

RaySafe i2

Installation and maintenance

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CONTENTS

INTRODUCTION	4
About the RaySafe i2 System	4
How the system works	5
About this user manual.....	5
INSTALLATION.....	6
Package contents	6
Real time display installation.....	7
Dose viewer installation	17
Dose manager installation.....	19
Dosimeter and dosimeter rack.....	20
SYSTEM FUNCTION TESTS	23
Expose dosimeter to radiation	23
Dose viewer/dose manager test	23
Real time display test	24
MEASUREMENT PERFORMANCE VERIFICATION.....	26
SOFTWARE UPDATE AND MAINTENANCE.....	27
Real time display software update	27
Dose viewer software update	27
Dose manager software update	28
Real time display touch screen re-calibration	28
TECHNICAL DATA	29
Real time display	29
Dosimeter	29
Cradle	30
Dosimeter rack	30
Radio communication	30
Climatic conditions	31
INSTALLATION SETTINGS FORM.....	32

INTRODUCTION

ABOUT THE RAYSAFE i2 SYSTEM



Figure 1. RaySafe i2 System overview

The RaySafe i2 System can contain the following components:

- dosimeter
- real time display
- dose viewer (computer software)
- dose manager (computer software)
- cradle (dock station used to connect dosimeters and computer)
- dosimeter rack (dosimeter storage)

HOW THE SYSTEM WORKS

The dosimeter measures and records X-ray exposure every second and transfers the data wirelessly, via radio, to the real time display.

The real time display shows real time dose exposure from up to eight dosimeters in range. Color indication bars (green, yellow, red) represents the intensity of the currently received exposure. The accumulated dose per individual is displayed next to the color indication bars. By tapping a dosimeter name the user can look at historical data in separate views.

When the dosimeter is not in use, it should be stored in the dosimeter rack, away from the real time display.

More detailed historical dose information can be transferred from dosimeters via the cradle connected to a computer and viewed using the computer software (dose viewer and dose manager).

The dose viewer software is also used for administrating dosimeters, change dosimeter names, colors and reset dose history. The dose manager software is an advanced software for analyzing, reporting and archiving dose information. It handles multiple dosimeters and can retrieve the dose information from multiple real time displays through the hospital network or via USB storage.

ABOUT THIS USER MANUAL

This user manual are intended to assist users in the safe and effective operation of the product described.

Before attempting to operate the product, you must read these instructions for use, noting and strictly observing all WARNINGS and CAUTION notices.

WARNING *A WARNING alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient.*

CAUTION *A CAUTION alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.*

NOTE *Notes highlight unusual points as an aid to an operator.*

These Instructions for Use describe the most extensive configuration of the product, with the maximum number of options and accessories. Not every function described may be available on your product.

INSTALLATION

PACKAGE CONTENTS

NOTE: *The content is dependent of purchased configuration.*

RAYSAFE i2 PACKAGE

- RaySafe i2 real time display
- Real time display power supply
- Power plug adapters: EU, UK, US, MCS
- Tie wraps, short (L200) and long (L300)
- VESA LCD wall holder
- 4 x RaySafe i2 dosimeter
- RaySafe i2 dosimeter Calibration Certificate
- RaySafe i2 cradle
- RaySafe i2 dosimeter rack
- RaySafe i2 dose viewer software and manuals
- Radiation protection poster
- RaySafe i2 installation and service manual

RAYSAFE i2 DOSE MANAGER PACKAGE

Extension package.

- RaySafe i2 dose manager software and manuals
- RaySafe i2 dose manager license key
- RaySafe i2 cradle

NOTE: *Ethernet cable (for network connection of the real time display) is not included.*

REAL TIME DISPLAY INSTALLATION

WARNING: *Switch off the system before starting any installation or replacement activities.*

NOTE: *The real time display is delivered with the required software installed.*

NOTE: *In multiple real time display setups, the individual real time displays should be placed in separate rooms.*

NOTE: *The user's software version may differ from the one on the screenshots in the manual, without any change in functionality.*

REQUIRED TOOLS

The following tools are required for mounting the real time display on a wall:

- one 8 mm masonry drill or one 3 mm wood drill
- one medium sized cross headed screwdriver
- one medium sized slotted screwdriver

REAL TIME DISPLAY INTERFACES



Figure 2. The real time display interfaces: 1: 12 V DC, 2: ethernet connection, 3: USB connection, 4: VESA 75 interface

MOUNT THE REAL TIME DISPLAY

The wall support kit contains:

- one VESA 75 wall mounting plate
- one VESA 75 real time display mounting plate
- fixation screws and plugs for the wall mounting plates

Follow the steps below to mount the real time display on a wall:

1. Mount the VESA 75 real time display mounting plate to the real time display using the screws provided with the real time display. Use 8 washers.
2. Place the VESA 75 wall mounting plate on the wall and mark the location of the mounting screws through the plate's mounting holes.

3. Drill the holes as marked, using the masonry or wood drill as appropriate.
4. Mount the VESA 75 wall mounting plate to the wall using the provided screws and plugs.
5. Position the real time display with its mounting plate on the wall mounting plate.

POWER SUPPLY

A 12V power adaptor (Astec DPS53-M, FW7556M/12) powers the real time display.

Insert the output connector of the power adaptor to the back of the real time display, and the AC power cable to a grounded electrical outlet socket.

You may use the included tie wraps to attach the power adaptor if needed.

WARNING *To avoid the risk of electric shock, the real time display must only be connected to a supply mains with protective earth.*

CAUTION: *The real time display battery should not be replaced due to risk of explosion if it is replaced by an incorrect type.*

CAUTION: *The electrical outlet socket should be near the real time display and shall be easily accessible.*

ETHERNET INTERFACE

The ethernet interface is used together with the dose manager application only.

Perform the following steps to connect the real time display to the hospital network:

1. Connect an ethernet cable (not included in the package) to the hospital's network.
2. Connect the ethernet cable to the ethernet connector at the back of the real time display.

CONFIGURE THE REAL TIME DISPLAY

Follow the instructions below to enter the real time display settings view:

1. Tap the settings menu symbol in the upper left corner of the online view.
2. Enter configuration values by tapping the buttons in the respective menus.

NOTE: *Make all real time display set-up configurations in the system settings menu.*

USER SETTINGS MENU

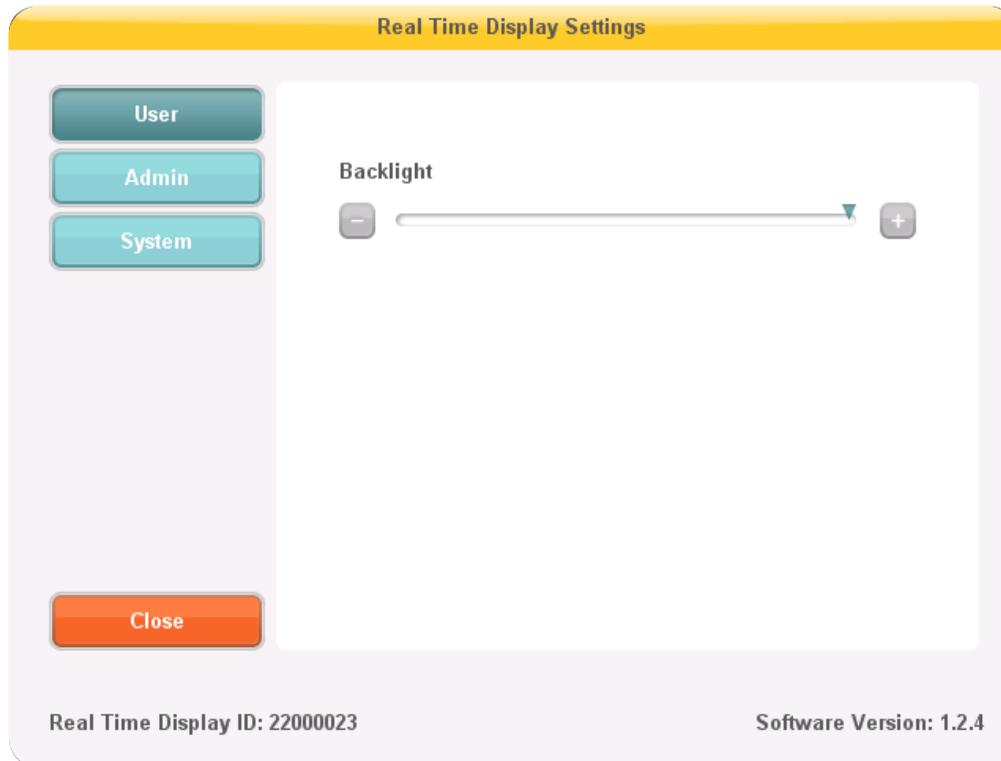


Figure 3. The user settings menu consists of one screen.

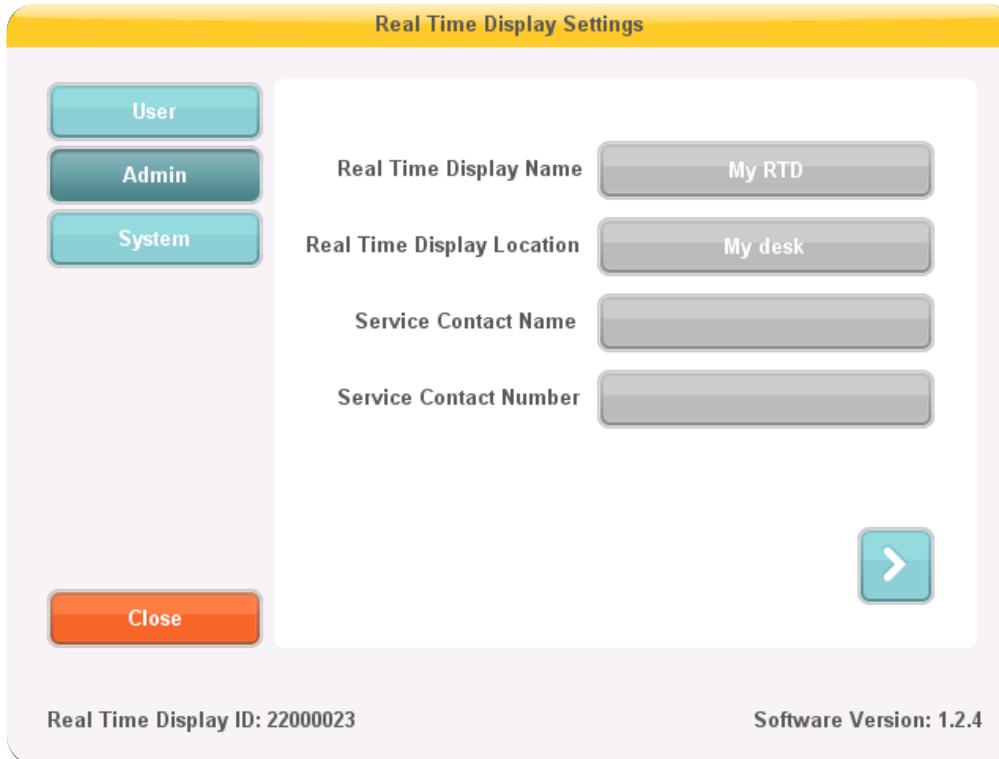
Adjust the backlight level of the screen by moving the bar horizontally.

This change will take effect immediately.

ADMIN SETTINGS MENU

The admin settings menu consists of four screens. Access these screens by tapping the arrow buttons in the lower right corner of each screen.

Real time display name and location menu



The screenshot shows a mobile application interface titled "Real Time Display Settings". On the left side, there are three stacked buttons: "User" (light blue), "Admin" (dark blue), and "System" (light blue). Below these is an orange "Close" button. The main area contains four input fields: "Real Time Display Name" with the value "My RTD", "Real Time Display Location" with the value "My desk", "Service Contact Name" (empty), and "Service Contact Number" (empty). A blue arrow button is located in the bottom right corner of the main area. At the bottom of the screen, it displays "Real Time Display ID: 22000023" on the left and "Software Version: 1.2.4" on the right.

Figure 4. The real time display name and location menu.

Enter appropriate name and location of the real time display. This information is used to identify the real time display so that it can be found in dose manager.

Enter service contact name and number to your local RaySafe i2 system manager.

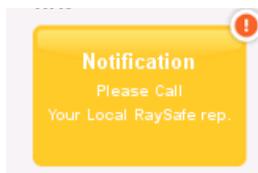


Figure 5. The notification area in the personal dose overview

The service contact information will appear in the notification area, on the left side in the personal dose overview.

Reserved slots menu

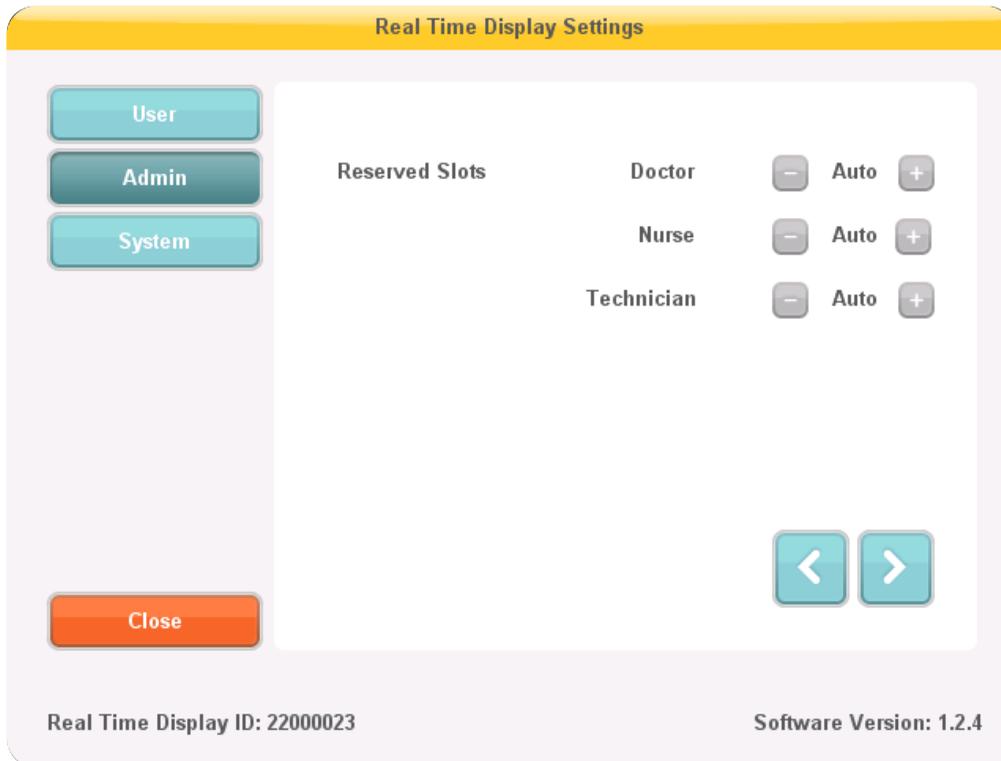


Figure 6. The reserved slots menu.

This is an optional setting, which you can use to reserve a number of slots in the online view for the clinical roles doctor, nurse and technician. If you, for example, have reserved three slots for doctors but the real time display detects only one, there will be two empty slots before the first nurse appears.

If you want to reserve slots for nurses, you also have to reserve slots for doctors. If you want to reserve slots for technicians, you also have to reserve slots for doctors and nurses.

The default behavior “Auto” is first-come, first-served, which means that dosimeters will appear on the screen in the order the real time display detects them, sorted after their clinical role: doctor, nurse, technician, other. This is the recommended setting.

Network setup menu

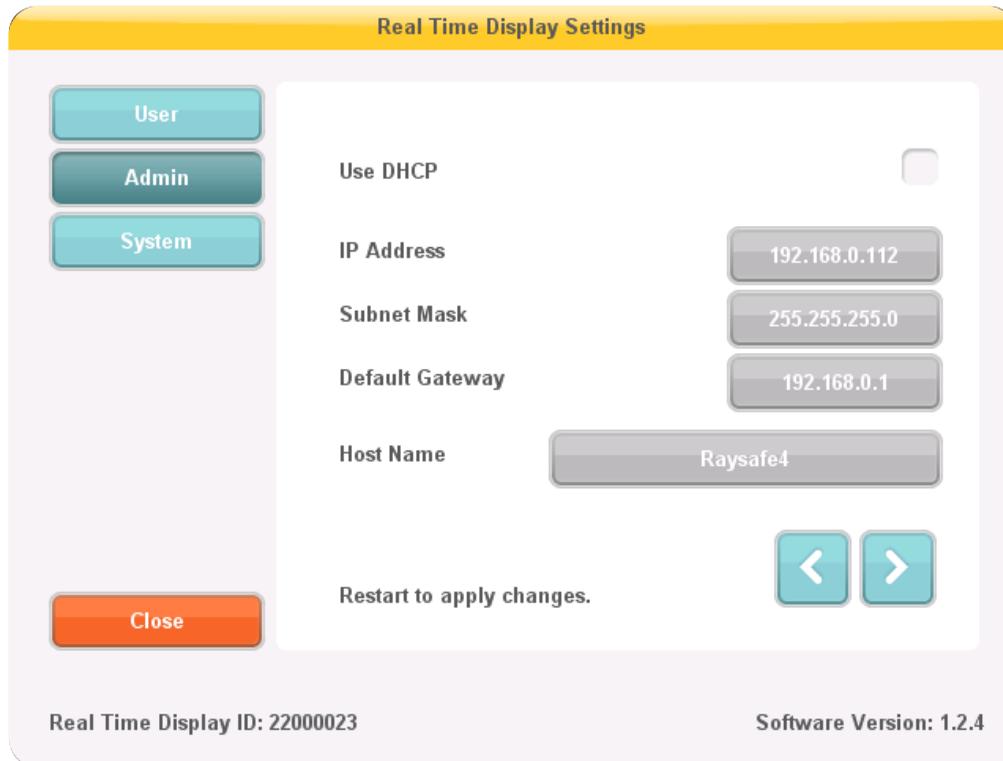


Figure 7. The network setup menu.

Configure the network connection between the real time display and the dose manager. You might have to contact the local IT department to receive the IP address.

If you change this information, the real time display requires a restart.

NOTE: *Network setup is only applicable if you are using the dose manager software.*

Time and date menu

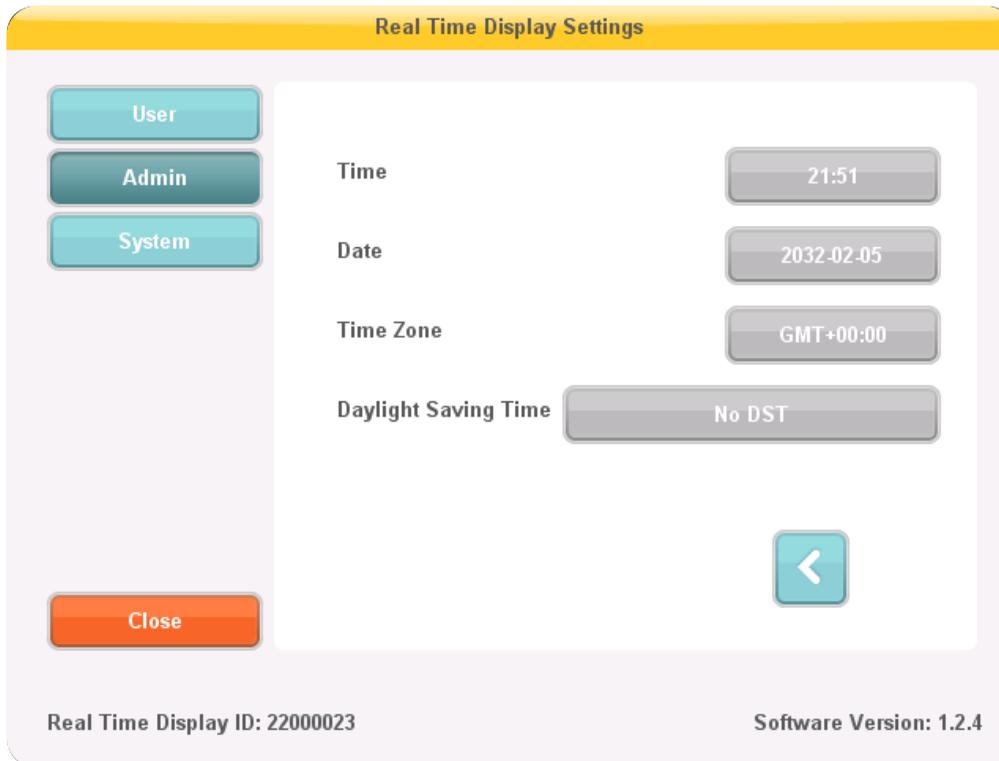


Figure 8. The time and date menu.

Set time, date, time zone and manage daylight saving time for the real time display.

For daylight saving time, you can select to manage it manually or by selecting a daylight settings region for your time zone. The possible regions available for daylight saving time are different depending on your current time zone.

If you choose to manage daylight saving time manually, you can choose to set it to wintertime (+0 hours) or summer time (+1 hours). If a region is selected, the change between winter/summer time will be done automatically.

SYSTEM SETTINGS MENU

The system settings menu consists of three screens. Access these screens by tapping the arrow buttons in the lower right corner of each screen.

Touch screen menu and dose

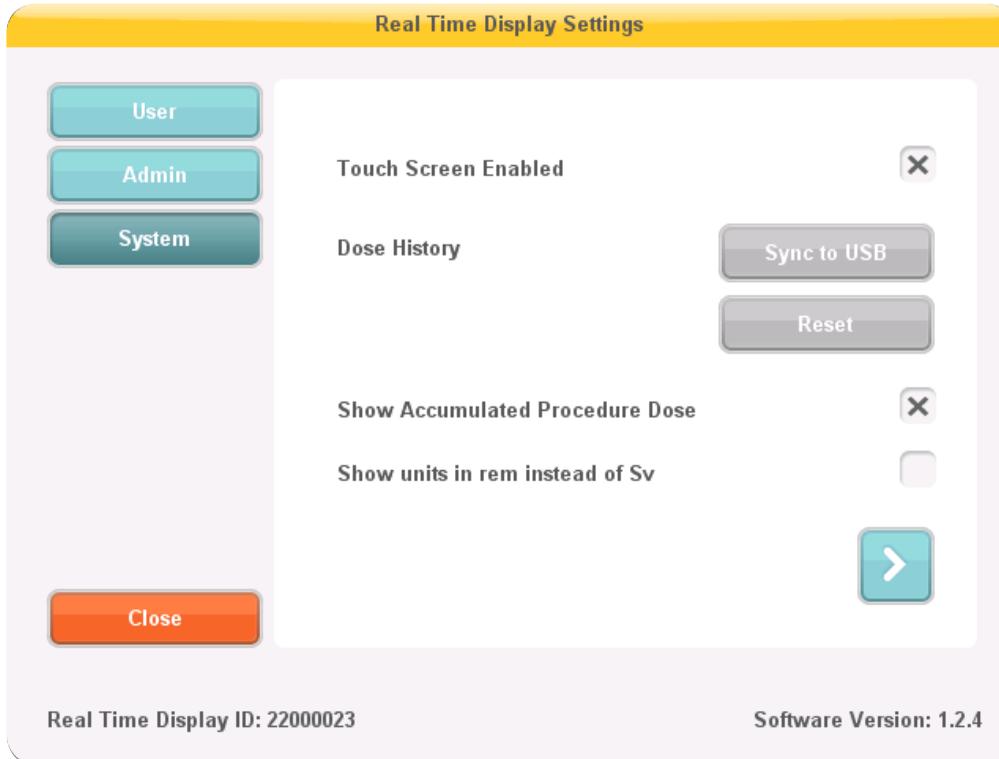


Figure 9. The touch screen and dose menu.

If the touch screen is disabled in the online view; enable it by checking the touch screen check box.

NOTE: *The settings button and menu is always active.*

Follow the instructions below to synchronize the dose history that is stored in the real time display to a USB memory:

1. Insert a USB memory at the back of the real time display.
2. Press the button Sync to USB. The synchronization will start. This may take a while, depending on how much data that is stored in the real time display. Reset the dose history stored in the real time display by pressing the button Reset.

Check the box Show accumulated procedure dose to show a column with the accumulated dose since last tap on the reset button in the lower right corner of the online view. The accumulated dose per examination will also be reset when restarting the real time display.

NOTE *The accumulated dose per examination is only recorded in the real time display memory. The values recorded in the dosimeter is not affected.*

Check the box Show units in rem instead of Sv if you want to view all measurements in rem. (Conversion factor 1 Sv = 100 rem is used.)

DOSIMETER COMMUNICATION RANGE MENU

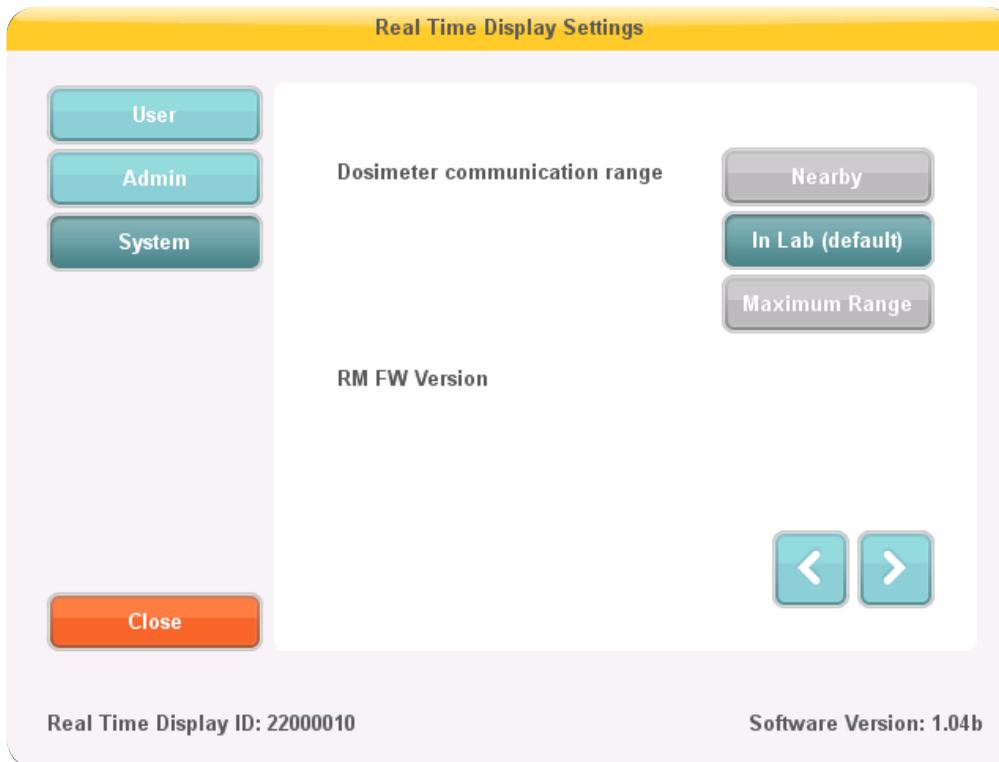


Figure 10. The dosimeter communication range menu.

In Lab is the default communication range setting. If you have problem with the communication between dosimeter and real time display, change the range.

- If you have several real time displays and dosimeters show up on an undesired display, select Nearby.
- If you have trouble with dosimeters **not** showing up on the desired display, try the Maximum Range setting.

NOTE: *To prevent dosimeters not currently in use to show up on a real time display, the dosimeter rack should be located preferably more than 10 meters away from the real time display and not in line of sight.*

LANGUAGE MENU

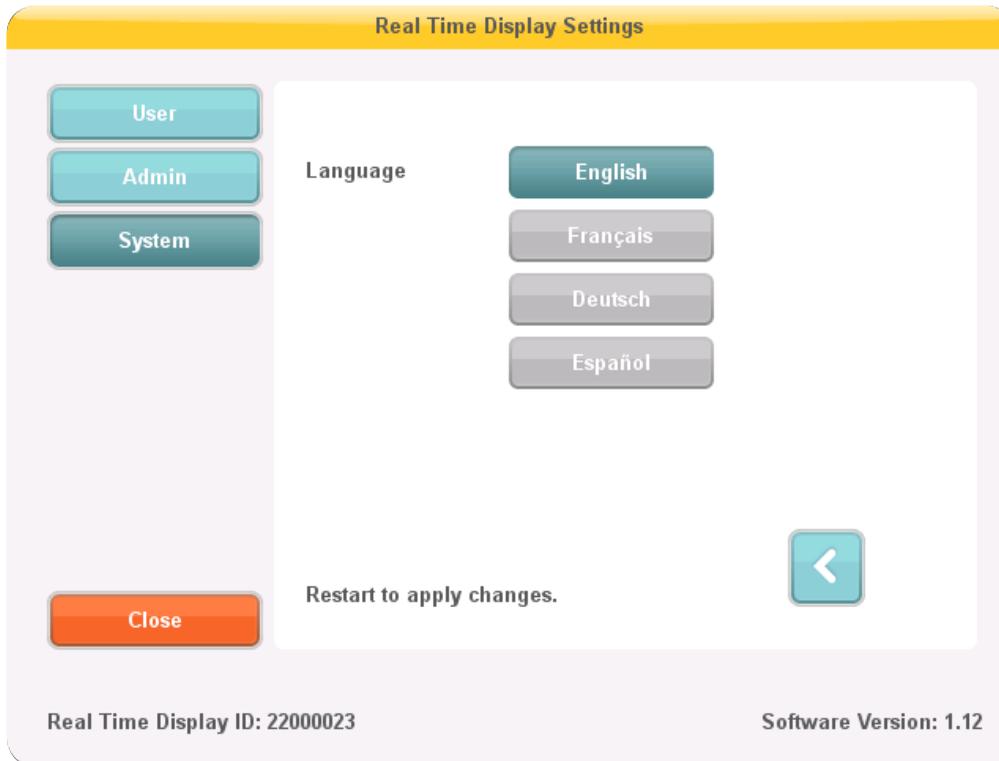


Figure 11. The language menu.

Follow the instructions below to change the language in the real time display:

1. Choose your preferred language. The change will take effect after a restart, see steps 2–3 below
2. Disconnect the power supply.
3. Re-connect the power supply.

DOSE VIEWER INSTALLATION

SYSTEM REQUIREMENTS

- Operating systems: Windows 7, Windows Vista or Windows XP
- .NET 3.0

- One USB port available
- 1 GB of system memory available
- 40 GB hard drive with at least 15 GB of memory available
- Recommended screen resolution at least 1024 x 768

INSTALLATION

Follow the instructions below to install the dose viewer application and the cradle driver:

NOTE: *Do not connect the cradle to the computer until dose viewer is properly installed.*

1. Log on as local administrator on the computer on which to install dose viewer.
2. Insert the dose viewer CD into the computer's CD drive. The dose viewer install wizard will start automatically.
3. Follow the instructions on the screen.
4. Check the box "Launch dose viewer" to start the dose viewer application. The installation procedure will finish by creating a dose viewer icon on the desktop.
5. Connect the cradle to the computer using the USB cable. Dose viewer will detect the cradle within 30 seconds.

TROUBLESHOOTING

If the installation procedure fails, verify that:

- the system requirements are met.
- you are logged on as local administrator.
- there is no previous version of dose viewer installed on the computer (see "Dose viewer software update" on page 27).

If Windows does not automatically install the cradle driver when the cradle is first connected to a PC, you need to install it manually. All the driver files are located on the installation CD in the folder "CradleDriver". These files are also copied to the application installation folder when dose viewer is installed. When Windows detect a connected cradle and the dialog about driver installation is displayed, select to use the driver files located on the CD or in the application installation folder.

DOSE MANAGER INSTALLATION

SYSTEM REQUIREMENTS

- Operating systems: Windows 7, Windows Vista or Windows XP
- .NET 3.5
- One USB port available
- 2 GB of system memory available
- 40 GB hard drive with at least 15 GB of memory available
- Recommended screen resolution at least 1280 x 1024

INSTALLATION

Dose manager and real time display are connected using the local hospital network. A network connection can also be established using a crossed TP cable.

Follow the instructions below to install the dose manager application and the cradle driver:

NOTE: *Do not connect the cradle to the computer until the cradle driver is installed.*

1. Log on as local administrator on the computer on which to install dose manager.
2. Insert the dose manager CD into the computer's CD drive. The dose manager install wizard will start automatically.
3. Insert the license key that is written on the label on the dose manager box.
4. Follow the instructions on the screen.
5. Check the box "Launch dose manager" to start the dose manager application. The installation procedure will finish by creating a dose manager icon on the desktop.
6. Connect the cradle to the computer using the USB cable. Dose manager will detect the cradle within 30 seconds.
7. Connect real time display and dose manager to the hospital network or directly connect them via a crossed TP cable.

TROUBLESHOOTING

If the installation procedure fails, verify that:

- the system requirements are met.
- you are logged on as local administrator.
- there is no previous version of dose manager installed on the computer (see “Dose manager software update” on page 28).

If Windows does not automatically install the cradle driver when the cradle is first connected to a PC, you need to install it manually. All the driver files are located on the installation CD in the folder “CradleDriver”. These files are also copied to the application installation folder when dose manager is installed. When Windows detect a connected cradle and the dialog about driver installation is displayed, select to use the driver files located on the CD or in the application installation folder.

DOSIMETER AND DOSIMETER RACK

Check with the local organization where the dosimeters will be stored, this must be a location outside the X-ray room to prevent registration of X-ray dose when not in use. A dosimeter rack provides room for 5 dosimeters and can be mounted on the wall of for example the control room.

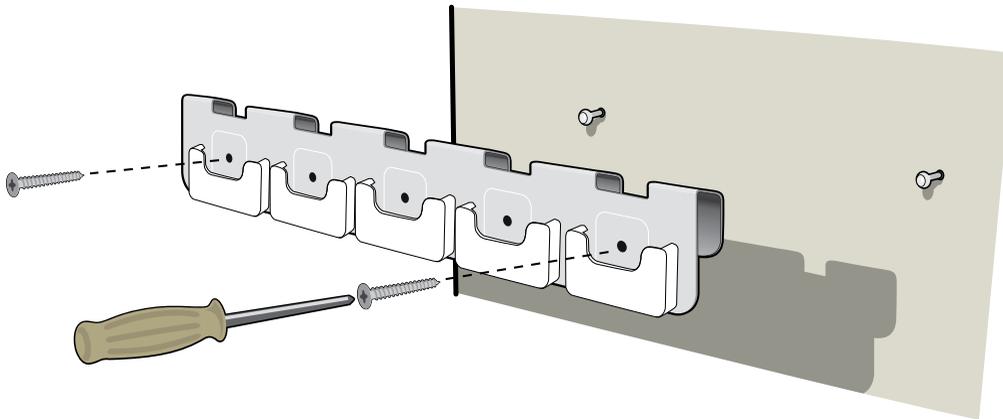


Figure 12. The dosimeter rack mounting

1. Mount the rack with 2 screws to the wall.
2. Clip-on the dosimeters.

NOTE *To prevent dosimeters not currently in use to show up on a real time display, the dosimeter rack should be located preferably more than 10 meters away from the real time display and not in line of sight.*

CONFIGURE THE DOSIMETER IN DOSE MANAGER OR DOSE VIEWER

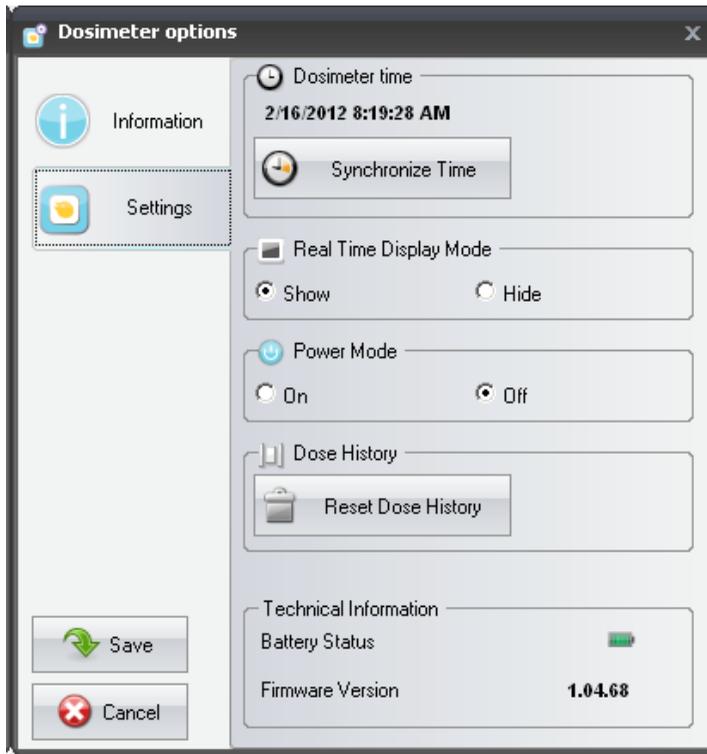


Figure 13. The dosimeter options dialog box

Follow the steps below to configure a dosimeter:

1. Put the dosimeter in the cradle. Within a few seconds dose viewer/manager will have detected the dosimeter.
2. Dose view/manager will start loading the dosimeter dose history. Follow the progress in the progress bar in the lower left corner.
3. Open the dosimeter options dialog box. Press the Settings tab and make the following adjustments:
 - Set the dosimeter's Power mode to On. This starts the radio communication and the dosimeter is ready to start logging dose data.
 - Set the real time display mode to Show, which makes the dosimeter appear on the real time displays.
 - Verify that the Windows time settings on the PC are correct. Synchronize the dosimeter's clock with the computer's clock. (Be sure to do this for all dosimeters in one lab to get them synchronized.)
 - Select Reset Dose History.
 - Verify that Battery Status is green or orange.

- Press the Information tab and select Displayed symbol corresponding to the dosimeter's real color.
 - Press the Save button.
4. Wait for a couple of seconds before you remove the dosimeter from the cradle after you have saved the changes.

WARNING: *Always power OFF the dosimeters before transport.*

SYSTEM FUNCTION TESTS

We recommend these tests in order to verify the correct installation and configuration of the RaySafe i2 system.

EXPOSE DOSIMETER TO RADIATION

Follow these steps to expose a dosimeter to scattered radiation in the other tests described below:

1. Place the dosimeter outside the primary beam, close to a phantom placed in the X-ray beam, so that the dosimeter receives scattered radiation. Make sure that the dosimeter is within range of a real time display.

NOTE: *Keep the dosimeter outside the primary X-ray beam.*

2. Expose the dosimeter to scattered X-ray radiation for one minute, by turning the X-ray machine on.

DOSE VIEWER/DOSE MANAGER TEST

Follow the instructions below to verify that dose viewer detects the dosimeter:

1. Expose a dosimeter to scattered radiation (see “Expose dosimeter to radiation” on page 23).
2. Connect the cradle to the PC running dose viewer/dose manager.
3. Put the dosimeter in the cradle. Dose viewer/dose manager will detect the dosimeter within a few seconds. Ensure that dosimeter and dose data is presented in the main window (see figure below).

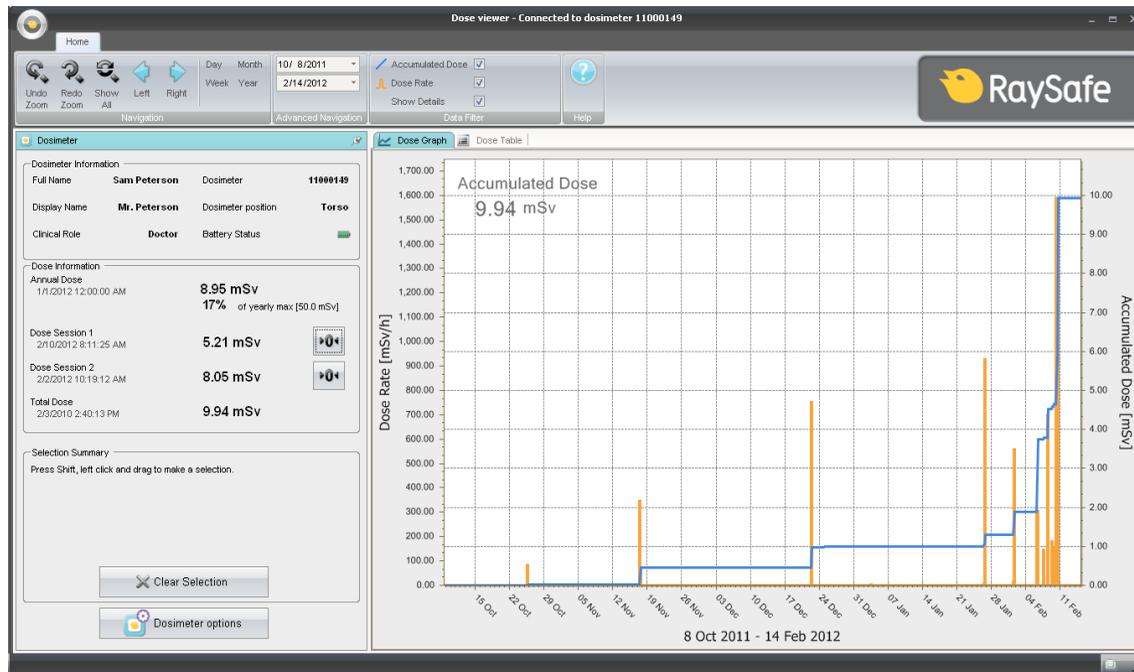


Figure 14. Dosimeter data in dose viewer

REAL TIME DISPLAY TEST

ONLINE VIEW TEST

Follow the instructions below to verify that the dosimeter appears in the real time display:

1. Check that the dosimeter appears in the real time display's online view within 30 seconds.
2. Expose the dosimeter to radiation (see "Expose dosimeter to radiation" on page 23). The real time display will show the dose instantaneously (see figure below).

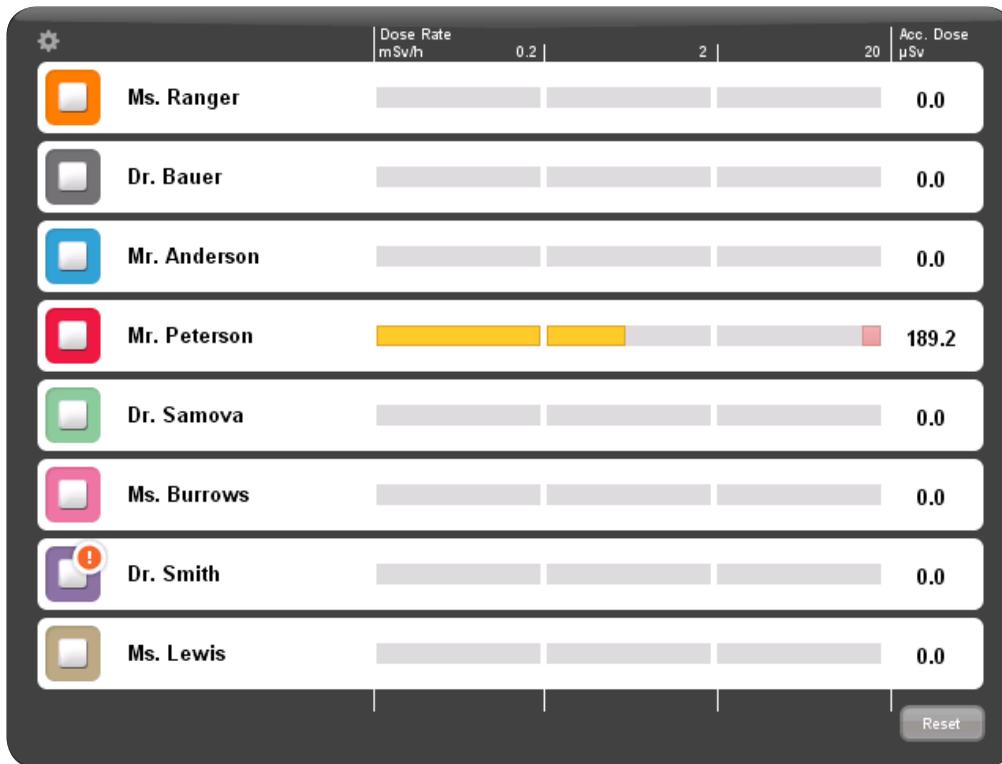


Figure 15. The real time display Online View

COMMUNICATION RANGE TEST

Check that the dosimeter communication range configuration is correctly tuned, that is, dosimeters stored away from the real time displays shall not appear on the real time displays online view, but will appear when they approach the display. See section “Dosimeter communication range menu” on page 16.

NOTE: *Perform next steps only when multiple real time displays are installed.*

1. Visual check that dosimeter is shown on real time display ‘A’.
2. Move dosimeter within range of real time display ‘B’.
3. Visual check that dosimeter remains visible on real time display ‘A’ for three minutes after the move.
4. Visual check that dosimeter is shown on real time display ‘B’ within 30 seconds after it has reached within range.

MEASUREMENT PERFORMANCE VERIFICATION

The purpose of this test is to verify the measurement performance of dosimeters using scattered radiation from diagnostic X-ray units. Unfors RaySafe recommends the following arrangement:

CAUTION: *Do not expose yourself to X-ray radiation.*

You need the following equipment to perform a measurement performance verification:

- A reference instrument measuring $H_p(10)$ (for example a known reference dosimeter, or some other meter).
- Two 20x20x5 cm³ PMMA phantoms or similarly scattering material.
- Dosimeters for test
- Real time display

Follow the instructions below:

1. Place one of the phantoms on the patient support.
2. Place the other phantom at the same height, but 0,5 m on the side from the first one.
3. Place the additional $H_p(10)$ meter on the center of the second phantom.
4. Place the dosimeters that have to be tested on the phantom around the additional $H_p(10)$ meter.
5. Expose with a field covering the first phantom, at 80 kVp set, 4 mA, for 60s. If needed, adjust the distance or the mA to get a dose rate of about 1 – 10 mSv/h.
6. Compare the dosimeter readings with the additional $H_p(10)$ meter. Readings should be within specifications for the different meters.

SOFTWARE UPDATE AND MAINTENANCE

A software update package consists of a new version of the application in question.

REAL TIME DISPLAY SOFTWARE UPDATE

Follow the instructions below to update the real time display software:

1. Save the entire folder 'swupdate' from the update package to a USB memory.
2. Press and hold on the welcome screen that appears during real time display startup for 10 seconds to enter the Setup view.
3. Insert the USB memory at the back of the real time display.

NOTE: *It can take up to one minute for the real time display to detect the USB memory.*

4. Tap the Update real time display button to have the new software installed. This will take up to two minutes.
5. Click the OK button in the 'Update succeeded' dialog box.
6. Click the Start real time display button.

The software update procedure makes the real time display start on the new software version.

NOTE: *Configuration and dose data from the previous version of the real time display software will remain unaffected by the software update.*

TROUBLESHOOTING

If the update procedure fails, make sure that the update package is saved correctly on the USB memory.

If you get the message "USB memory not found", try to remove and replace the USB memory. Tap the Update real time display button again.

NOTE: *If the software update fails, the real time display will stop at the software update screen during next start up.*

DOSE VIEWER SOFTWARE UPDATE

Follow the instructions in section "Dose viewer installation" on page 17 to update the dose viewer software.

NOTE: *Configuration and dose data from the previous version of the dose viewer software will remain unaffected by the software update.*

TROUBLESHOOTING

If the update procedure fails, remove any previous versions of the dose viewer application and re-install the software update package.

NOTE: *Removing a previous version of the dose viewer application will cause the dose history and the passwords settings of that version to be deleted.*

DOSE MANAGER SOFTWARE UPDATE

Follow the instructions in section “Dose manager installation” on page 19 to update the dose manager software.

NOTE: *Configuration and dose data from the previous version of the dose manager software will remain unaffected by the software update.*

TROUBLESHOOTING

If the update procedure fails, remove any previous versions of the dose manager application and re-install the software update package.

NOTE: *Removing a previous version of the dose manager application will cause the dose history and the passwords settings of that version to be deleted.*

REAL TIME DISPLAY TOUCH SCREEN RE-CALIBRATION

If the touch screen does not respond correctly to user interaction, a touch screen recalibration may be needed. Follow the instructions below to perform a re-calibration:

1. Press and hold on the welcome screen that appears during real time display startup for 10 seconds to enter the Setup view.
2. Follow the instruction on the bottom of the screen and the subsequent instructions in the next views.

TECHNICAL DATA

REAL TIME DISPLAY

CHARACTERISTIC	MEASURE
Weight	1.2 kg
Dimensions	297x243x51 mm (WxHxD)
Display	10.4" touch screen, 640x480 pixels, 65 000 colors
Power supply	12 V, 2 A (Astec DPS53-M, FW7556M/12)
Memory	512 MB
Storage	290 hours of dose history for each of 50 dosimeters
Backlight life time	Approximately 50000 hours
Maximum heat dissipation	25 W
Network	Ethernet 10/100 Mbps
USB	1.1 host for USB Mass Storage Device
Radio frequency	868.3 MHz, 918.3 MHz, 927.9 MHz (depending on purchased configuration)

The product label is located at the back of the real time display.

DOSIMETER

CHARACTERISTIC	MEASURE
Weight	30 g
Dimensions	44x45x10 mm (WxHxD)
Fastening	Clip and lanyard holder

CHARACTERISTIC	MEASURE
Radio frequency	868.3 MHz, 918.3 MHz, 927.9 MHz (depending on purchased configuration)

The product label is located at the back of the dosimeter.

CRADLE

CHARACTERISTIC	MEASURE
Weight	50 g
Dimensions	64x61x59 mm (WxHxD)
Cable length	1,5 m
Power	via USB
Communication with computer	USB 2.0

The product label is located at the bottom of the cradle.

DOSIMETER RACK

CHARACTERISTIC	MEASURE
Dimensions	399x63x19 (WxHxD)

The product label is located at the back of the dosimeter rack.

RADIO COMMUNICATION

- The communication range between a dosimeter facing a real time display and the real time display is at least 10 meters in open air inside an operating room.
- Communication radio, Europe, complies with 1995/5/EC Radio and Telecommunications Terminal Equipment (R & TTE)
- Communication radio, US, complies with FCC Declaration of Conformity

CLIMATIC CONDITIONS

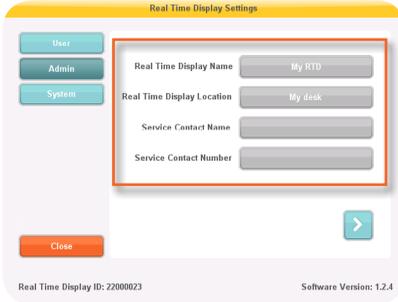
Classes: C1

Indoors, temperature controlled

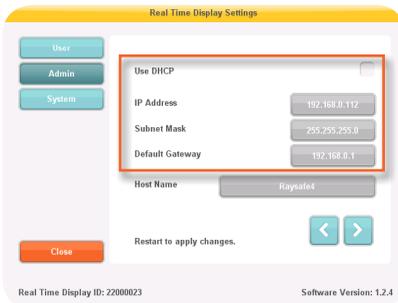
PARAMETER	MEASURE
Temperature levels:	
– for performance	+15°C to +35°C
– for safety	+10°C to +40°C
– for storage	-25°C to +70°C
Temperature rate of change	< 0.5°C/minute
Relative humidity	
– for performance	20 to 80 %
– for safety	20 to 80 %
– for storage	5 to 95 %
Condensation	No
Air pressure	
– for performance	70 to 110 kPa
– for storage	70 to 110 kPa
Air velocity	not relevant
Gas pollution	–
Sand and dust	–
Salt particles	–
Water – mist	
– liquid	drip/spilling

INSTALLATION SETTINGS FORM

Fill in the settings in the following tables when installing the real time display and return this form to Unfors RaySafe.



Real time display name:	
Real time display location:	
Service contact name:	
Service contact number:	

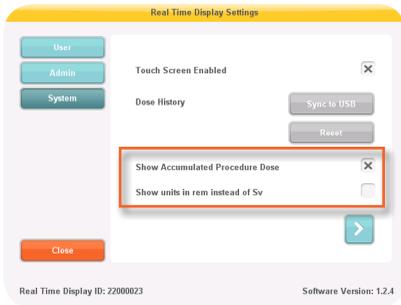


Use DHCP (<i>enabled</i> or <i>disabled</i>):		
If DHCP disabled :	IP address:	
	Subnet mask:	
	Default gateway:	



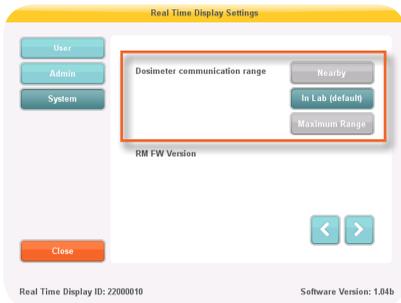
Time zone:

Daylight saving time:



Show Accumulated Procedure Dose (*enabled* or *disabled*):

Show units in rem instead of Sv (*enabled* or *disabled*):



Dosimeter communication range: