handled. In the same way, the user can filter the notifications that contain (or not) a comment in the study details, by using the "study comment" filter. These comments include the ones coming from the Live Dashboard, the Pop-up Agent and the dosimetry webservice.



Study comment filter

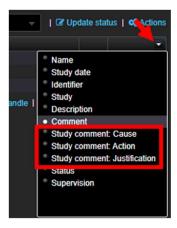
These comments will appear in different columns in the notifications list.



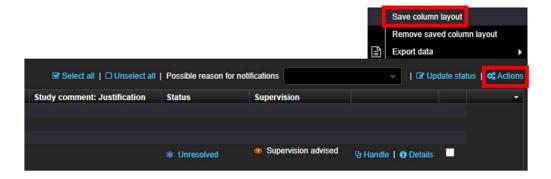


Study comment columns in the notifications overview

The columns may not be visible by default: the user can select the desired columns by clicking on the small arrow at the top right of the table.

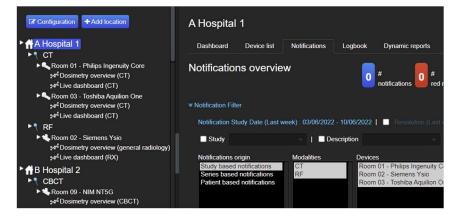


The columns can be made visible by default by clicking on *Actions* (top right) and then *Save column layout*.



The content of these columns can be exported via $Actions \rightarrow Export data$.

Notifications can be searched for and handled on site level by accessing **Notifications** when clicking on the site name on **Device** level. In the same way, on Device level the user will have only the notification from the selected device.





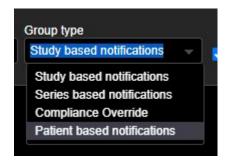
For more information, refer to the video *How to use Notifications Level* in our online training center.

7.3. Notification Center

Any user whose role includes the "Notification administrator" functionality has access to the **Notification Center** with **Settings**, where various notification rules can be configured.

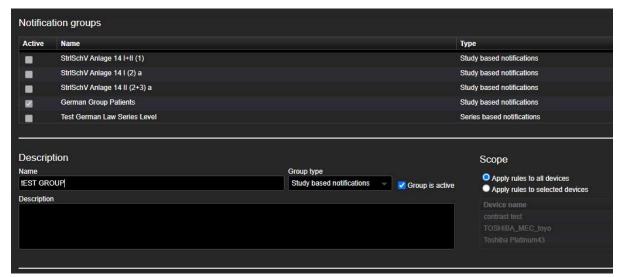


Customized groups with specific rules can be configured here. These rules can be based on study, series or patient parameters. The user has also the possibility to make a notification to overrule the compliance alerts. Compliance monitoring will still apply, but the specified alert type will be overruled.



To configure a new notification center group, follow the steps below:

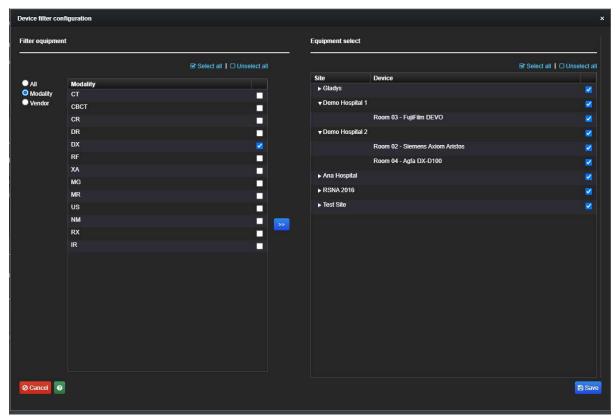
- 1. Access **Settings** → **Notification Center**
- 2. Click on **Add** in the upper-right corner to start a new group
- 3. Indicate the notification group description and select a **Group Type**
- 4. Mark it as "Active" for the rules to apply to incoming/existing studies
- 5. Select a **Scope** by indicating the devices it will affect



Notification Center



- if rules should be applied to all the devices, select Apply rules to all devices or Apply rules to selected devices and click on Edit filter
- A window will pop-up allowing the selection of specific devices
- The modality/modalities can be selected, then the >> button to select the desired devices from the resulting sites
- Finally, click on **Save**



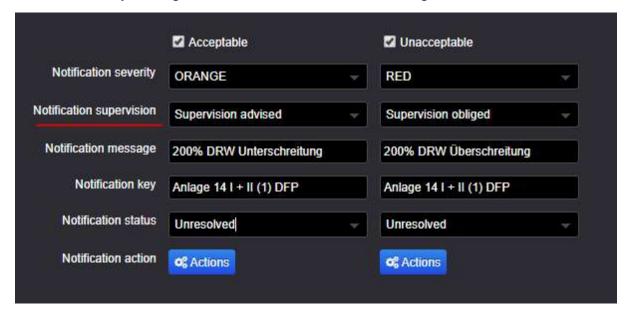
Device filter configuration

6. The rules for the group can now be defined. To add a rule, click on the green button +Add rule and fill in the necessary parameters and values. Once a group is created (don't forget to click on the green disk icon to save), the rule will apply to new studies. Pay attention, because creating duplicate rules will cause duplicate notifications.





7. Details of the notification can be configured by clicking on **Show notification configuration** (e.g. the severity, supervision status, message, notification key and status). By clicking on **Actions**, email alerts can be configured.



When notifications with advised/obliged supervision are created, an orange/red eye symbol will appear in the study list in a column called *Justification*.



The following table summarizes the different rules (comparison types) available in the Notification Center, in which levels (group types) they can be found and to which parameters they can be applied:

Rule in DOSE	Study	Series	
% fixed value	CTDI, DAP, DLP, Dose at ref. Point, Effective dose, Entrance dose, Fluoro time, OrganDose [MG],	CTDI, Compression Force, DAP, DLP, Deviation Index, Effective dose,	



	Organ doses, PSD, Radioactivity Administered, Radioactivity Administered per kg, Weighted CTDIvol	Exposure Index, OrganDose [MG], Organ doses	
Equals	CTDI, DAP, DLP, Dose at ref. Point, Effective dose, Entrance dose, Fluoro time, OrganDose [MG], Organ doses, PSD, Radioactivity Administered, Radioactivity Administered per kg, Weighted CTDIvol	CTDI, Compression Force, DAP, DLP, Deviation Index, Effective dose, Exposure Index, OrganDose [MG], Organ doses	
Range fixed value	CTDI, DAP, DLP, Dose at ref. Point, Effective dose, Entrance dose, Fluoro time, OrganDose [MG], Organ doses, PSD, Radioactivity Administered, Radioactivity Administered per kg, Weighted CTDIvol	CTDI, Compression Force, DAP, DLP, Deviation Index, Effective dose, Exposure Index, OrganDose [MG], Organ doses	
German Regulation - Group of patients [Annex 14 I/II.1]	DAP, DLP, Organ Dose [MG], Radioactivity Administered, Radioactivity Administered per kg, Weighted CTDIvol	CTDI, DAP, DLP, Organ Dose [MG]	
German Regulation - CT CTDI Single patient [Annex 14 I/II.2a]	CTDI	CTDI	
German Regulation - DR DAP Single patient [Annex 14 I/II.2a]	DAP	DAP	
German Regulation - XA DAP Single patient [Annex 14 II.2/3a]	DAP	DAP	
German Regulation - Eff. Dose Single patient [Annex 14 I/II.2a]	Radioactivity administred	N/A	



Highest organ dose	Organ doses	Organ doses		
Group notifications	Notification			
Joint commission Fluoroscopy	DAP, Dose at ref. Point, PSD			
Available in list	Patient ID, Patient Name, Study description	Filter [MG], XRay target [MG]		
Text contains	Patient ID, Patient Name, Study description	Filter [MG], XRay target [MG]		
Text ends with	Patient ID, Patient Name, Study description	Filter [MG], XRay target [MG]		
Text equals	Patient ID, Patient Name, Study description	Filter [MG], XRay target [MG]		
Text starts with	Patient ID, Patient Name, Study description	Filter [MG], XRay target [MG]		

Besides Study and Series, there are other 2 special group types: Patient and Compliance override:

	Patient	Compliance override
Cumulative value	Effective dose	
Compliance monitoring		Administered Radioactivity, CTDI, DAP, DLP, Dose at ref. Point, Effective dose, Entrance dose, Event count, Fluoro time, MGD, Organ Dose [MG], PSD, Prepared Radioactivity, SSDE, Scanlength

For further information, refer videos within the **Notification Center** section of our online training center.



7.3.1. Description of rules

7.3.1.1. % FIXED VALUE

In this rule, the user can enter a reference value and the different percentages that will be used for the different notifications.

For example, in the image below, the reference is set to 100dGy·cm², the achievable levels to 5% and the acceptable levels to 10%.



That means that the resulting levels will be as follows:

Lower Acceptable=90dGy·cm² Lower Achievable= 95dGy·cm² Upper Achievable=105dGy·cm² Upper Acceptable=110dGy·cm²

This way, when a study arrives, the system will check the selected parameter (e.g. DAP) against all these levels, following this logic:

If the parameter is

- 1. above the upper acceptable (110dGy·cm²) or
- 2. below the lower acceptable (90dGy·cm²) levels,

it will create an "Unacceptable" notification, that by default is set to color RED.

If the parameter is

- c. between the upper acceptable (110dGy·cm²) and the upper achievable (105dGy·cm2), or
- d. between the lower acceptable (90dGy·cm²) and the lower achievable (95dGy·cm²)

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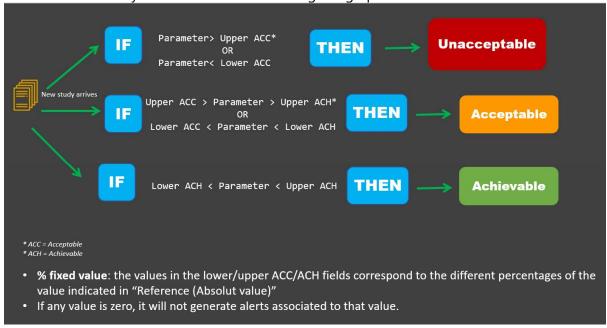


It will create an "Acceptable" notification that by default is set to ORANGE.

If the parameter is between the lower achievable and the upper achievable, then the notification will be marked as "Achievable" with default color GREEN. Normally this notification is deactivated by default.

NOTE: If any of the above levels is set to zero, it will not generate notifications associated to it.

You have a summary of this rule in the following infographic:



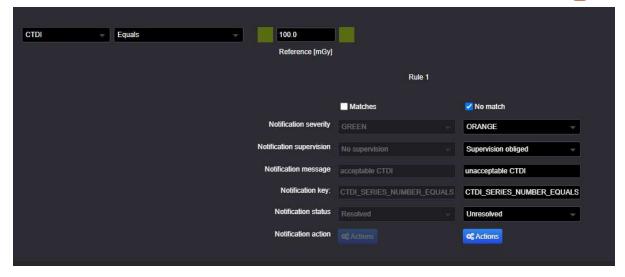
7.3.1.2. EQUALS

If the received value

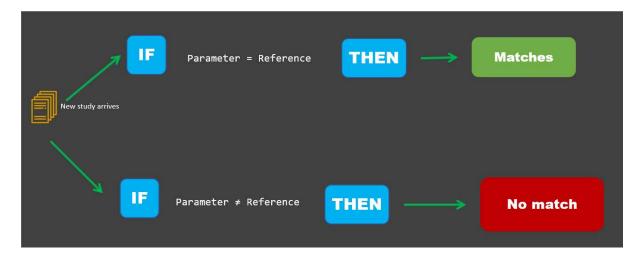
- a) equals the reference value, it will create a 'Matches' notification (e.g. GREEN)
- b) if it is not the case, it will generate a 'No match' notification (e.g. RED)

It is possible to just activate only one of the notifications. Like you can see in this example:



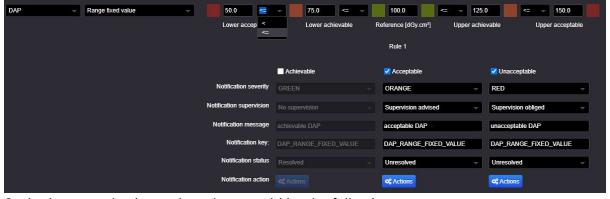


Below you have an infographic that summarizes this rule:



7.3.1.3. RANGE FIXED VALUE

This rule is similar to the "% fixed value", but instead of percentages, you need to enter absolute values. Here the "Reference" value can be any value between the lower ACH and the upper ACH, but no calculation will be done with this value.



So, in the example above, the values would be the following:

Lower Acceptable=50dGy·cm²



Lower Achievable = 75dGy·cm² Upper Achievable = 125dGy·cm² Upper Acceptable = 150dGy·cm²

And the value of 100 dGy·cm² is purely indicative.

As the previously described rule, there are 3 possible scenarios

- 1. If the parameter is
 - e. above the upper acceptable (150dGy·cm²) or
 - f. below the lower acceptable (50dGy·cm²) levels,

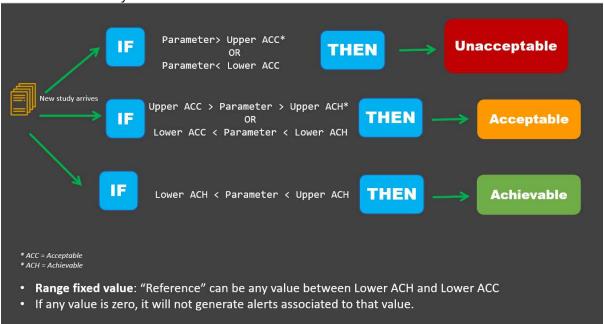
it will create an "Unacceptable" notification, that by default is set to color RED.

- 2. If the parameter is
 - g. between the upper acceptable (150dGy·cm²) and the upper achievable (75dGy·cm²), or
 - h. between the lower acceptable (50dGy·cm²) and the lower achievable (75dGy·cm²)

It will create an "Acceptable" notification that by default is set to ORANGE.

3. If the parameter is between the lower achievable and the upper achievable, then the notification will be marked as "Achievable" with default color GREEN. Normally this notification is deactivated by default.

Below the summary of this behaviour:

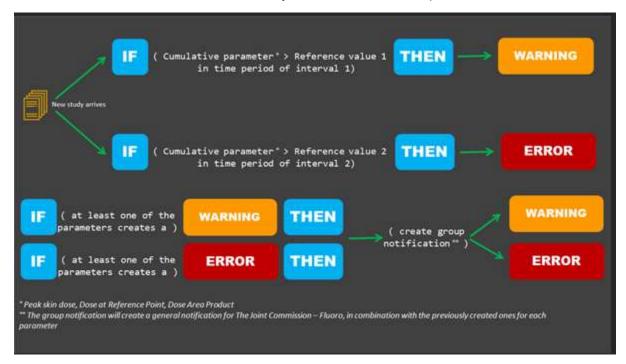


7.3.1.4. JOINT COMMISSION REQUIREMENTS FOR FLUOROSCOPY

The notification rules can be configured to look in a certain time period if a patient had an exam with a chosen threshold. In the image below you can see how we implanted the



Join Commission (JC) requirements for Fluoroscopy. In this example, every time a new study comes in the system, there is an automatic checking to see if there are other studies for the same patient and then the cumulative parameters (PSD, DAP, Dose at Reference Point) are checked to see if they fulfil the criteria to report to JC.

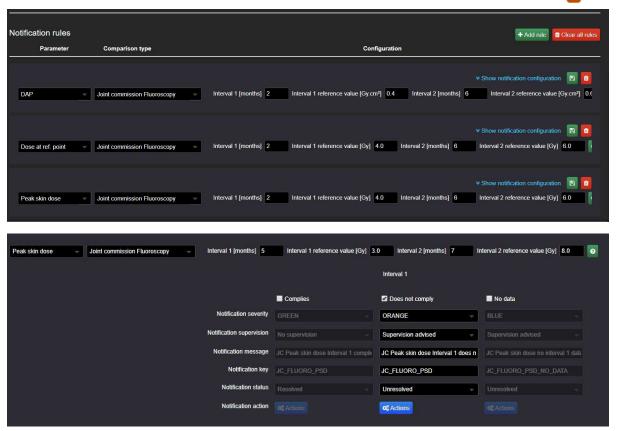


JC requirements as deployed by DOSE:

- Peak skin dose:
 - o in 2 months, PSD>3Gy → orange notification
 - o in 6 months, PSD>15Gy → red notification
- Dose at reference point: same rules as PSD (some interventional systems may be lacking RDSR, so there needs to be a second check)
- Dose area product:
 - o in 2 months, DAP>300Gy·cm² → orange notification
 - o in 6 months, DAP>1500Gy·cm² \rightarrow red notification
- If one of the three above criteria produces an orange notification, then there is a orange group notification generated. If one of the three is red, then group notification is red. (To configure this, check the next rule explanation "Group notifications").

These rules are easily configurable by the user, just add the parameters DAP, Dose at RP and PSD with the comparison types "Joint Commission Fluoroscopy" and modify the applicable values, if needed.

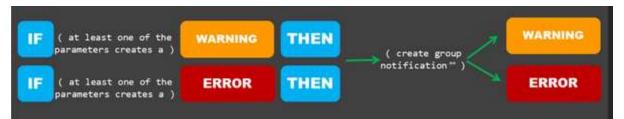




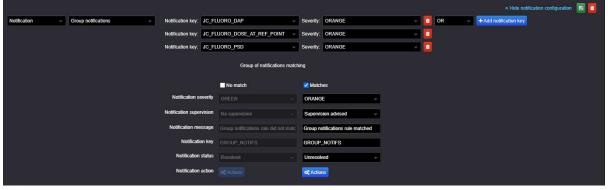
7.3.1.5. GROUP NOTIFICATIONS

These rules work with an AND/OR logic and can be used to create notification escalations.

In the following example, a group notification has been configured to comply with the second part of the Joint Commission Requirement.



Second part of the Joint Commission Requirement



Group notification ORANGE if any of the selected notifications (keys) is ORANGE



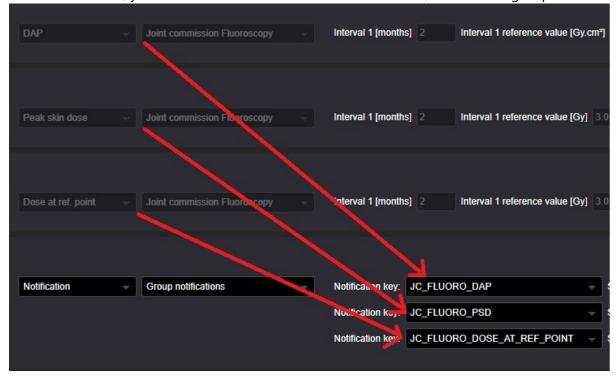


Group notification RED if any of the selected notifications (keys) is RED

To create a group notification, select "Notification" as parameter and "Group notifications" as comparison type. Then choose an AND/OR logic.

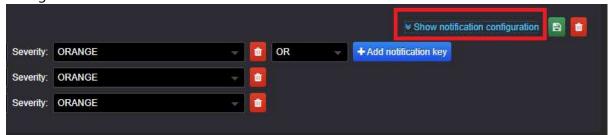


Then click on **+Add notification key** and select a key from the drop-down menu. The notifications whose keys you can select are the ones inside the same notification group. That means, for example, that if you want to create the group notification (scalation) for the Joint Commission rules, you need to create the individual rules before, in the same group.

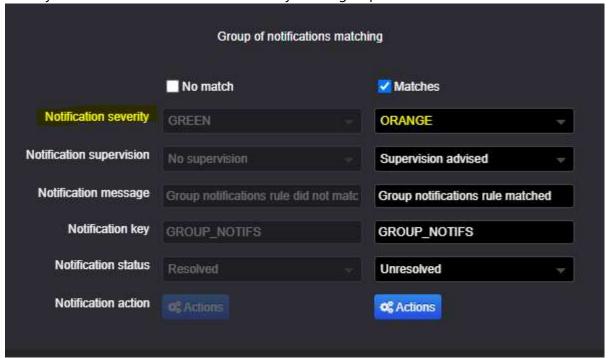




Once you have selected the keys, select the "Severity" and click on "Show notification configuration".



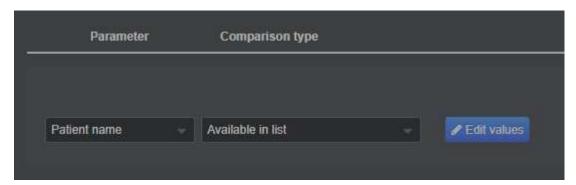
There you will be able to choose the severity of the group notification.



7.3.1.6. TEXT-BASED NOTIFICATIONS

The parameters Patient ID, Patient Name and Study Description (at study level) and Filter [MG] and XrayTarget [MG] (at series level) can be tracked with text-based notifications. The possible rules are:

 Available in list: where you can click on Edit values and write down a list of possible names.







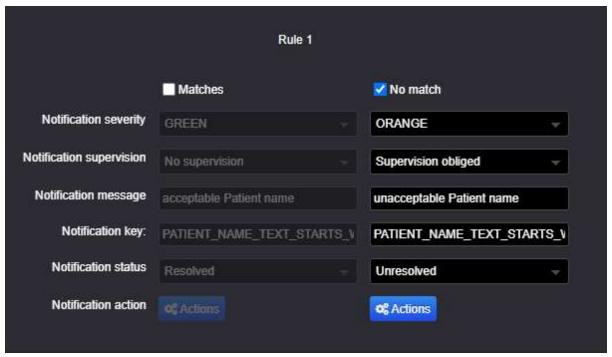
• Text contains/ends with/equals/starts with



You can ignore Upper-/Lowercase at any time by checking the corresponding box.

If you click on "Show notification configuration" you can choose what will happen if the study "Matches" or "Not matches" the entered text.

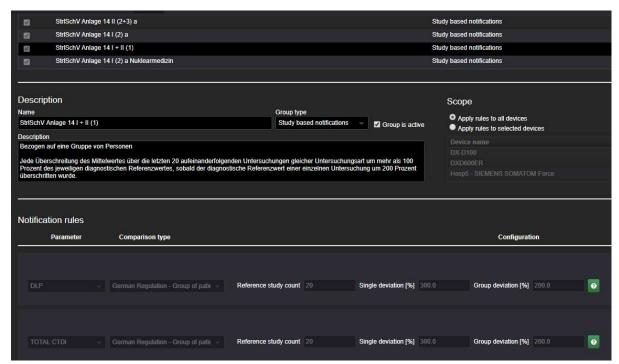




Notification when "No match" is produced

7.3.1.7. GERMAN REGULATION NOTIFICATIONS

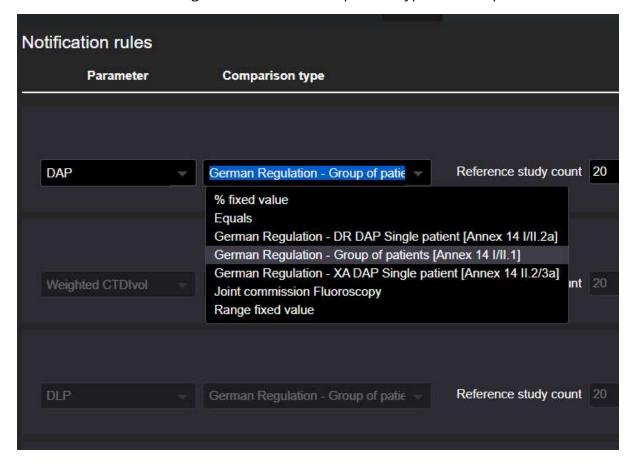
Normally, if you are a German customer, all the notifications rules will be already configured for you, ordered by groups and with references to the text in the regulation.



German regulation notification groups

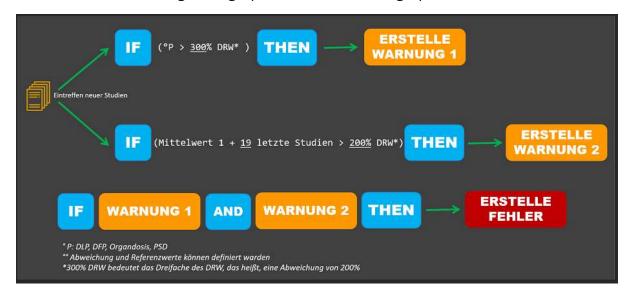


Nevertheless, these rules are useful to monitor outliers and they could be interesting for other users as well. If you wish to configure them by yourself, just add all the rules that contain « German Regulation » in their comparison type for each parameter.



7.3.1.7.1. GERMAN REGULATION - GROUP OF PATIENTS [ANNEX 14 I/II.1]

This rule works following the logic presented in this infographic:

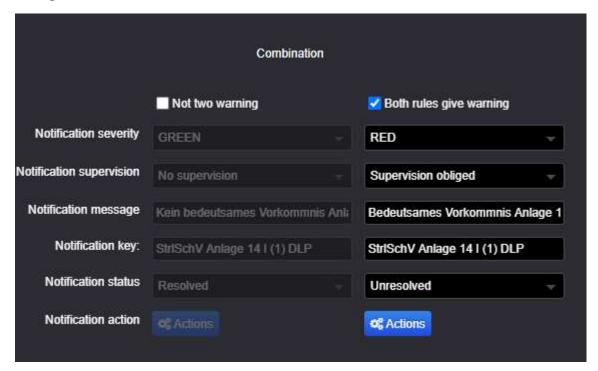




Thus, 3 notifications are created:

- 1) an orange notification is created when the dose parameter is above 300% of the DRL (deviation of 200%)
- 2) A second orange notification is created if the average value of that dose parameter for the last 20 studies of the same type (study group) is above the 200% of the DRL (deviation of 100%).
- 3) If both cases happen, then a red notification will be created.

Note that for this rule no "Group notification" is needed, since the scalation is already included in this special rule. You can check this by clicking on "Show notification configuration".



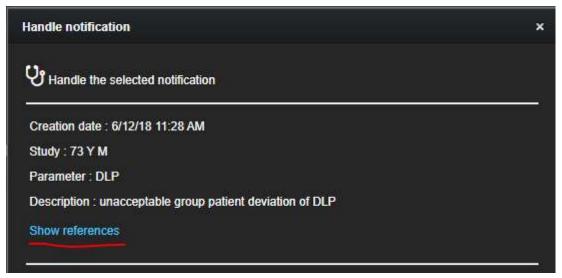
Of course, if you wish to use this rule with other values, you can change them:



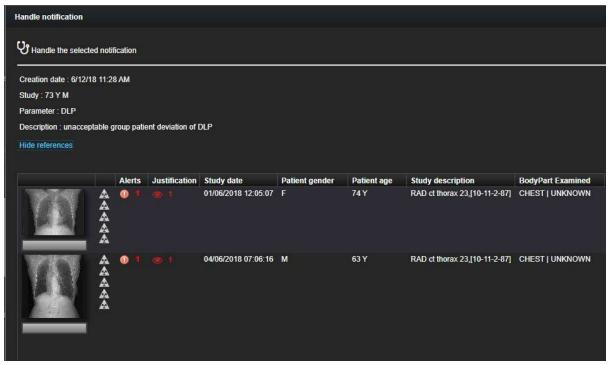
For more information about this rule and the criteria to select the last 20 examinations in both STUDY and SERIES level, please refer to the document information document *GERMAN LAW NOTIFICATIONS - Group of patients [Annex 14 I/II.1*].

When handling this type of notification, a « Show references » button will appear and by clicking on it, the user will be able to see the last 20 studies that were used for the average calculation.





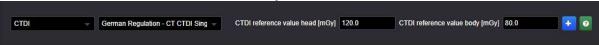
Show references for a German group notification



List of studies used for the German group notification

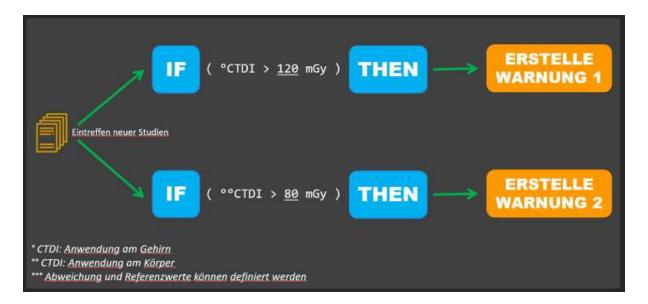
7.3.1.7.2. GERMAN REGULATION - CT CTDI SINGLE PATIENT [ANNEX 14 I/II.2A]

With this rule, the user can stablish two different reference values for CTDIvol: one for the head and one for the rest of the body:



If any of the two values is exceeded for the corresponding phantom (16 or 32cm), a notification can be created. Here you can see the example with the values of the German Legislation:





This rule has a slightly different operation depending on whether it is configured in "Study-based notifications" or "Series-based notifications".

a) Study-based notifications

The system will check the phantom of each series and will sum up the values for each phantom. So, the CTDI for

- i) head will be the sum of all the CTDIs of the series whose phantom is 16cm.
- ii) body will be the sum of all the CTDIs of the series whose phantom is 32cm.

Each one of these values will be checked against their corresponding reference one, and if they exceed it, a notification will be created.

b) Series based notifications

The system will compare individually the values from each series against the reference value, so

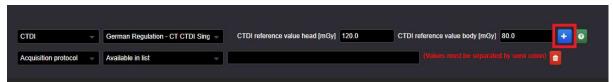
- i) each series with phantom 16cm will be checked against the reference value for head, if the value is higher than the reference, a notification will be created.
- ii) each series with 32cm phantom will be checked against the reference value for body, if the value is higher than the reference, a notification will be created.

Exclusion rules

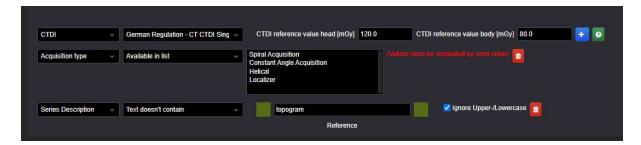
It is possible to restrict this rule for CTDI on series level to specific series, based on the following parameters: Acquisition Protocol, Acquisition type, Series Description, Study Description-Acquisition Protocol, Study Description-Series Description.

There is a blue '+' button next to the rule configuration:





After the blue '+' is clicked, the configuration appears, allowing the user to select rule restrictions for several parameters. These restrictions can be based on a list of values or on parts of text:



This way, constant angle acquisitions can be excluded from this rule, to not generate undesired notifications.

7.3.1.7.3. GERMAN REGULATION - DR DAP SINGLE PATIENT [ANNEX 14 I/II.2A]

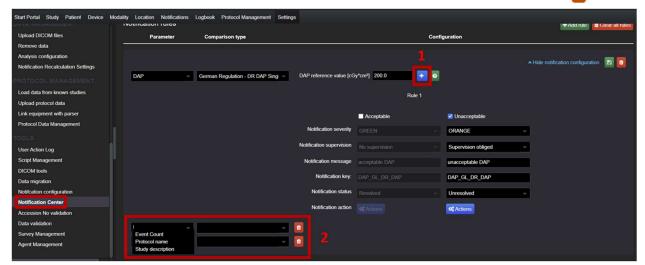
This rule allows to set a limit for the DAP in general radiology devices:



The same way as in the previous section, **exclusion rules** can be added on study level (also possible for the XA DAP Single Patient Annex 14 I/II.2/3A described in the next section).

There is a blue '+' button next to the rule configuration, labelled as "1" below.





After the blue '+' is clicked, the configuration labelled above as "2" appears, allowing the user to select rule restrictions for event count, protocol name and study description.



In case of event count, the user can choose a comparison operator of less than, greater than, equal to, or not equal to. The desired value can be input as shown above.

In the case of protocol name and study description, the rule allows to enter a list of names or part of a name:





7.3.1.7.4. GERMAN REGULATION - XA DAP SINGLE PATIENT [ANNEX 14 II.2/3A]

This rule is summarized in the following infographic:



- If the DAP is higher than the first reference value (e.g. 20.000cGy·cm2), an ORANGE alert will be created.
- If the DAP is higher than the second reference value (e.g.50.000Gy·cm2), another ORANGE alert will be created.
- If the second warning is created and there are manual comments about deterministic effects within a certain number of days (e.g. 21 days), a RED notification will be created.

The values of the reference levels and the period can be adjusted.



Additional exclusion rules can be configured on study level, as described in <u>GERMAN</u> <u>REGULATION - DR DAP SINGLE PATIENT [ANNEX 14 I/II.2A]</u> above.

7.3.1.7.5. GERMAN REGULATION - EFF. DOSE SINGLE PATIENT [ANNEX 14 I/II.2A]

This rule refers only to the effective dose and organ doses in Nuclear Medicine.

Notifications for effective dose and organ doses are calculated based on study groups and on injected activity thresholds, as suggested by the Bundesamt für Strahlenschutz.

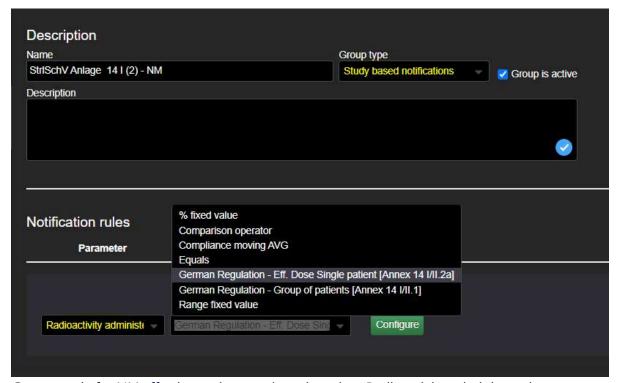


tadio- harmakon	Untersuchung	Limitierende Dosis	Dosis- koeffizient		Aktions- schwelle
^{99m} Tc- Pertechnetat	Schilddrüse- Szintigraphie	Effektive Dosis	9,7E-03 ¹	2000 ²	
^{99m} Tc- MDP/DPD/HDF	Skelett- Szintigraphie	Organdosis (Harnblase)	2,8E-02 ¹		55 ³
^{99m} Tc- Sestamibi	Perfusion/Vitalität- Szintigraphie - Ruhe	Effektive Dosis	6,9E-03 ¹	3300 ²	
	Perfusion/Vitalität- Szintigraphie - Stress	Effektive Dosis	6,0E-03 ¹	3700 ²	
	Nebenschilddrüse- Szintigraphie	Effektive Dosis	6,9E-03 ¹	3400 ²	

Example of action levels for administered radioactivity by the Bundesamt für Strahlenschutz

The mapping of the study groups and the thresholds are configurable.

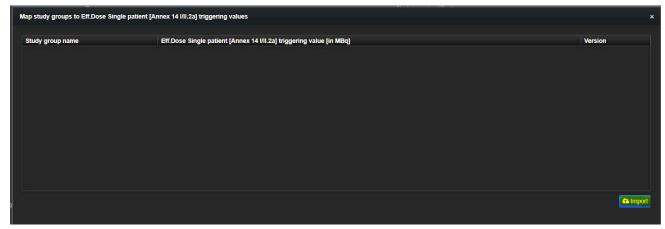
This rule can be found under group type "Study based notifications" and it's only available for the "Radioactivity administered" parameter.



German rule for NM effective and organ doses based on Radioactivity administered.

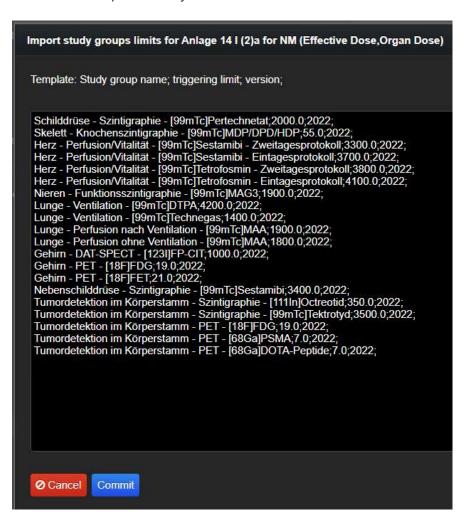


In "Configure", users can import the csv file with the action level values provided by the BfS for each study group by clicking on "Import".



Click on "Import".

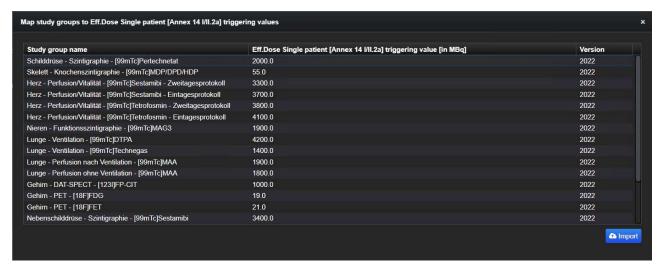
This file can be provided by Qaelum.



Action levels based on pre-existing study groups.



Click on "Commit" to visualize the values:



Imported values

Close this window and save both the rule and the notification group.

7.3.1.7.6. HIGHEST ORGAN DOSE

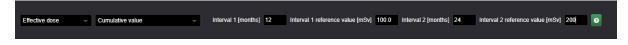
This rule refers to Nuclear Medicine devices as well, it allows to set a limit for the highest organ dose.



- a) If the notification is created as STUDY-based, it will compare the maximum value of the organ doses at STUDY level (sum of doses for each organ at series level)
- b) If the notification is created as SERIES-based, it will compare the maximum value or the organ doses of each individual SERIES.

7.3.1.8 CUMULATIVE VALUE

This rule is only available in "Patient-based notifications" and for Effective dose (all modalities).

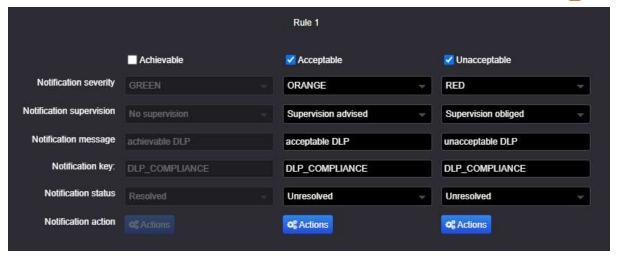


It works similarly to the one of Joint Commission but for effective dose.

7.3.1.9 COMPLIANCE MONITORING

This rule is found inside the group type "Compliance Override". It can be used for any parameter that used in the study groups as a limit. The rule allows you to "override" the severity (color), supervision, message, key and status of the compliance notifications.



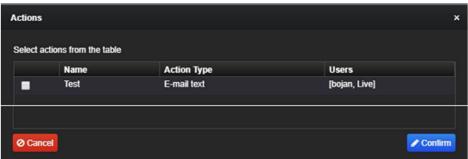


Please note that compliance notifications are created based on the study group limits with the logic =>, that is, a notification is created if the parameter is equal to or greater than the achievable/acceptable level.

7.3.2. E-mail notifications

E-mail sending can be configured every time a notification is generated. To do so, click on "Actions" and select an e-mail sending job for the user(s).





For more information on the configuration of the e-mail sending job, please refer to *Notification configuration*.

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7.3.3. Import and export of notification rules

Notification rules can be imported and exported to save time on configurations or to keep a backup of the already configured rules.

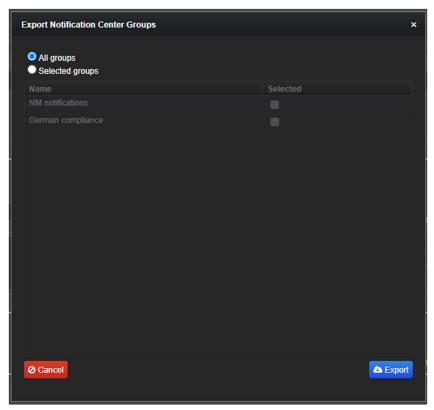
7.3.3.1. EXPORT OF NOTIFICATION RULES

To export notification configurations from the **Notification center**, click on the *Export* button (blue button with a cloud downward icon).



Export notification groups

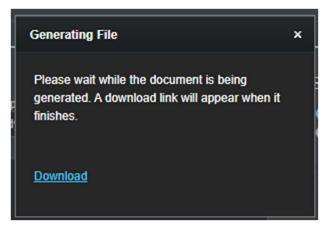
A popup will appear where the user can choose to export all groups or select individual groups.



Select groups to export

By clicking on *Export* (bottom right of the window), the download will begin.





Download window

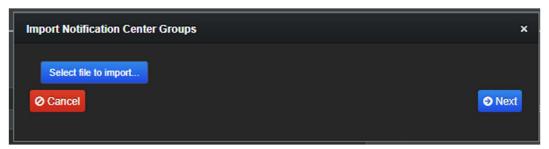
By clicking on *Download*, the export will be downloaded to the predefined export folder according to browser settings (by default C:\Users\username\Downloads) as a json file.

7.3.3.2. IMPORT OF NOTIFICATION RULES

To import previously exported rules in the **Notification center**, click on the *Import* button (blue button with a cloud upload arrow).



A popup will appear allowing to select a previously exported json file for import.

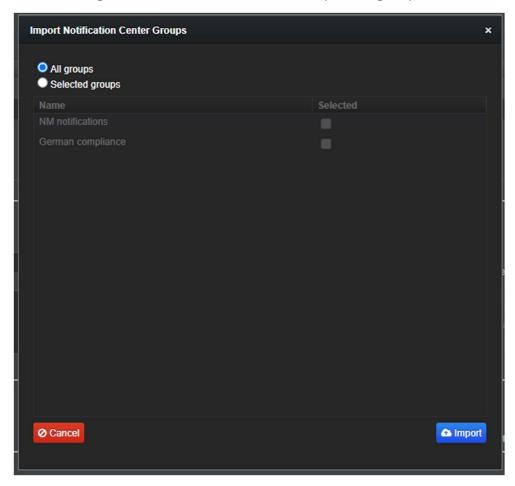


Select file to import





After clicking *Next*, the user can choose to import all groups or select individual groups.



Begin the download by clicking on *Import* (bottom right of the window). Additional configurations may be required if the export file originated from a different DOSE installation. Please find more details below.

7.3.3.2.1. IMPORT FROM THE SAME DOSE INSTALLATION

When importing from the same DOSE installation, no additional configuration is required: all notification groups will be saved automatically, and the rules will be effective immediately.



7.3.3.2.2. IMPORT FROM A DIFFERENT DOSE INSTALLATION

When importing from another DOSE installation, additional configuration may be required, depending on the rule customization at the source:

A) ORIGINAL RULES WERE APPLIED TO ALL DEVICES AND NO EMAIL ACTION WAS SET UP

If the exported notification groups were applied to all devices (see <u>Notification Center</u>) and no email actions were configured for the rules (see <u>E-mail notifications</u>), no additional configuration is required. All notification groups will be saved automatically, and the rules will be effective immediately.

B) ORIGINAL RULES WERE APPLIED TO SELECTED DEVICES AND/OR EMAIL ACTIONS WERE SET UP

If the exported notification groups were applied to specific devices (see <u>Notification</u> <u>Center</u>) and/or email actions were configured for the rules (see <u>E-mail notifications</u>), then the following steps should be followed for notification group import:

- 1. Import one group at a time.
- 2. Once the group is imported, change the scope to *Apply rules to all devices*.

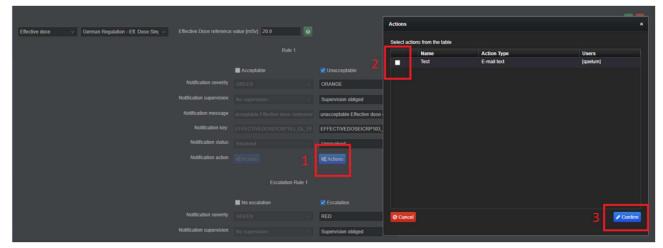


3. Click on *Show notification configuration* and activate the editing mode.

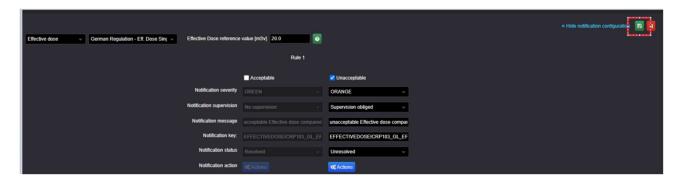


4. For each rule, verify that no email action is activated.





5. Save and repeat for each rule.



6. Once all rules have been imported, save the notification group.



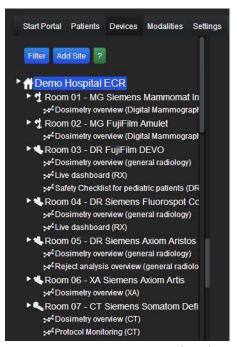
7. Repeat for any other groups that need to be imported.



8. Device level

The device dashboard is represented as a tree with two levels: Site (e.g. hospital, department, group of devices) and Device.

Each device can have one or more data panels: users with edit permissions can choose the available panels in the Edit device section.



Tree structure on Device level

8.1. Site section

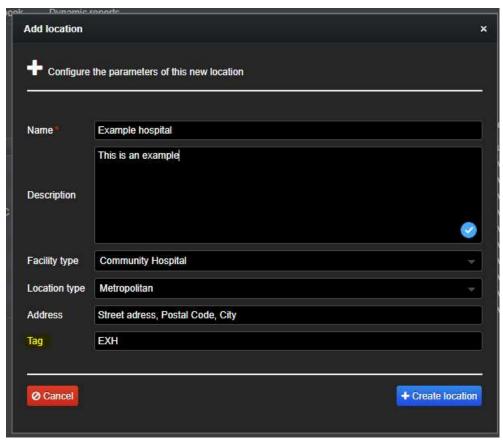
8.1.1. Add site

Users with the *Site management* functionality within their role can add a site by clicking on the *Add location* button. This button is located on the left side of the view and on the top of the site tree. The new site needs to consist of a name and a description. The site name needs to be unique in the application.



Configuration and Add location buttons





Register new site

A 3-character "tag" (see image above) can be added to easily identify the hospital in *Modality* comparisons.

By using the filter or grouping tool in the *Configuration* button, the tree structure overview will be clearer.



Filter and grouping screen

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8.1.2. Edit site

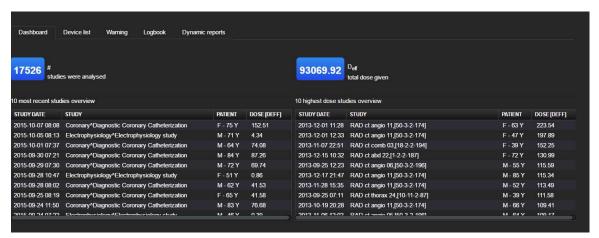
A user with editing permissions can modify a site by clicking "Edit Site" following the "actions" button, which is located on the right-upper side of the view. Site ID is not editable.

8.1.3. Remove site

The remove button is located in the "Edit Site" window on the upper-left side. Removing a site will lead to removing all the site's information and all the devices that apply to that site but will not erase dose data. User needs to have modification rights.

8.1.4. Dashboard

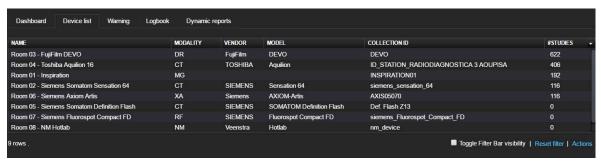
In this dashboard, the general overview of the site is shown: the user can find information about the amount of analyzed studies, the total effective dose for the devices, the 10 last analyzed studies and the list of the 10 highest dose studies.



General overview of studies performed on a specific device

8.1.5. Device list

List with all the devices available at the chosen site.



Device list

8.1.6. Dynamic reports

Dynamic reports provide users with periodic reports of any dashboard in DOSE. This report can be scheduled to be created on a regular interval (days/weeks/months/...) and

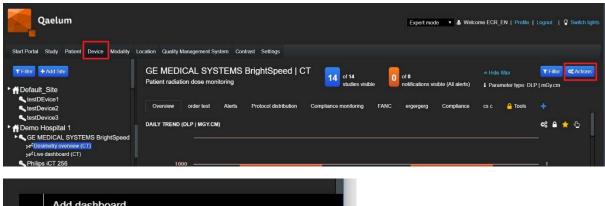


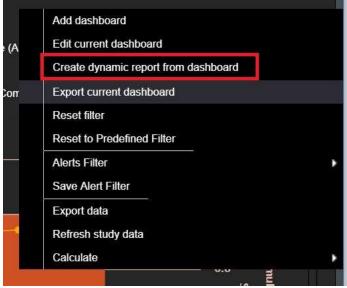
contain data that is up to date for the specified time period. This allows users to monitor dashboard data without having to log in to DOSE and find or re-configure the required dashboards.

Dynamic reports provide two report options: a URL link to the dynamic report, and a static PDF report. The dynamic report is sent as a URL that will open the interactive report data within DOSE. The generated PDF of the report is sent as an email attachment and is static.

The remainder of this document explains how dynamic reports can be created. For certain actions, only specific roles are have permissions to perform the required changes.

The dynamic report creation tab can be found under the upper-right action button on **Device** level.



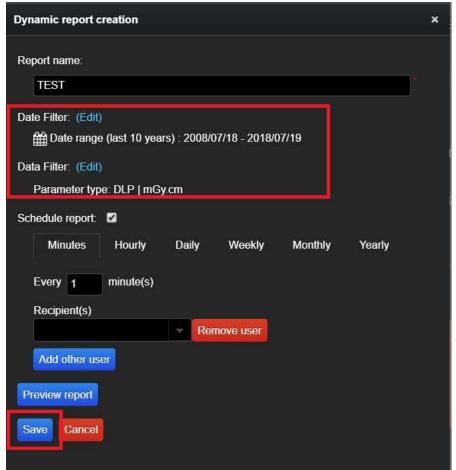


Please follow the steps below to create a customized dynamic report:

- The first step is to create a new dashboard (or use existing dashboard on device level), with the graphs presenting the data that you would like to receive in your report. The following two aspects are important before creating the dynamic report":
 - a. The date range. As the Dynamic Reports are often requested to be send on a periodic time interval, it is advised to put the DOSE daterange equal to this time interval. This way the report will always contain complete up-to-

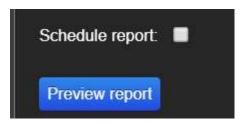


- date information for this time range (e.g. for a weekly report it is advised to put the time range on "last week"). If overlap of data is prefered, the data range can be chosen otherwise.
- b. The graphic filter. Each graphic allows you to put a specific graphic filter. Configure this filter correctly so that the data in the chart corresponds to the data that you want to be visible. The specific chart filter can be configured by clicking on the padlock symbol on the chart. Check that the general panel filter is temporarily configured to show all data. For more information about the graphic and general filters, check the user's manual. In the example, a filter has been configured to show only the effective dose of studies with a combination of specific series, since this type of studies can be the scope of a practical case.
- After all the graphs in the newly created dashboard are presenting you the requested data, a dynamic report can be created from the current status. This report will save the current filter and date range settings. The filter and the date range can additionally be adjusted/double checked during the creating of the report.



3. The last step is creating a scheduler job to create and send this report that you have just created. For this, activate the check box "schedule report".

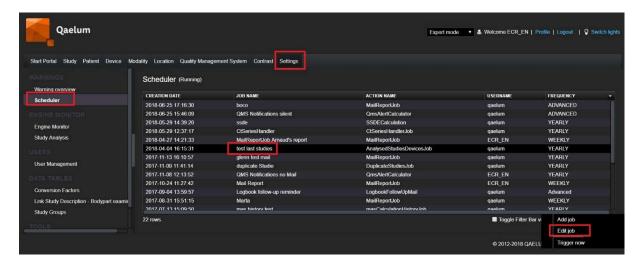




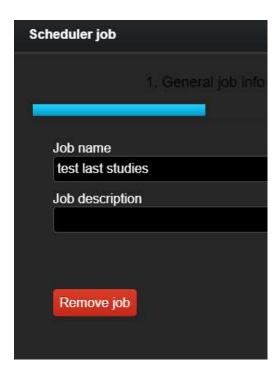
- 4. The creation of the job, consist of the following steps:
 - a. Provide a job name
 - b. Check/adjust the date and the filter
 - c. Now select the time interval for which you would like to receive an email with the Dynamic Report
 - d. Add the recipient(s)
 - e. Click on "save"

For more information, refer to the video *How to create Dynamic Reports* in our online training center.

- 5. Delete the dynamic report/scheduler job
 - a. The created report can be deleted via Settings → Scheduler → search for the right dynamic report → Actions (right below) → Edit job → Remove job







8.2. Device section

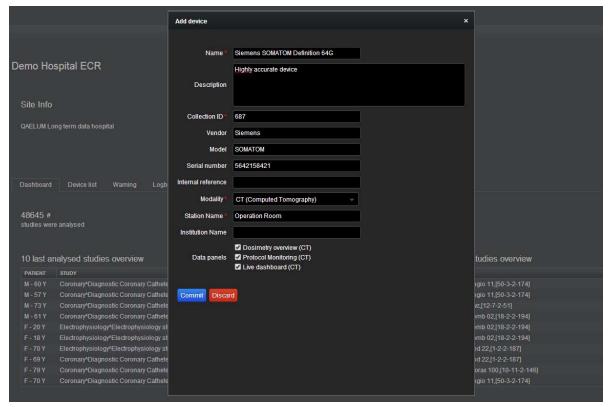
8.2.1. Add Devices

A user with editing rights can add a device by clicking the **Add device** button, found in the **Actions** menu in the upper right corner of the site Dashboard. To add a new device the user will need to fill in the device name, collection ID, station name and the DICOM modality. The user can also decide which data panels are shown for the selected device.



Add device in **Actions**





Add new device configuration

8.2.2. Add/Edit station name

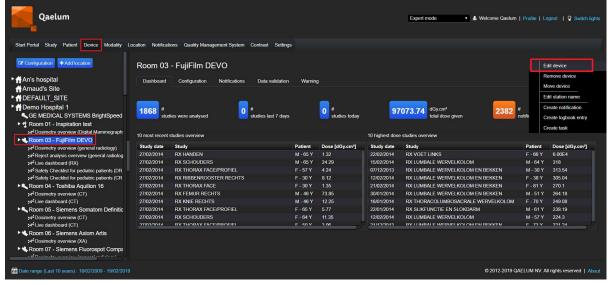
During configuration, it is necessary to fill in a primary station name for the device. It is possible to change, to delete or to add other station name for the same device by clicking on the "Edit Station Name" button. This button is located in the "Actions" menu on the right upper corner of the Device main dashboard. A device needs to have at least one station name. User needs to have modification rights to access to this section.

Remark: Please inform us if the station name of a device was changed after maintenance. If the station name is modified and it is not communicated to us, there might be missing data.

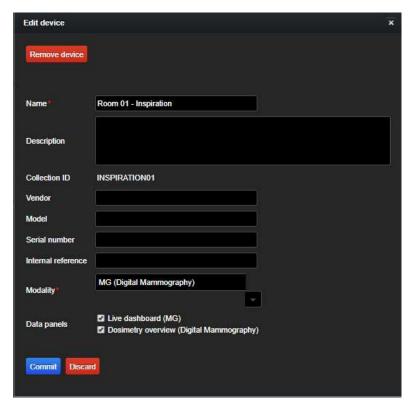
8.2.3. Edit device

A user with editing permissions can change device information, specifications, main parameter/units and data panels by clicking on "Edit Device", located within "Actions" in the upper right corner of the Device information page.





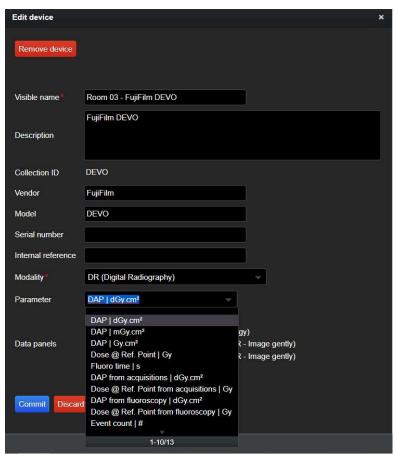
Device Level



Edit device

The user may be interested in changing the main parameter and/or units shown for the device for either functional or legal purposes. To do so, click on the "Parameter" dropdown menu to see the possible options, and select the appropriate one.





Change parameter/units

8.2.3.1. SPECIAL CASE: GENERAL (DX, DR, CR) AND INTERVENTIONAL (XA) RADIOLOGY

For these modalities, the units of the total DAP can be changed (however not for acquisition or fluoroscopy DAP). The unit for other parameters is predefined.

Parameter	Units
	dGy·cm²
	mGy·cm ²
DAP	Gy·cm²
	cGy·cm²
	µGy·cm²
DAP from	dGy·cm²
acquisitions	
DAP from	dGy·cm²
fluoroscopy	

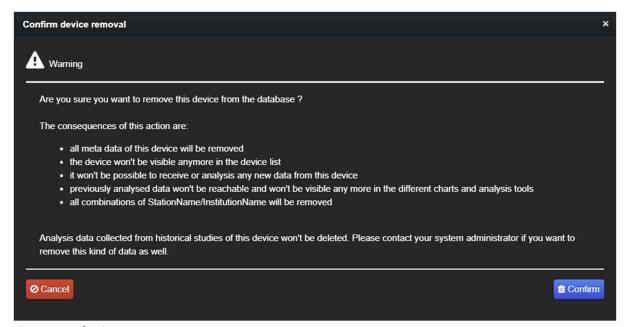
For more information, refer to the video *How to change parameter units on Device Level* in our online training center.

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8.2.4. Remove device

The "Remove device" button can be found in **Actions**, as well as within the "Edit Device" window. Removing a device will lead to the deletion of all device information, but the dose data will not be erased. Modification rights are needed to be able to delete the dose data.



Remove device

8.3. Configuration

The **Configuration** tab can be also found when clicking on the device name.

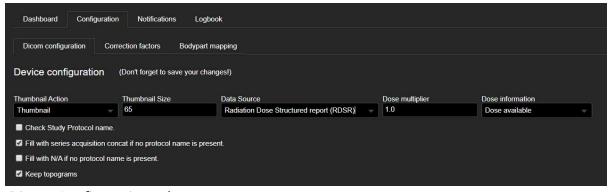
8.3.1. DICOM configuration

A user with the *Device Integration Manager* role can edit the DICOM configuration for the device.

In this tab, it is possible to change the data source. Also, the absence or the presence of a thumbnail can be selected here.

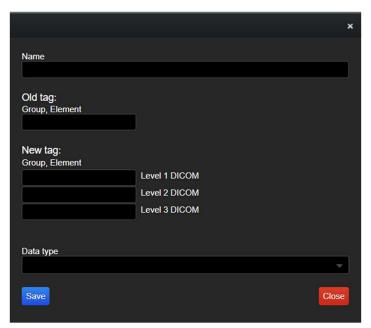
Note that changing the data source can lead to loss of data. A data source can be a combination of more than one source (i.e. DICOM header and MPPS).





Dicom Configuration tab

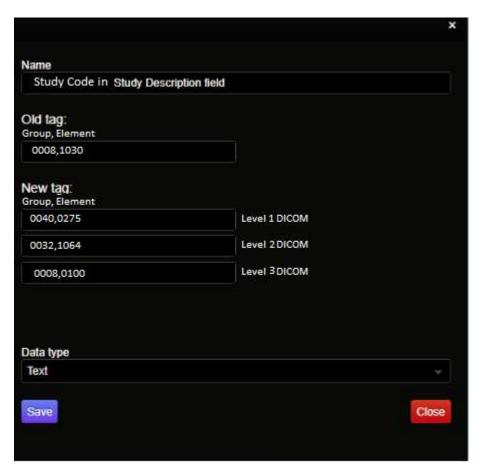
It is possible to add or replace a DICOM tag. In *Actions*, by clicking on *Add tag*, the user is able to configure the new tag.



Add tag

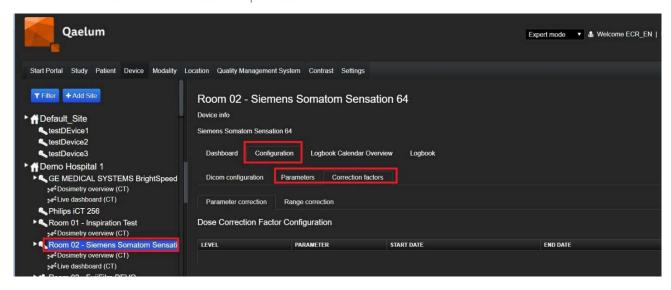
DOSE allows using subtags for this mapping, for example, if we want to replace dicom tag (0008, 1030) with the tag (0008,0100), which is a subtag of 0032,1064 and 0040,0275 respectively, the configuration should look as the following:





If only 2 levels are present, level 3 should be empty. If there are no sublevels, only Level 1 should be used.

8.3.2. Correction factors/parameters



Correction factor configuration



 The user can add a correction (calibration) factor for dosimetric indices and the corresponding dose values arriving on the system from this point on will be multiplied by this factor.

This configuration can be performed on Device level by clicking on the device in the device tree > Configuration > Correction factors. This dashboard provides 2 types of correction factors: parameter and range correction factors.

- The **parameter correction** will apply a correction factor to a single parameter (e.g. global correction of DAP as DICOM data (0018,115E) is reported in cGy and officially DICOM expects dGy).
- Using the range correction, the user can select parameters that this calibration factor will depend on. The parameter that will change is called a "target" and the parameter that the correction is based on is called a "trigger". For example, a calibration factor can be set for DAP (i.e. the target, called *Target* in the Dose Correction Factor Range Configuration) if tube voltage (i.e. the trigger, called *Parameter*) is in the range of 50-80 kV, and another one if it is in the range of 80-125kV.
- The user can set the correction date range starting from the date of the configuration (no historical data are affected, only new data arriving following the correction configuration). The end date can be set or remain empty.

Warning: this influences the dose calculation and we strongly recommend to contact Qaelum for any change.

Correction factors will only be applied to analyses of new studies, applying correction factors for historic studies is thus not possible through the application. Correction factors on SERIES will result in a recalculation of the total value on STUDY level. For that reason, we advise never to apply a correction factor on both levels. Take also into account that for RDSR, the study values are by default collected from the study values in the RDSR. Having correction factors on series level will then result in the sum of corrected series values being taken as study values.

Please consider that Correction Factors can be Added or Edited, but can't be deleted as this is the only way in which there is track of the applied correction factors to the studies that fall within the start and end date ranges.

8.3.2.1. PARAMETER CORRECTION

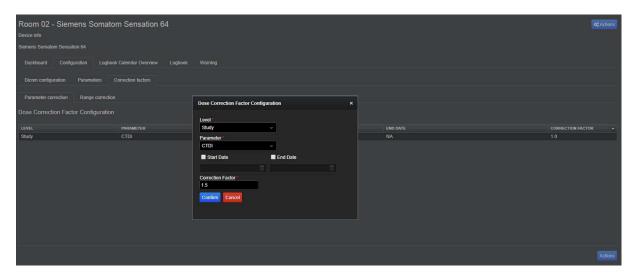
As explained above, this functionality offers a correction for a collected parameter on STUDY or SERIES level. To configure a correction factor, simply click on the Actions button in the lower right corner, Add row and make the correct configurations.

• Select STUDY or SERIES level in order to determine on which level the correction should occur. Consider that corrections on SERIES level will automatically result in a sum of the corrected SERIES values to the according STUDY level value.



- After having selected a level, DOSE will provide you with the possible parameters to which a correction factor can be applied. This is modality dependent.
- Optionally you can select a start or end date at which these corrections should be applied.

Last you can fill in the correction factor (multiplication value) that should be used.



8.3.2.2. RANGE CORRECTION

This correction is similar to the above but will only be applied if the specified trigger is valid. For example, the SERIES have a trigger parameter "kV" with a "Range start" 80 and a "Range End" 90 with a target parameter "DAP". In this case the correction factor will be applied for any series of this device with a value in the range of 80-90kV.

Please follow the steps below for range correction configuration:

 Select STUDY or SERIES level to specify on which level the correction should occur. Trigger and Target parameters will always be set up for the same level.

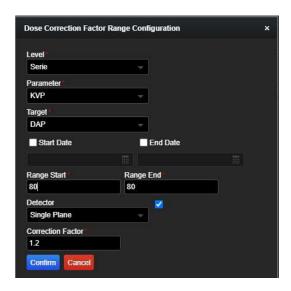
NOTE: Consider that corrections on SERIES level will automatically result in the sum of the corrected SERIES values for the corresponding STUDY level value when the data source is DICOM Header.

- After having selected a level, select a trigger parameter from the possible parameters offered by DOSE.
- Then select a target parameter from the dropdown menu. The target is the parameter to which the correction factor should be applied when the trigger falls within the configured range.
- Assign a start (lower limit) and end range (upper limit).
- Optionally a start and/or end date can be selected to limit the date range for which these corrections should be applied.



NOTE: Remember that correction factors will only be applied to analyses of new studies, thus applying correction factors for historic studies is not possible through the application.

- For RF and XA devices, a specific detector can be selected in the 'Detector' field to limit the correction to Single Plane, Plane A or Plane B detector, when applicable.
- Lastly the correction factor (multiplication value) can be filled in.



8.3.3. Bodypart mapping

The DICOM standard bodypart is used in DOSE for effective dose calculation. In some cases, the device reports a body part that is not a DICOM standard, e.g. 'Abd' instead of 'Abdomen'. Non-DICOM standard bodyparts can be mapped to standard bodyparts in DOSE. In cases when bodyparts are not reported by the device, bodyparts can be mapped to the acquisition protocol, series or study description, and combinations of study description-series description and study description-acquisition protocol.

Certain cases were determined where series data is not available:

- No series: HL7, MPPS, Dose Report, Exam protocol
- No data at series level: HL7 + DICOM, MPPS + DICOM

In these cases, an option to calculate effective dose based on the Study Description or Protocol Name on study level is possible.

Series level is the predefined and preferred method, as different anatomical regions may be present in each series, and other derived parameters (e.g. organ doses) can only be calculated at series level.



8.3.3.1. MAPPING AT SERIES LEVEL

The following options are available for the bodypart mapping at series level:

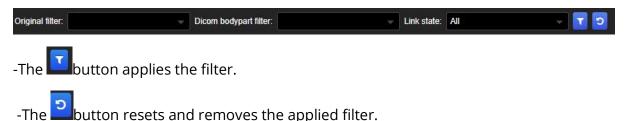
- Standardized bodypart: if the reported DICOM Header body part is not an official DICOM body part then it can be converted to an official bodypart based on the mapping between the DICOM Header reported bodypart and the official body part.
- **Acquisition Protocol:** the body part will be based on the reported Acquisition Protocol of the series.
- **Series Description:** the body part will be based on the reported Series Description of the series.
- **Study Description Series Description:** the body part will be based on the reported combination of Study Description-Series Description of the series.
- **Study Description Acquisition Protocol:** the body part will be based on the reported combination of Study Description-Acquisition protocol of the series.

The user can map the correct body part for every device in *Configuration/Bodypart mapping and effective dose/series* to the original bodypart, acquisition protocol, series description, combination of Study description and Series Description or the combination of Study Description and Acquisition Protocol.



Bodypart mapping at series level

The configuration layout has a filter at the top that allows the user to filter on the original value (the value being mapped to a bodypart), the rules mapping to a certain bodypart and the link state (entries that are or are not mapped).



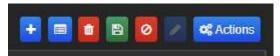
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The table below the filter shows the current mappings and for most mappings also the (auto-generated) not yet mapped value options. By pressing the edit (pencil) button at the top right, you can enter edit mode to alter the mappings.

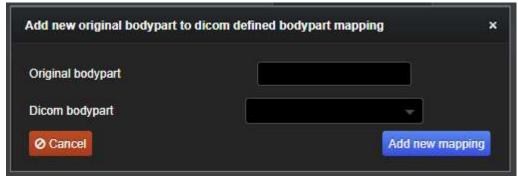


Now mappings can be changed by altering or removing the dicom bodypart description from the dropdown. After editing, changes can be saved or cancelled from the menu on the top right. Saving or cancelling exists the editing mode.



Add, mass map, delete, save, cancel changes

The "add new mapping" button opens a new window where a new mapping for an original value not currently already in the table.

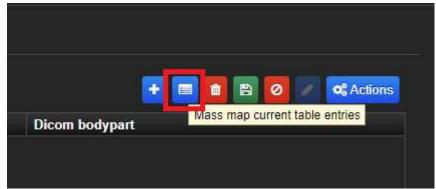


After filling in the fields, a check for duplicate values is performed and depending on the result, it informs the user or adds the new entry to the table.

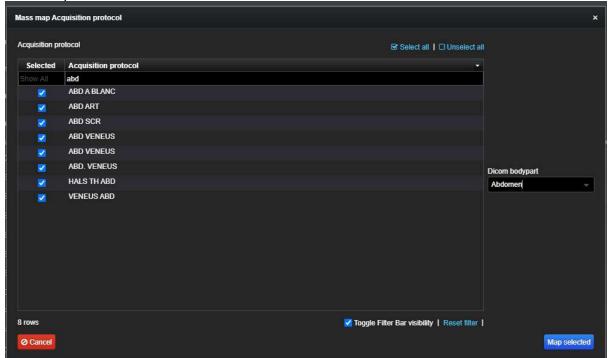
In order to simplify and speed up the user's procedure, it is possible to perform a multiple selection, similar to the mapping of study groups in the option "Study group combinations".

To access the body part mass mapping, click on **Edit (pencil)** and then on the **"Window"** button.





Mass map button

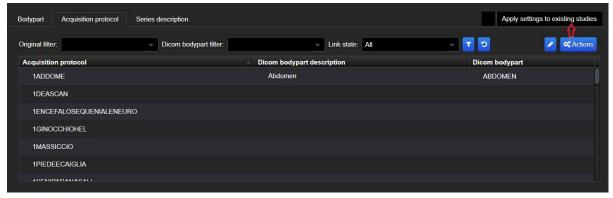


Mass map window

Here you can select several entries at the same time, with help form the Filter Bar that can be found on the lower-right corner. After the selection has been done, you can select a "Dicom bodypart" from the drop-down menu on the right side of the window and click on the "Map selected" button to save it.

There's also the possibility to add this mapping to the already existing studies in DOSE and recalculate the effective dose. To do so, the user must click on the "Actions" button and select "Apply settings to existing studies".





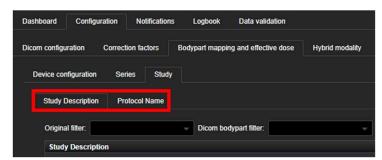
Apply settings to existing studies

8.3.3.2. MAPPING AT STUDY LEVEL

The same process as described above can be followed to map bodyparts at study level, based on either the:

- Study description
- Protocol name

In *Device Overview* → *Configuration* → *Bodypart mapping and effective dose* → *Study*, the user can perform the mapping at study level.



Bodypart mapping at study level

NOTE: We recommend that this mapping is done only in the cases where series data information is missing, since effective dose calculation will be more accurate at series level.

8.3.3.3. DEVICE CONFIGURATION

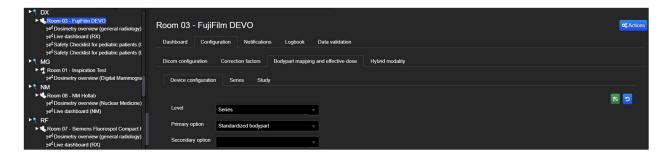
The default methodology for determining the bodypart in case the configuration has not been altered is as follows:

- 1. Attempt to map the bodypart to dicom bodypart at series level, as described above .
- 2. If no matching bodypart is found and the bodypart is actually filled in dicom header or RDSR, it's taken from there.



3. If the bodypart is empty or does not exist, it's filled in "UNKNOWN".

This methodology can be altered by creating a different configuration in **Configuration/Bodypart mapping/Device Configuration.**

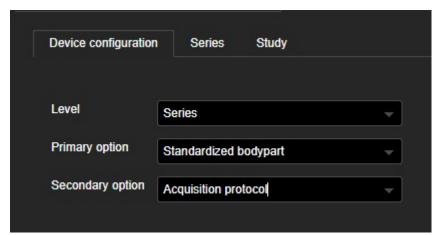


For each device, the user can select the *level* for effective dose calculation via a dropdown menu:

- Series (predefined)
- Study



Based on the choice above, it is possible to choose the mapping in case the bodypart is not available in the data source.



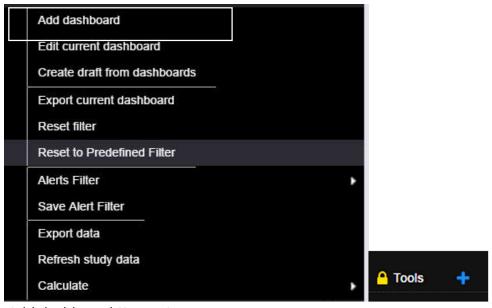
Here a primary option can be selected and this method will be attempted first. Only if through mapping no dicom bodypart can be determined, the program will attempt the secondary option, if one was selected. If, in the end, no dicom bodypart could be found, steps 2 and 3 from above will be used.



8.4. Device dashboards

Data panels consist of different dashboards, themselves consisting of different components showing specific data for the current device in graphs, charts and tables in a very specific date range.

In the *Dosimetry Overview*, the user with "Dashboard management" rights can add other dashboards by selecting the voice "Add dashboard" located in the "Actions" menu on the right upper corner of the Data panel, or by clicking the plus-sign on the tab sheet.

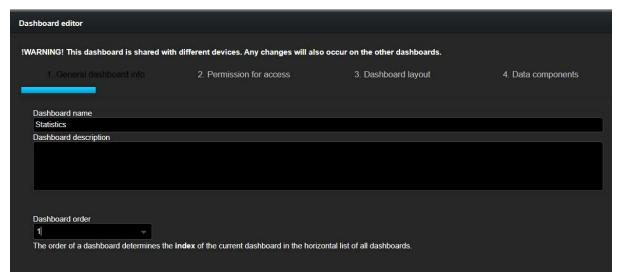


Add dashboard (2 ways)

When adding a new dashboard, the user will have to select the number and the type of the components. The dashboard order determines the place the dashboard will have in the data panel.

In the first step (general dashboard info), the user is asked to fill in the dashboard's name, the description and the dashboard order.

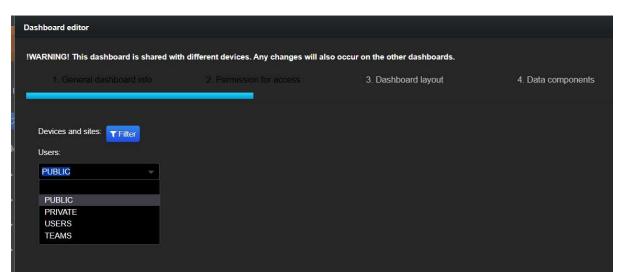




Dashboard editor (step 1)

In the second page of the dialog, the dashboard can be set to be:

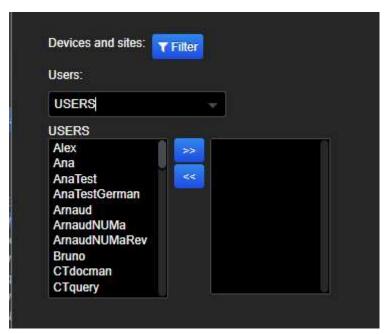
- Private: only the user can see it
- Group of users: the user can define which users can see it
- Group of teams: the user can define which users can see it, based on the teams they belong to
- Public (predefined): all users can see it.



Dashboard editor (step 2)

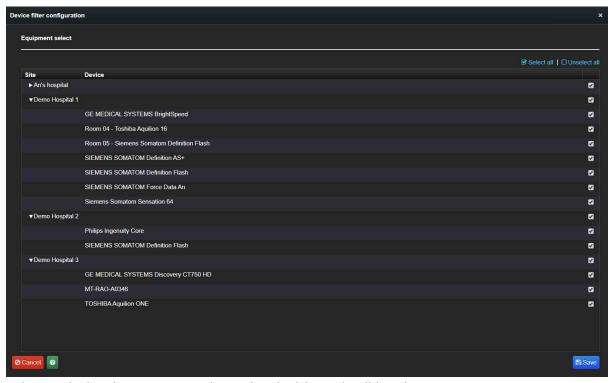
To add some users/teams, the user just needs to add them to the list.





Adding a dashboard to specific users

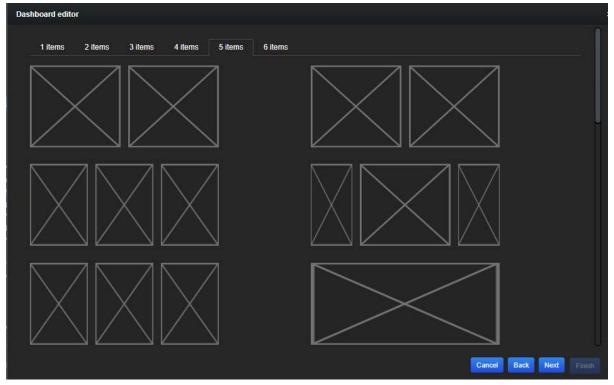
It is also possible to select the devices and/or sites where the dashboard will be shown by clicking on Titler.



Filter with the devices/sites where the dashboard will be shown

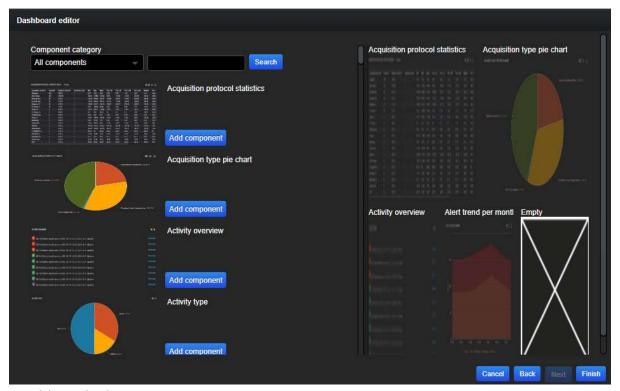
In the next step (dashboard layout) the user needs to select the layout of the dashboard. The dashboard layouts are grouped for each amount of data components per dashboard. With a maximum of 6 items.





Dashboard editor (step 3)

The fourth and last step (data components) of editor wizard contains the data components that can be added to the dashboard. The user can choose the position of the component by selecting the desired place on the dashboard preview at the right of the window, and hereafter selecting the component.



Dashboard editor (step 4)



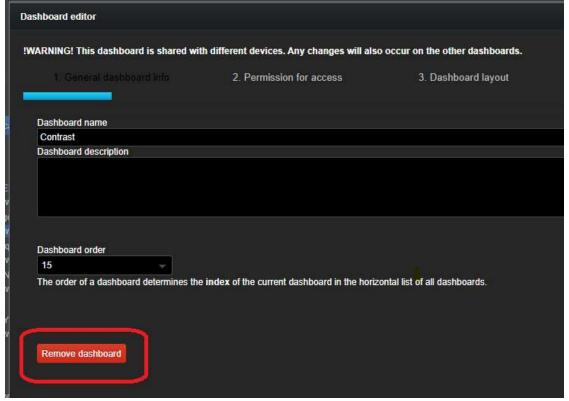
After clicking on *Finish*, a new dashboard is created and will be available for all the devices or/and sites and/or users/teams (when chosen in step 2).

To edit any of the above mentioned aspects of an existing dashboard, the user must select the dashboard and click on *Actions/Edit current dashboard*.



Edit a dashboard

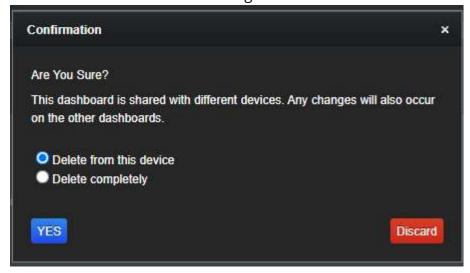
When editing a dashboard, the user can choose also to remove it.



Remove a dashboard



In that case the system will ask if the user would like to remove the dashboard only for that device or for all devices among which the dashboard is shared.

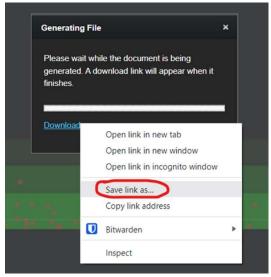


Confirmation for removing a dashboard

For more information, refer to the videos *How to create dashboards*, and *How to delete dashboards* in our online training center.

8.4.1. Import of dashboards

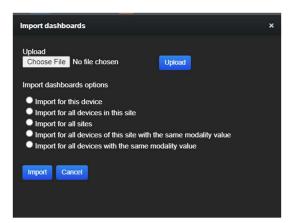
The user has the possibility to import dashboards already created in another device. First, the dashboard must be exported, in *Actions*, in the upper right corner on **Device** level, by clicking on *Export current dashboard*. A download link will appear, and the user can save it by right clicking on *Download* and *Save link as*.



Save a dashboard



In the device chosen to import the dashboard, the user can import it by clicking on *Import dashboard* in *Actions* button. Users can upload the dashboard and choose between 5 import options. The 2 last options enable the user to import the dashboard to one modality type.



Dashboards import option

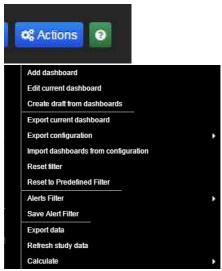
Warning: imported dashboards are public by default, and visible to all DOSE users with 'Device level' access. Access to the dashboard(s) can be restricted after the import is complete by clicking on Actions/Edit current dashboard.

8.4.2. Export

The export button can be found in *Actions* in the upper right corner on **Device** level. The user has the possibility to export data from a certain device on study/series level by clicking on *Export data*. The parameters that will be exported on study and/or series level can be selected by the user. The export scheme can be saved, and preloaded for the next export to save time.

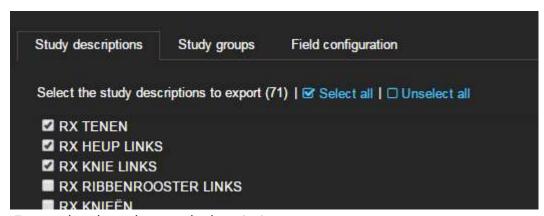


For more information, refer to the video *How to export data on Device Level* in our online training center.



Export data

The user can select the study descriptions or study groups (created in Settings/Study Groups e.g. for compliance purposes) in order to export the specific fields for these studies.



Export data based on study descriptions

In the field "Configuration" the user can select the parameters for export based on:

- Device fields
- Study fields
- Series fields

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Please note that when exporting PATIENT_AGE, PATIENT_AGE_TYPE should also be selected to indicate if the age is in years, months, etc.



Field configuration of the data to be exported

Any filter applied to the dashboards also applies to the exported studies.



Filter configuration

The main parameter units will be taken into account for exporting (e.g. DAP in dGy·cm²).

The data is exportable in CSV or XLSX format, and easy to generate. The export schemes can be personalized and saved under a specific name for quicker exporting in the future.

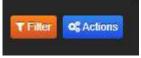


Saving an export scheme for future use

For more information, refer to the video *How to export data on Device Level* in our online training center.

8.4.3. Advanced filter

The advanced filter (found in the upperright corner) allows the users to go more in depth. Filter configurations can also be saved for future use, using the save and load functions, and can be accessed from other devices. The filters are user-specific.



Filter button



User action	Application	Print screen
User selects a device and clicks on <i>Dosimetry overview</i>	The system loads all the dashboards created for the device.	Section and final round has been considered in the section of the
User clicks on the Filter button	The system shows Edit filter and Reset filter dropdown box; when "Edit filter" is selected the user can load a <i>Saved filter</i> , change the <i>Parameter</i> , or add any number of filters using the <i>Filter On</i> dropdown menu.	Filter configuration Saved filters Load Save Action Parameter ward2 ward Filter On Filter On CTDIvol mGy DLP mGy.cm Filter On Effect ive Dose ICRP 60 mSv Number of series # Operator Nam Parameter Scanlength mm
User clicks on the Load button	The system loads the saved filter configuration, showing a dropdown box and minus button for each filter (Age, Gender, etc.) in the selected filter configuration.	Filter configuration Saved filters 4 events DLP mCy cm Filter On Event count 4 Apply only for this device Apply filter Apply for this device Apply filter
User clicks on "minus" button	The system removes filter.	
User clicks on Apply filter button	The system applies the filter only for the current session.	Apply filter
User clicks on the Save button	The system saves the filter configuration.	Load Save Action
User clicks on the Save button next to <i>Saved filter</i>	The Save filter configuration window opens, allowing the user to assign a name (using letters, numbers, underscore) and select a Scope (Global or Modality) for the filter configuration. If the file name already exists, an error message will appear. The Action will always be Save as a new filter for	Saved filters Torso_3events_Age Load Save Action Parameter Effective_Dose ICRP_103.1 m. Save filter configuration Filter On Body Part Examinx Event count Patient Age Scope Global Modality Modality Apply only for this device Apply filter Apply filter



	new filter configurations, or <i>Overwrite</i> for existing filters, allowing the user to edit the configuration.	
User clicks on Action / <i>Set filter as my predefined</i>	The system shows all the previously saved filter configurations.	Filter configuration Saved filters ward Load Save Action Set filter as my predefined Load from History ward ward ward Filter On Patent Age Filter On Patent Age
User clicks on one of the available filters	The system sets the chosen filter as <i>predefined</i> for current user.	
User clicks on Action/Load from History/ 10 most used filters	The system shows the 10 most used filters.	
User clicks on one of the 10 most used filters	The system loads it into the filter configuration.	Saved filters ward Parameter DLP mGy.cm Filter On Patient Age FILTER ON Ward Apply this titer X Cancel
User clicks on Action/Load from Historyl 10 last used filters	The system shows the 10 last used filters.	
User click on one of the 10 last used filters	The system loads it into the filter configuration.	Saved filters Lond Save Action Parameter DLP mGy.cm Filter On Patient Age FILTER ON VALUE Event count 3 Operator Name Operator 10 Patient Age Paediatrics (0-18 years) Apply this filter Cancel



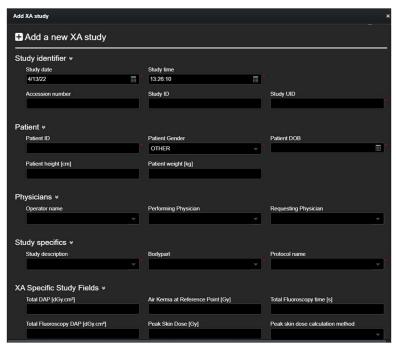
The following filter parameters are available for all modalities:

Type of variable	Name
Events	Event count.
Patient characteristics	Body Mass Index, Body Mass Index Group, Patient Age (D, W, M, Y), Age Group (Adults, various Pediatric groups), Patient Gender (M,F,O), Patient ID, Patient Weight range (kg), Patient Weight Group (kg).
Study	Accession Number, BodyPart Examined, Hide All Zero Dose Studies, Protocol Name, Show Ignored Studies, Study Composition, Study Description, Study Group, Study ID, StudyUID.
Responsible	Contributing Physician Name, Operator Name, Performing Physician Name, Reading Physician Name, Requesting Physician, Requesting Service, Responsible Physician Name, Ward.
Software	Software version.

For more information, refer to the videos *How to filter data and change* parameters and *How to omit studies from the statistics* in our online training center.

8.4.4. Manual entry of an XA study

Users are able to manually add an interventional procedure for an XA device. A new study can be added by clicking on *Actions* on *Dosimetry Overview*, and selecting *Add study*.



Add a new XA study manually



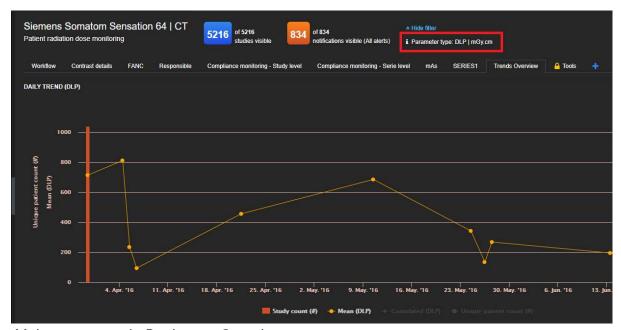
The following fields are mandatory:

- Study date and time
- Study UID
- Patient ID
- Patient date of birth
- Bodypart
- Protocol name or study description
- At least one dose indicator

The feature is available for all users whose role contains the *Data management* functionality.

8.4.5. Dosimetry overview

This data panel shows to the user many analyses based on different parameters.



Main parameter in Dosimetry Overview

The user can choose the main variable by changing the parameter in the advanced filter mentioned before. The available parameters include the following list:

Type of variable	Name	Modality
Dose	DLP, max CTDIvol	CT
	Weighted CTDIvol	CT, CBCT
	DAP	CBCT, CR, DR, DX, RF,
		XA
	DAP (acquisition or fluoroscopy), dose	CR, DR, DX, RF, XA
	at Reference point (total, acquisition	
	or fluoroscopy), Entrance dose,	
	Cumulated REX	



	Peak Skin Dose (PSD)	XA	
	Organ dose, Glandular dose, MGD	MG	
	Effective dose ICRP 103	CT, CBCT, CR, DR, DX,	
		RF, XA, MG	
	Effective dose ICRP 60	CBCT*	
	Effective dose ICRP 128	NM	
Radioactivity	Administered, Administered per kg,	NM	
	Prepared		
Absorption Rate	SAR	MR	
Time	Fluoro time	RF, XA	
	Total Exposure Time	CBCT	
Scan range	Scanlength	CT	
Events	Event count, , Number of sequences	CR, DR, MG, XA	
	Number of series	СТ	
	Number of sequences	MR	

^{*}Effective Dose ICRP60 is also calculated in DOSE for all modalities and can be exported, but it's not included as main parameter in the filter.

The following table shows the units available for each parameter.

Parameters	Units
DLP	mGy.cm
max CTDIvol, Weighted CTDIvol, Entrance	mGy
dose, Organ dose, Glandular dose, MGD	
DAP	dGy·cm², cGy.cm², mGy·cm²,
DAF	Gy·cm ²
DAP from acquisitions, DAP from fluoroscopy	dGy·cm ²
Dose at Reference point (total, acquisition or	Gy
fluoroscopy), Peak Skin Dose	
Effective dose ICRP 103, ICRP 60, ICRP 128	mSv
Radioactivity (administered and prepared)	MBq
Radioactivity per kg (administered)	MBq/kg
SAR	W/kg
Fluoro time	S
Total Exposure time	ms
Scanlength	mm

The data panel consists in many different dashboards, which users can edit or remove as they want. They can even create a new dashboard, as explained above in the first part of this chapter.



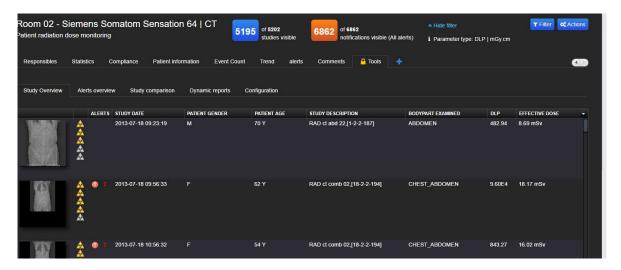
These are <u>some</u> examples out of the possible dashboards:

Name	Description	Modality
Trends	Daily, Monthly, Weekday and hourly trend charts	All
		modalities
Workflow	Workload analysis and Moment evaluation: Mean	All
	dose evaluation per weekday and hour and the	modalities
	usage of a device	
Statistical	Minimum, maximum, mean and percentiles per	All
overview	study description, age groups	modalities
Workload	Hourly average volume chart and hourly dose	All
	spider chart: Charts showing the device actual	modalities
	usage	
Protocol	BodyPart/Protocol distribution and	CR, DR, DX,
distribution	BodyPart/Protocol dose distribution	RF, XA
Analysis	Average dose per thickness and view, Summary of	MG
	most used settings and dose/thickness scatter	
	chart: Analysis based on specific variables for MG	
	(e.g. thickness, type of anode)	
Settings	Breast thickness histogram, compression force	MG
	histogram and image view distribution: Charts	
	based on specific variables for MG (e.g. thickness,	
	compression)	
Reference	Dose-compression chart, with reference to EU and	MG
	BEDRL	
Volumetric breast	Charts and analysis based on breast density values	MG
density	(applicable only when a third party software like	
	Volpara [®] Density™ is available)	
Patient	Patient age/gender distribution	CR, DR. DX.
information		RF. XA
Responsible	Mean parameter per requesting physician &	All
	operator, volume per requesting physician &	modalities
T .	operator: Charts based on human variables	A 11
Tools	See next subparagraph	All
		modalities

Note that statistics are shown only when the asked kind of data is available.



8.4.6. Tools dashboard



This dashboard contains many features which can be used by users:

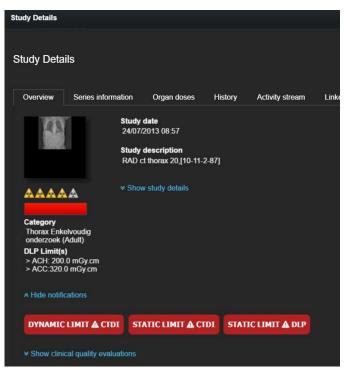
Name	Description
Study overview	This is the list of all the examinations of the selected device. By clicking the Actions button, situated on the lower right part of the dashboard, a user with permissions can edit, remove or disable examinations. The same menu allows to set body part or to recalculate effective doses, too.
Alerts overview and Configuration	This is the list of all the alerts for the device
Study comparison	This feature helps the customer comparing different patient's populations
Dynamic reports	The reporting feature enables a user to create reports that contain the data components as they are shown in the device its dashboards
Configuration	Configuration of dynamic limits and linking of exciting study groups.

8.4.6.1. ALERTS

It is possible to create alerts for examinations which dose is outside acceptable range. A user can create dynamic acceptable and achievable ranges in the $Tools \rightarrow Configuration$ dashboard: here the user can choose the lower and higher percentiles for each group and the date ranges. By clicking on the Action button (upper right part of the page) and then Calculate, the system will automatically mark as alerts all the outliers.

The user will find a clickable alert in the Study details page. There is a differentiation between the static limit on certain parameter (study groups) and the dynamic limits (based on you own configuration). See example:



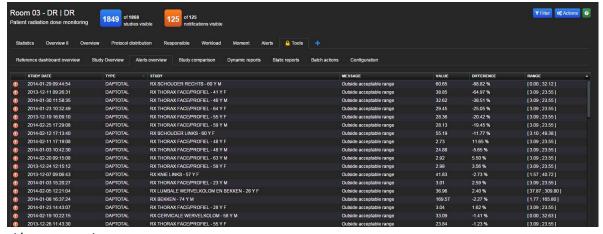


Dynamic and static notifications

The red bar under the thumbnail corresponds to the static limit (with the study group mentioned under "Category") and the notifications below correspond to both dynamic and static limits.

If there is at least one acquisition protocol/series description red/orange, the color on the study details will be red/orange.

The list of all the alerts can be found in the Tools \rightarrow Alerts overview dashboard.



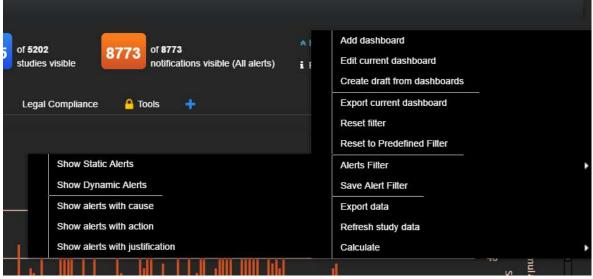
Alerts overview

The same alerts list can be also found by clicking on the orange button with the number of alerts. If the user is only interested in Static or Dynamic alerts, there is a possibility to filter on this parameter via Action button on Device level.



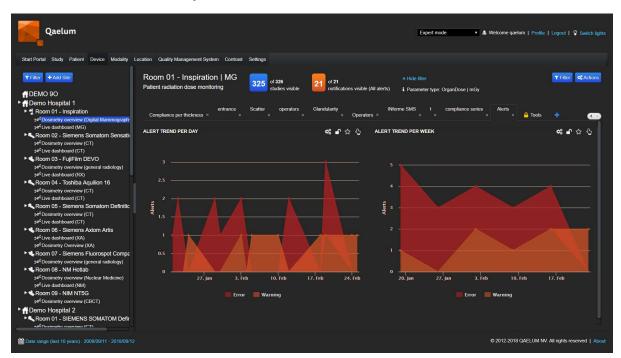


Orange button (all alerts)



Choose static or dynamic alerts

You can also see the alerts trend. This graph is clickable but note that there all 2 types of alert mixed (static and dynamic).



You can also configure the graphs including the alerts trends into a dynamic report (see *Dynamic Reports*).

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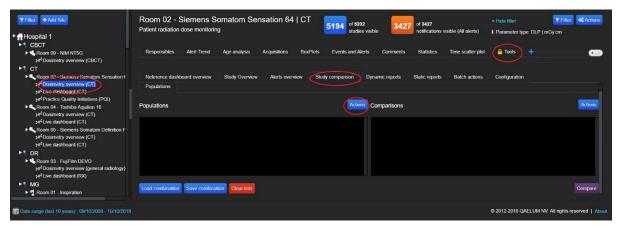


8.4.6.2. STUDY COMPARISON

This feature enables the user to compare groups of studies defined by some kind of population (e.g. age range, sex, body part, examination date...). This comparison can be shown with different tables and charts.

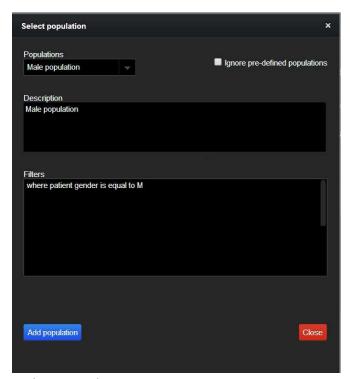
8.4.6.2.1. ADD A POPULATION

The user can select a population by using a preset or by creating a new one: to add a population the user must click on the Action button.



Study comparison

A population is defined with a name and a description.

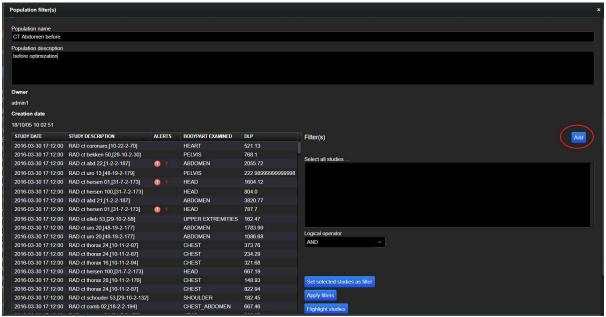


Select population

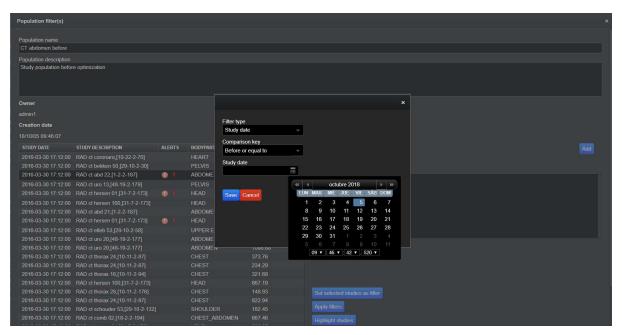
The user can create his own population by setting up specified filters.





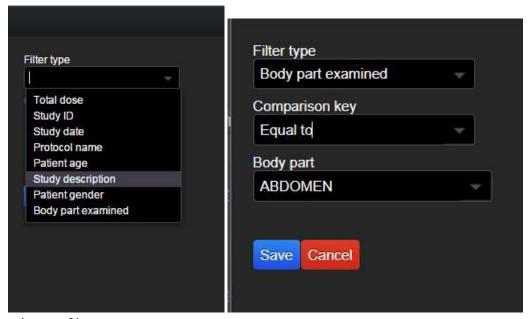


For example, you can select the "Study Date" filter, setting it to "Before or equal to" the desired date for the first population, you can choose "After" for the second population so you can compare 2 populations before and after an optimization.



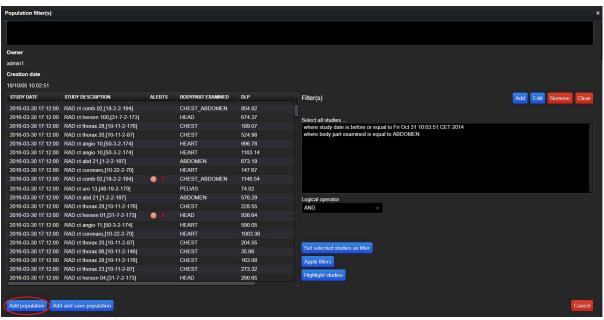


You can also add additional filters; all the possibilities are listed on the screenshot below. For example, if you select "Body Part Examined" and choose ABDOMEN you will have a population that includes all the protocols linked to that body part.



Choose filter

Once you have all the filters you want for the population, you can Add Population.



Population filter

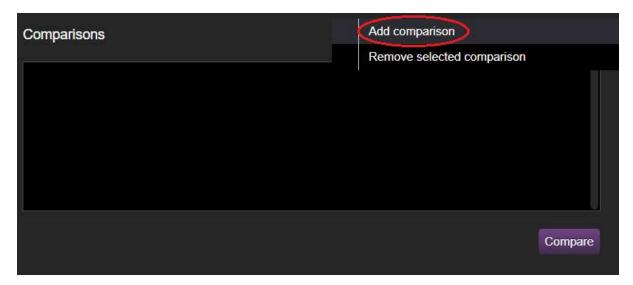
You can follow the same steps to create as many populations as you need.

NOTE: Be careful to click always on "Add population" every time you Edit a population, if you do not do this, the population will be removed.

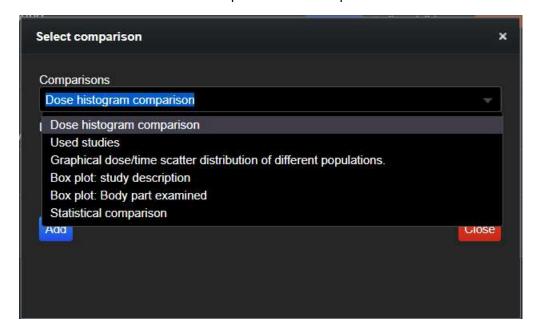


8.4.6.2.2. ADD A COMPARISON

In the same way, the user can choose a tab or a chart to show the comparison. A new comparison can be added by clicking on the Actions button on the Comparisons side.



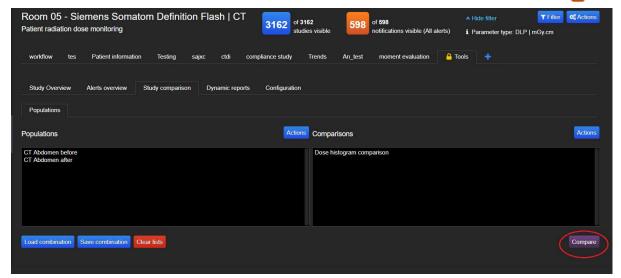
You must choose from a list of predefined comparisons.



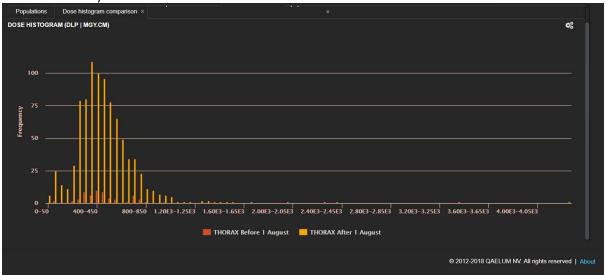
8.4.6.2.3. COMPARE POPULATIONS

After having chosen at least two populations and a comparison, graphs and tables are shown when the user clicks the Compare button.

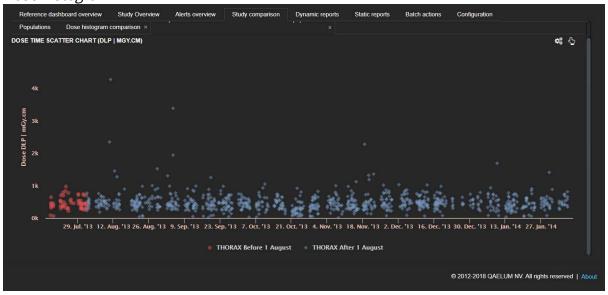




Clink on "Compare" button



Dose histogram



Dose vs Time scatter plot

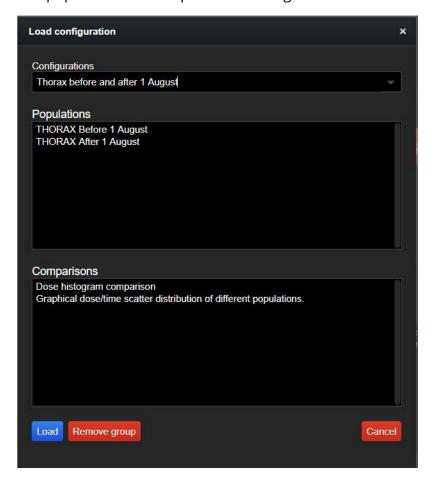


8.4.6.2.4. SAVE AND LOAD COMBINATIONS

A combination of populations and comparisons can be saved by clicking on *Save combination* and indicating a name.



The populations can be preloaded using *Load combination* when needed.



For more information, refer to the video *How to use study comparison on Device Level* in our online training center.

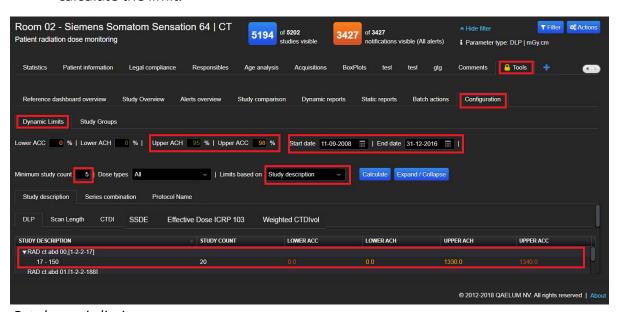


8.4.6.3. DYNAMIC LIMITS

Dynamic limits can be configured based on the lower/upper acceptable (ACC) and lower/upper achievable (ACH) limits using device data collected by DOSE. Percentiles for the calculation of the limits are configurable by users with the *Alerts Management* functionality. Limits can be based on the study description, series combination (acq. protocols) or protocol name. When limit configurations are modified click on *Calculate* for the changes to go into effect.

Dynamic limits are automatically calculated using the data of the selected studies of the local device. They can be recalculated when necessary to allow for comparison with the current local practice. For configuration, follow the steps below:

- Select a device → Dosimetry overview → Tools → Configuration → Dynamic limits
- The following must be entered:
 - o Lower and upper ACH and ACC limits (in percentages).
 - o Date range.
 - o Select whether the limits should be based on the: Study description, series combination or protocol name. In the case of MG, limits can only be recalculated for a **series combination**, please verify this option has been selected. In the future, it will be possible to also choose 'series description' and 'acquisition protocol.'
 - o Minimum study count: minimum amount of a series combination in order to calculate the limit.

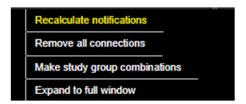


Set dynamic limits

- Click on Calculate
- In the table below, the calculated dynamic limits per study description/series combination/protocol name will be displayed.



From now on, when a new study arrives, the system will check if its dose is above the dynamic levels and create a notification accordingly. If notifications of past studies need to be recalculated, the user must click on **Recalculate notifications** inside the **Actions** button of the "Study groups" tab (located next to the 'Dynamic Limits' tab).



Recalculate notifications

To remove the dynamic limits, all the lower/upper ACH/ACC fields must be to zero and recalculated by clicking on **Calculate**. To remove the associated notifications, click on **Recalculate notifications**.

For more information, refer to the video *How to configure dynamic limits & alerts* in our online training center.

8.4.7. Export/Save data

The system allows users to export or save dashboards' data and charts in different

Export data as	Save a chart as
XLS	PNG
PDF	JPEG
CSV	SVG



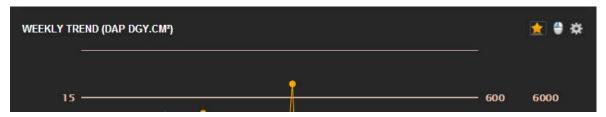
formats.

Export and save dashboard

The user can save a graph or export data by clicking the machinery button which is located in the upper right part of every data component.

8.4.8. Favorite dashboard

To mark a chart or a table as favorite, the user can use the star button in the upper part of every element.



Set graph as favorite



The starred data components will be copied automatically to the personal Start portal: the user can decide to show the same graph or table in the Overview page by right clicking on it.



Add favorite graph to the Overview page (Start Portal)

8.4.9. Compliance monitoring

As many countries have different regulations about Diagnostic Reference Limits (DRLs) and the way to report each device's performances, it is important to choose the legal limits properly. In DOSE, compliance is done with the help of "Study Groups" that have some "Limits" (DRLs) associated to them and to which several kinds of studies can be mapped.

8.4.9.1. COMPLIANCE CONFIGURATION

Compliance configuration consists of 4 steps:

- 1. First the exam type categories ("Study groups") must be defined, where different studies are combined based on different parameters.
- 2. Then the DRL version is defined, indicating which limit to apply depending on the date range.
- 3. After that, "Limits" are defined, taking into account the version name.
- 4. Finally, the studies are mapped to the Study Groups on Device level.

8.4.9.1.1. STUDY GROUPS

The study groups are defined in Settings → Study Groups.

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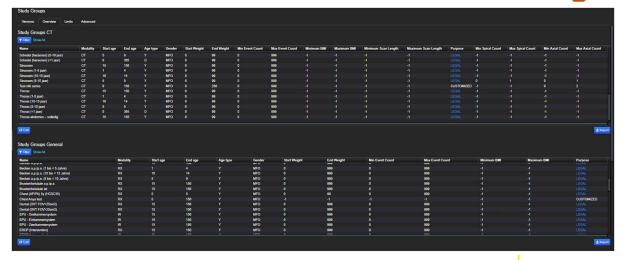


There are 4 sections: Study Groups CT, Study Groups General (RX, IR, CBCT, NM), Study Groups MG, CT SSDE Study Groups.

Each category has the following properties:

- Group name
- Modality (CT / MG / RX / IR / NM / CBCT)
- Start age (min age of the category)
- End age (max age of the category)
- Age type (D / Y) (Day/Year)
- Gender (M / F / MF / MFO / O)
- Start weight (CT, General) / Min Breast thickness (MG)
- End weight (CT, General)/ Max Breast thickness (MG)
- Min event count (min number of series)
- Max event count (max number of series)
- Minimum BMI (min Body Max Index)
- Maximum BMI (max Body Mass Index)
- Minimum Scan Length (CT)
- Maximum Scan Length (CT)
- Minimum spiral count (CT)
- Maximum spiral count (CT)
- Minimum axial count (CT)
- Maximum axial count (CT)
- Start Eff. Diameter (SSDE)
- End Eff. Diameter (SSDE)
- Start WED (SSDE)
- End WED (SSDE)
- Start LAT Thickness (SSDE)
- End LAT Thickness (SSDE)
- Purpose (Legal/Customized)



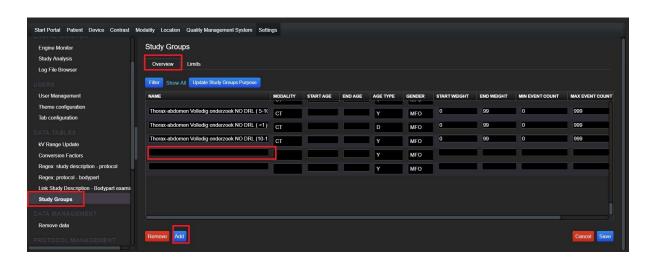


Configure study groups

Note: when a parameter is set to -1 it is not taken into account in defining the study group. By setting the value to an integer value above zero, the field is taken into account. For example for CT study groups, setting Min Spiral Count=2 and Max Spiral Count=4 means that only studies which contain either 2, 3 or 4 spiral series are included in this study group. Setting Min Spiral Count=-1 and Max Spiral Count=-1 means that studies are included in this study group independently from how many spiral series are present.

A new study group can be added in **Settings** \rightarrow **Study Groups** \rightarrow **Overview**.

- a. Select the modality tab and click on Edit Add.
- b. An additional empty line is added below.
- c. Fill in all the required fields (name, modality, age etc.)
- d. The purpose can be LEGAL or CUSTOMIZED.
- e. Click on Save.



A study group can be edited in **Settings** → **Study Groups** → **Overview**.

- a. Select the modality tab and click on Edit
- b. Edit the value which requires an edit



- c. Click on Save to commit the changes.
- d. If the MG modality is selected, it will appear in the **Study Groups MG** list. In that case, click on Edit and modify **Max. Breast Thickness** to indicate the desired range.

A study group can be removed in **Settings** \rightarrow **Study Groups** \rightarrow **Overview**.

- e. Select the modality tab and click on Edit
- f. Click on the Study Group line and this will be highlighted
- g. Then click on Remove
- h. Click on Save.

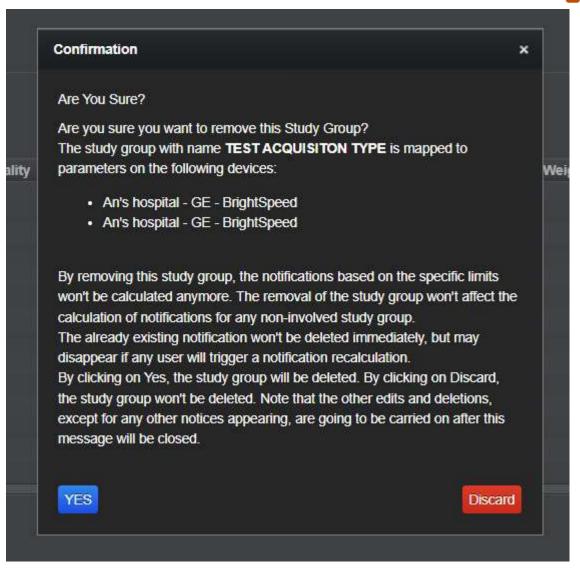


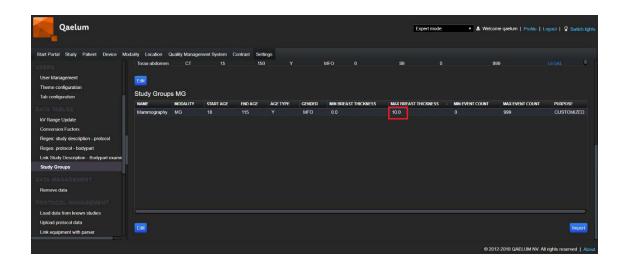
Deleting a Study Group which is actively used may result in missing notifications. For this reason, the deletion of Study Groups is regulated in DOSE.

When a Study Group gets marked for deletion:

- If the Study Group is not mapped to any device, then it is considered as inactive and it gets deleted
- If the Study Group is mapped to one or more devices, then it is considered as active and the user is asked to confirm the deletion. For each Study Group, the user is provided with the list of mapped devices and with a description of the consequences of the deletion



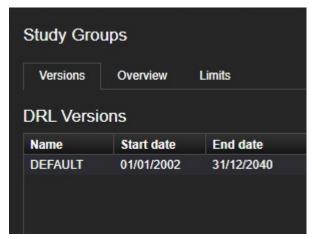






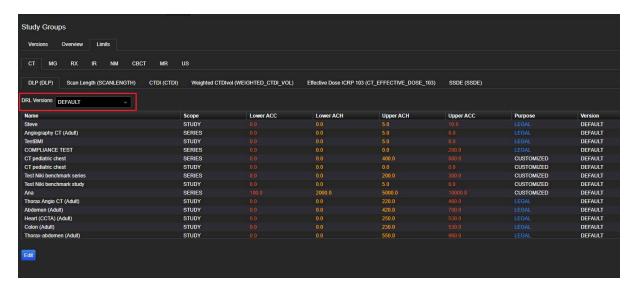
8.4.9.1.2. VERSIONS

Diagnostic reference levels (DRLs) are supposed to change throughout time; therefore, studies should be evaluated based on the applicable and most up-to-date DRLs. For this reason we have in DOSE a way to have a track of the different versions of DRL's.



DRL versions

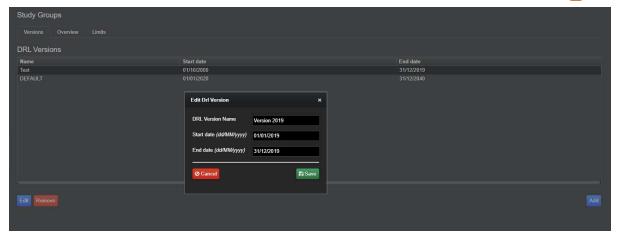
It is possible to filter by version on the Limits table by using a dropdown menu.



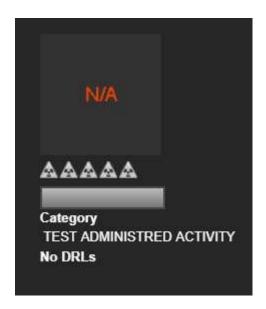
When calculating the notifications, the date range is therefore taken into account.

To add a new version, go to **Settings** \rightarrow **Study Groups** \rightarrow **Versions**. Here you can click on "**Add**" to write a version name and define the date range.





Note: date range of the versions cannot overlap; however, it is possible to have date ranges without any version applicable. When this is the case, a message is displayed in "Study Details" stating that the study is linked to a Study Group (Category) but it has not limits applicable:



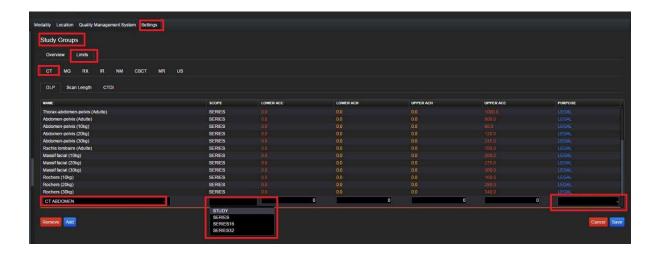
8.4.9.1.3. LIMITS

After you have defined the different groups and versions, you can assign for each parameter type static limits to the groups. To do so:

- a. Go to Limits
- b. Choose the right modality (CT, RX, MG...) and parameter (CTDI, DAP, MGD...) for the limit configuration.
- c. Click on Edit Add
- d. In the dropdown menu you can choose customized made study group and fill in the corresponding limits.
- e. It is possible to create a study group with the limits based on SERIES/STUDY. You can even specify SERIES16 (cm phantom) or SERIES32 (cm phantom) only for CT of course or in general all SERIES.



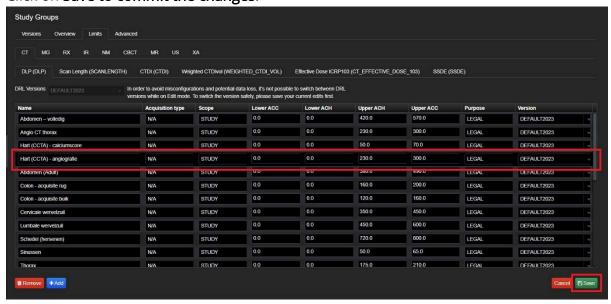
NOTE: For Mammography, it only makes sense to create a study group with the limits scoped on **SERIES**. The other options appear (STUDY, SERIES16, SERIES32) but they are not suitable since DRLs for mammography are defined only on SERIES level.



f. For limits with scope SERIES, the Acquisition Type (Helical, Spiral...) can be defined. In order to use this feature, a list of acquisition types must be defined first. Refer to <u>Advanced</u> for more details.

A study group limit can be edited in **Settings** → **Study Groups** → **Overview**.

- a. Select the modality tab and click on Edit
- b. Edit the value which requires an edit
- c. Click on Save to commit the changes.

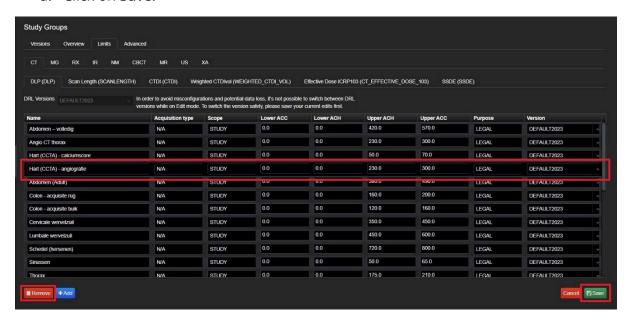


A study group limit can be removed in **Settings** → **Study Groups** → **Limits**.

a. Select the modality tab and click on Edit



- b. Click on the Study Group Limit line and this will be highlighted
- c. Then click on Remove
- d. Click on Save.

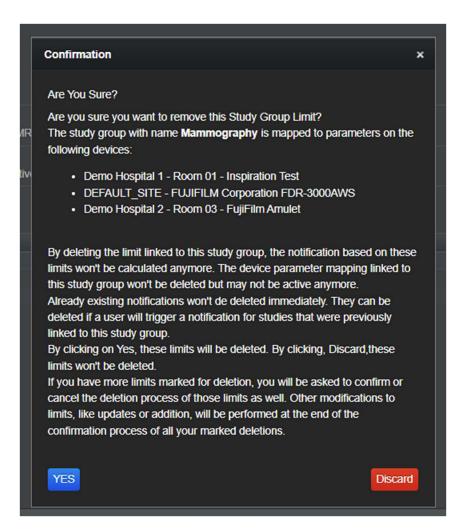


Deleting a Study Group Limit which is actively used may result in missing notifications. For this reason, the deletion of Study Group Limits is regulated in DOSE.

When a Study Group Limit gets marked for deletion:

- If the Study Group is not mapped to any device, then it is considered as inactive and it gets deleted
- If the Study Group is mapped to one or more devices, then it is considered as active and the user is asked to confirm the deletion. For each Study Group, the user is provided with the list of mapped devices and with a description of the consequences of the deletion





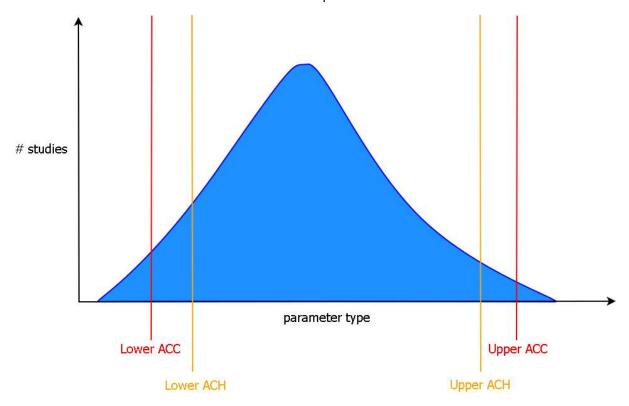
The following parameter types can be assigned for each modality:

СТ	MG	RX	IR	NM	CBCT
DLP	OrganDos	DAP	DAP	Radioactivity	DAP
ScanLengt	е	EntranceDose	EntranceDose	(administered	EffDose10
h	MGD	FluoroscopyTim	FluoroscopyTim)	3
CTDImax	EffDose10	е	е	Radioactivity	
wCTDIvol	3	EffDose103	Event count	(prepared)	
EffDose10			EffDose 103	EffDose	
3			PSD	ICRP128	
SSDE			Dose at ref	Radioactivity	
			point	per kg	
				(administered	
)	

If studies are outside the acceptable (ACC) limits this should be considered as critical for the specific category and parameter type. If the studies are outside the achievable (ACH) limits and still below the ACC limits, this should be considered as a warning. If only one upper limit is defined, we assign the same value to ACH and ACC and if no lower limit is



applicable, we assign the value 0. All the studies between the lower and upper ACH boundaries are considered to have a normal parameter value.



Lower/higher ACC/ACH

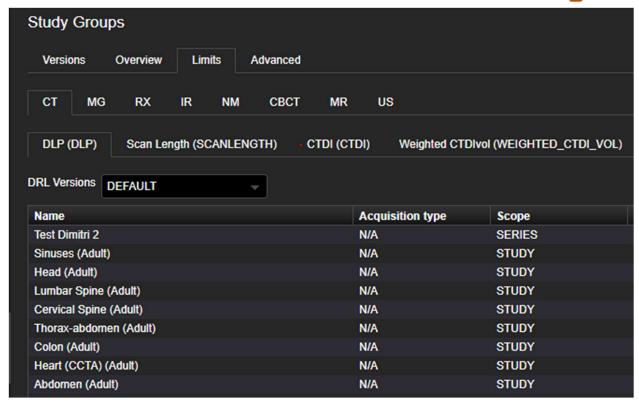


Set limits for the study groups

8.4.9.1.4. ADVANCED

Constant angle acquisition notifications can be avoided by filtering by "Acquisition type". This filter is present in the definition of limits since different acquisition types may have different DRLs.

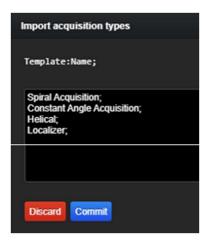




In order to use this feature, a list of acquisition types must be defined first. Qaelum provides a list with the most typical cases, but the user may change this at will. To do so, go to Settings/Study Groups/Advanced and click on Import.

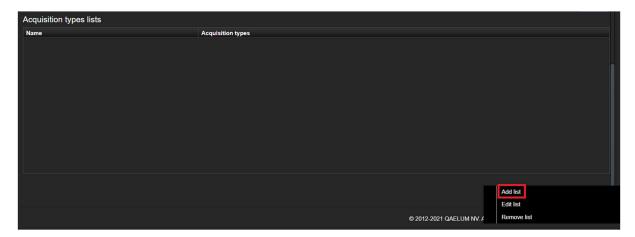


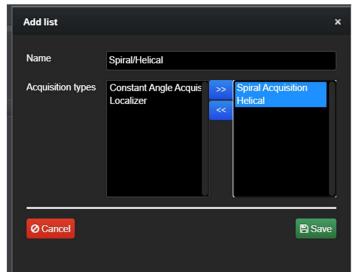
Indicate the list of acquisition types that should be included in some rules:



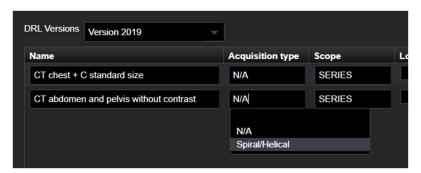


Then, a list of certain values must be created by in **Acquisition types lists**, by clicking on **Actions/Add List**:



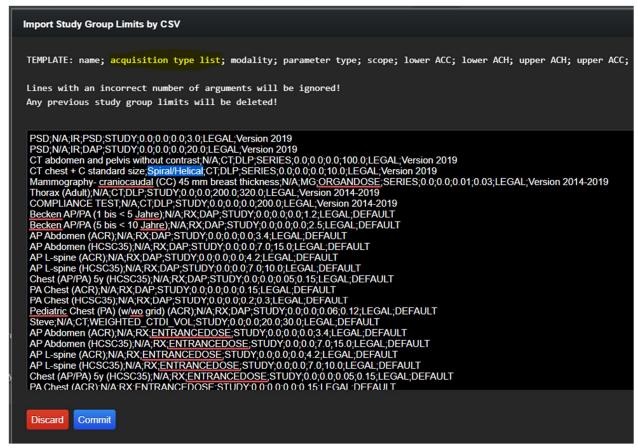


If the Limits are edited, the user will see the following dropdown menu:



If the "Import" option is used, an existing acquisition type list must be indicated.





This way, if a limit is defined for "helical" acquisitions only, and there are two series with the same name, one helical and one topogram, only the helical acquisition will be taken into account.

8.4.9.1.5. COMPLIANCE MAPPING

Once the study group and its corresponding limits are created, studies from the device can be linked to the user defined study groups. Several connection options are possible:

- o At **study** level (groups with limit scope STUDY or SERIES can be selected):
 - Study description
 - Series combination
 - Protocol name
 - Radiopharmaceutical (only for NM)
- At series level (groups with limit scope SERIES can be selected):
 - Acquisition protocol
 - Series description
 - Study Description Series Description (combination)
 - Study Description Acquisition Protocol (combination)

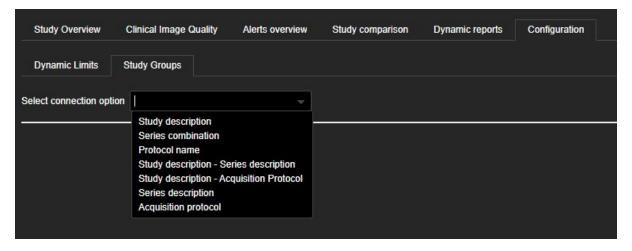
The following table presents a summary and explanation of these rules:



DRL SCOPE Linked parameter	STUDY	SERIES (all) SERIES32 (CT) SERIES 16 (CT)
STUDY DESCRIPTION PROTOCOL NAME SERIES COMBINATION RADIOPHARMACEUTICAL (NM)	√	All series of the study will be considered as belonging to the study group and checked against the series DRL
SERIES DESCRIPTION ACQUISITION PROTOCOL STUDY-SERIES DESCRIPTION STUDY DESC. – ACQ. PROTOCOL	X Not possible as it would lead to multiple repeated notifications	√

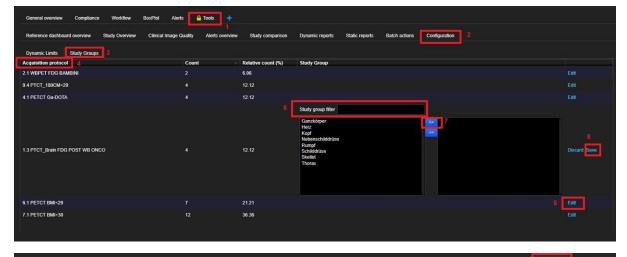
To perform the mapping, access **Dosimetry Overview** (Device level) ⇒ **Tools** ⇒ **Configuration** ⇒ **Study Groups**.

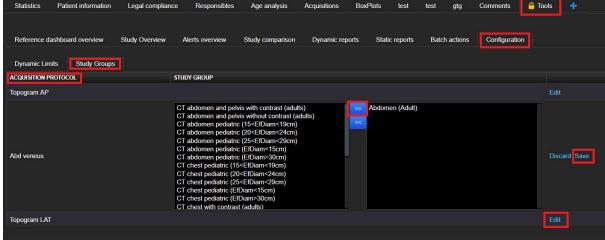
The desired connection option from the list above can be selected from the dropdown menu.



For example, if "Acquisition protocol" is selected (only possible if the scope of the study group(s) is SERIES), click on **Edit** (5), select the desired study group, click on the >> (7) button to select the study group(s) and click on **Save** (8). Each acquisition protocol name can be linked to as many study groups as needed (e.g. adult and pediatric, encompassing different ranges of BMI, event count etc.), as long as the study group population is not exactly the same (as defined in Settings/Study Groups/Overview). The "Study group filter" (6) can be used to filter out specific study groups. Repeat the steps to map as many device acquisition protocols as needed.



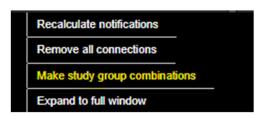




NOTE: Only one connection option can be mapped for each study group, i.e. if a study group is mapped using the "acquisition protocol" connection option, the same group cannot also be mapped using the "series description" connection.

The data displayed to the user during study group mapping corresponds to the selected device and date range.

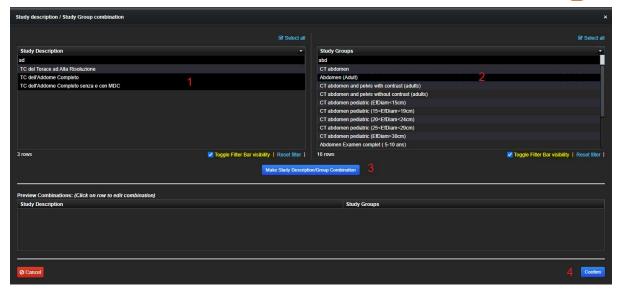
Alternatively the *Make study group combinations* tool in *Actions* can be used:



Actions menu

Filters can be used (*Toggle filter bar visibility*) to find the desired studies and study groups and make several mappings at the same time.





Make Study description/Study Group combinations

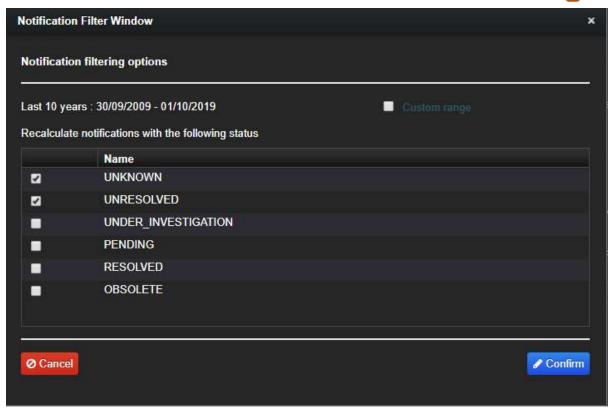
After the study groups have been mapped, alerts can be recalculated by clicking on **Actions** ⇒ **Recalculate notifications**.



Recalculate notifications

NOTE: Every time the user recalculates notifications, they will be prompted to select the notification types to be recalculated based on notification resolution type (e.g. "unknown", "unresolved", etc.). This way when notifications are recalculated the resolution will not be set back to "unresolved".





The default recalculation settings (deletion and data migration) can be configured in Settings. See Notification Recalculation Settings for more information. Please be aware that recalculation of notifications may lead to lose some preexisting notifications if the recalculation configuration has not been carefully done.

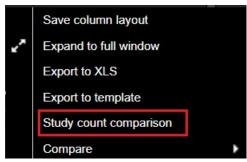
8.4.9.1.6. COMPLIANCE MONITORING TABLE

If the studies are linked to a category, we can add the **compliance monitoring** widget (a dashboard on device level) in order to evaluate the defined categories with the assigned studies. We can choose between the overview on study level or series level (acquisition protocol, series description, combinations between study description and series information). The compliance table is sorted automatically from maximum to minimum amount of studies per study group. The comparison column at the right side shows if the category is between the earlier defined limits.



Each record in the compliance monitoring has now two "traffic light" statuses: one which is conform with the date range and another one conforms with date range and last (default 100) studies ready for export to a template. The user can adjust it via changing the "Study count comparison" in the gear button. Here you can also save the column layout.





A Sparkline give the customer a sense in what direction (trend) the dose is going to. This Sparkline is showing the trend of the full date range with a resolution of 30 days, combined inside the traffic lights.

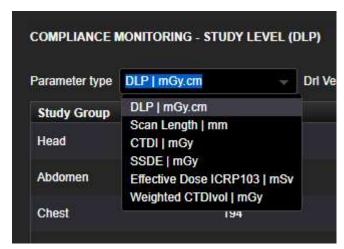
Change study count comparison

- RED the studies are outside the acceptable limits
- ORANGE the studies are outside the achievable but between the acceptable limits
- GREEN the studies are between the achievable limits

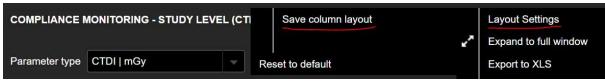


Compliance monitoring based on study level

The parameter type (DLP, CTDI, DAP, etc) can be changed in the dropdown menu and the default/favorite one can be saved by clicking on the engine button on the upper-right part and selecting *Layout Settings/Save column layout*.



Select parameter type



Save favorite parameter type

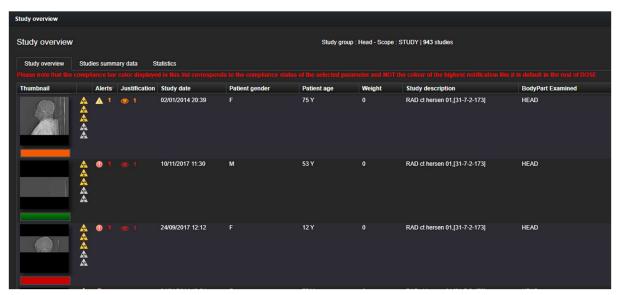


The DRL version against which the studies are being compared can also be selected from the dropdown menu for *Drl version*.



Select the DRL version

If a category is double clicked in the compliance table, studies assigned to the category can be viewed.



Studies assigned to compliance category

NOTE: the compliance bar color displayed in this list corresponds to the compliance status of the selected parameter and NOT the color of the highest notification, as default in the rest of DOSE.

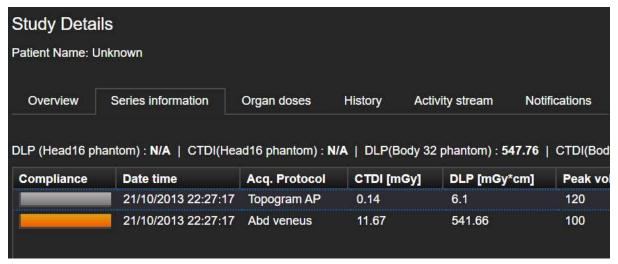


Details of studies not assigned to a study group

At top, an indication is made of the amount of studies which are not assigned to a study group yet and which studies are not applicable to a certain limit. Clicking on the indications gives an overview of the studies which are not assigned yet or don't correspond to a certain limit. There is the posibility to exclude the free, stationary and/or series with small scan length (<20mm) out of the compliance statistics table, to do so, click on the blue "i" button and uncheck the boxes.



When the compliance is configured to SERIES level, you must use the Compliance monitoring table at series level and when clicking on a study, color bars will appear also at series level. In this case, the color bar at study level will be the one with the highest severity (e.g. 2 series, one orange and one red, color at study level will be red).



Color bars at series information

NOTE: In general the compliance bar will correspond to the most severe color of all the parameters mapped to that series. For example, if there is an orange alert for DLP and a red alert for CTDI, then the color bar of the series will be red. The only exception to this is opening studies from the compliance monitoring table, in this case the color of the parameter selected in **Parameter type** will prevail.

There are different user rights concerning Compliance. A user only with *Compliance* rights is able to visualize the compliance table, but not edit its configuration (mapping). *Compliance Management* rights are needed to edit the configuration.

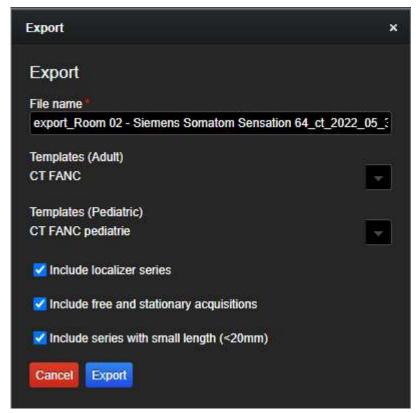
The *Export to template* option within the gear button can be used to export the compliance table to one of the predefined legal export templates.



Export to template



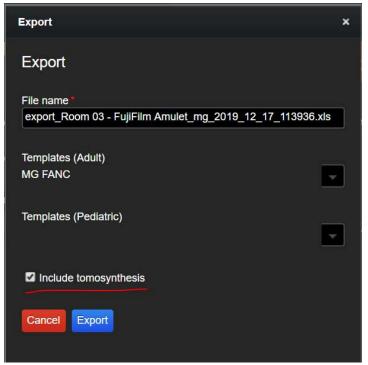
All the available templates can be found here (e.g. Belgian, Polish, Danish, Swedish) and the export filename can be changed. For CT, localizers (topogram), free and stationary acquisitions and short length acquisitions can be excluded from the export. Desired adult and pediatric group templates can be selected.



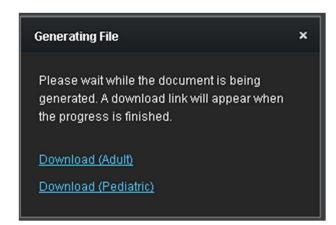
Export in legal template

When exporting the mammography compliance to the Belgian template, tomosynthesis can be included. Tomosynthesis series are currently identified as containing "tomo" in their series description.





Include tomosynthesis series in export to legal template



Generating file

The result will be an excel file where each category is defined in a worksheet. For every category, the studies are sorted ascending by study date.

For more information, refer to the videos in the *DOSE Advanced Training/Legal compliance* section of our online training center.

8.4.10. Optimization Gain Prediction widget

Among many other charts, tables and widgets, there is a particular one whose working needs some explanation in this manual. It is the "Optimization gain predictor", that can be added in any CT dashboard.

This widget evaluates the impact on DLP when CTDI or scanlength are reduced for a particular type of exams (based on bodypart/study description/etc) in an optimization procedure.

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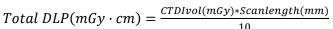


For example: by selecting CTDI 5% (relative) and scanlength 10mm absolute you can see how the total doses and the dose of each study description or body part would change (in DLP) if you lowered the CTDI of each case by 5% and/or shortened the scanlength of an examination.



You can fill one of the fields with "0" to simulate variations only on CTDI or scanlength. The widget takes into account only helical/axial acquisitions (to avoid having localizers and stationary acquisitions affecting the results).

The change in DLP is calculated for all axial/helical acquisitions for the selected category (e.g. bodypart, study description, etc).



Analysis results					
Total dos	se DLP (mGy*cm)	Total scanlength (mm)			
Before optimization	3692538	2925934			
After optimization	3333322	2823392			
Gain (absolute)	359216.779	102542.000			
Gain (relative)	9.728 %	3.505 %			
Category	Count (#)	Relative count (%)	Total DLP (mGy*cm)	Total Scanlength (mm)	Gain Total (in DLP %)
RAD ct hersen 01,[31-7-2-173]	945	18 %	5.27E5	1.58E5	16 %
RAD ct comb 02,[18-2-2-194]	848	16 %	7.02E5	7.39E5	7 %
RAD ct abd 22,[1-2-2-187]	309	6 %	1.88E5	1.92E5	8 %
RAD ct comb 05,[18-2-2-194]	229	4 %	1.88E5	1.95E5	7 %
RAD ct thorax 24,[10-11-2-87]	193	4 %	6.24E4	7.05E4	8 %
RAD ct thorax 23,[10-11-2-87]	190	4 %	8.27E4	1.41E5	8 %

All those values are summed up and displayed above under "Total Dose DLP (mGy*cm)" for before and after the optimization. The Gain (absolute) is calculated by the difference of "Before-After", the Gain (relative) is calculated as follows:

$$\textit{DLP Gain (relative)} = \frac{\textit{Total dose DLP before} - \textit{Total dose DLP after}}{\textit{Total dose before}} * 100(\%)$$

The same logic applies to the gain in scanlength.

8.5. Optional features

These tools are enabled depending on customer's licenses agreements, and they can require extra connections and / or data provided by the customer.

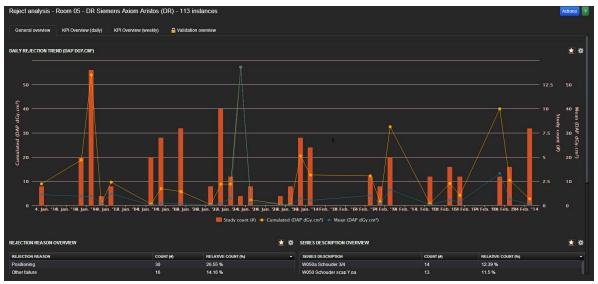
8.5.1. Reject analysis

This tool is designed to help users reviewing the errors that lead to rejected images in general radiology and can be added as data panel to this kind of devices. This feature requires direct connection to the device, so that the system receives all the images performed by it.



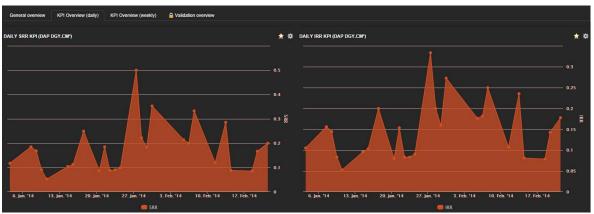
Rejected analysis data panel consists of 4 preset dashboards, and others can be added as for the Dosimetry overview data panel.

The general overview contains one chart for daily rejection trend and the lists for reject reasons and series descriptions.



Reject analysis general overview

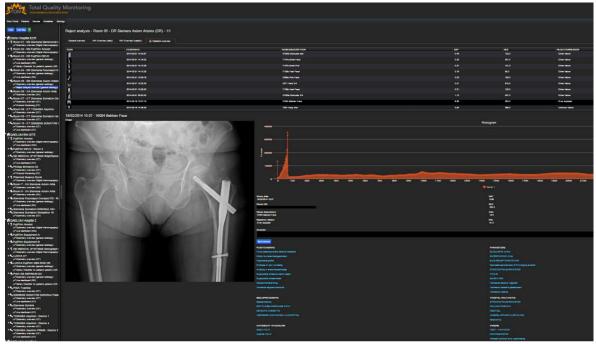
The KPI overview tabs show trends in terms of Study Related Rejection Rate (SRR), Instance related Rejection Rate (IRR), Dose related Rejection Rate (DRR) and Effective dose related Rejection Rate (ERR).



Daily SSR Daily IRR



Validation overview is the only tab which cannot be edited. In this dashboard, the rejected image and its histogram are shown, so that the user can fill in the reason for it to be



rejected.

Validation overview of the rejected analysis

8.5.2. Contrast Administration Monitoring

When detailed contrast media data is available, it is displayed in the tab of interventional radiology or CT Study details page. If the data is available, patients' length/weight, the injected volume (ml), peak flow (ml/s) and peak pressure (Pa) can be analyzed.

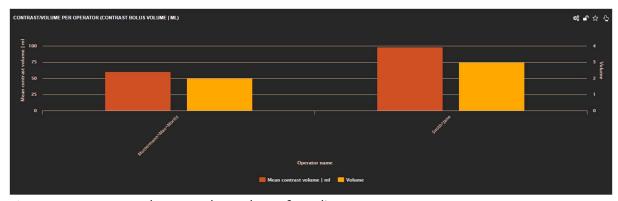


Contrast administration monitoring

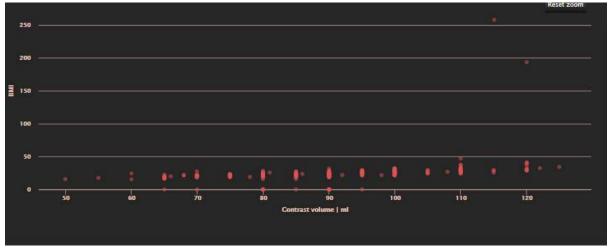
Additionally, direct integration with the contrast injectors from Ulrich Medical and Nemoto is possible. These injectors will appear as different "devices" of the CONTRAST modality. Integration with other vendors may be developed upon request.



Among the available charts are the injected volume per operator (can be study specific), daily/weekly/monthly trends for the used contrast volume, scatter plots of contrast volume versus patient age, weight or BMI and pie charts for contrast/operator name.



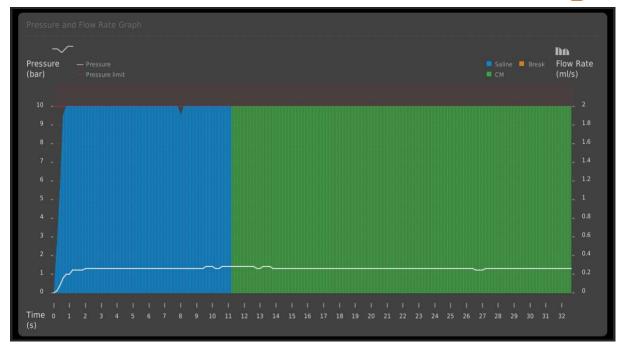
Average contrast volume and number of studies per operator



BMI vs contrast volume

Furthermore, for Ulrich injectors, Ulrich reports are integrated into the study details:





Pressure and flow rate graph



Injection sequence graph

8.5.3. Virtual Dosimetry

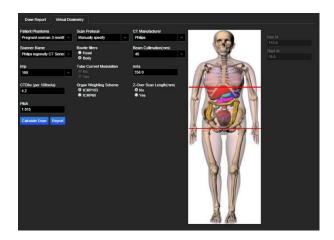
8.5.3.1. VIRTUAL DOSE FOR CT

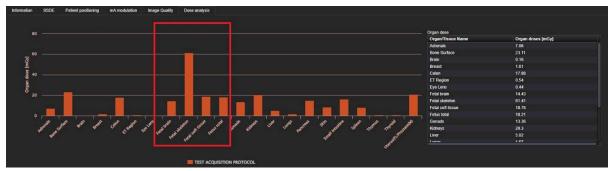
In the 'Virtual Dose' tab, within 'Dose analysis' that appears when the user clicks on a CT series, phantoms and scan parameters can be changed to recalculate organ doses. By default, the system selects the appropriate phantom for the particular patient, the scanner used for the examination and parameters like kVp, mAs, collimation and pitch. The scan length is also shown as a red area on the phantom, and is automatically taken from the series information, together with the body part. If the bowtie filter type (head or body) is omitted, the head filter is assumed for scans of the head and neck region, and the body filter is assumed for all other regions.

The user can select one of the phantoms from the library (including adult/paediatric, normal weight/overweight/obese I and II/morbidly obese, male/female and pregnant woman in three gestational stages 3m-6m-9m). Then, select an automatic body region or manually modify the scanned area on the phantom. The software includes all vendors and many scanners. When all the fields are filled in, the user can click on the "Calculate Dose" button, and resulting organ doses will be displayed in the Dose Analysis tab.



For example, for a pregnant woman, fetal doses can be calculated and exported as a report to provide to gynaecologists.





Simulation results of organ doses

- The scan length of the series is taken into account together with the body part, which is prerequisite. The user must check if the boundaries that are shown on the phantoms are as scanned on the patient, as this is performed automatically, and may have differences from the actual scanning of the patient. If there is tube current modulation, then the reconstructed volume is sent as scan length (and not the DICOM value) to match the tube current modulation entries. Patient height is included in the parameters, to better match the scan length on the patient. If this is not available, the default height of each phantom is shown.
- Tube current modulation (TCM) is taken into account in Virtual Dose calculations if it is available for the patient. In this case, option yes/no for TCM is open in the Virtual Dose input parameters and the user can check the doses in both cases. As the dosimetric calculation will be affected by the TCM, the user should ensure that the display on the phantom matches the scanned area on the patient. The user must be careful when sending scan length information, because the DICOM value for scan length includes the overscan, while the reconstructed volume does not. The comparison of doses should be performed on the same scan length.



Please note that the dose values are indicative and should be evaluated by an expert (medical physicist or radiation protection expert).

For more information, refer to the videos *All about Virtual Dose CT by Qaelum in 30 seconds!* and *How to access Virtual Dose for computer tomography* in our online training center.

8.5.3.2. VIRTUAL DOSE FOR IR

As interventional procedures usually consist of multiple irradiation events, it is not easy to perform the calculation manually. This task is facilitated in DOSE, as the integration of Virtual Dose for Interventional Radiology (VDIR) allows the automatic calculation without the need for manual input by the user.

The calculation of organ doses in VDIR requires fields that are either general for the whole study or they are specific to each irradiation event. Some of the necessary fields, like DAP, tube voltage, primary and secondary angle etc are extracted by the RDSR. There are however some fields that are not included in the RDSR, like the source to skin distance, and these fields are calculated by the in-house Peak Skin Dose module.

The phantom is selected based on age and gender for pediatric patients and age, gender and size (height/weight) for adult patients. Please note that patient height and weight are mandatory fields for the calculation of virtual dose IR for all age groups.

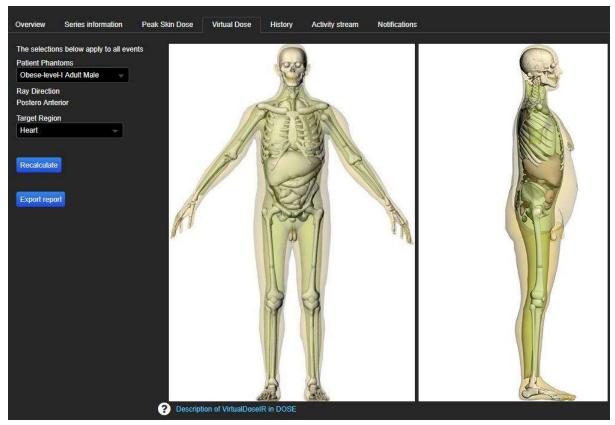
The main dosimetric parameter that is sent as input to VDIR is the DAP. The direction of the beam is defined for each irradiation event by the primary and secondary angle. The center of irradiation is defined by the target organ, which is a generic field applied to the whole study

8.5.3.2.1. VISUALIZATION

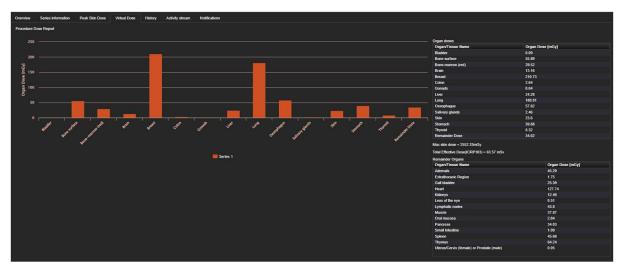
calculation.

In a separate tab on study details from a XA study, the user can see the calculated effective and organ dose values, as well as the selected phantom and the target area.





The automatically selected phantom is the Obese-I Adult Male and the target region "Heart".



The dose values are displayed in a chart and in a table.

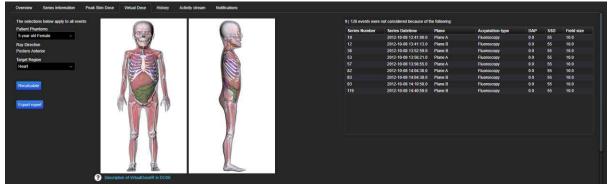
The user can perform simulations by changing the selected phantom or the target region. This can be used to evaluate the effect on a pregnant patient or if initially the size of the patient is not known.

8.5.3.2.2. MISSING FIELDS

In case some of the necessary fields are not included in the RDSR or cannot be calculated, then the calculation is performed without these irradiation events. In this case, the events



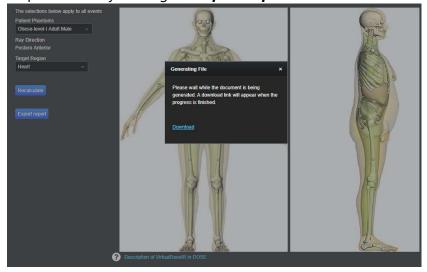
that were not considered for the calculation are displayed in a table. This way, the user is always informed about which dose percentage was not included in the calculation.



Example of a case where the DAP was zero in the RDSR for some irradiation events. In this case, these events were not included in the calculation. The user is notified by a window on the right side, where each event and the corresponding fields are reported

8.5.3.2.3. REPORTING

The user can export all the calculated values and the settings/parameters in excel. This can be performed by clicking the *Export Report* button.

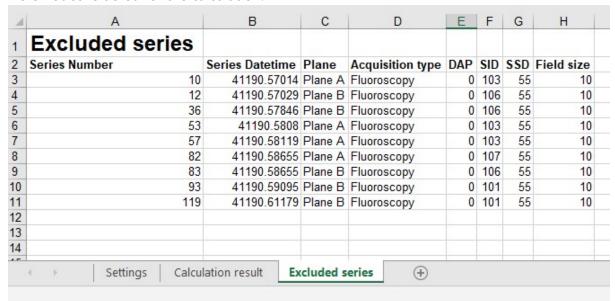






Example of a generated report. The user can see the calculation but also the settings that were considered for the calculation

In the case of missing fields, an additional excel sheet includes the irradiation events that were not considered for the calculation.



An additional sheet in the exported report shows the irradiation events (series) that were not included in the calculation.

For more information, refer to the video *All about Virtual Dose IR by Qaelum in 30 seconds!* in our online training center.



8.5.4. Global Noise Level

As it is important for medical imaging to combine dose information together with a satisfactory image quality, the automatic calculation of an image quality index as described in the literature has been implemented in DOSE. In particular, the selected image quality parameter is a noise index called Global Noise Level (GNL), published in well-known journals. The purpose of this feature is to evaluate image quality in combination with other parameters, like dose, patient size and positioning, and provide all the important information for identification of outliers and optimization.

8.5.4.1. CALCULATION

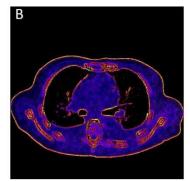
The calculation methodology of GNL is described in the literature by Christianson et al. (AJR. 2015) and Ria et al. (Med Phys. 2017):

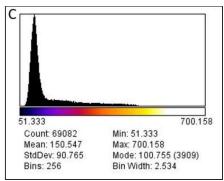
- 1. First the images are segmented into tissue types according to the Hounsfield Unit (HU) values:
 - a. Soft tissue
 - b. Bone
 - c. Air

Soft tissue and fat were merged by extending the considered HU range (Ria et al, Med Phys 2017).

- 2. For each pixel of a tissue type, the standard deviation is calculated in a central kernel. This results in a noise map with the standard deviation (in HU) of the surrounding kernel for each tissue pixel (Figure B).
- 3. A histogram of the tissue noise map (with the standard deviations) is generated. The global noise of that slice is determined as the mode of the histogram peak (Figure 1C).







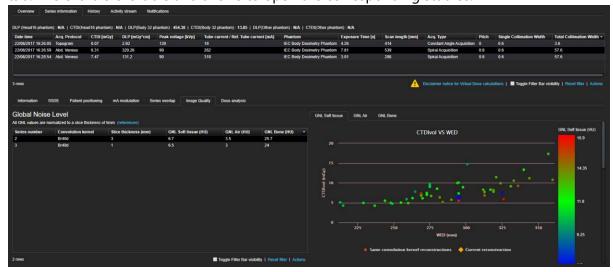
Schematic overview of the noise detection algorithm from Christianson et al. (AJR 2015). A) Original Image, B) Noise map of soft tissue, C) Histogram of soft tissue noise map.

The calculation is performed for every convolution kernel and every slice thickness of each acquisition. These values are then normalized to a 5mm slice thickness, as described in Ria et al (AJR 2019).



8.5.4.2. VISUALIZATION

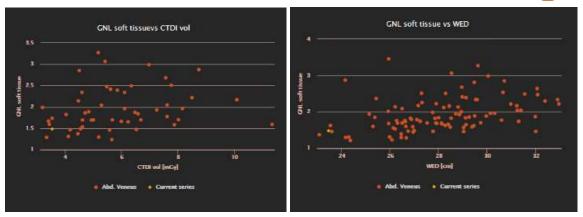
Global Noise Level can be used as an absolute number, according to recent studies (Ria et al. 2019). However, it is mainly meant to be used as a relative value to identify outliers and potential errors and initiate optimization projects (Dedulle et al. 2019). For every CT acquisition (series), under the "Image Quality" tab, a table shows the values of GNL for every convolution kernel and every slice thickness. The GNL values are normalized to 5mm, although the original slice thickness is also reported. By clicking on each row, the user can see a colored chart correlating the CTDIvol to patient size (Water Equivalent Diameter-WED) and GNL for all series with the same acquisition protocol, the same convolution kernel and the same original slice thickness for this device. The chart follows the general date range selected on the system. The GNL is the parameter indicated by colors. The colored legend changes dynamically, which means that the outer colors correspond to the maximum and minimum values of the shown data points. There is the option to see the same chart for soft tissue, air and bone, by selecting a different tab. The chart is clickable and allows to open the corresponding studies.



Visualization CTDIvol versus WED and GNL to facilitate identification of outliers. The current acquisition is indicated by a larger point of different shape as now the color has a different meaning (color indicates GNL value based on the colored legend).

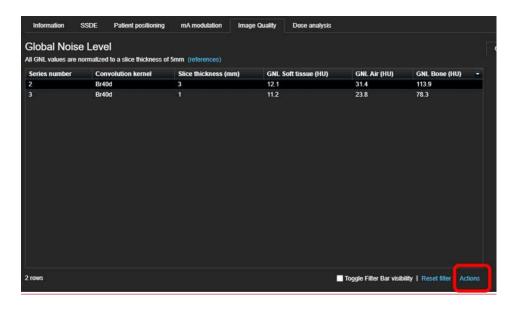
The GNL is also displayed as a function of CTDIvol and water equivalent diameter (WED) of the patient (attenuation-based metric for the patient size). The current acquisition is visualized in yellow in the cloud of data points.



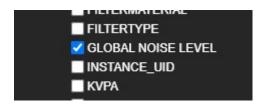


Visualization of the GNL versus CTDIvol and WED for soft tissue, with the current acquisition indicated in yellow.

GNL is exportable in two ways; for the current acquisition, the table with GNL values can be exported from the actions button below the GNL table.



For a large-scale export of GNL values and combination with other parameters, GNL can be exported on Device level using the **Export data** functionality (See <u>Export</u>). Under Field configuration, GNL can be found as **Global Noise Level** in the column with series level fields.



By selecting the "Global Noise Level" and exporting, all the relevant fields are automatically exported to allow for further handling.



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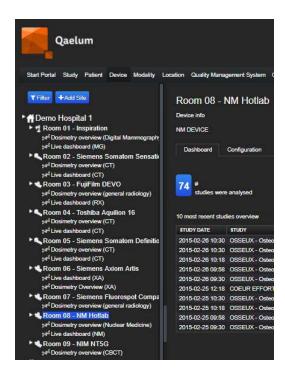


Example of exporting the Global Noise Level field in excel. Six columns are automatically exported.

For more information, refer to the video **All about Global Noise Level by Qaelum in 30 seconds!** in our online training center.

8.5.5. Nuclear Medicine

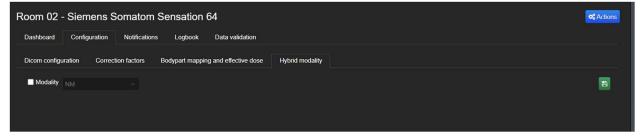
The Nuclear Medicine department can be monitored and managed by DOSE. The source of information can be the hotlab management system or the NIS (via HL7 connection), or the PACS (via DICOM header analysis). The source of information (e.g. the hotlab management system, the PET etc) will be shown as a separate "room" or "device" in the device level tree.



Different levels of analysis on the upper horizontal line (study, patient, device). Tree of devices shown vertically on the left side, where the Hotlab/PET etc is also included as a separate room/device.

Devices can be configured as "hybrid modalities" (e.g. PET/CT, SPECT/CT) so that DOSE can show linked studies of different modalities (e.g. NM and CT) in *Study details* (sharing the study UID but of a different modality). Users whose role contains the "Device management" functionality can edit the configuration in *Device Overview* \rightarrow *Configuration* \rightarrow *Hybrid modality*.





Configure device as hybrid modality

From the different levels of system, the user has the option to search for a specific study, a specific patient or a specific "device" (in this example: the hotlab) and get a full overview of the hotlab and the department in general.

The Nuclear Medicine module is only available to customers with the corresponding license.

8.5.5.1. DOSIMETRY

8.5.5.1.1. EFFECTIVE DOSE AND ORGAN DOSE CONVERSION FACTORS

Effective dose and organ doses are calculated for all radiopharmaceuticals available in the ICRP Publication 128 (Radiation Dose to Patients from Radiopharmaceuticals: a Compendium of Current Information Related to Frequently Used Substances).

The **Conversion factors** are displayed in **Settings**, under **Data tables**, in a separate tab, next to the one of Radiology. The unit of the conversion factors for effective dose is mSv/MBq and for organ doses mGy/MBq.

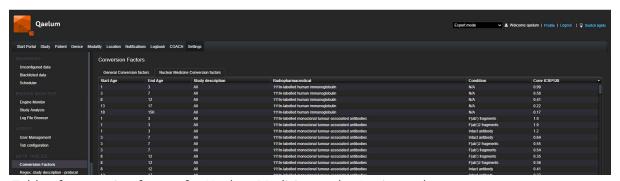


Table of conversion factors for Nuclear Medicine under Settings tab.

In the displayed table, each row shows the effective dose conversion factor for a particular age range and radiopharmaceutical. In order to see or edit the corresponding organ dose conversion factors, **right click on the row** and **edit conversion factors**. A new window will show all the conversion factors of the particular case. In the case of an organ, for which a conversion factor is not provided by ICRP 128, the conversion factor is displayed as -1. This is often the case for salivary glands, for which only some radiopharmaceuticals have a conversion factor.







Window with the corresponding conversion factors that appears when right clicking on a row. Conversion factors can be edited. In the example, salivary glands have a factor of -1, meaning that there is no available conversion factor for this case.

Below the table and at the right, the **action** button includes "**Insert data**" option.



Insert data by the actions button below the table allows for visualization and editing of the conversion factors or the corresponding parameters.

By selecting it, the user opens the window with all the entries of the table and above this, the valid template for new entries.

```
Template: age_start.age_stop.study
description:radiopharmaceutical:radiopharmaceuticalCondition;conv_icrp_128.adrenals.bone_surfaces;brain;breasts.gall_bladder_wall.stomach_wall.small_intestine_wall.colon_wall.upper_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.tower_large_intestine_wall.
```

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In this window, the user can edit conversion factors or add new ones for radiopharmaceuticals that are not available in the list. The exact template is shown above.

In this page, the users can edit the entries with their own responsibility. They can also add new conversion factors for radiopharmaceuticals not available in the list by following the indicated **template**. If they just want to add a new radiopharmaceutical with effective dose conversion factor but not organ dose conversion factors, they must fill in (-1) to the other organs (28 in total), following this entry:

which the user can copy and paste directly and change only the radiopharmaceutical name, the effective dose conversion factor and the age range if needed (the aforementioned refers to adult age range).

When all changes are ready, click **Commit** and **Confirm** if you agree to change the factors by your own responsibility.

Changes can also be made in individual rows by selecting the **Edit** option in the **Actions** button below the table.



Edit conversion factors

8.5.5.1.2. DOSIMETRY FOR DIFFERENT CONDITIONS AND STUDY DESCRIPTIONS

In addition to patient age and radiopharmaceutical, the nuclear medicine conversion factor table includes fields for "Study description" and "Condition", features that allow more flexibility and advanced patient-specific dosimetric calculations.

Condition refers to the description of the specific conversion factors, as mentioned in each table in ICRP128. For example, 51Cr-EDTA includes three conditions: 1. intravenous administration-normal renal function, 2. intravenous administration-abnormal renal function, 3. oral administration. As each condition corresponds to a different table and different conversion factors, they are separated in DOSE.



ICRP Publication 128

Table C.41. Absorbed doses for 51Cr-ethylenediaminetetraacetic acid.

Organ	Absorbed dose per unit activity administered (mGy MBq-1)				
	Adult	15 years	10 years	5 years	1 year
Intravenous administration	ı, normal rena	l function			
Adrenals	7.3E-4	9.1E-4	1.4E-3	2.1E - 3	3.9E - 3
Bone surfaces	8.2E-4	1.0E - 3	1.5E - 3	2.1E - 3	3.8E - 3
Brain	4.8E - 4	6.0E - 4	9.8E - 4	1.6E - 3	2.9E - 3
Breast	4.3E-4	5.6E-4	8.2E-4	1.3E - 3	2.5E - 3
Gallbladder wall	7.9E-4	1.0E - 3	1.7E - 3	2.3E - 3	3.4E - 3
Gastrointestinal tract					
Stomach wall	6.9E - 4	8.5E-4	1.3E - 3	2.0E - 3	3.4E - 3
Small intestine wall	11E-3	14E-3	2.1E-3	31E-3	4 8E-3

Example from the ICRP Report 128 of what is mentioned as Condition in DOSE.



Example of a radiopharmaceutical with multiple "Conditions".

Thus, the same radiopharmaceutical and the same age group can have different conversion factors depending on the condition. This will be indicated in DOSE by separate rows in the conversion factor table.

Not all radiopharmaceuticals have different conditions in ICRP128. In the case of a radiopharmaceutical with only one set of conversion factors, the "Condition" field in DOSE will be "N/A".

"Condition" can also refer to the patient condition (e.g. normal – abnormal renal function) or to the type of examination (e.g. intravenous or oral administration, rest/exercise etc.).

The **Study description** field allows to differentiate conversion factors based on the study description. As the pharmacokinetics is not always the same, the conversion factors will not be the same either. This can be helpful in cases when the study description indicates the type of examination and the corresponding conversion factors can be matched. If there is no need to use different conversion factors for different study descriptions, then the "Study description" field in DOSE should indicate "All".





Example of mapping a study description to a radiopharmaceutical and to specific conversion factors.

The study description for a particular row can be edited either by clicking on **Insert** data or the **Edit** button (found in **Actions**). When using the latter, a dropdown list of study descriptions of nuclear medicine devices is shown.

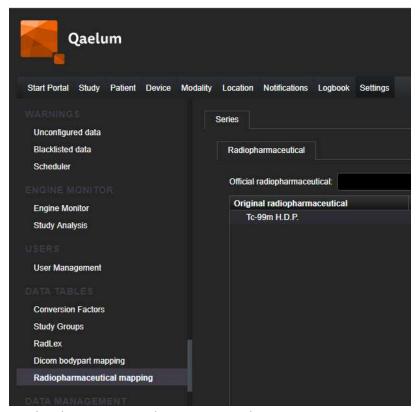


Edit study description in NM conversion factors

8.5.5.1.3. MAPPING OF RADIOPHARMACEUTICALS

Nuclear medicine conversion factors for effective dose and organ doses use the standardized naming of radiopharmaceuticals, as reported in ICRP Publication 128. As different hospitals may use different names for the radiopharmaceuticals, a tool to map the original radiopharmaceutical, as reported in the data source, to the standardized radiopharmaceutical, as indicated in the conversion factors table, exists in **Settings**.

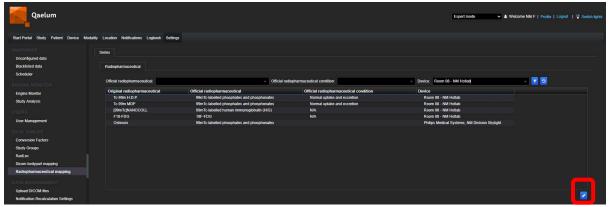




Radiopharmaceutical mapping under Settings.

Radiopharmaceutical mapping is crucial in order to perform dosimetric calculations. Otherwise the system cannot match the original radiopharmaceutical coming from the data source to the conversion factors for effective and organ dose calculations. This process needs to be performed only once unless there is a new radiopharmaceutical or a new radiopharmaceutical name.

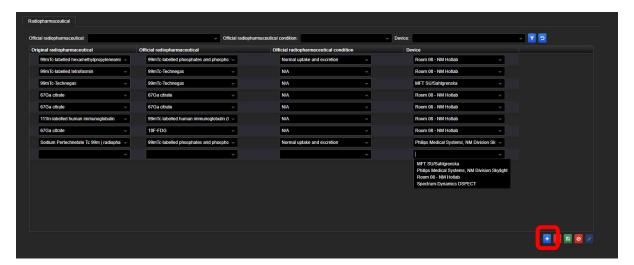
The mapping can be performed as follows: click on the **Edit** (pencil) button in the bottom left corner.



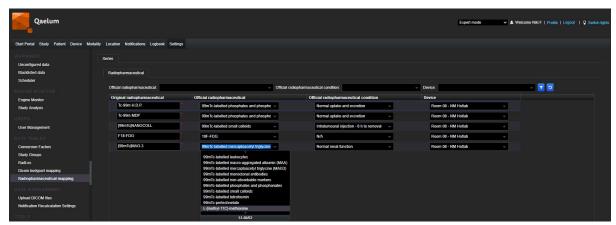
Edit button in Radiopharmaceutical mapping.



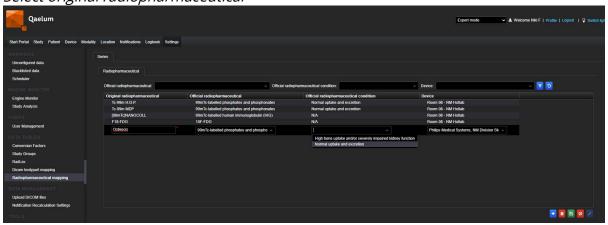
Then select the + button to add a new row. First select the device in the "device" field on the right. Based on the device, the available original radiopharmaceuticals will appear in a dropdown list.



Perform the mapping by selecting the official name and condition using the dropdown menu for every original radiopharmaceutical, as shown in the example.



Select original radiopharmaceutical



Select condition

Then click the **Save** button (floppy disk).



If multiple original radiopharmaceuticals refer to the same official radiopharmaceutical, then this step must be performed for each one (e.g. Tc-99mMDP, HDP, 99mTc-Osteocis, Tc-99mMDP must correspond to 4 lines in the mapping, all mapped to the same official radiopharmaceutical).

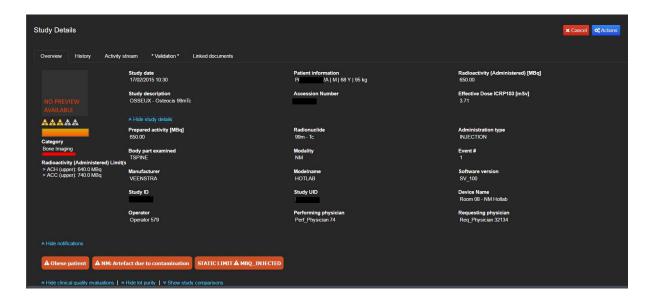
For the condition, it is advised to use a default condition for a radiopharmaceutical (when multiple are available). This can be changed in an individual study depending on the condition of the patient or the particular examination. For example, when normal and abnormal renal function is available, it could be prudent to map the normal function and then change the individual conditions of patients with abnormal renal function, as otherwise dose values will be under- or overestimated for all patients. Thus, it is good to know that changing radiopharmaceutical and condition is also possible for an individual study, and particularly from series level (*Series information*).

Users whose role includes "Physical parameters management" or "Dose management" functionality can access the radiopharmaceutical mapping in Settings.

8.5.5.2. STUDY LEVEL

8.5.5.2.1. STUDY OVERVIEW

Details of the study are shown in the *Overview* tab. This includes patient weight, administered radioactivity, administered radioactivity per kg, prepared radioactivity and radiopharmaceutical administration type (e.g. injection, ingestion, etc.). The radionuclide and radiopharmaceutical are indicated in separate fields. Effective dose and organ doses calculated by DOSE are displayed. Effective dose is displayed in the *Overview* tab, while organ doses are displayed in a separate tab "Organ doses" (see <u>Organ Doses</u>).





Overview of the study: parameters, such as patient weight, administered activity and effective dose are shown in Study Details. In this example the study description has been added to the study group "Bone imaging" and an alert for administered radioactivity has been generated.



Example of an examination where the administered activity is lower than the prepared activity. The user can add a comment (e.g. the patient showed up late for the appointment). Effective dose is calculated based on the activity that was actually administered to the patient

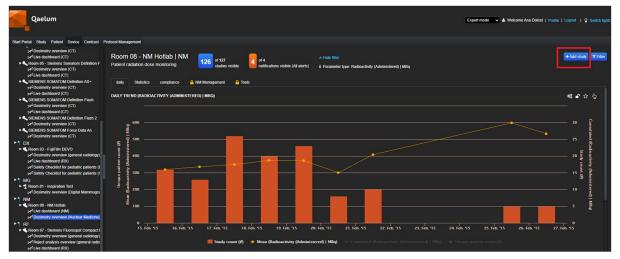
Additional studies of other modalities (e.g. CT) are shown in the *Hybrid* tab, appearing when a study with the same UID of the linked hybrid modality is present.



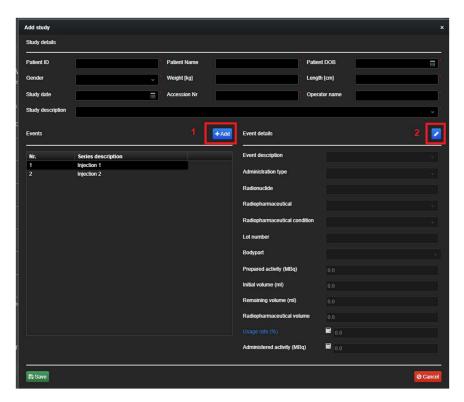
Hybrid study

It is possible to manually add NM studies to DOSE. To do so, the user must go to Device Level/NM device/Dosimetry Overview and click on **+Add study**:





A window will pop up allowing the user to fill in all the details. As many injections as necessary can be added (1) and activity details can be edited by clicking on the pencil button (2):



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The usage rate and the administered activity are calculated according to the formulas below:

$$\textit{Usage rate} = \frac{\textit{initial volume} - \textit{remaining volume}}{\textit{initial volume}} * 100$$

 $Administred\ activity = Prepared\ activity* Usage\ rate$

8.5.5.2.2. LOT NUMBER PURITY

When users perform a quality control of the pharmaceutical, LOT number purity can be registered in the corresponding DOSE Logbook. Examinations with this LOT number can then be linked and the pharmaceutical purity will be shown in the study overview.



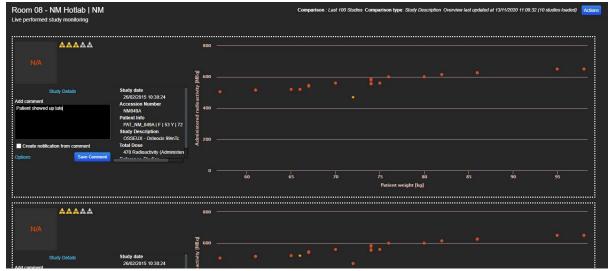
a) LOT number linked to this study together with the measured purity, b) when purity is below 95% an orange light is shown

For more information, refer to the video *How to view nuclear medicine study information on Study Level* in our online training center.

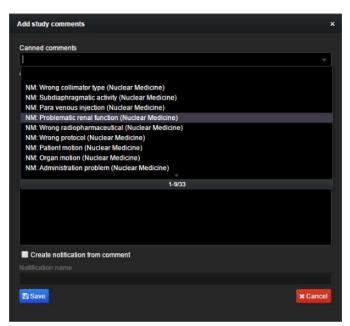
8.5.5.3. ALERTS & JUSTIFICATIONS

Notifications or alerts can be manually or automatically created for Nuclear Medicine and displayed in the study overview. The automatic notifications that relate to study groups and compliance are explained in *Compliance configuration*. The automatic notifications that are generated by the Notification center are explained in the Notifications Chapter. For manual notifications, the user can add a comment for the study, e.g. to justify a high activity or an artefact either through the <u>live dashboard</u> or via the study details (Tab Activity stream). Comments do not always have to create a notification; the user can decide. There is already a list of predefined comments especially for Nuclear Medicine for easy and quick handling (e.g. impaired renal function) but additional ones can be also added.





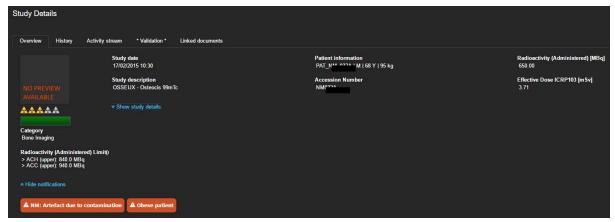
Live dashboard for Nuclear Medicine. The user can add a comment in the comment field and select if a notification is needed or not. Under the options button, predefined comments, general and specific to Nuclear medicine, are included



Predefined comments for Nuclear Medicine. The user can select the one that fits or create a new one and Save.

Alerts / notifications can be generated from the comments and handled through the <u>Notifications Module</u>.





Example of alerts in a study. The contamination could cause an artefact that affects the image.

For more information, refer to the video *How to create nuclear medicine notifications using Live Dashboards* in our online training center.

8.5.5.4. SERIES INFORMATION

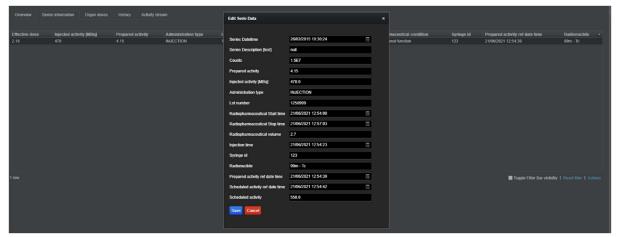
The evaluation of Nuclear Medicine examinations usually happens at study level. However, there are cases where the examination consists of multiple syringes with the same or different radiopharmaceutical. To avoid missing information, DOSE can show multiple syringes as different series. If the data source only includes information about one administered radiopharmaceutical, then there is one series with the same radioactivity and radiopharmaceutical as mentioned on study level. The administered radioactivity of study level is the sum of all the series. If there are different radiopharmaceuticals involved, then on study level the radiopharmaceutical is a concatenation in alphabetical order and the effective dose is the sum of effective dose from different series. Details of the series can be exported by the Actions button below the series table.



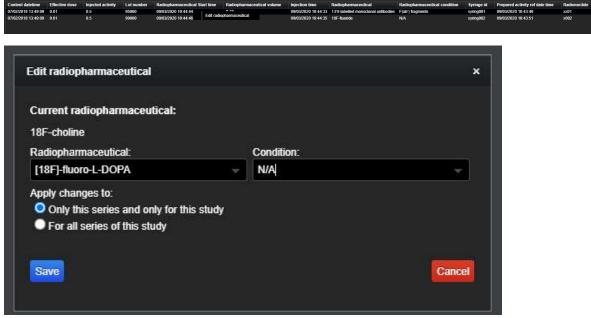
Series analysis for one examination. Information for every syringe, like radiopharmaceutical, administered activity, prepared activity, volume, administration time, effective dose etc. are displayed.

If a series needs to be edited, this can be done by opening the 'Series Information' tab and right-clicking on the particular series to select 'Edit Serie Data'.





Effective dose is calculated for every series based on the age of the patient, the radiopharmaceutical of the series, and the study description (in case a link with the specific study description has been made in the Conversion factor table (as described in *Dosimetry for different conditions and study descriptions*). For more flexibility in the dosimetry of each patient, there is the option to change the radiopharmaceutical and/or the condition for each series of the individual study. By right clicking the selected series and **edit radiopharmaceutical**, a pop-up window allows to change the radiopharmaceutical (if the data source was not correctly filled) or the condition (if the patient differs from the default condition as selected in the <u>mapping of the radiopharmaceuticals</u>. The user can select if the change will apply to the current series or to the whole study and click **Save**.

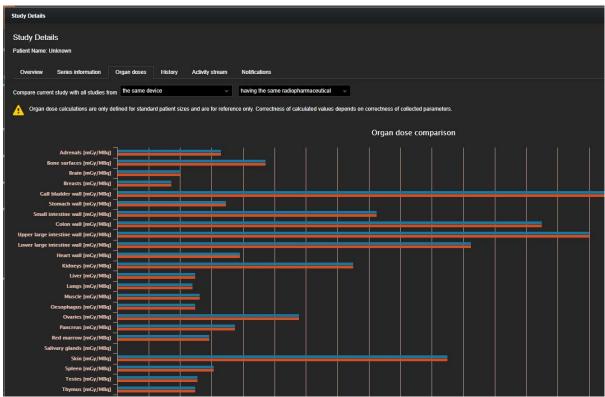


Right click on the series to edit radiopharmaceutical and/or condition for the selected series and/or study helps to make the calculation of effective and organ doses more patient-specific.



8.5.5.5. ORGAN DOSES

Organ doses are calculated on study level by summing the organ doses of individual series. They are displayed in a tab called "Organ doses" next to the Series information. The visualization is similar to the in-house Organ dose calculation in CT (see <u>Organ Doses</u>).



Organ dose calculation for a specific study (red bars). The results displayed are the sum of absorbed doses from individual series for each organ.

The organ doses of the study (red bars) can be compared against the same radiopharmaceutical, the same study description or the same radiopharmaceutical and condition to allow for more relevant comparisons. The selected filter applies on the calculation of the 25th, 50th and 75th percentile, which can be compared with the current study.



The organ doses of the current study can be compared with similar studies based on the criteria of the right drop-down menu.



8.5.5.6. MANAGEMENT LOGBOOKS

Multiple logbooks must be kept in Nuclear Medicine in order to manage all the aspects of daily routine. Management logbooks centralize all data, link it to the studies, and export when needed. An overview of issues is possible by checking the statistics above every logbook.



Quality Control of pharmaceutical. The purity is recorded. Double click on an entry will provide the studies that were performed under this LOT number. Purity below 95% is highlighted with orange



Contamination logbook. Every contamination event is recorded with the radionuclide, the contaminated area and the person who handled the problem. This could give interesting information, like for which radionuclide the personnel could use extra training



Functional logbook. The user records errors, malfunctions etc by the dropdown menus (for all the cameras). The user can check if the company was contacted and what is the status of the events. The time needed to solve malfunctions or damages is estimated



Nuclear Waste Management. The user fills in the waste from radionuclides with half-lives that exceed 1 day. The system calculates the date that the waste for each bin can be liberated, when the reference activity is below 0.37MBq (10µCi).

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For more information, refer to the video *How to view nuclear medicine data on Device Level* in our online training center.



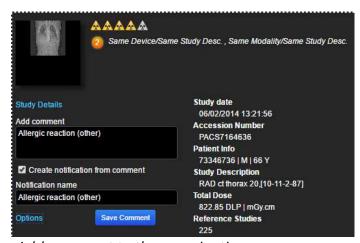
9. Live dashboard

The Live dashboard can be found within each device on Device level. The Live dashboard tab shows the latest studies performed using the selected device. For each study, users can see the study information and the dose histogram. The orange arrow in the dose histogram shows the position of the current study dose among other studies with the same study description.



Live dashboard

This allows immediate direct feedback to the radiographer following an examination.

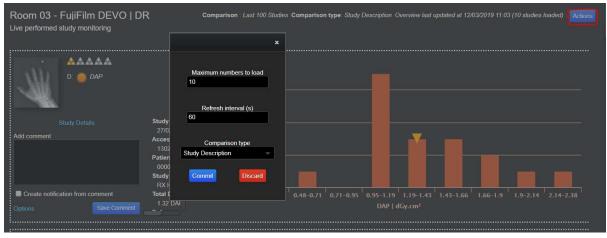


Add comment to the examination

There is a possibility to look into the study details by clicking on the information button and add a comment to this study. You see immediately if this study contains alerts or not. In addition, a clinical quality evaluation can be done immediately from the Live Dashboard.

The users can configure the Live Dashboard view via Action Button in the right corner.



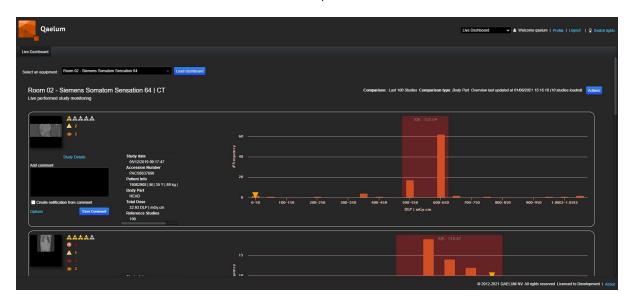


Configure dashboard

Another way to access the Live Dashboard is from the dropdown menu on the top-right corner. Users whose role contains "Live Dashboard" and/or "Live Dashboard Modality" functionalities can see this. This is recommended for radiographers.



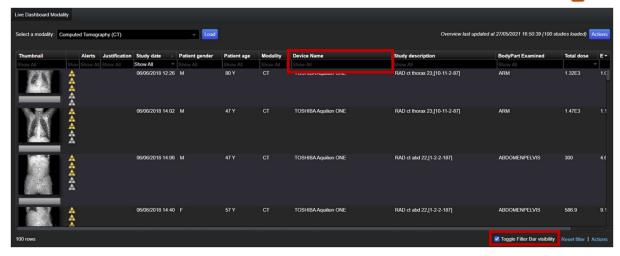
In "Live Dashboard" select the desired device, and click "Load Dashboard".



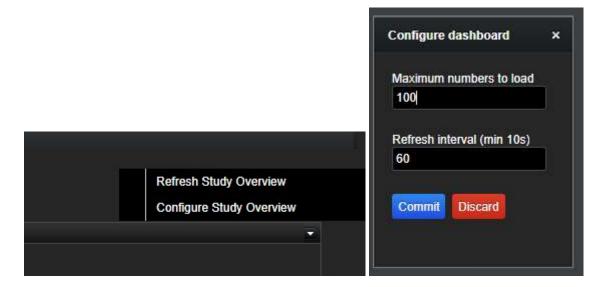
While in "Live Dashboard Modality" select a modality and click "Load".

A list of the last studies performed by any device of the selected modality will appear. The toggle bar filter can be used to filter by device and see as many studies as necessary (in "Live Dashboard" a maximum of 10 studies can be displayed).





The number of displayed studies can be configured in **Actions/Configure Study Overview**.

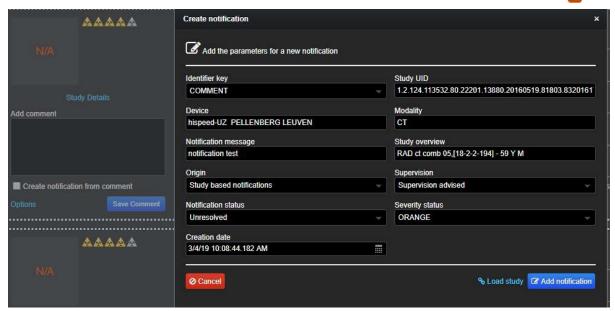


9.1. Notifications from the Live Dashboard

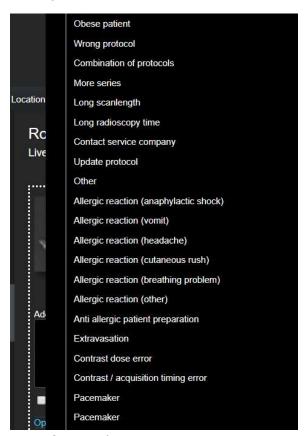
Notifications can be created in the Live Dashboard using predefined canned comments, or by typing free text. These canned comments can be configured to automatically generate notifications.

Using the **Add comment** window: enter a comment \rightarrow tick the **Create notification** from comment box \rightarrow indicate an 'Identifier key' (this can be used to categorize notifications and find them when using the search on the **Notifications** level).





If using a canned comment: choose one of the canned comments \rightarrow create notification.



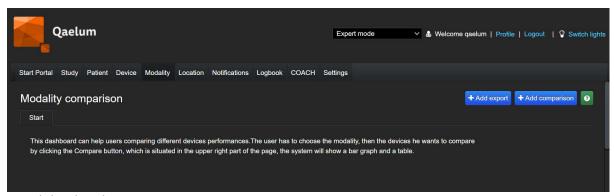
List of canned comments

For more information, refer to the video **How to use the Live Dashboards** in our online training center.



10. Modality level

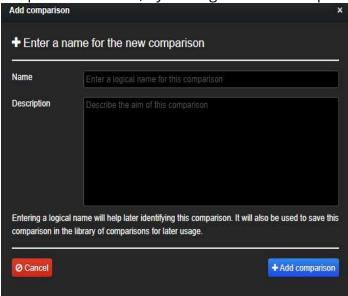
This module contains two tools: modality comparison and modality export.



Modality level

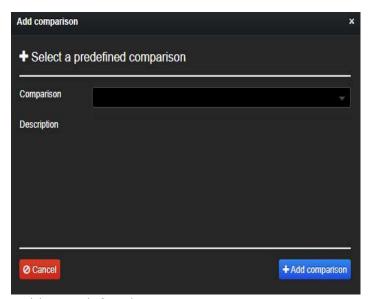
10.1. Modality comparison

This dashboard can help users to compare the performance of different devices. Users can customize their own comparison, to do so, they need to add first a comparison or to load one of the predefined ones, by clicking on "+Add comparison".



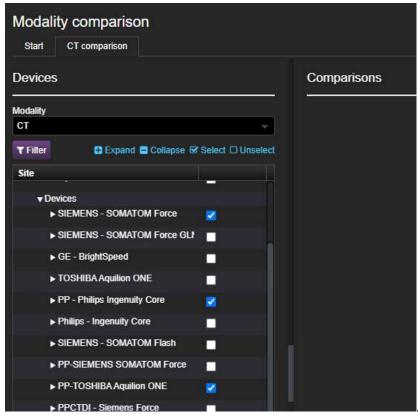
Add a new comparison





Add a predefined comparison

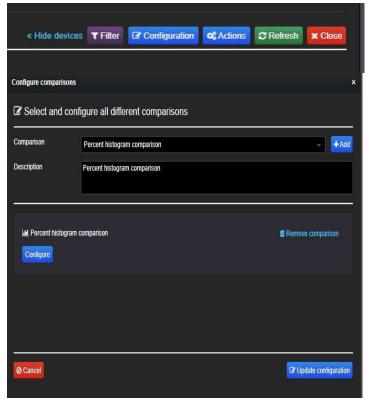
For a new comparison, choose the modality and the devices intended to compare from the left side of the screen.



List of modalities and the corresponding sites/devices. Select by clicking the boxes or select all from the button **Select**.

Then click on Configuration, here the user will be able to choose which kind of graph he/she wants to use for comparison.





Configuration window

In the Actions button, the user can save the comparison in order to make it predefined.



Actions button for handling the comparisons (save/remove)

For a more specific comparison, it is possible to apply filters: by filtering, it is possible to choose the type of variable the user wants to compare, or to compare studies with a specific study description, study group or involving a specific body part. The filter works with the same logic as on **Device** level (see <u>Advanced Filter</u>).



Filter for the selected configuration

If the selected devices or the configuration are changed, then the refresh button will update the comparison.



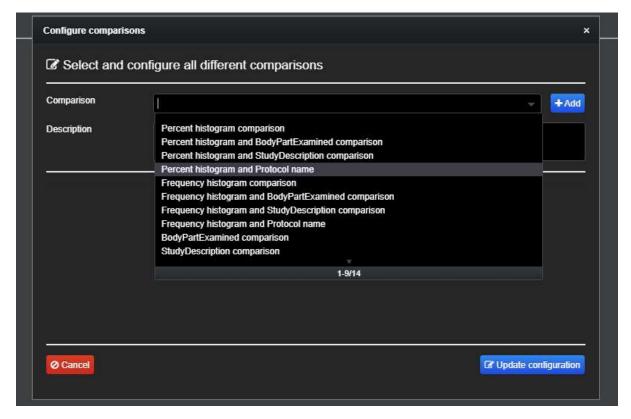


Refresh button for changes in the comparison

For more information, refer to the video *How to use the Modality Level* in our online training center.

10.1.1. List of configurations

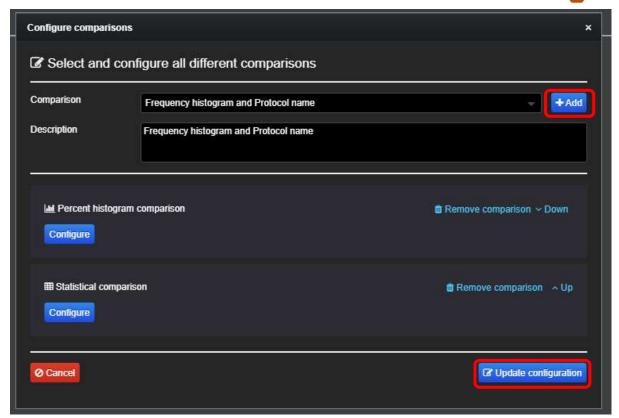
In the configuration window, a list of predefined comparisons is available. Histograms, tables, statistical analysis, trend analysis, either general or based on study description, protocol name, body part are available.



Window to select the comparison type

Every time a new comparison is selected, the *Add* button will include it in the list. Multiple comparison types can be added at once. At the end of the selection, *Update the configuration*.

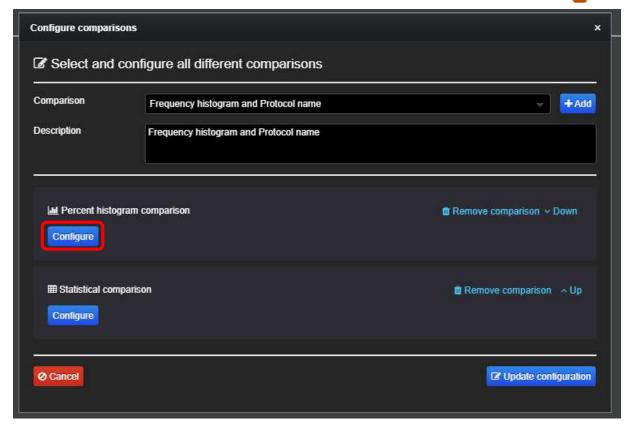


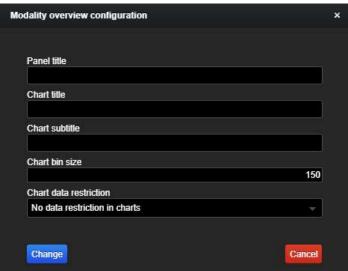


Add button to add the selected comparison type in the current comparison page. When the desired comparison types have been selected, the button update configuration shows the comparison page.

In some cases, a comparison type may need adjustments. For example for a bin size that is too big, a smaller one can be selected. This happens by the **configure** button of the specific comparison type.

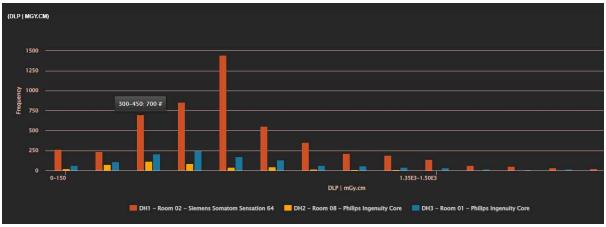






To configure a specific comparison type, select the configure button. This can be useful for example to change the bin size of a histogram.





Example of a histogram comparison

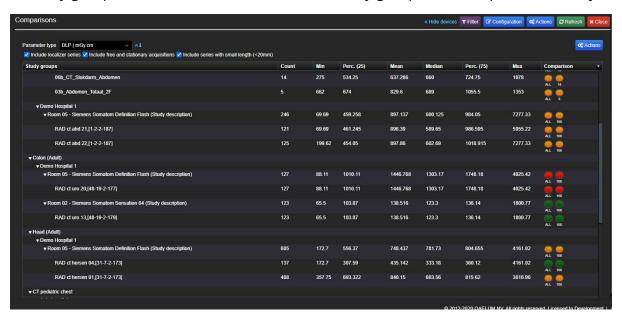
To easily identify the site (hospital) to which each devices belongs, the 3-character tag that was defined in the Add Site section is included before the name of the device.



Site tags before the name of the devices

10.1.1.1. COMPLIANCE BENCHMARK

One of the available comparison types is the **compliance benchmark**. This table is the same as on device level (see <u>Compliance Monitoring</u>) but includes and compares data for all study groups and all devices (linked to these study groups) for the specific modality.



Compliance benchmark for CT.



The table shows, not only how the different scanners perform for each study group, but also how the mapping was done (based on protocol name, acquisition protocol etc) and how the individual protocol performs.

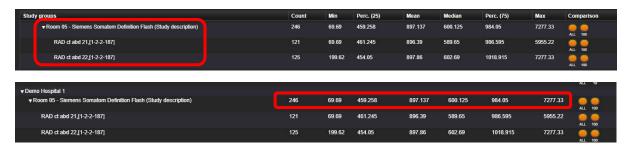
For each study group (in this example "Thorax adult"), the devices linked to this study group are displayed. In the following example, 1 CT scanner from Demo Hospital 2 and 2 CT scanners of Demo Hospital 1 are linked to "Thorax adult". In the case of Room 1, the mapping was based on protocol name, while for the other two scanners, the mapping was based on the Study description.



As seen, for Room 1, there is 1 protocol linked to the study group, which can be seen below the name of the CT scanner.



In the following example of the study group "Abdomen", the particular scanner (Room 5) has two study descriptions linked to this study group and thus the values shown for the specific scanner (upper row) take into account both study descriptions. (The number of studies is the sum of studies of both scanners, the minimum value is the minimum of both, the average is the average of both).



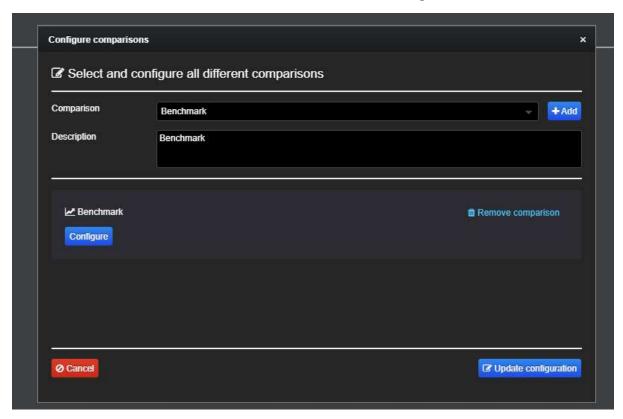


The table can be exported in the Actions button, right above the table.



10.1.1.2. CONFIGURABLE BENCHMARK FOR CT AND MAMMOGRAPHY

For CT and mammography, there is the option to add a configurable comparison. This feature is called "Benchmark" and can be found in the Configuration.



Benchmark: configurable comparison.

This configurable comparison gives the option to select many variables; protocol or study group, series level or study level, chart type, parameter(s), statistical measure.

Type: depending on the device and possibilities, users can select between Study group (on study or series level), Study or series description, Protocol or acquisition protocol, depending on what they want to compare. Only devices that have the selected group/description/protocol will have values in the chart. Selecting between study or series level will affect the list of available parameters. For example, for CT devices, SSDE is only available on series level.





Category: depending on the selection in "Type", the options will appear.

Chart: Column chart, Scatter plot or Box and whisker plot. Depending on the selection of chart, different options open for parameter selection. A scatter plot needs two parameters; for x and y-axis. A box and whisker plot needs one parameter. A column chart gives the option to select two parameters (left y-axis and right y-axis) and also the statistical measure to compare (mean, median, percentiles, total etc).



The **Generate chart** button will provide the configured comparison.



Example of CT benchmark: a column chart with two parameters, for the left one (effective dose) the median value is compared and for the right one (volume) the total number is compared.





Example of mammography benchmark: a scatter plot representing the organ doses as a function of breast thicknesses.

10.2. Modality Export

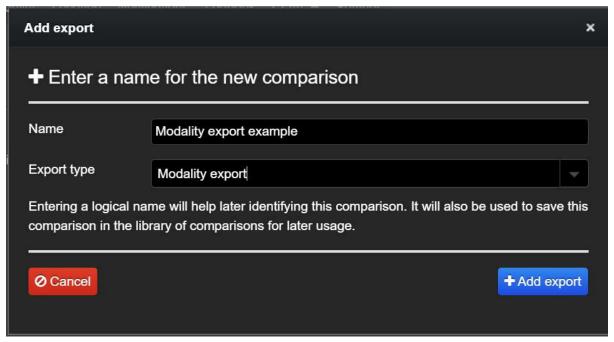
This tool enables users to export study data from several devices of the same modality at the same time. There are different options available depending on your country: Modality Export (general), SSM Export (Sweden) and Full Export (Norway).

10.2.1. Modality export

This feature is similar to the one described in section *Export*.

To access it, click on "+Add Export", enter a name and select "Modality Export" from the dropdown menu.





Add export

Select the modality and the desired devices before clicking "*Export*", where a new window will open where the desired export fields can be selected.

Please note that when exporting PATIENT_AGE, PATIENT_AGE_TYPE should also be selected to indicate if the age is in years, months, etc.



Select a modality and the devices





Select the desired fields to export

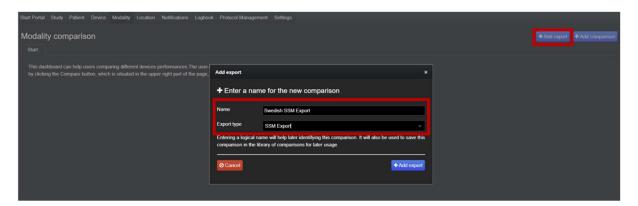
Then click on "*Export*" and the data spreadsheet will be generated.

For more information, refer to the video *How to export on Modality Level* in our online training center.

10.2.2. SSM Export

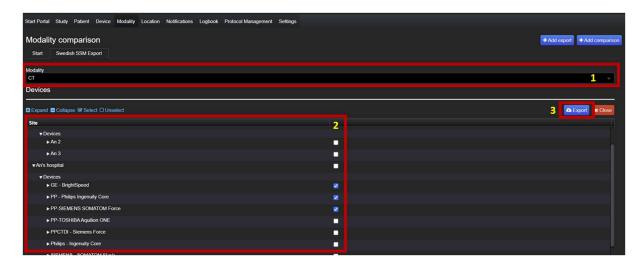
The SSM file is meant to comply with the Swedish regulation. Each report consists of multiple Excel files (one per device) that are grouped together in a zip file for one download. SSM export can be accessed in Modality level following the steps below:

- 1. Click on **Add export** in the upper right corner.
- 2. Provide an export name, and select 'SSM Export' from the dropdown menu in 'Export type'.





- 3. Click on Add export.
- 4. Select the modality from the dropdown menu.
- 5. Select the necessary devices from the list and click on 'Export'.



6. Once the file has finished generating, a 'Download' button will appear.

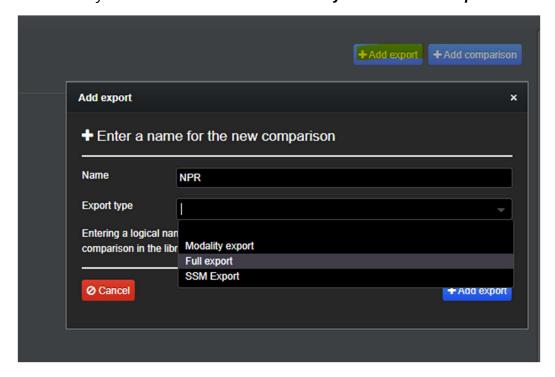
10.2.3. Full export

The NPR report was developed to be exported on **Modality** Level, so information about several devices and modalities can be exported at once. The resulting export is in XML format and can be included in the required general XML report for the Norwegian authorities.

Example of NPR export



Any user with a Norwegian license whose role includes the "Modality level" and "Export" functionality can access this feature in **Modality Level** \rightarrow **+Add Export** \rightarrow **Full Export**.



The necessary devices must be selected, and the report is generated when clicking on *Export*.



It consists of two files:

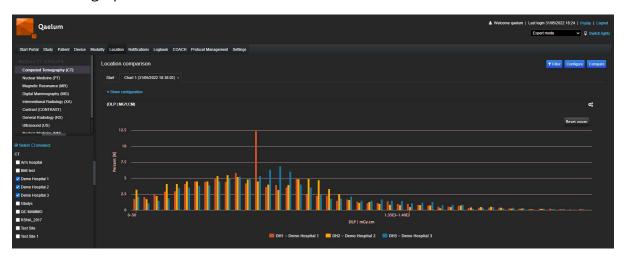




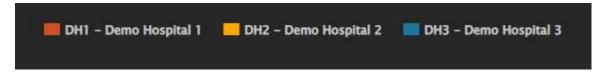
- Dose data file (RAD) that contains an internal PID, study and dose information
- Patient data file (IDE) that contains a link between the internal PID and the Social Security Number-

11. Location level

This dashboard can help users comparing different location performances. The user has to choose the location, then the modality they want to compare: by clicking the *Compare* button, which is situated in the upper right part of the page, the system will show a bar graph and a table.



The 3-character tag will displayed next to each site name, as configured in the section <u>Add Site</u>.



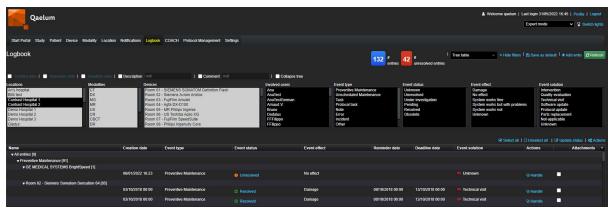
The user can analyze the data in a similar way as in modality comparison.

For more information, refer to the video *How to use the Location Level* in our online training center.



12. Logbook

The logbook is available at institution, hospital and device level. It is the place where the user can register events that happen unexpectedly or are scheduled. The user can filter and export the logbook entries, attach documents and track everything that happens. This can be also used to set tasks with reminders and receive an email e.g. Event: unscheduled maintenance Indicate from when to when the system was down and who needs to be notified.

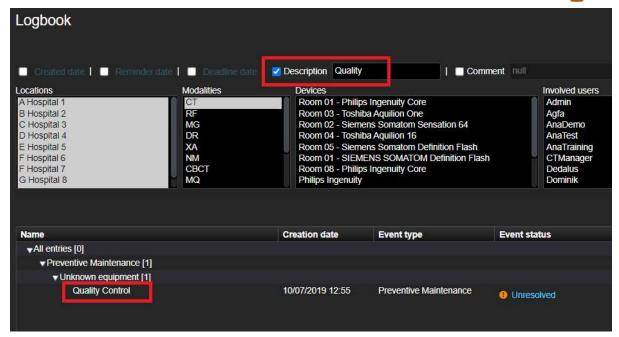


Logbook at institution level

The filter can be used to find events of interest. Besides the main filter, additional filter fields can be activated: Created date, Reminder date, Deadline date, Description and Comment.

For example, users can search for events containing "Quality Control" in their description by activating the "Description" filter field, typing "Quality" and clicking on "Refresh".



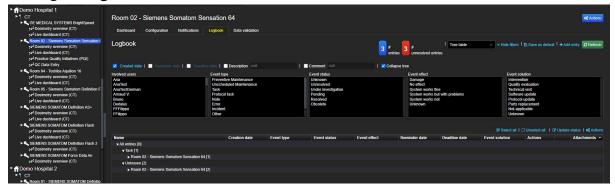


Search by "Description" of the event

For more information, refer to the video *How to use Logbook on Device and Hospital Levels* in our online training center.

12.1. Device level

Device specific logbooks can be accessed on **Device** Level, by selecting the device and clicking on **Logbook**.



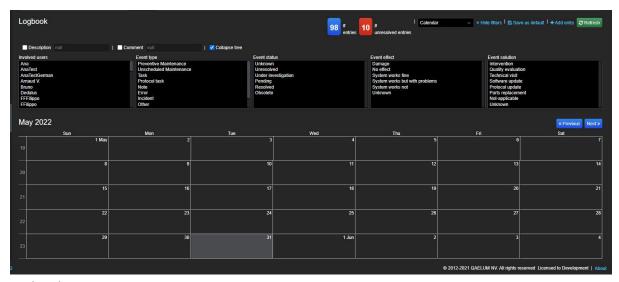
Logbook on **Device** Level

Users can select between the *Tree table* and the *Calendar* views.



View selection in the upper right corner

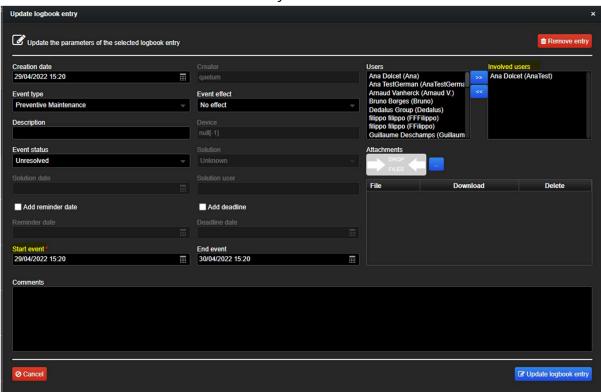




Calendar view

To register a new event, click on *+Add entry* in the upper-right corner.

A new window will open where specific event details can be customized. The **Start event date** will be the used to place the event in the calendar, and will automatically take the creation date when the field is omitted by the user.



Create logbook entry



Attachments can be added (documents, PDFs, pictures, etc.) by dragging and dropping or selecting the file after clicking on the "..." button.



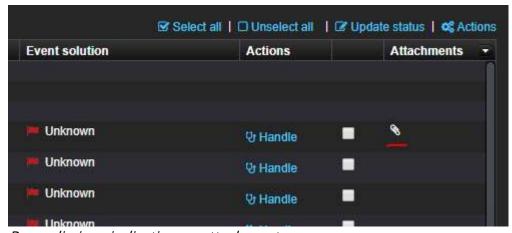
Attaching a file

After the upload is complete, it will be visible in the attachments list, where it can be downloaded or removed.



List of attachments

When an event has an attached file, a paperclip sign will be displayed under *Attachments.*.



Paperclip icon indicating an attachment

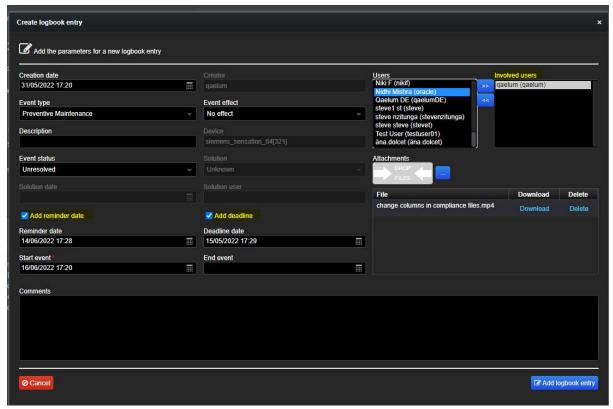
The column can be added or hidden using the dropdown arrow:





Add "Attachments" column

Reminder dates and deadlines can also be indicated; they can be used to e-mail the involved users when the event date is approaching.



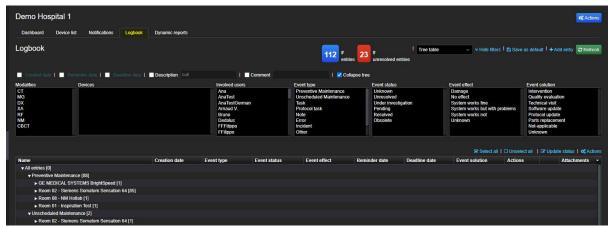
Add reminder date

E-mail alerts must first be configured in **Settings**, see <u>Configuration of e-mail sending in Logbook</u> for further details.



12.2. Hospital level

A site level logbook can be accessed on **Device** Level by clicking on the site and selecting the **Logbook** tab. All the site-specific logbook entries will be displayed here.

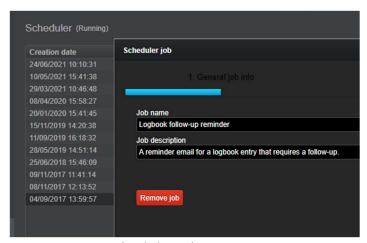


Logbook at hospital level

New logbook entries can be created here and will be automatically linked to the selected site.

12.3. Configuration of e-mail sending in Logbook

For reminder e-mails to be sent, a specific job must first be configured in *Settings -> Scheduler*. To configure a new job, access **Actions/Add job** at the bottom right corner, and after indicating a job name and description, select **Logbook follow-up reminder**:

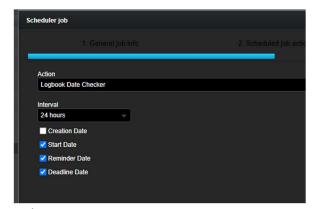


Create a new scheduler job

C€ 1639

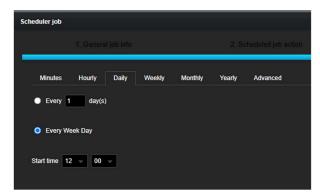


E-mails will be sent to all involved users according to the configured settings. Users can choose to receive emails to notify all assigned users upon event creation (Creation Date), as reminders on the start date (Start Date), reminder date (Reminder Date) or deadline (Deadline Date). The configuration can be customized by checking the required boxes, as shown below:



Job settings

As all scheduler jobs, they can be programmed to run with a certain frequency. Upon each trigger of the job, based on the set frequency, DOSE will check for any logbook entries with selected datetime within the configured time interval i.e. the last 5 minutes to the last 24 hours before the triggered job time.



Set the job frequency

This can be configured by users with the functionality "Scheduler management" in their role.



13. Webservice integration

Webservice is part of DOSE by Qaelum's Expert license: however, setting up these services requires third party support in order to configure the URLs. The configuration of the webservices is done upon request.

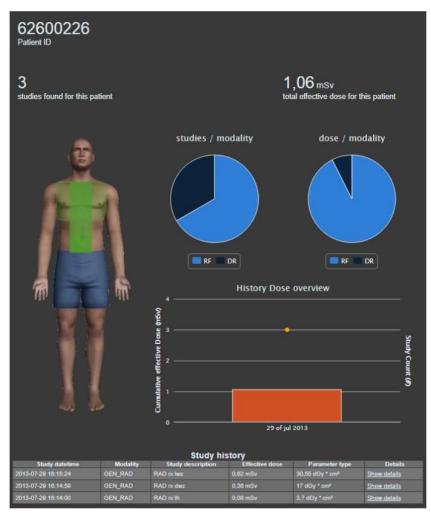
All Qaelum's webservices requires the port 10525 to be opened in order to show results to final users. On request, Qaelum may set another port.

13.1. PACS: Patient Dose passport

This webservice is designed to show the patient's dosimetric passport, as well as dose for the specific examination. There is a possibility to have a webservice called by patient ID that includes:

- total dose
- number of studies
- phantom with most irradiated areas
- list of studies performed.

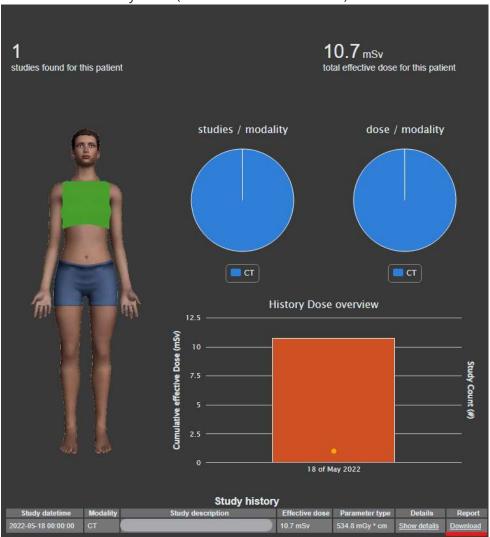
Individual studies can be opened from the study history by clicking on *Show details*.



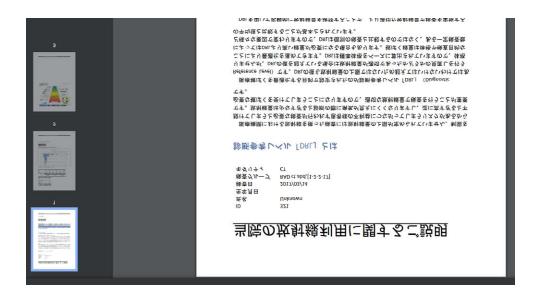
Webservice by patient ID



NOTE: those installations which include the license DOSE_PATIENT_REPORT can export the Japanese patient dose report directly from the webviewer, by clicking on the "Download" link, available in the study table (bottom of the webservice).



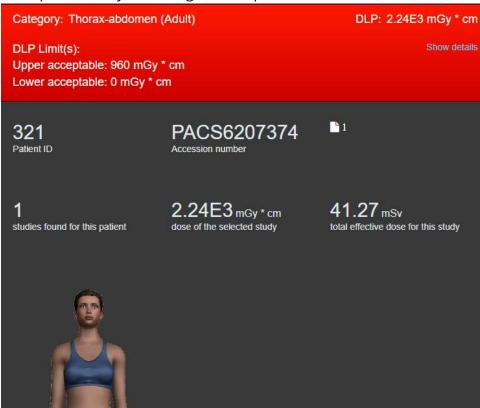
Download the Japanese patient dose report





Japanese patient dose report

There is also the possibility of calling a study by its StudyUID or a combination of Accession Number and Patient ID. This will result in a webservice showing the details of that specific study, including the compliance colour.



Webservice by Study UID or accession number

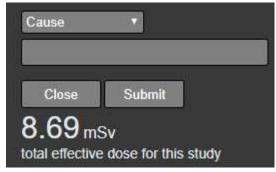
A "Comments" icon is present, and comment content is be displayed when the user hovers over the icon.

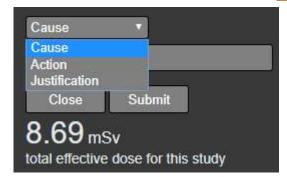


Study comments

If the icon is clicked, comments can be entered to be added to *Cause/Justification/Action* in the *Activity Stream*.

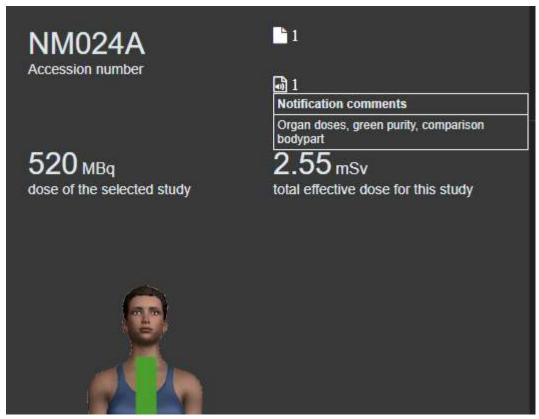






Add a comment

When notification comments are present the icon shows a warning (loudspeaker) sign.

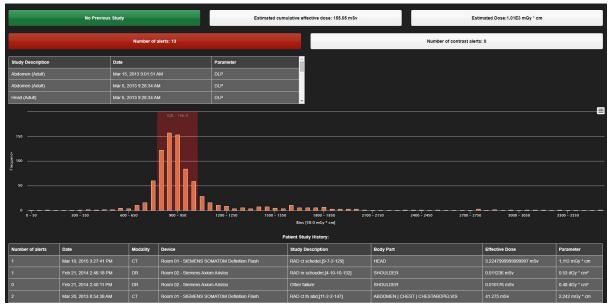


Webservice by Study UID or accession number with study comments (above) and notification (below) comments

13.2. Proactive warning

This webservice provides some information that is useful when ordering or performing the exam, including but not limited to possible pregnancy risk, patient radiological history, patient cumulated dose and contrast related issues.





Proactive dose warning webservice

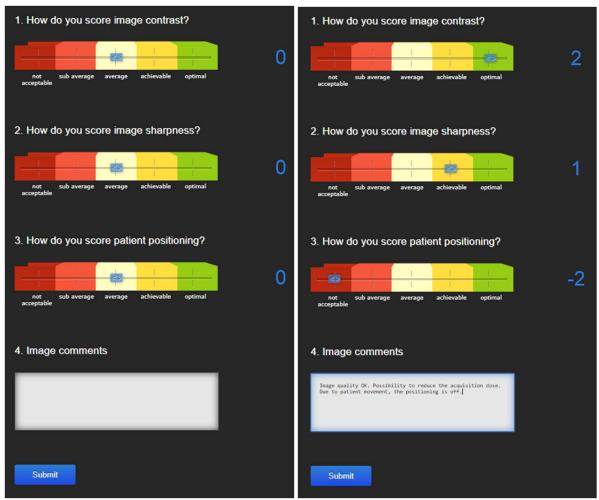
13.3. Clinical quality evaluation

This interactive webservice allows the radiologist to evaluate the quality of the images. The evaluations are based on a -2 to +2 scale and refer to several modality-specific quality indicators.

The webservice can be integrated into the radiologist's PACS viewer, allowing users to score image quality alongside the images.

After clicking a link previously enabled link in the PACS interface, a window (webservice) with the layout shown below appears, allowing the user to click on the color scale and score the three criteria of image quality. A free text box for comments is also available.

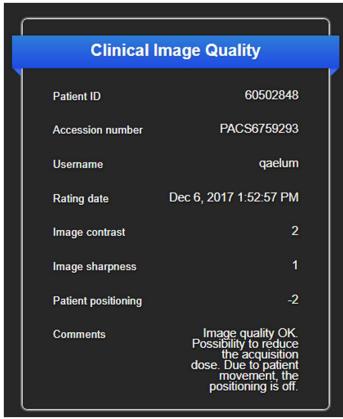




Visualization of the webservice before and after image quality scoring

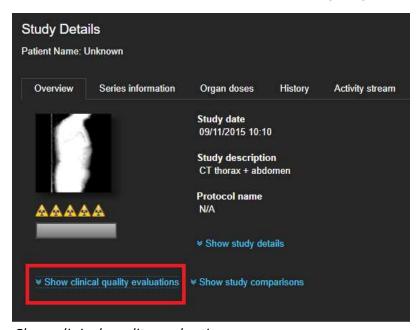
After submitting the score, the user will see a summary of the evaluation. This evaluation cannot be edited but a new evaluation can be added. This way multiple observers can evaluate the same study and the average scoring is automatically calculated.





Window with the scoring results as shown to the user

After submitting the score, the evaluation will be automatically added to the study details in DOSE. The user must click on *Show Clinical quality evaluations* to view it.

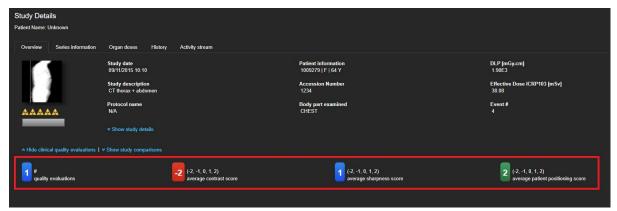


Show clinical quality evaluations

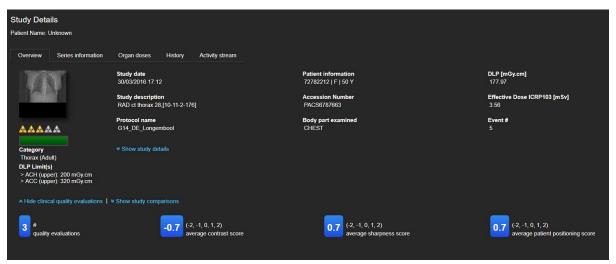
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Four tags will appear with average values from all submitted evaluations. The colors red/blue/green, respectively, indicate if the average value is unacceptable/acceptable/optimal.

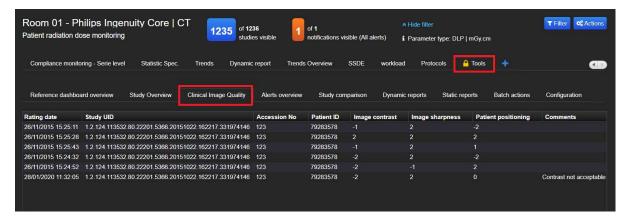


Study with one quality evaluation



Study with three quality evaluations showing the average values

In the dosimetry overview of a device, the user can see all the added evaluations under the tab *Clinical Image Quality* in *Tools*.



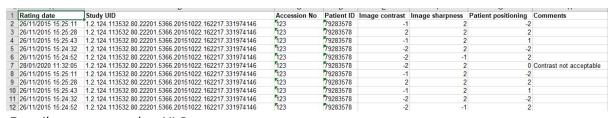


Details of every performed evaluation in the device, i.e., rating date, study UID, Acc. number, patient ID, image contrast, image sharpness, patient positioning and comments can be viewed here.

This data can be exported by clicking on the *Actions* button in the lower right corner.



Export to XLS



Details as exported to XLS

An *Image quality* table is also available in the *Dashboard editor*.

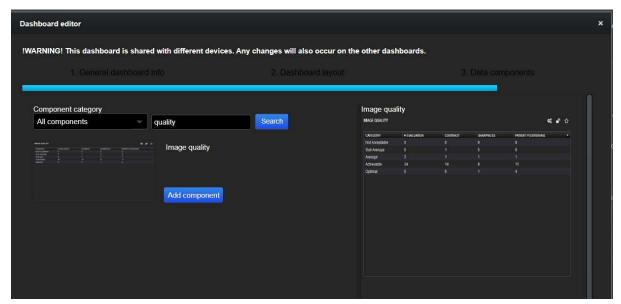


Image quality table in the Dashboard editor

This table presents a summary of all performed image quality evaluations on the current device.



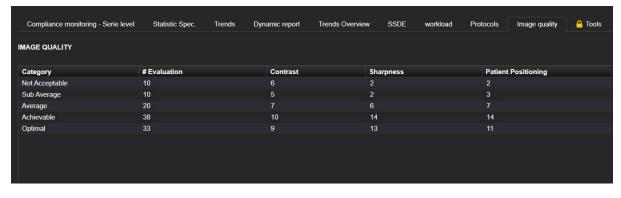


Image quality table within a **Device** level dashboard



14. Settings

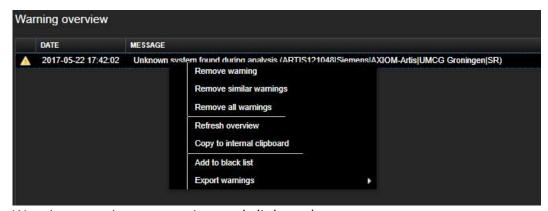
All the actions described here are available depending on the role of the user. So not everyone has access to see all the information. For further information consult section <u>User Management</u>.

14.1. Warnings

14.1.1. Unconfigured data

When the system receives a study from an unknown device, the images are not processed until the device is configured. Users can find the list of images from unknown devices in this overview.

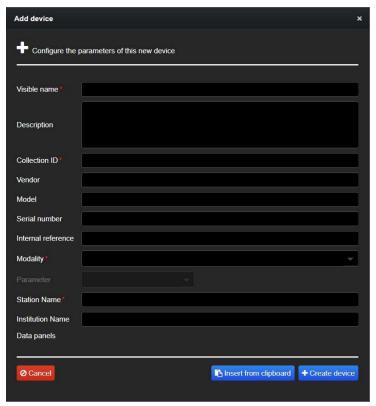
A user can add a new device copying its information to a site's device list. To copy the device's information the user must right click the row and then choose Copy to internal clipboard from the menu.



Warning overview copy to internal clipboard

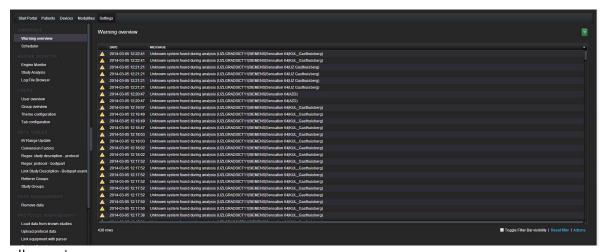
After the information is copied, it is possible to copy it by clicking "Insert from clipboard" in the Add device page.





Add device by inserting from clipboard

After the warning is reviewed, the user can remove it by right clicking on it and then choosing Remove Warning from the menu. By clicking on Remove similar warnings the user will delete all the warning concerning the same device. It is also possible to remove



all warnings.

Warning overview

All these tasks can be performed also by clicking on the Action button, which is located in the lower right part of this page.



14.1.2. Scheduler

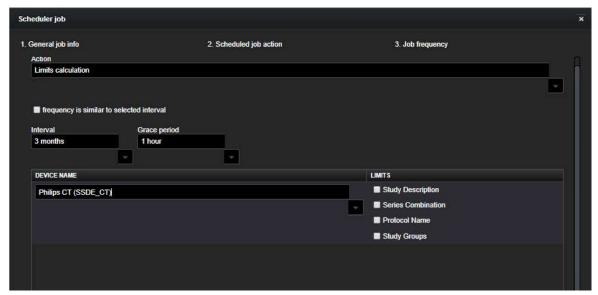
The scheduler is a stand-alone application which is running next to the main web application. By using the scheduler, the user is able to schedule reoccurring jobs (e.g. reports, alerts calculation, DICOM Q/R ect.), which are going to be done automatically.

In the left top corner, the user can check the status of the scheduler (Running / Not running). The table shows scheduled jobs.

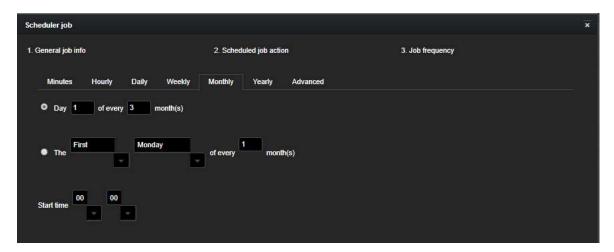


Scheduler

The user can add, edit or trigger jobs by clicking on the Action button, which is located in the lower right part of this page. When adding a job, the user needs to configure the frequency the job needs to be triggered and an action. The frequency of the job can be configured in very detail. The user can select a frequency category or write one's own regular expression



Scheduled job action





Job frequency of the scheduler job

For the SAR, organ dose and alerts calculations the user can choose the grace period. The grace is needed to avoid calculations on studies that are still not completely analyzed.

For the limits calculation, the user can also choose the time interval between the limits calculations.

14.2. Engine monitor

14.2.1. Engine Monitor

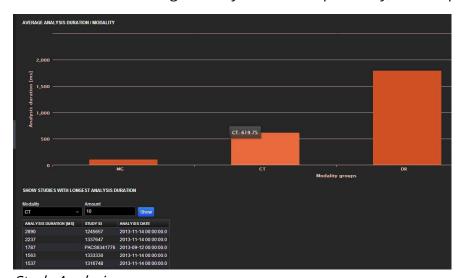
This tab shows the user general statistics for the system, such as the number of analyzed studies and the overall cumulative dose.



Engine motor: details of analyzed studies

14.2.2. Study analysis

This tool shows the longest analysis duration per study, filtered per modality.



Study Analysis

14.2.3. Log file browser

Here the user has a list of the latest log files created. They can click on them to see the details and download the file itself.



```
► TQM log files
     tqm_2020_01_19.log
      tqm_2020_01_18.log
tqm_2020_01_17.log.121243179
      qm_2020_01_17.log.121003863
           2020_01_16.log
        m 2020 01 15.log
                                                                      work of XStream not initialized, XStream is pro
ATASET START PORTAL ==
            020_01_14.log
              20_01_13.log
           2020_01_12.log
2020_01_11.log
           2020_01_10.log
2020_01_09.log.145209313
             020 01 09.log
             020_01_08.log
           2020_01_07.log
           2020 01 06.log
            020 01 04.log
              20_01_03.log.153113566
           2020 01 03.log
                                                                                                                                                                                                                                     Download file
           2020 01 01.log
```

Log file browser

14.3. Data tables

14.3.1. Conversion factors

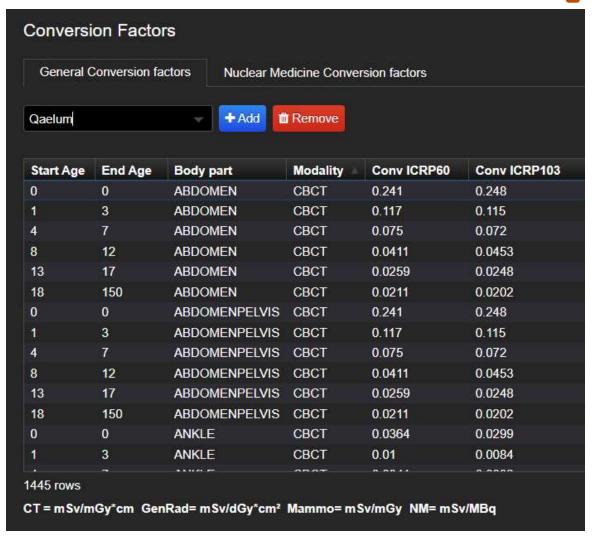
In DOSE, effective dose is calculated for all ionizing radiation modalities. The calculation is based on conversion factors that depend on modality, age group and body part. The effective dose is calculated as the product of the dosimetric parameter of every modality (DAP, DLP, etc) with the age & body part-specific conversion factor.

EffDose = DoseParameter * ConversionFactor(age, bodypart)

For Mammography, since the scattered radiation on other organs is not available, effective dose is calculated based on the glandular dose. For Nuclear Medicine, the conversion factors depend, besides the radiopharmaceutical, on the age and study description or condition (see <u>Dosimetry</u>).

This table shows all the conversion factors calculated by Qaelum for the calculation of effective dose ICRP60 and ICRP103, grouped by age category, body part and modality.





Conversion factors by Qaelum

The conversion factors by Qaelum are derived by dosimetry tools available for patients of all different age groups (newborn, 1-year-old, 5-year-old, 10-year-old, 15-year-old and adult) and for the typical settings of an examination. For Nuclear Medicine, they are based on published data from the ICRP reports.

The Qaelum CT conversion factors are based on simulations performed with the ImpactScan dosimetry tool for the standard settings of a typical examination. The pediatric CT conversion factors are based on the ones of adults, multiplied by an age/body part-dependent factor.

<u>Note</u>: In the case of head conversion factors for CT, the head phantom is considered, while in the case of neck examinations, the body phantom is considered. In case that a hospital uses the head phantom for neck protocols, it is suggested to replace the CT conversion factor of the neck with the following:

Bodypart	Adult	15 yo	10 yo	5 yo	1 yo	0 yo
			0.006	0.009	0.012	0.013
NECK	0.0055	0.0061	9	1	1	5



As it is not straightforward to perform simulations on all different body areas, some body parts follow the conversion factors of the closest common body area.

Example cases for CT:

- Coccyx, Lspine and Hip follow Pelvis
- Tspine and Thorax follow Chest
- Clavicle follows Shoulder
- Humerus, Scapula, Heart follow Chest
- Skull, Brain, Mouth, Jaw follow Head

Example cases for DR/RX/DX/CR/RF/XA:

- Coccyx and Lspine follow Pelvis
- Shoulder, Cspine, Tspine and Thorax follow Chest
- Abdomen, Pelvis, Abdomenpelvis have the same factors
- Spine is the average of Cspine Tspine Lspine

Conversion factors for CBCT currently follow projection radiography.

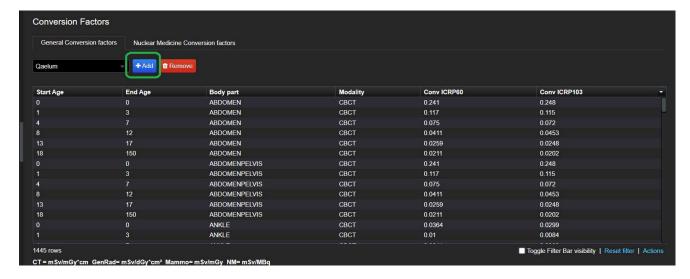
14.3.1.1. CONVERSION FACTOR TEMPLATES

Sometimes there is a need to use different sets of conversion factors for the effective dose for different sites. Those sets, which are called Templates in DOSE, can be created, edited and assigned to sites and devices from the web application by any user with "Physical Parameters Management" functionality in their role.

Each action which is performed at Conversion Factors level is logged for auditing purposes.

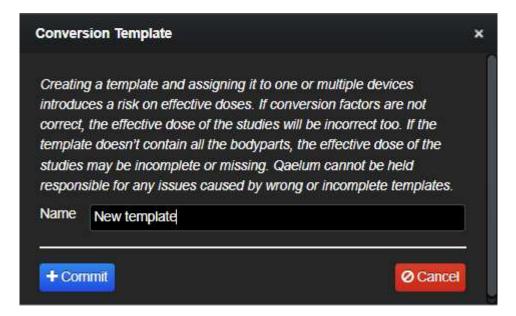
To create a template:

- 1. Go to Settings \rightarrow Conversion factors.
- 2. Click on Add.





3. Insert the name of the template, then click on Commit.



Templates are created as duplicates of the predefined template provided by Qaelum, so to prevent users from having to recreate all cases.

To edit a template:

- 1. Go to Settings \rightarrow Conversion factors.
- 2. Select a template.



3. Click on Actions \rightarrow Insert data.

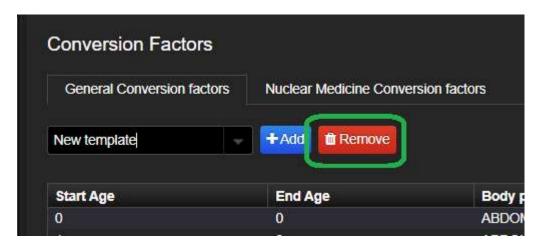




4. Once the edit is complete, click on Commit.

To delete a template:

- 1. Go to Settings \rightarrow Conversion factors.
- 2. Select a template.
- 3. Click on Remove.

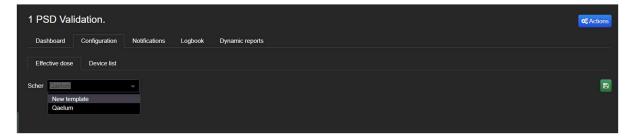


4. Click on OK.

Users are only allowed to remove templates which are not assigned to sites or to devices.

To assign a template to a site and all the devices belonging to the site:

- 1. Go to Device \rightarrow Site overview.
- 2. Click on Configuration, then on Effective dose.
- 3. In the dropdown Template, select a template.



4. Click on the Save button.

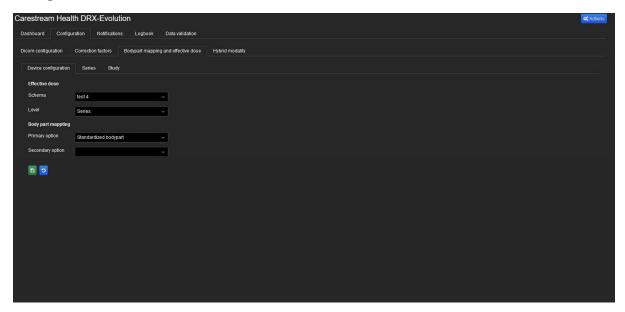


5. Click on Commit.

Every newly created device is assigned to the Template of the site to which the device belongs to.

To assign a template to a device:

- 1. Go to Device \rightarrow Device overview.
- 2. Click on Configuration \rightarrow Bodypart mapping and effective dose \rightarrow Device configuration.



- 3. In the dropdown Template, select a template.
- 4. Click on the Save button.

14.3.2. Study Groups

With this tool the user can create, edit and delete population groups (based on modality, age range and gender), for which it will be possible to configure acceptable and achievable dose limits. Afterwards those study groups can be used on device level for the export and filter function. For more information, see <u>Compliance Configuration</u>.



Study groups overview



14.3.3. Dicom bodypart mapping

Here the user can manage the bodypart mapping described in <u>Mapping at series level</u> in a centralized way. Select the device in the dropdown menu in the upper-right corner.



Dicom bodypart mapping

14.4. Data management

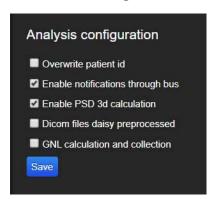
14.4.1. Remove data

When a site or a device is deleted, studies data is not removed. To delete dose and contrast data, the administrator must use this tab. By clicking on a device, the user can decide to erase contrast data or all data for it.

Both methods will erase the data without leaving any revision or retrace possibility.

14.4.2. Analysis configuration

Here some configurations for the analysis are enabled/disabled.

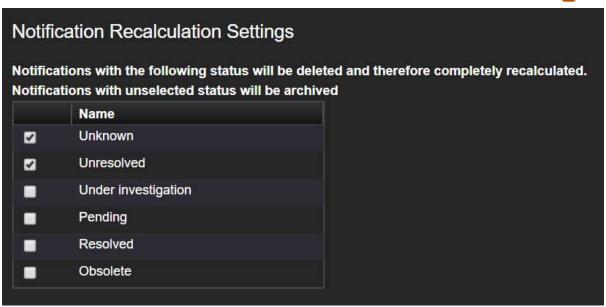


Analysis configuration

14.4.3. Notification Recalculation Settings

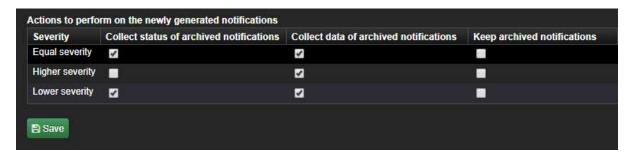
The default notification recalculation settings can be configured here. The selected configuration will be displayed in the Notification Recalculation window (see section *Compliance Configuration*).





Default settings for recalculation

Here the user can also configure what will happen to the information within archived notifications i.e. notifications that have been recalculated and therefore overwritten.



In the table above, three types of severity for the newly calculated notifications are shown:

- Equal severity: the new notification has the same severity (color) as the old notification (e.g. ORANGE -> ORANGE, RED -> RED)
- Higher severity: the new notification is more severe than the old notification (e.g. RED -> ORANGE, ORANGE -> GREEN)
- Lower severity: the new notification is less severe than the old notification (e.g. ORANGE -> RED, GREEN -> ORANGE)

For these three cases the user can configure what happens to the information within old notifications as follows:

- Collect the status of archived notifications: e.g. if the old notification was "resolved", the new notification will be automatically marked also as "resolved".
- Collect the data of archived notifications: if anything was added in the old notification (e.g. comments in "Handle"), that data will be transferred to the new notification (except its status).



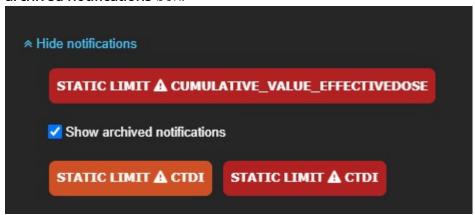
 Keep archived notifications: both old and new notifications will be kept and shown.

If the archived notifications are kept, they can be visualized in the Notifications tab by checking the **Include archived** box located above the Notifications filter.



Include archived notifications

Archived notifications can be visualized in the Study Details by checking the **Show archived notifications** box.

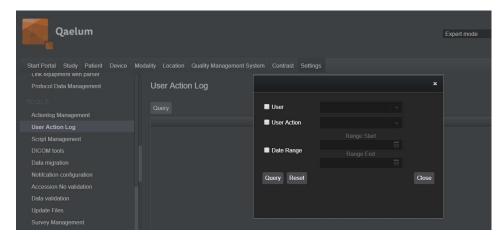


Show archived notifications in Study Details

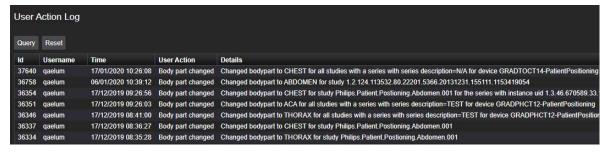
14.5. Tools

14.5.1. User Action log

The User Action log allows the possibility to track specific actions user per user within a certain date range. Click on **Query**, select a user to be tracked, the specific action and the date range.



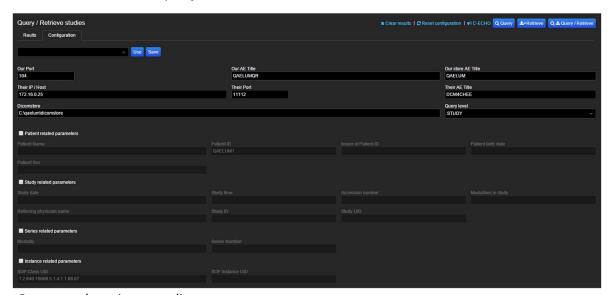




User action log

14.5.2. DICOM Tools

This tab contains the query / retrieve (Q/R) tools.



Query and retrieve studies

The first line is for saved configurations. By clicking **Save**, the current configuration will be saved so that you will be able to reload it by clicking Use.



All general info about the DOSE server and PACS

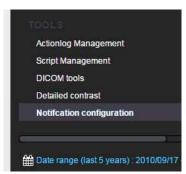
This section contains all information about the DOSE server and the PACS to be added to Q/R. Is it possible to query on Patient, Study, Series or Instance levels. The parameters for such levels are shown in the following sections.

It is possible to run only queries, to retrieve the studies based on query selection or to query / retrieve.



14.5.3. Notification configuration

The goal is to notify users when there is a specific problem on a study. It can be done by using predefined scripts or selecting an alert level for a specific parameter. The study's where the users want to have a notification of can be on site, modality or equipment level. Furthermore, users can make an action object whereby they can select which people will get a notification and which type of message.



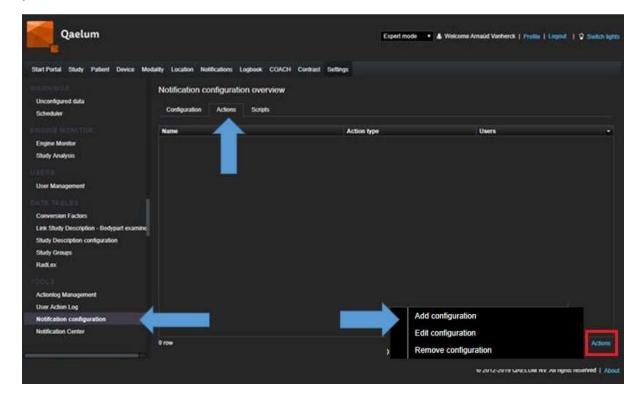
Notification configuration

The steps for this procedure are:

- 1. Create an email notification action
- 2. Create a **configuration** (alert) and link it to the action.

14.5.3.1. CREATE AN E-MAIL NOTIFICATION ACTION

When logged in in DOSE, please select Settings, then Notification configuration. There, please select the second tab (Actions).



By clicking on Actions in the lower right side of the page, a menu will appear, select Add configuration.

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The popup will allow you to create an action. In this context, an action is a group of users which need to be notified when an alert is created.

Each action requires a name and at least one user or Team. Please type the name in the correspondent field and select the users by clicking on their name and then clicking on the symbol. As this happens, the users or teams are moved to the right table.

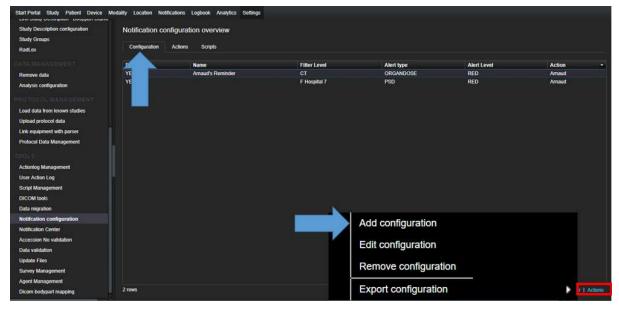


You can unselect a user by clicking on the name in the right table and then on Save, please click on **Commit**.

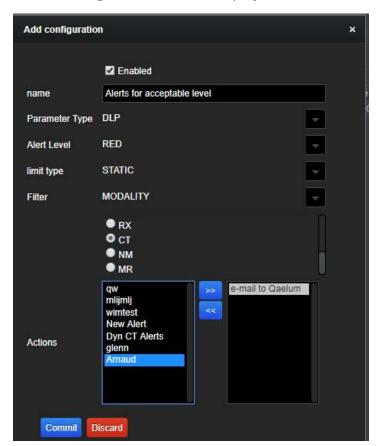
14.5.3.2. CREATE AN E-MAIL ALERT

E-mail alerts can be configured for exceeding static and/or dynamic limits. To add a new e-mail alert access the **Configuration** tab, click on the *Actions* button in the lower-right corner and select *Add configuration*.





The following window will be displayed:



And the following alert fields can be configured:

- alert name
- parameter type
- severity level to be alerted of (orange/red)
- limit type (static/dynamic)
- filter by hospital, modality or device to be alerted for



An action (e-mail sending) can be linked to this alert. In the above example, the user Qaelum will receive an e-mail for each time that the DLP from any CT of any site is above the static acceptable (red) level.

Remark: each alert level should be configured separately. For example, configuring an orange alert level for DLP will not automatically trigger the red alert level for this parameter. For more information, refer to the video *How to configure e-mail sending for compliance notifications* in our online training center.

15. Integrations

Several integrations, described below, are available.

- **DICOM.** This integration is mandatory, as it is needed in order to collect data. DOSE contains a DICOM SCP for C-STORE, to which the PACS and/or the modalities can send the studies. For a description of the supported DICOM objects, please refer to the DICOM Conformance Statement.
- MPPS. DOSE can also contain an MPPS receiver. The messages are analysed and collected similarly to other DICOM objects.
- **HL7.** DOSE uses a customized installation of Mirth connect in order to collect and send data from/to third party via HL7. The following kind of messages are supported:
 - o Inbound:
 - ADT. This kind of messages is used to edit patient data.
 - ORM. This kind of message is used to create studies for which no DICOM data is available, or to add some details.
 - Outbound:
 - ORM. This kind of messages is used to export dose data.

Additional details can be found in the HL7 Conformance Statement.

• **Webservice.** DOSE can be integrated in third party software via webservice. This allows showing information like patient passport directly on the third party.



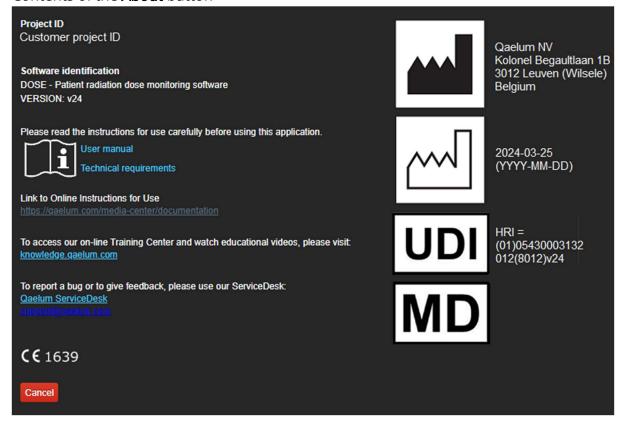
16. About

All information about the system and its producer are shown in the lower right corner of every page.

By clicking on the **About** button, the user can find information about the project ID, the software version, the company ID and contacts, and a link to this manual. It is also possible to report a bug and/or give feedback.

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Contents of the About button



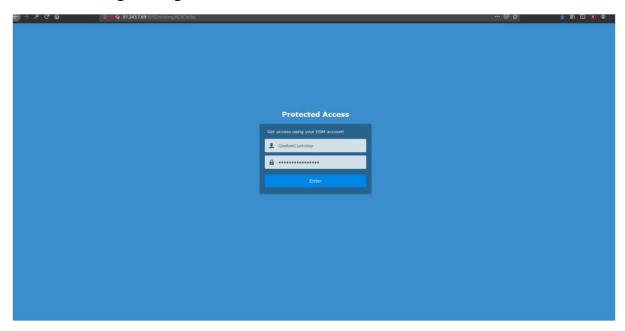
The most up to date external user manual can be accessed using the <u>Qaelum Disk Station</u> website link provided in the **About** box (see above), using the following credentials, given in the F20 Installation and Configuration report (chapter 3 Installation and configuration checklist):

Username: QaelumCustomer

Password: QaelumCustomer01

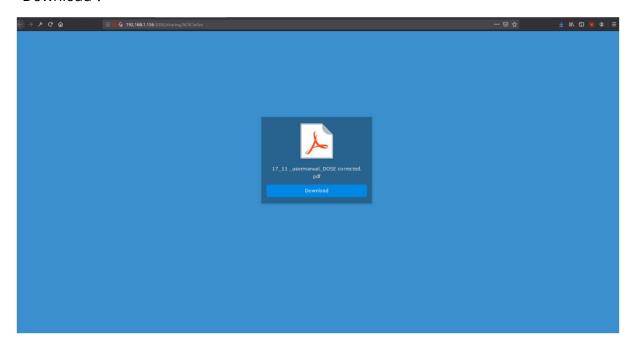


The user can log in using the screen below:



Log-in screen to access the user manual

The latest applicable version of the user manual can be downloaded by clicking on the "Download".



User manual download

16.1. Online Training Center

Qaelum's online training center is a tool that aims to support DOSE users once the personalized training is finished. This center contains explanatory videos that show all the steps necessary to obtain the desired results in the application. They are sorted by



theme, with titles in the format "How to configure...", "How to use...?" and includes a search tool.

16.1.1. Sign in

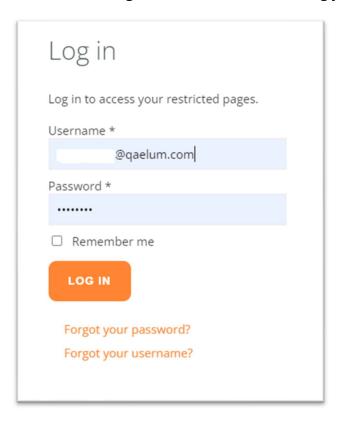
To access the training center, the following link can be used:

knowledge.qaelum.com

Registration can be completed via the following link:

https://qaelum.com/training-registration

Following registration, Qaelum will activate the user accounts and a confirmation e-mail will be set. Once activated, the training center can be entered using your credentials.



Username and/or password can be changed by clicking on *Forgot your password/username?*

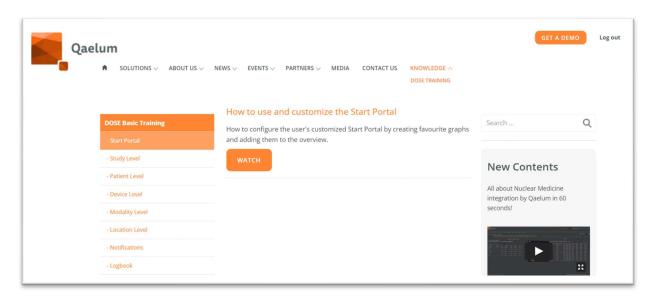
Once logged in, the *Knowledge* section will appear on the left-hand side of Qaelum's website menu. Once accessed, users will be redirected to the **DOSE training** section, where the training center is located.





16.1.2. How to find a video

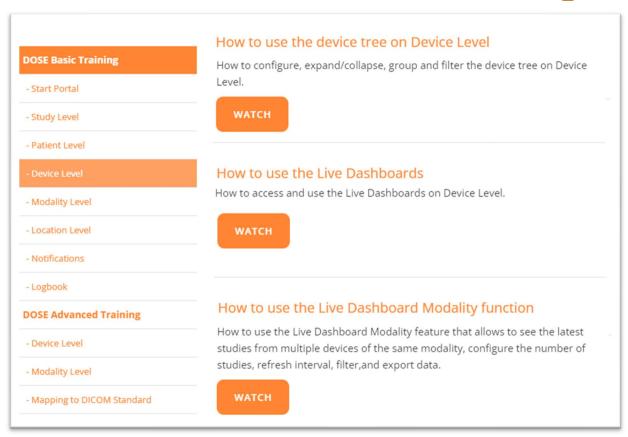
In the training center, the videos are grouped according to the user level (basic and advanced) and by topic. Each video is accompanied by a brief description. Click on *Watch* to access a video. Additionally, a search tool is available in the upper right corner. Keywords can be entered here to search for the desired videos according to video title and caption.



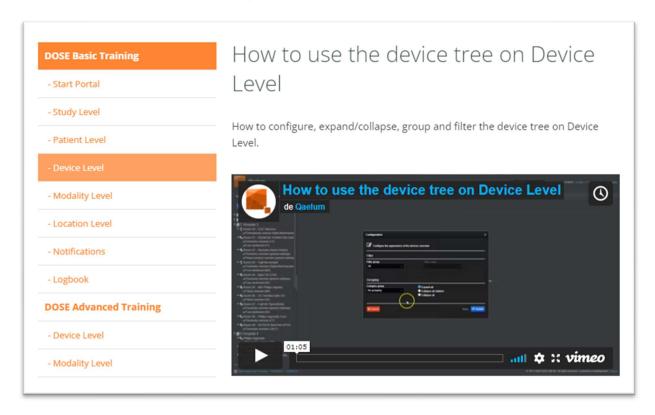
16.1.2.1. MENU BY TOPIC

To find a video, you can search the menu by training level (basic or advanced) and within the level, by topic. For example, to find a basic training video related to Device Level, the *DOSE Basic Training/Device level* section is accessed:





When the relevant video is located, click on Watch.

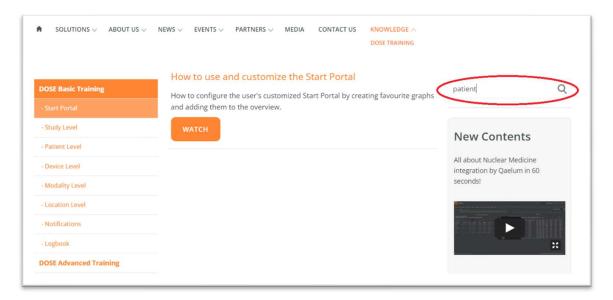




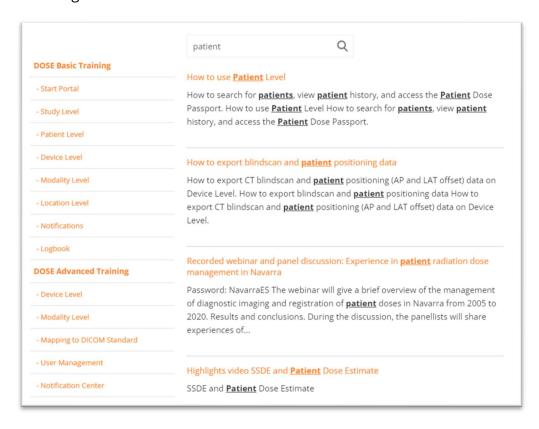
16.1.2.2. SEARCH TOOL

A keyword search engine can be found in the upper right corner. This will return results based on video title and description.

For example, to find a video related to patient information, "patient" can be entered in the search engine:

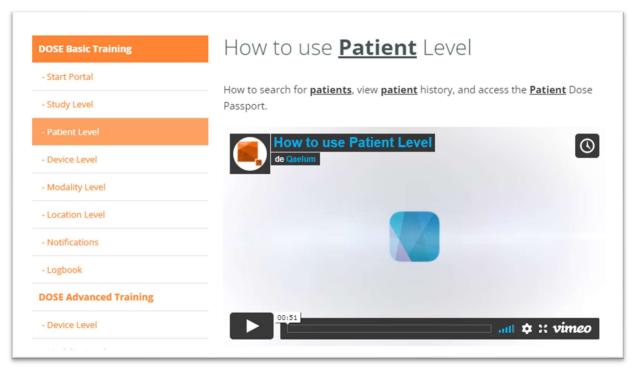


Returning a list of results:



Clicking on any of the results will navigate directly to the video page.

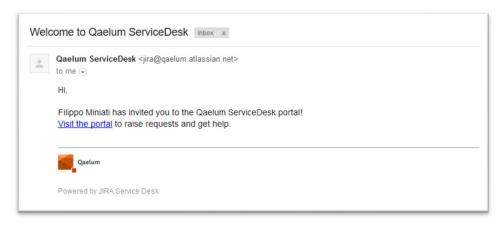




16.2. Service desk

16.2.1. Invitation for Service Desk

An invitation to the Service Desk is sent to the contact email provided to Qaelum.



Qaelum Service Desk



16.2.2. Configure your login details

When clicking on the link "Visit the portal", you are directed to the configuration window for setting up your log-in information.

Your email is automatically generated as your username.

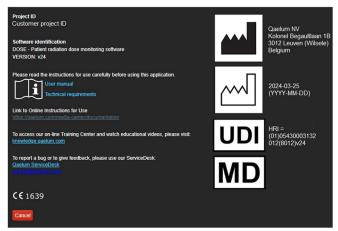
Provide your full name and the password you would like to use. In case you would like to see the password, click on the check box "Show password".



16.2.3. Reporting via Service Desk

In order to create your ticket, you can use the following URL:

https://gaelum.atlassian.net/servicedesk/customer/portal/2

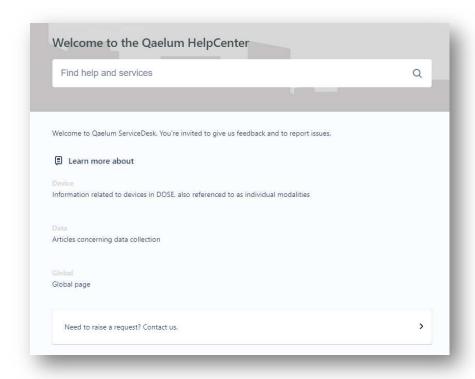


A direct link to our Service Desk can be found in the **About** box of all Qaelum products.

Log in with your credentials to start using the Service Desk.

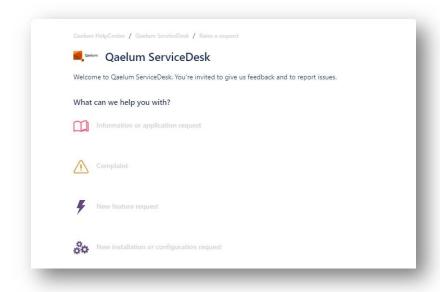
After log-in you are directed to the start portal of the Service Desk. This page contains links to some FAQs and basic troubleshooting that can answer the common questions or complaints. We would appreciate if you first check to see if your complaint is related to a document that can clarify and possibly solve your issue immediately. Otherwise feel free to raise a request.





FAQs in the Service Desk

Please select the type of issue that you would like to report to us.



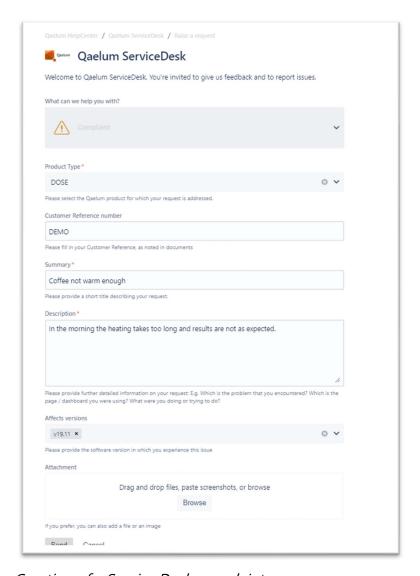
Issue types in the Service Desk

16.2.3.1. COMPLAINT REPORTING

Reporting a complaint requires some mandatory fields to be filled in. In the "Product type" dropdown please indicate which product the issue is related to. Identify the problem with



an accurate title and add it to the "Summary" box. Provide us with a detailed description of the problem in the "Description" box. In the "Affects version", please specify which version of our product your complaint is about. In case you would like to share a screenshot or other files, you can upload it in the "Attachment" box. Finally, please indicate your customer reference number, which is provided to you by our installation team.

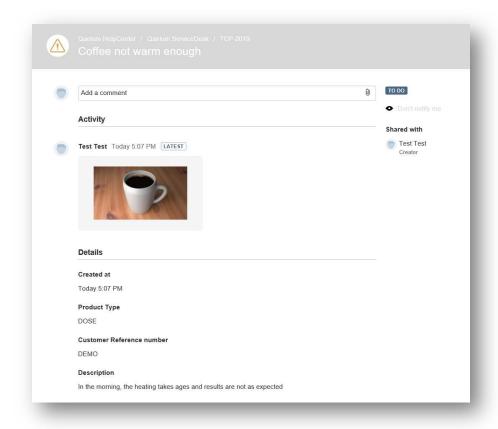


Creation of a Service Desk complaint

To send your issue, click "Create".

After creating the issue, you can view the issue summary. You can add extra comments or attachments.

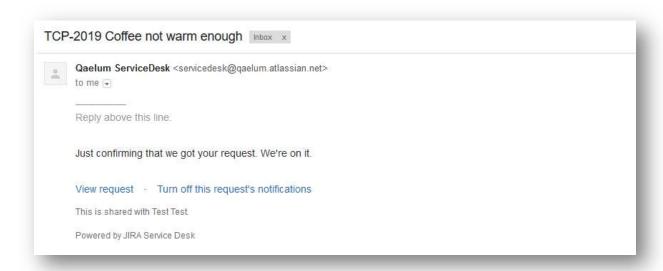




Service Desk complaint

Other members of your team will be automatically added as viewers of the ticket. Please let us know if you would like to limit the viewers.

An email will be sent to you, notifying that your ticket was received.



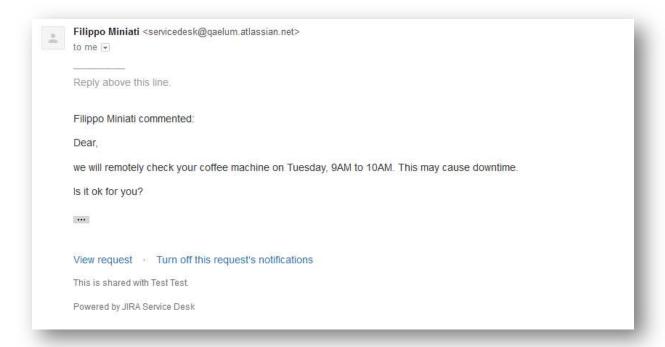
Email confirmation of Service Desk ticket receipt

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Every new change, modification, development, and update of your issue triggers automatic email notifications. This way every step in the handling of your issue can be tracked.

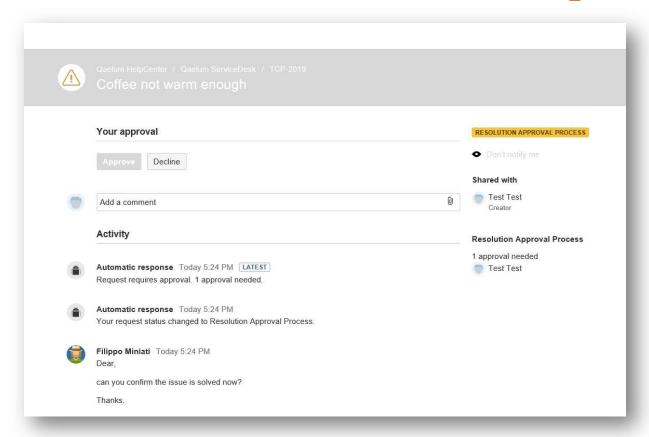
Throughout the process of handling the issue, our Service Desk agents will provide you with feedback, and if needed your confirmation or input may be asked. We kindly ask you to reply to these requests so that we can continue handling your complaint in a timely fashion according to our SLAs. You can reply via the Service Desk webpage or by simply replying to the email.



Email from the Service Desk

After the resolution has been deployed, your approval will be asked. You can approve the resolution by simply clicking on "Accept" in the Service Desk.





Resolution approval

Automatic resolution acceptance will occur after a time period of 7 working days following the deployment of the resolution.

After the issue is considered resolved, you may receive an additional email, allowing you to evaluate Qaelum's customer care.





16.2.3.2. OTHER REQUESTS

Similarly to complaint reporting, you can also report the requests listed below.

16.2.3.3. NEW INSTALLATION OR CONFIGURATION REQUEST

Please use this request type for adding new modules, devices / modalities or hospitals to your existing installation.

16.2.3.4. INFORMATION OR APPLICATION REQUEST

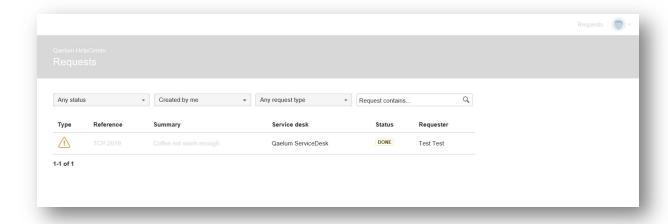
Sometimes you may simply need an explanation of a feature: in this case, or when you need a training, this request type can be raised.

16.2.3.5. NEW FEATURE REQUEST

Please use this kind of request to suggest new tools/features. We will consider them for the following releases!

16.2.4. All requests overview

When you log in to Service Desk, in the top right corner of the start portal, you can see "Requests" with a number indicating the number of open requests.



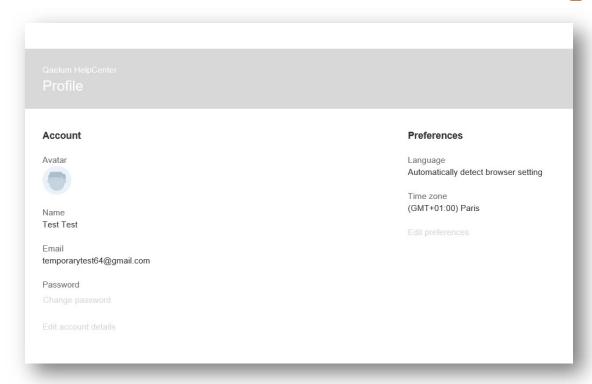
Requests in Service Desk

When you click on it, you receive an overview of all requests you and your team have sent to us. In addition, you can also search the requests and filter by all, open or closed requests.

16.2.5. Profile

In the top right corner of the start portal, you can find an icon for your profile. By clicking on your profile, you can personalize or change the information in your profile. You can change the icon that appears, your password, name, and time zone.





Profile details in the Service Desk

16.3. Symbols

	ymbols	
Symbol	Symbol Definition	
i	This symbol indicates to read the instructions for use and links directly to the user guide.	
	Symbol for Manufacturer	
	Symbol for Date of manufacture	
UDI	Symbol for UDI Carrier	
REF Symbol for Manufacturer's Catalog Number		
MD	Symbol for Medical Device	



17. Supported browsers

DOSE is a zero-footprint software web application. This means that it requires no client-side application install and has no OS dependency. The application can be accessed from anywhere within the hospital network by browsing to the URL set up for DOSE. We support the following browsers:

- ✓ Google Chrome 80+
- ✓ Mozilla Firefox 70+
- ✓ Internet Explorer 11
- ✓ Microsoft Edge

Please see the Technical Requirements document for more information

18. Minimal hardware requirements

These requirements are only applicable to small installations (10 devices / 50.000 studies per year) when redundancy is not required. For further details on bigger installations, please see the Technical Requirements document or ask Qaelum for the Project Proposal.

RAM memory	12 GB
CPU	4 CORES +2GHz
Hard Disk	60GB for OS & application[C:/] 150GB data drive [e.g. D:/] 50GB cache drive[e.g. E:/]
Network connection	LAN and static IP address
Operating System	Windows Server 2012 R2 or newer



19. Functional description

19.1. Background

A quantity of ionizing radiation is related to each examination performed in radiology. Even today, when most systems are working according to the ALARA principle ("as low as reasonably achievable"), it is important to have an overview for all the study types and given doses per X-ray device and the received doses over time for each patient. For X-ray devices, the monitoring of typical dose values is needed for optimization reasons. For patients, the tracking of these doses is needed due to the potential deterministic effects. In digital radiology this dose information is often stored together with the clinical images in the PACS (Picture Archive and Communications Software). This can be done in the form of dedicated and sometimes private DICOM header values, printed as an image in SC (Secondary Capture) images, as SR objects (Structured Reports) or in log files stored on the console of the X-Ray device. Thus, the analysis of total patient dose, the monitoring of protocol quality, and the comparison of the used settings (physical-technical and configured) of different devices needs to be addressed, preferably within a single system.

19.2. Description of the solution

We aim to overcome the above problems with the software solution DOSE.

Using this software, it is possible to:

- analyze all types of clinical images for the received dose information
- store them in a separate database, apart from the PACS, for further future access
- Allow to view these data on patient level (historical overview of patient dose) and to compare the mean doses per study of the different X-Ray devices
- Analyze the workload/flow
- Compare the modalities

In addition, it is possible to:

- Analyze and track the different commonly used modalities (DX, CR,MG,CT,XA,RF,US,MR)
- Have a solution that is integrated into the clinical workflow, without impacting the normal workflow
- Have a vendor-neutral system
- Present this data to all stakeholders in the radiology department in the most optimal form. If needed, we will develop integration modules to bring this data closer to the end user and find new ways to present the collected data



- Extract other types of data related to the exposure parameters, in addition to the dose information, in order to simplify the understanding of what went wrong if dose values are exceeding limits
- Compare the extracted dose values with national/predefined reference values

19.3. Supported modalities

- ✓ General radiology (DR, DX. RF, CR)
- ✓ Computed tomography (CT)
- ✓ Interventional radiology (XA)
- ✓ Mammography (MG)

As an additional option, we can also analyze MR (including specific absorption rate, SAR) and US workflow and workload.

19.4. DOSE: Individual patient benefits

- DOSE can access all the available radiation dose information from PACS and from the devices directly, create reports that include previous examinations with the cumulative effective dose, calculated depending on age and body parts, and thus provide patient radiation dose history. The patient dose history can be used for individual risk assessment. Although this information is not used for justification of a future exam, it can be used to optimize the workflow for the patient benefit. If, for example, a department has two scanners and scanner 1 has a chest protocol with relatively lower dose than the same protocol on scanner 2, then, a patient of high cumulative dose that needs to do a chest CT can be sent to scanner 1. This feature can be also used to identify subgroups that receive high doses and pave the way towards a better clinical follow up protocol and/or specific device protocols to optimize their exposure without jeopardizing the benefits.
- The user can assess the radiation dose to the patient skin from a specific procedure or from multiple procedures. If this is high and a skin reaction is expected, the patient can be pro-actively referred to another specialist (e.g. dermatologist) to treat the specified deterministic effects as soon as possible. Additionally, high doses increase the possibility of radiation-induced stochastic effects (e.g. neoplasm), and this is also something that users may want to follow up with the goal to optimize and potentially reduce doses for next exams. The analysis of patient skin doses can help the users to optimize their practices for future patients. In cases that the complexity of the procedure allows it, different geometry and different angulations may be used to improve the outcome with respect to patient skin dose and minimize the risk for stochastic effects for future procedures.
- DOSE can make comprehensive reporting about patient organ doses. This can ensure that potentially pregnant women, pediatric patients, and other patients at



risk receive optimal doses for the clinical goal. The reporting of organ doses helps users to see the levels of exposure and evaluate the risk for stochastic effects for patients that undergo each exam type. Therefore, this allows to optimize the procedure as much as possible and minimize the risk for radiation-induced effects.

- The Live Dashboard feature in DOSE allows radiographers to see the given dose to the patient and any raised alerts immediately after the examination. Thus, the radiographer can contact the radiologist directly and discuss any potential problem/harm to the patient resulting from the examination, as well as image quality issues.
- The analysis of image noise and of the subjective image quality allows users to combine image quality with dose data in order to improve the practice based on the ALARA principle but having in mind also the adequate diagnostic result of the exam.
- Patient radiological data can be benchmarked against:
 - Similar examinations: this is based on dynamic limits that help radiographers understand if the examination that the patient has just undergone, had a higher or lower dose if benchmarked against similar examinations from the same device or modality, having the same study description, composition, protocol name or body part.
 - Ages/patient sizes: this comparison takes the age and size of the patient into account, which is important for the calculation of the individual patient dose. This is especially important for the pediatric patients and some body parts (e.g. breast, thyroid, uterus...) because they are more sensitive to radiation.
 - o Thresholds set by scientific guidelines or national authorities: By providing a report with this information and by generating notifications, DOSE increases awareness for the patient to ensure that the dose level is reasonable for this study type and patient characteristics (e.g. size). This way, the patient can be followed up, while errors can be found faster and ensure avoidance for future patients.
- Legal compliance: this is based on the static limits per study category that the national authorities provide each year. The exams are benchmarked automatically against exams of the same group, and if the overall group exceeds the defined thresholds, the system highlights it. By providing a report with this information, DOSE informs users to optimize this group for future patients and ensure that the level of dose is reasonable for this study type, following the ALARA (as low as reasonably achievable) principle.



19.5. DOSE residual risks

QAELUM is performing advanced risk reduction of all risks related to the software and its specific versions. However, the following list summarizes the **residual risks**:

- 1. No access to, or, no/delayed/incomplete availability of patient exam dosimetry data that may lead to missing potentially linked alerts. This can be due to:
 - a. Temporary inaccessibility of the system; e.g., due to lack of electricity, network problems or OS updates performed by local IT departments.
 - b. VM shutdown; e.g. due to human error or hardware failure.
 - c. Insufficient disk space; e.g., due to unexpected large amounts of data incoming from the PACS. Disk space is also used to collect thumbnails and quality control images: as the amount of analyzed data grows, QAELUM may ask the IT department to add disk space. If the IT department does not timely reply, the system may stop working.
 - d. Vendors or customers (i.e., users having access to the appropriate Functionalities) can change the device-data linking identifiers (e.g. StationName 0008,1010) without notifying QAELUM of this change.
- 2. **Inability to provide support by QAELUM**. This can be due to:

Temporary inaccessibility of VPN. The local IT department may not grant access to the DOSE server, so the QAELUM team may not be able to solve problems quickly.

- 3. Unauthorized actions performed on the physical or virtual server(s) hosting the product, without approval of QAELUM or 3rd party Supplier, can lead to disruption and incorrect functioning of the product. This can be due to:
 - a. Processes stopped. The local IT department has the possibility to connect to the DOSE server, as they are responsible for hardware and the operative system: they may stop or remove some QAELUM related services.
 - b. Database corruption. Often DOSE databases are administered by customers: therefore, they could use their access rights to accidentally remove data, modify the structure and/or change configurations, without first consulting with the Supplier.
 - c. Post-production installation of antivirus software (at customer server, by the local IT department and without informing QAELUM proactively) can be a problem for less common tools, like DOSE, as typically only executables known by the antivirus company are trusted.
 - Remark: If this is done prior to production, QAELUM will report on any negative effects of the antivirus on the performance of DOSE so the necessary actions can be taken prior to production use.
- 4. Emails (notifications, reports, password resets, ...) not reaching the destination user.
 This can be due to:
 - a. Incorrect set or outdated email on user profile or email misconfiguration.



- b. Customer email server that considers emails as spam (e.g. because of setting up email rules that generate too many emails in a predefined timeframe).
- c. Changes in the smtp connection details without identifying QAELUM or 3rd party Supplier.
- 5. Not following QAELUM's advice on backup procedures and time frames can, in case of data corruption, lead to loss of data or delay in data recovery/catch up. The backup guidelines are part of the DOSE technical instructions/documentation, but the customer is responsible to set the configuration and maintenance plan, corresponding to local needs and policies. Whenever the database gets corrupted and the backup is not present, then some data may be lost.
- 6. Using the product interface on a **monitor with resolution requirements below 1024x768 or using unsupported browsers** can lead to sub-optimal display/user experience and possibly wrong actions or conclusions. For more information, please check the DOSE technical instructions/documentation.
- 7. Giving users access to Functionalities with which they are insufficiently familiar (e.g., lack of knowledge, training, etc.), can lead to modifications that in turn can lead to data modification, corruption, errors, or loss. For example, users with administrative roles may remove data by mistake and/or may misconfigure devices by adding the wrong device-data linking identifiers (e.g. StationName 0008,1010). Please assign Functionalities with care and provide user training. We expect users to have sufficient understanding of radiology, anatomy, and radiation, to avoid incorrect action or drawing inappropriate conclusions. Dose indicators should always be used according to legal and scientific guidelines. This product should not be used outside of its intended use.

19.6. DOSE intended user and training

DOSE is a state-of-the-art software offering a vast variety of functionalities. This software is intended for use by medical professionals only – radiographers, radiologists, the management of radiology departments, medical physicists. Therefore, software training by an expert from QAELUM is required before users can have access and start using the software.

19.6.1. Intended Use

DOSE is intended to extract, analyze and monitor patient radiation dose of the individual patient who undergoes X-ray examinations. The intended users are the medical professionals in radiology departments or diagnostic imaging facilities. Its use is independent of patient disease or condition, frequency of imaging, patient characteristics, or the imaged anatomy. It can assist the user in evaluating dose levels and potential improvements for individual patient examinations, and thus improve diagnosis and determine optimal treatments. Additionally, it helps the user to manage all the



patient radiation related data that is available in the imaging department in a faster and more efficient way.

The software allows:

IU#	Intended use
101	The software extracts radiation dose and other parameters for every acquisition or examination of the patient's medical exposure. This will allow the end-user to have easy access to all the details of the acquisition/examination and evaluate the situation for the patient.
IU2	The software calculates dose and dose-related indices for every acquisition/examination taking into account as many details as possible. This helps to provide a more individualized assessment for each patient and helps identifying the shortcomings with respect to procedures, techniques, workflows, persons for further improving the patient quality of care.
103	The extracted and/or calculated dose and dose-related indices are used to manually and/or automatically evaluate and assess the level of exposure of the patient. Based on these numbers the end-user can decide whether or not to take actions to optimize exams for all future patients.
IU4	Calculating the local reference levels and comparing with national and international DRL values allows to monitor the exposure levels for each exam type on the specific device/hospital and optimize when needed. This will allow for optimized exams for all future patients.
IU5	Benchmarking between similar studies allows for better evaluation of the practice and optimization of the technique/dose/performance and therefore outcome for patients that undergo the same exam.
IU6	After the assessment of dose and dose-related indices, the system notifies the end-user for potential outliers or situations that can have an impact on diagnosis or patient's health
IU7	Analyses and assesses the cumulative dose and dose-related indices over all examinations of the patient.
IU8	The system collects, analyses and assesses the image quality of a patient's exam in order to ensure proper diagnostic exam quality for current and future patients
IU9	Sharing or exporting patient exam data to facilitate data access without the need to connect directly to our system.
IU10	Evaluation and assessment of parameters related to device usage and performance which will benefit the patient by facilitating the optimization of the clinical imaging pathway

19.6.2. Medical conditions

DOSE is used after the medical exposure is finished, and there are no medical conditions that do not allow the use of the product.



19.6.3. Contraindications

There are no contraindications. DOSE patient radiation dose analysis can be calculated for any patient who undergoes a medical imaging examination.

19.6.4. Performance of the device

Accuracy of measurement(s)

The accuracy of the measurements and calculations that are performed in DOSE depends on the modality and the dosimetric parameter. In some cases, it is also linked to other parameters like the examined body part or the protocol used.

In all cases, when percentiles are calculated, the minimum value of the parameter is expected to be smaller than the maximum and the 25th, 50th (median) and 75th percentiles should be values between the minimum and maximum. The mean value is expected to be (Max-Min)/2.

These rules should apply, unless there is only 1 study taken into account and then Minimum=Maximum and all the other percentiles are the same.

Additionally, if a study is selected to be ignored from the statistics (manually, by the user), then the system should exclude it from the analysis of the particular study group/study description/protocol. In this case, the statistics/percentiles are expected to be different than before.

Below an analysis per modality follows. Most of the values mentioned are indicative and should not be evaluated for an individual study, but as a measure for the majority of studies and the expected order of magnitude.

Computed Tomography (CT)

The unit of CTDIvol in DICOM standards is mGy, and therefore is mGy in DOSE. The expected range for CTDIvol of one acquisition 0-150 mGy. Even though 150mGy is quite a high number, it can occur in a protocol that does not comply. Also, in the case of stationary acquisitions, if the operator scans using long exposure time, then the CTDIvol can be high. Thus, individual studies may reach these values, and then they are considered outliers and the user must justify them. To consider the reading of DOSE accurate, the majority of studies (excluding the aforementioned outliers), should have a CTDIvol that does not exceed the aforementioned values. The same stands for DLP (suggested range 0-2000 mGy•cm for an acquisition).

DOSE also calculates SSDE in mGy. The expected range of SSDE is 0.22•CTDIvol < SSDE < 2.76•CTDIvol for one acquisition, as these correction factors (0.22 for a very big patient and 2.76 for a very small patient) are the extreme values in the tables in the AAPM reports 204 and 220.

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For patient positioning, the values are shown in mm. Vertical or horizontal offsets should be in the range of 0-150 mm as usually there is no space for the patient to be positioned in a larger offset.

For the in-house organ dose calculation, depending on the body part examined, the highest dose values are expected in specific organs:

Chest	hest Breast-Lung-Heart-Thymus-Thyroid		
Abdomen	Colon-Kidneys-Liver-Spleen-Stomach		
Chest-abdomen	Breast-Lung-Liver-Spleen-Thymus		
Pelvis	Muscle-Prostate/Uterus-Small	Intestine-Testes/Ovaries-	
	Urinary bladder		
Abdomen-pelvis	Kidneys-Liver-Spleen-Stomach-Urinary bladder		
Chest-abdomen-	Breast-Lung-Liver-Spleen-Thymus		
pelvis			

Interventional Radiology (XA)

Peak skin dose map should have colors on the dark background in order to check that a calculation is performed. Also, the colors should form a shape on the map and the dark background should be visible, at least in a small part of the map.

The peak skin dose value is reported in Gy. Thus the expected range is 0.01 – 30 Gy. A PSD of 30 Gy can happen and does not indicate a calculation problem in DOSE.

The same stands for the Dose at Reference Point, which should have the same range.

Conventional radiography (DR-DX-CR-RX)

For conventional radiology, there are two parameters that should be evaluated, DAP and exposure index. However, the exposure index is not always used by the manufacturers with the standardized calculation methodology. If the standardized exposure index is used, then it is normally expected <1000 for an image (to be checked further).

DAP for an image should normally be <100 dGy•cm².

Mammography (MG)

Organ dose which indicates the mean glandular dose of the breast is in mGy.

Organ dose for each series should be below 10 mGy. This is a large number, but it is indicative of the expected order of magnitude. Cumulative organ dose of a study should be below 50 mGy.

Capacity performance

DOSE is designed as a modular, easy to scale-up system: each component can be replicated several times in order to increase the system capacity. Based on the expected

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volumes, Qaelum provides customers with an architecture proposal: this is meant to guarantee availability and speed of the system.

DOSE is able to deal with projects for up to 20 different hospitals, 300 devices, yearly study volume of 3M, and 200 users. Bigger projects are also manageable, and scalability improvements are developed regularly.

Speed performance

Qaelum team configures each DOSE system in order to provide customers with the best user experience. Speed is granted by using the correct architecture, hardware, and database, as discussed during the project technical meetings. Improvements are regularly deployed together with the software updates. Hardware usage is evaluated regularly, and requests for upgrades are made in case of need.

During trainings users are suggested to improve their experience by using broader date ranges (>6 months) only in case of need. A shorter date range (e.g. 3-4 weeks) is usually adequate to evaluate the current trends. As a general rule, the longer the date range, the longer the loading time: while showing graphs for one device with 2 weeks of data takes less than one second, showing several years (or tens of thousands of studies) may take up to 10 seconds.

Besides this, the loading of some components is naturally slower because of the amounts of calculations to be performed: for example, the legal compliance can usually take up to 5 seconds to be shown, depending on the amount of configured study groups.

Lastly, saving configurations that require the recalculation of data (for example the study group configuration) may take several seconds to be completed, depending on the amount of studies.

Compatibility with browsers and operating systems

DOSE is a zero-footprint software web application. This means that it requires no client-side application install and has no OS dependency. The application can be accessed from anywhere within the hospital network by browsing to the URL set up for DOSE. We support the following browsers:

- ✓ Google Chrome 80+
- ✓ Mozilla Firefox 70+
- ✓ Internet Explorer 11
- ✓ Microsoft Edge



20. Incident reporting

In case any serious incident has occurred in relation to the device, please report this to Qaelum. You can do this by phone, mail or through our ServiceDesk portal. The details for these ways of communication are available in section 16 of this document.

In case of need Qaelum will contact the competent authority of KINGDOM OF SAUDI ARABIA. You are allowed to contact the competent authority yourself, but always first inform Qaelum so we are also aware of the incident.

21. Glossary

- Accession number unique identifier assigned to a study within the PACS
- **ACC** acceptable
- **ACH** achievable
- ADT Admission, Discharge, Transfer HL7 message
- **AEC** Automatic Exposure Control
- **AFCN** Agence Fédérale de Controle Nucléaire
- AGD Average Glandular Dose
- **CBCT** Cone Beam Computer Tomography
- Collimation width width of the collimation to restrict radiation to the required dimensions
- **Compression force (N)** force of breast compression (in Newtons)
- **CR** Computed Radiography
- **CSV** Comma-Separated Values
- **CT** Computer Tomography
- **CTDI** Computed Tomography Dose Index
- **DAP** Dose Area Product
- **Device** equipment unit used for imaging
- **DICOM** Digital Imaging and Communications in Medicine
- **DLP** Dose Length Product
- **Effective dose** sum of equivalent doses to all organs, accounting for their respective radiation sensitivity (in mSv)

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- **Exposure time** length of time that the patient is exposed to radiation
- FANC Federaal Agentschap voor Nucleaire Controle
- **Flow rate** the volume of fluid that passes per unit time
- **Catheter gauge** plate consisting of holes of various size used to determine the size of a catheter
- ICRP 106 International Commission on Radiological Protection publication 106
- **Isocentre** the point in the patient through which the central ray of the radiation beam passes
- **JPEG** Joint Photographic Experts Group
- **mA** milliamperage i.e. tube current
- **mAs** tube current-exposure time
- **MG** mammography
- Modality a type of equipment group used for imaging
- MPPS Modality Performed Procedure Step
- MR Magnetic Resonance
- **Organ dose** energy absorbed per unit mass in an organ
- **ORM** Order Request Message in HL7
- PACS Picture Archiving and Communication System
- **PDF** Portable Document Format
- **Kilovoltage peak (KVp)** peak potential applied to the x-ray tube, affecting the quantity and quality of photons
- **Pitch** table distance travelled in one rotation of the gantry
- **PNG** Portable Network Graphics
- **PSD** Peak Skin Dose, the highest dose to a single area of the skin
- **RDSR** Radiation Dose Structured Report
- **RX** general radiography
- **SAR** Specific Absorption Rate, rate of energy absorbed per unit mass by a human when exposed to a radio frequency field
- **Scanlength** length of table travel during a CT scan
- SSDE size-specific dose estimates
- **Study ID** study identification

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- Study UID study unique identification
- **SVG** Scalable Vector Graphics
- **US** Ultrasound
- XA DICOM modality that includes x-ray angiography, interventional radiology
- XLS excel Spreadsheet