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DoseAware Base Station Package

INSTRUCTIONS FOR USE

Document version 1.2

English

DRAFT

PHILIPS

Philips Healthcare
9896 002_16623

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DRAFT

1 Introduction

1.1 About the DoseAware System

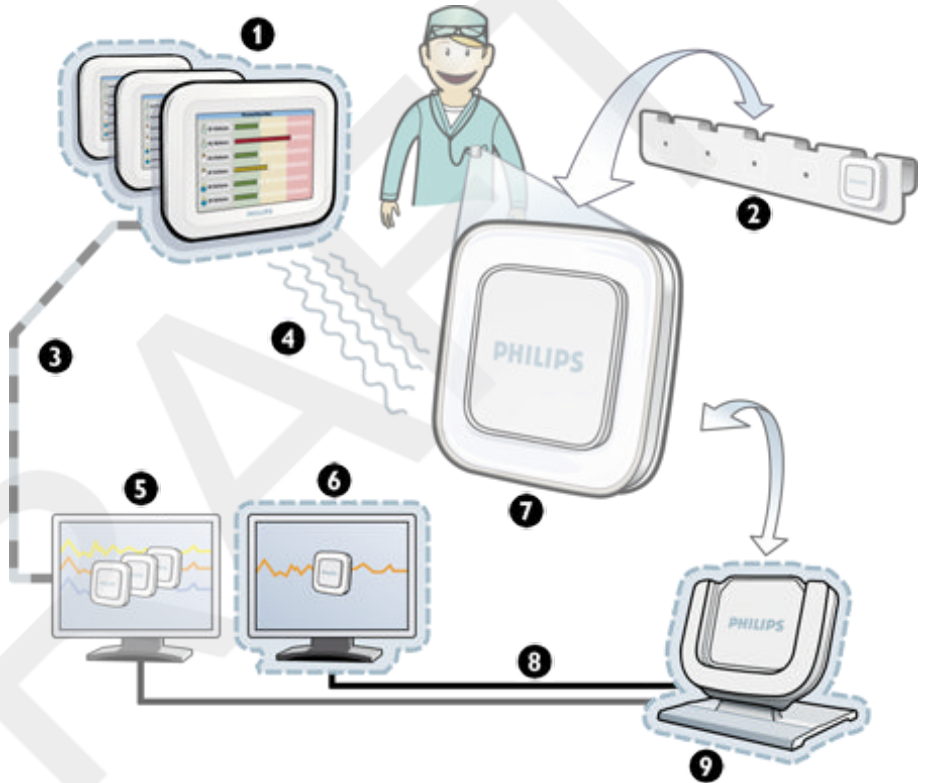


Figure 1.1 DoseAware System overview with Base Station Package components highlighted

Legend

1	Base Station	2	PDM rack
3	Ethernet	4	Radio
5	Dose Manager	6	Dose View
7	PDM	8	USB
9	Cradle		

8
9
10 The DoseAware System can contain the following components:

- 11 • Personal Dose Meter (PDM)
- 12 • Base Stations (display unit)
- 13 • DoseView (computer software)
- 14 • Dose Manager (computer software)
- 15 • Cradle (dock station used to connect PDMs and computer)
- 16 • PDM Rack (PDM storage)

17
18 The Base Station Package consists of:

- 19 • Base Station, power adaptor, MCS bracket and wall mount kit
- 20 • DoseView (CD)
- 21 • User manual (CD)
- 22 • Cradle, USB cable

23
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25
26
27 **1.2 About these Instructions for Use**

28
29 These Instructions for Use are intended to assist users in the safe and effective operation of the product described.

30
31 Before attempting to operate the product, you must read these Instructions for Use, noting and strictly observing all **WARNINGS** and **CAUTION** notices.

32
33 Pay special attention to all the information given and procedures described in the **Safety** section.



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.

These Instructions for Use describe the Base Station Package. In order to get an immediate hands-on experience of the Base Station Package, we recommended that you interact with the Base Station, DoseView, and Cradle in parallel to reading these Instructions for Use.

1.3 Intended use of the DoseAware System

This Philips product is intended to be installed, used and operated only in accordance with the safety procedures and operating instructions given in these Instructions for Use for the purpose for which it was designed. The purpose for which the product is intended is given below. However, nothing stated in these Instructions for Use reduces users' responsibilities for sound clinical judgment and best clinical procedure.

The DoseAware System is an electronic X-ray dose monitoring system. The intended use is to improve the awareness of people who work with or are in the presence of X-Ray imaging equipment, about their occupational dose (also known as staff dose).

The awareness focuses on:

- a graphical visualization of the real-time staff dose rate while working with X-Ray equipment in examination rooms during medical procedures;
- instant access to historical staff dose for reporting and analysis purposes.

The benefits of the DoseAware System are to:

- make people aware of their received staff dose during clinical work with X-ray imaging equipment;
- instantly visualize the result of reducing measures of occupational dose by, for example, changing a person's position in the examination room.

8
9
10 The DoseAware System may not be used as a legal staff dose recording
11 solution. The DoseAware System is not intended for patient use.

12 **NOTES**

- 13 • ***Do not expose the PDMs in direct X-ray beam. They are designed to be exposed to***
14 ***scattered radiation only.***
- 15 • ***The Dose Manager, DoseView, Cradle and PDM Rack are not intended to be used***
16 ***inside examination rooms.***
- 17 • ***The DoseAware product is not a replacement for a TLD (ThermoLuminescent***
18 ***Dosimeter) or similar product.***

19
20 Installation, use and operation of this DoseAware System is subject to the
21 law in the jurisdiction(s) in which the DoseAware System is being used.
22 Operators must only install, use and operate the DoseAware System in such
23 ways as do not conflict with applicable laws, or regulations, which have the
24 force of law.

25
26 Uses of the Allura CV20 for purposes other than those intended and Uses of
27 the DoseAware System for purposes other than those intended and expressly
28 stated by the manufacturer, as well as incorrect use or operation, may relieve
29 the manufacturer (or his agent) from all or some responsibility for resultant
30 non-compliance, damage or injury.

31 **1.4 Compatibility**

32
33 The product described in this manual should not be used in combination
34 with other products or components unless such other products or
35 components are expressly recognized as compatible by Philips Healthcare.
36 (A list of such products and components is available from the manufacturer.)
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Changes and/or additions to the product should only be carried out by Philips Medical Systems or by third parties expressly authorized by Philips Medical Systems to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.



WARNING

Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Philips Medical Systems warranty being voided. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the product and of personal injury.

1.5 Compliance

The Philips DoseAware System complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips Medical Systems representative, or by the manufacturer.

1.6 Training

Users of this product must have received adequate training on its safe and effective use before attempting to operate the product described in these Instructions for Use. Training requirements for this type of device will vary from country to country. Users must make sure they receive adequate training in accordance with local laws or regulations.

If you require further information about training in the use of this product, please contact your local Philips Medical Systems representative. Alternatively, contact the manufacturer.

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1.7 System requirements

DoseView has the following system requirements:

- Operating systems: Windows Vista or Windows XP
- .NET 3.0
- At least one USB port available
- At least 1 GB of system memory available
- At least 40 GB hard drive with at least 15 GB of memory available
- Recommended screen resolution at least 1024 x 768

1.8 Other user manuals

- Dose Manager is described in a separate user manual, which can be found on the CD delivered in the box together with the Dose Manager package.
- The PDMs are described in the PDM Quick Guide, a leaflet that is delivered in the box together with the PDM.

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2 Safety

2.1 Important safety directions

If the DoseAware system is not functioning correct or damage is visible, inform a Philips service engineer, which will take appropriate actions in order not to harm personnel or patients.

Handle the hardware and software with care. Make sure that the hardware and software is used and stored in a secured environment to prevent unauthorized access.

Maintenance & faults



WARNING

Do not use the product for any application until you are sure that the user routine-checks have been satisfactorily completed, and that the periodic maintenance of the product is up to date. If any part of the product is known (or suspected) to be defective or wrongly adjusted, DO NOT USE the product until a repair has been made. Operation of the product with defective or wrongly adjusted components could expose the user or the patient to radiation or other safety hazards. This could lead to fatal or other serious personal injury, or to clinical misdiagnosis/clinical mistreatment.

Safety awareness



WARNING

Do not use the product for any application until you have read, understood and know all the safety information, safety procedures and emergency procedures contained in this Safety section. Operation of the product without a proper awareness of how to use it safely could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis/clinical mistreatment.

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WARNINGS

Adequate training



- *Do not use the product for any application until you have received adequate and proper training in its safe and effective operation. If you are unsure of your ability to operate this product safely and effectively, DO NOT USE IT. Operation of this product without proper and adequate training could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis/clinical mistreatment.*
- *Do not operate the product with patients unless you have an adequate understanding of its capabilities and functions. Using this product without such an understanding may compromise its effectiveness and/or reduce the safety of the patient, you and others.*

Safety devices



WARNING

Never attempt to remove, modify, override or frustrate any safety device on the product. Interfering with safety devices could lead to fatal or other serious personal injury.

Intended use and compatibility



WARNING

Do not use the product for any purpose other than those for which it is intended. Do not use the product with products other than that which Philips Medical Systems recognizes as compatible. Operation of the product for unintended purposes, or with incompatible products, could lead to fatal or other serious injury. It could also lead to clinical misdiagnosis/clinical mistreatment.

2.2

Electrical safety



WARNING

Do not remove covers or cables from this product. Dangerous electrical voltages are present within this product. Removing covers or cables could lead to serious or fatal personal injury.

Covers or cables should only be removed by qualified and authorized service personnel. Use this product in rooms or areas that comply with all applicable laws (or regulations having the force of law) concerning electrical safety for this type of product.

Electrically isolate this product from the mains electrical supply before cleaning, disinfecting or sterilizing it.

2.3 Mechanical safety

WARNING



Do not remove covers from this product. Removing covers could lead to serious or fatal personal injury.

Covers should only be removed by qualified and authorized service personnel. In this context, qualified means those legally permitted to work on this type of medical electrical product in the jurisdiction(s) in which the product is being used, and authorized means those authorized by the user of the product.

2.4 Explosion safety

WARNINGS



- ***Do not use this product in the presence of explosive gases or vapors, such as certain anesthetic gases.***
- ***Do not use flammable or potentially explosive disinfecting sprays.***
- ***Use of this product in an environment for which it was not designed can lead to fire or explosion.***

2.5 Fire safety

Use of electrical product in an environment for which it was not designed can lead to fire or explosion.

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10 Fire regulations for the type of medical area being used should be fully
11 applied, observed and enforced. Fire extinguishers should be available for
12 both electrical and non-electrical fires.



14
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16 **WARNING**

17 *Only use extinguishers on electrical or chemical fires, which are specifically labeled*
18 *for those purposes. Using water or other liquids on an electrical fire can lead to fatal*
19 *or other serious personal injury.*

20 If it is safe to do so, attempt to isolate the product from electrical and other
21 supplies before attempting to fight a fire. This will reduce the risk of electric
22 shocks.

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26 **2.6 Electrostatic discharge (ESD)**

27
28 **CAUTIONS**

- 29 • *Always wait at least ten seconds after the product is switched OFF before switching*
30 *the product back to ON.*
- 31 • *Always use proper static procedures, protection, and product prior to opening and*
32 *during handling of this product. This product contains components that are*
33 *electrostatic sensitive. Failure to use ESD procedures may cause damage to these*
34 *components. Such damage to components is not covered by Philips warranties.*

35
36 Connections to sensitive parts are identified by the ESD warning symbol as
37 shown.



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47 ESD can amount to a significant voltage, which may cause damage to PCBs
48 or other system components.

ESD damage is cumulative and may not be apparent at first, as indicated by a hard failure, but can cause degraded performance. Therefore, always use proper ESD handling procedures. ESD can result from low humidity conditions, use of electrical equipment on carpeting, linens, and clothing.

2.7 Electromagnetic Compatibility (EMC)

This Philips product complies with relevant international and national laws and standards on EMC (electromagnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from equipment and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

- Medical electrical products need special precautions regarding EMC, and need to be installed and put into service according to EMC information provided in the accompanying documents.
- The use of accessories and cables other than those specified may result in increased emission or decreased immunity levels.
- The product should not be used adjacent to or stacked with other products and that if adjacent or stacked use is necessary, it should be observed to verify normal operation.

This equipment is intended for use in a hospital environment. Operation in other than hospital environments may compromise electromagnetic compatibility.

The Base Station and PDM comply with part 15 of the FCC Rules. Operation is subject to the following conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to the equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

8
9
10 This device complies with Industry Canada license-exempt RSS standard(s).
11 Operation is subject to the following two conditions: (1) This device may
12 not cause interference, and (2) this device must accept any interference,
13 including interference that may cause undesired operation of the device.
14

15 *Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux*
16 *appareils radio exempts de licence. L'exploitation est autorisée aux deux*
17 *conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2)*
18 *l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même*
19 *si le brouillage est susceptible d'en compromettre le fonctionnement.*
20

21 This class A digital apparatus complies with Canadian ICES-003.

22 *Cet appareil numérique de la classe A est conforme à la norme NMB-003 du*
23 *Canada.*
24

25 The Base Station and PDM have been tested and found to comply with the
26 limits for a Class A digital device, pursuant to part 15 of the FCC Rules.
27 These limits are designed to provide reasonable protection against harmful
28 interference when the equipment is operated in a commercial environment.
29 This equipment generates, uses, and can radiate radio frequency energy and,
30 if not installed and used in accordance with the instruction manual, may
31 cause harmful interference to radio communications. Operation of this
32 equipment in a residential area is likely to cause harmful interference in
33 which case the user will be required to correct the interference at his own
34 expense.
35
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38

39 **2.7.1 Mobile phones and similar RF equipment**

40 The DoseAware system is intended for use in the electromagnetic
41 environment in which radiated RF disturbances are controlled.
42

43 **CAUTION**

44 ***Portable and mobile RF communications can affect medical electrical equipment. Use***
45 ***caution when using such communication devices within the specified range of medical***
46 ***electrical devices.***
47
48
49

The customer or the user of the DoseAware system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DoseAware system as recommended below, according to the maximum output power of the communications equipment:

- A minimum distance of 20 cm between a PDM and a mobile phone or regular electronic device (e.g. a computer).
- A minimum distance of 50 cm between a PDM and a medical device or intended radiator (e.g. a wireless router).

NOTE

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.8 Modality specific safety



WARNING

During communication between the Base Station and PDMs, personal data is transmitted in open air.

Be careful when using a PDM while being near a patient and make sure that the PDM does not fall or comes in contact with other equipment (such as a catheter) to endanger the procedure.

Do not move a PDM to an unknown environment (for example another hospital). If you are visiting unknown environments, there is a risk that personal data is registered there. For correct registration of staff dose data, only use the PDM within designated environment.

Philips Medical Systems declares that all CE marked DoseAware products incorporating Radio and Telecoms Terminal Equipment functionality are in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

2.9 Network safety, security and privacy

Customer Role in the Product Security Partnership

We recognize that the security of Philips Medical Systems products is an important part of your facility's security-in depth strategy. However, these benefits can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, authentication technologies, etc.

As with any computer-based system, protection must be provided such that firewalls and/or other security devices are in place between the medical system and any externally accessible systems.

The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

For our product security policy statement and additional information, see the Philips Medical Systems product security website at:

<http://www.healthcare.philips.com/main/support/productsecurity>

2.10 Toxic or hazardous substances and elements

The following table details the toxic or hazardous substances and elements which are present in the DoseAware systems.

Toxic or hazardous substances and elements						
DoseAware component	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr6+)	Polybrominated Biphenyls (PBB)	Polybrominated Diphenyl Ethers (PBDE)
Base Station	○	○	○	○	○	○
PDM	○	○	○	○	○	○
○: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363–2006.						

Perchlorate materials

In this product, perchlorate material is present in lithium coin cells and/or batteries. Special handling may apply for these materials, for more information, go to:

www.dtsc.ca.gov/hazardouswaste/perchlorate

REACH Declaration

REACH requires Philips Healthcare (PH) to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the product weight. Components within electric and electronic equipment may contain phthalates above the threshold (e.g. bis(2-ethyl(hexyl)phthalate), CAS nr.: 117-81-7). The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold:

<http://www.philips.com/about/sustainability/reach.page>

China RoHS Hazardous Substances Declaration

For information, please see the Philips Medical Systems product sustainability website at:

<http://www.healthcare.philips.com/main/about/Sustainability>

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12
13 **2.11** **Equipment label overview**

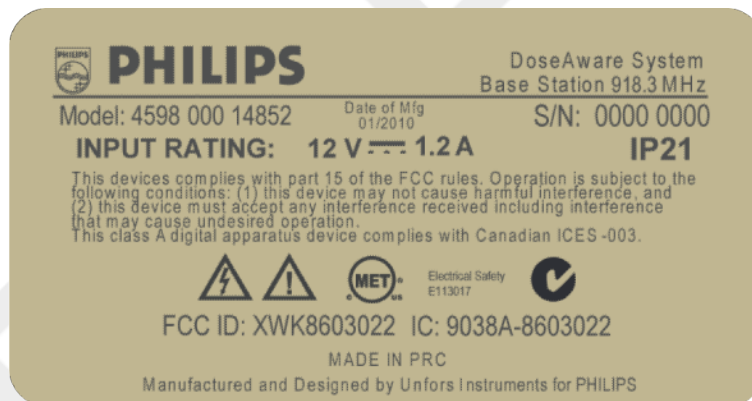
14
15 This section describes the DoseAware product labels and their locations.

16
17 **NOTE**

18 *Some of the information (such as frequency, type, date of manufacture, and other*
19 *markings) on the labels for your DoseAware product may vary from the examples*
20 *shown below.*

21 **Base Station product label**

22 The following Base Station product label is located on the rear side of the
23 Base Station.



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27
28
29 **Figure 2.1** Base Station label

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39 **Base station product label for products sold in the EU**

40 The following Base Station product label is located on the rear side of the
41 Base Station for products sold in European Union (EU) countries.
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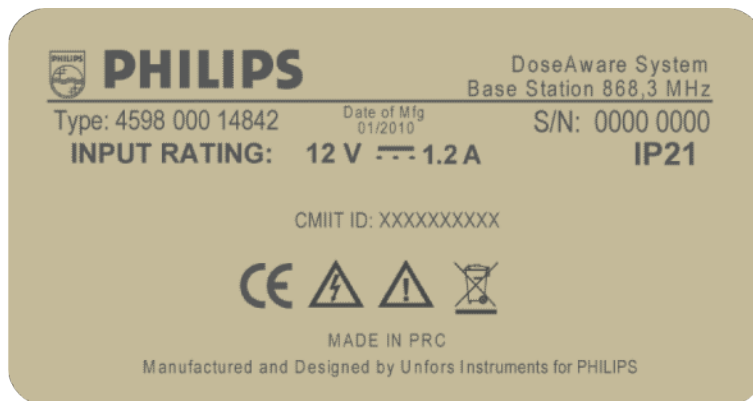


Figure 2.2 Base Station label for products sold in the EU

Cradle product label

The Cradle product label is located on the bottom of the Cradle.

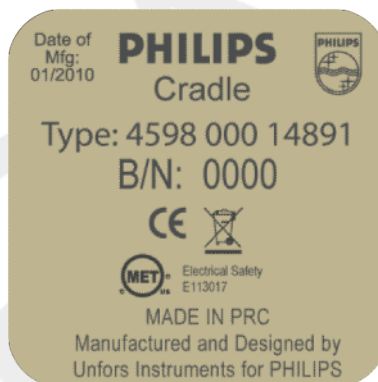


Figure 2.3 Cradle label

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10 **PDM product label**

11 The following PDM product label is located on the rear side of the PDM.



26 **Figure 2.4** PDM label

27 **PDM product label for products sold in the EU**

28 The following PDM product label is located on the rear side of the PDM
29 for products sold in European Union (EU) countries.



54 **Figure 2.5** PDM label for products sold in the EU

3 Using the Base Station

3.1 Introduction

The Base Station is the display unit in the DoseAware System. It communicates wireless with PDMs within radio range in order to collect, present and store PDM dose data.



The distance from which the Base Station detects a PDM depends on the settings that the service engineer made during the installation. If several Base Stations are installed close to each other, the Base Station detects PDMs that are located within a few meters. Otherwise the Base Station will detect PDMs from longer distances.

WARNING



Do not start up the product unless you and all other users present have read, fully understood and know all the safety information and emergency procedures given in the Safety section of these Instructions for Use. Operation of the product without having read, understood and knowing all the safety information and procedures in the Safety section could lead to fatal or other serious personal injury, clinical misdiagnosis, or clinical mistreatment.

3.2 Getting started

3.2.1 Starting the wall mounted Base Station

- 1 Connect the output connector of the power adaptor to the back of the Base Station, if needed.
- 2 Connect the input connector to an AC electrical outlet socket.

This will switch on the Base Station.

First a Philips start up screen will be displayed for a few seconds and after 30 seconds the system is ready to use. The Online View will display a maximum of 8 PDMs at a time. Only PDMs that are in range of the Base Station will be displayed.

The Base Station screen is a touch screen. Operate the Base Station by tapping buttons and graphs on the screen.

NOTE

PDMs are shown on a first come first serve principle (see “reserved slots menu” in section “Admin Settings menu” on page 3-12). PDMs that are not shown in the Online View still measure and store dose data.



WARNINGS

- **Do not cover the Base Station to prevent excessive temperatures.**
- **Be careful when moving other equipment in the vicinity of the Base Station.**

3.2.2 Starting the MCS mounted Base Station

- 1 Switch on the X-ray system and the Base Station will automatically switch on.

First a Philips start up screen will be displayed for a few seconds and after 30 seconds the system is ready to use.

The Online View will display a maximum of 8 PDMs at a time. Only PDMs that are in range of the Base Station will be displayed.

The Base Station screen is a touch screen. Operate the Base Station by tapping buttons and graphs on the screen.

NOTE

PDMs are shown on a first come first serve principle (see “reserved slots menu” in section “Admin Settings menu” on page 3-12. PDMs that are not shown in the Online View still measure and store dose data.

- 2 Position the Base Station similar to the other monitors in the MCS as much as possible.



WARNINGS

- Do not cover the Base Station to prevent excessive temperatures.
- Be careful when moving the MCS or other equipment because the Base Station may stick out and can be hit.

3.3 Base Station features

The Base Station offers:

- An Online View (see section “Online view – view current dose rates” on page 3-4 where you can:
 - view current Personal Dose Rate information for several PDMs at a time.
 - access the Walk-Up View by tapping the |Displayed Name| tag button of that PDM in the Online View.

- A Walk-Up View (see section “Walk-Up view – view detailed dose data ” on page 3-7) where you can view historical dose data for a PDM chosen from the OnLine View.
- A Base Station Settings View (see section “Base Station Settings view” on page 3-11) for administrator settings.

See the “Technical Data” chapter for technical details about how the Base Station displays dose data. In addition, the Base Station:

- Serves as an interim storage for the PDMs’ dose data to be further analyzed in the optional Dose Manager application.
- Is provided with a USB port for dose data download to USB memory (see the Dose Manager Package user manual).

NOTE

When the Base Station memory is full, the oldest data will be overwritten with newer data. For storage capacity examples, see section “Base Station memory” on page 10-2.

3.3.1 Online view – view current dose rates

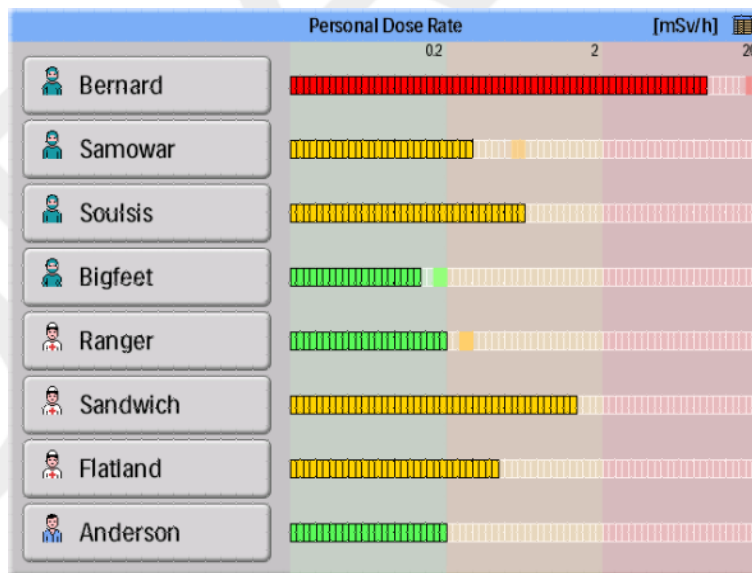


Figure 3.1 The Online View

The Online View displays the current personal dose rates and peak dose rate indicators, for up to 8 PDMs within range of the Base Station.

NOTE

PDMs are shown on a first come first serve principle (see “reserved slots menu” in section “Admin Settings menu” on page 3-12). PDMs that are not shown in the Online View still measure and store dose data.

The icon in the upper right corner gives you access to the Base Station settings view (see section “Base Station Settings view” on page 3-11).

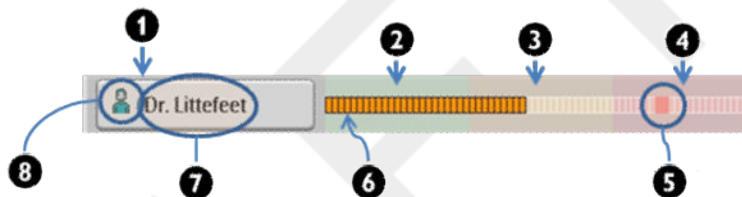


Figure 3.2 The online view elements

Legend

1 Walk-up View access button	2 Scale green zone
3 Scale yellow zone	4 Scale red zone
5 Peak Dose Rate indication	6 Scale Block
7 Displayed Name	8 Displayed Symbol

The | **Displayed Name** | button identifies the PDMs. It may be truncated on the button due to lack of space.

By tapping the | **Displayed Name** | button of a PDM, you will enter the Walk-Up View of that PDM.

The dose rate scale is divided in three zones:

- Green zone indicates good working habits. Proper actions have been taken to avoid exposure for unnecessary radiation.
- Yellow zone indicates higher doses, which can be acceptable for shorter periods of time, for example if you need to stand closer to the patient during a procedure. If you are exposed to radiation in the yellow zone frequently, you need to take actions to minimize the dose exposure.
- Red zone dose indications should not occur during normal procedures. If you are exposed to radiation in the red zone, you need to take actions to minimize the dose exposure.

When a PDM moves out of range of the Base Station, its button will remain visible in the Online View for two minutes. The button will then remain grayed out for another eight minutes before it disappears. This feature allows people to temporarily leave the room without losing their position in the list. When a button is grayed out, it is not possible to access the Walk-Up View.

If no PDM has been within range of the Base Station for 30 minutes, the Online View will enter screen saver mode. In screen saver mode the Base Station displays a black screen. The Base Station screen starts up when a PDM connects to the Base Station or when the user taps the screen.

3.3.2 Walk-Up view – view detailed dose data

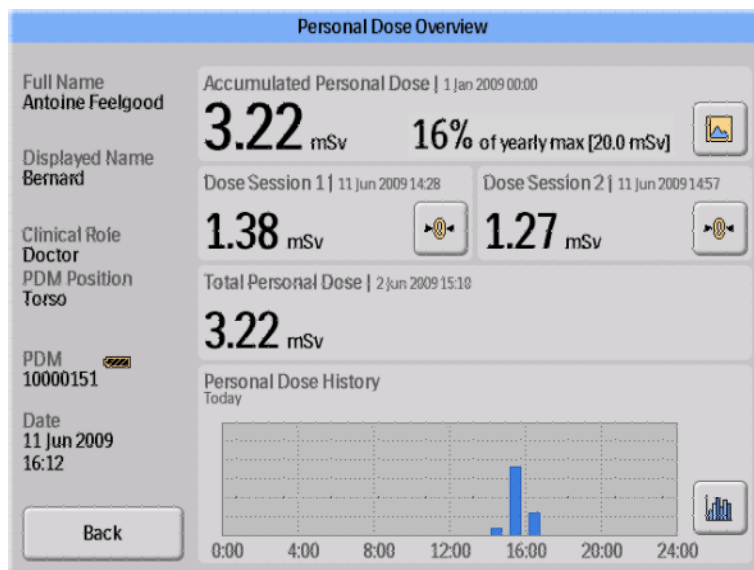


Figure 3.3 Personal Dose Meter Information panel

Enter the Walk-Up View of a PDM by tapping the **[Displayed Name]** button of that PDM in the Online View. On the left hand side of the Walk-Up View a Personal Dose Meter Info panel is displayed (see figure above). It displays:

- **Full Name**
- **Displayed Name** - the name that is displayed in the Base Station Online View
- **Clinical Role** - Doctor, Nurse, Technician or Other
- **PDM Position** - Head, Torso, Hand, Belly, Leg or Other
- **PDM** - a unique ID per PDM
- **Battery status**
 - 2-4 blocks indicate normal use.
 - 1 block indicates that you need to change the battery.
- **The PDM's date and time**

The Walk-Up View also consists of the Personal Dose Overview (see section “Personal Dose Overview” on page 3-8), which is the default Walk-Up view. It has two sub views:

- the Annual Personal Dose view (see section “Annual Personal Dose” on page 3-9)
- the Personal Dose History view (see section “Personal Dose History” on page 3-10)

Personal Dose Overview

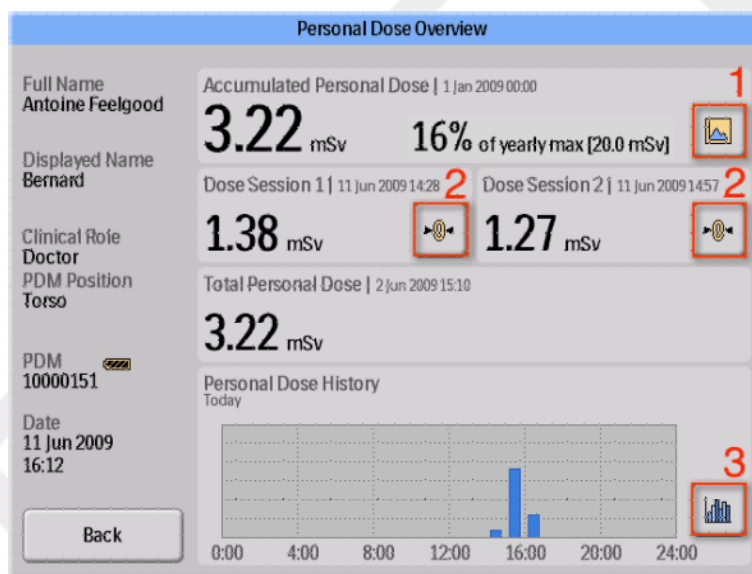


Figure 3.4 The Personal Dose Overview view

When you enter the Walk-Up View you will see the following information:

- The Accumulated Personal Dose since January 1st of the current year, or since last reset. This value is also shown as a percentage of the yearly max dose.
- Access to the Annual Personal Dose sub view (1), see section “Annual Personal Dose” on page 3-9.
- Dose Session 1 and 2 values, date and time. Use the Dose Sessions to measure dose for specific time spans, for example a specific procedure or a working day. The value shows the accumulated dose for a session since

last Dose Session reset, measured in Sv. Use the reset buttons (2) to reset a Dose Session to zero. Information about dose session reset will appear as an event in Dose Manager.

- Total Personal Dose since the last Dose History reset.
- The current day's Personal Dose History graph. You can also access the Personal Dose History sub view (3), see section “Personal Dose History” on page 3-10.

Annual Personal Dose

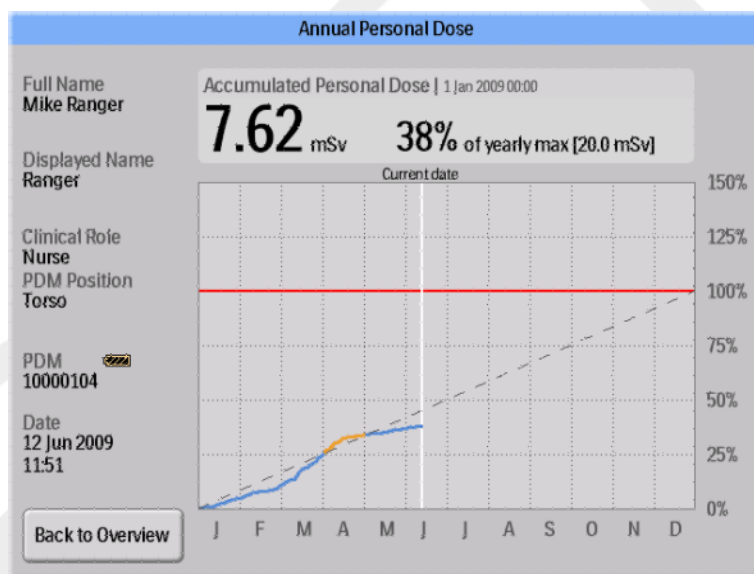


Figure 3.5 The Annual Personal Dose view

In this screen you can find the following information:

- Today's date (white line).
- Annual dose limit (red line). Set this value in DoseView or Dose Manager, see section “Change PDM options” on page 4-7.

- The annual dose limit distributed over the full year (dashed line). As long as the accumulated dose stays below this value, the annual dose limit will not be exceeded for the full year.
- Accumulated dose in relation to the annual dose limit for the current year (blue/orange line). When the accumulated dose exceeds the distributed annual dose limit, the color will change from blue to orange in order to alert the user to take actions.

Personal Dose History

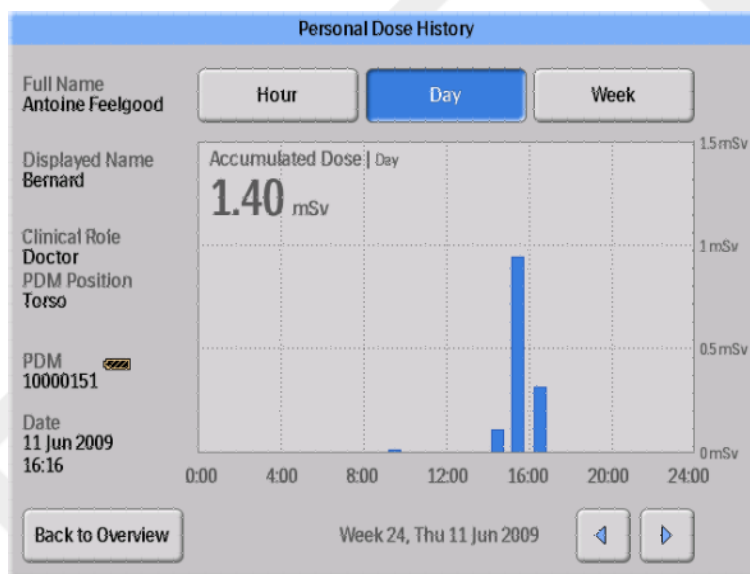


Figure 3.6 The Personal Dose History view, with Day selected

In this view, you can view Hour, Day and Week overviews by tapping the respective buttons on top of the screen.

In the Hour time span you can view a Dose Rate graph spanning $\frac{1}{2}$ hours. Each data point in the graph represents the maximum dose rate during the surrounding 15 seconds.

In the Day/Week time spans you can view accumulated dose value bars. Each bar represents the accumulated dose during one/four hours, respectively. Within the Day and Week time spans, tapping a dose bar in the diagram will zoom into the larger underlying time scale (that is Week -> Day and Day -> Hour).

Within each time span (Hour/Day/Week) you can step forward and backward in time with the arrow buttons on the bottom of the screen. By pressing and holding the arrow buttons you will scroll along the time axis within the chosen zoom level.

NOTE

Switching between Hour, Day and Week will set the view to the current date and time.

In the upper left corner of the chart, the value of the Accumulated Dose during the chosen time span is visible.

3.3.3

Base Station Settings view

The Base Station Settings View is where administrators configure the Base Station. Follow the instructions below to enter the Base Station Settings View:

- 1 Tap the | Settings| menu symbol in the upper right corner of the Online View.
- 2 Enter configuration values by tapping the buttons in the respective menus

In the lower part of Base Station Settings, the Base Station ID/serial number and the software version is displayed. This information can be used as assistance for support issues

User Settings menu

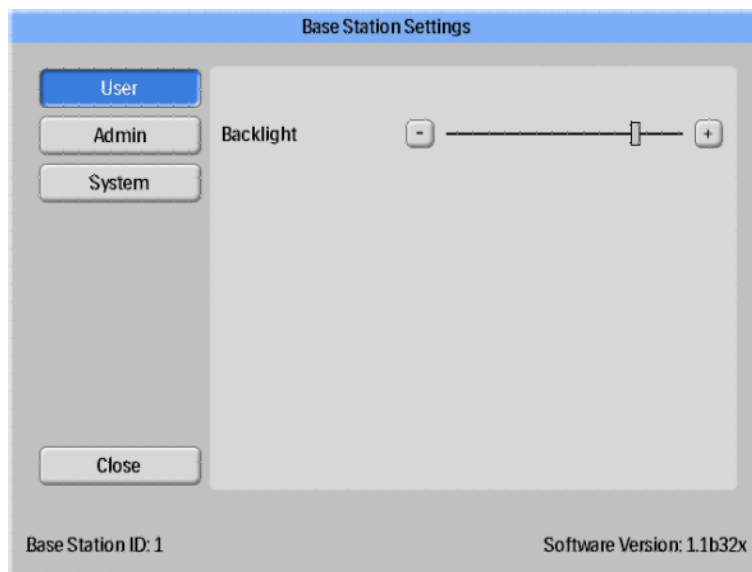


Figure 3.7 The User Settings menu

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.

Base Station Name and Base Station Location menu

Enter name and location of the Base Station (see figure below). This information is used to identify the Base Station so that it can be detected in Dose Manager.

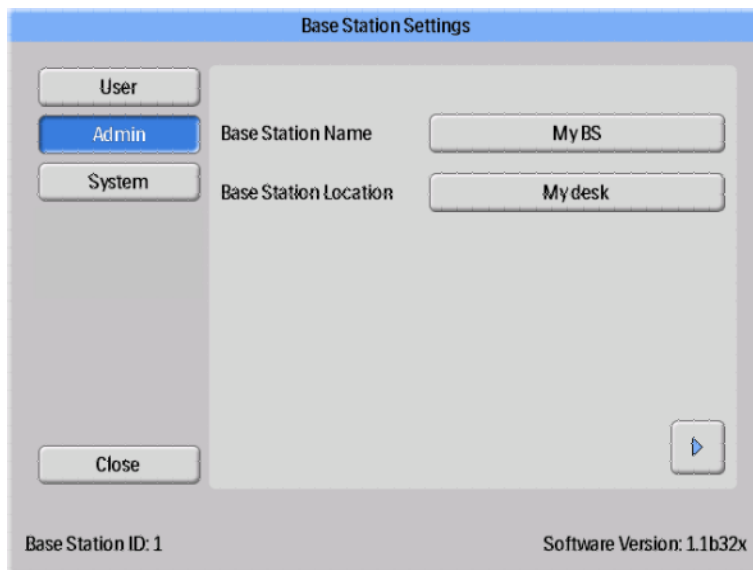


Figure 3.8 The Base Station Name and Base Station Location menu

Reserved Slots menu

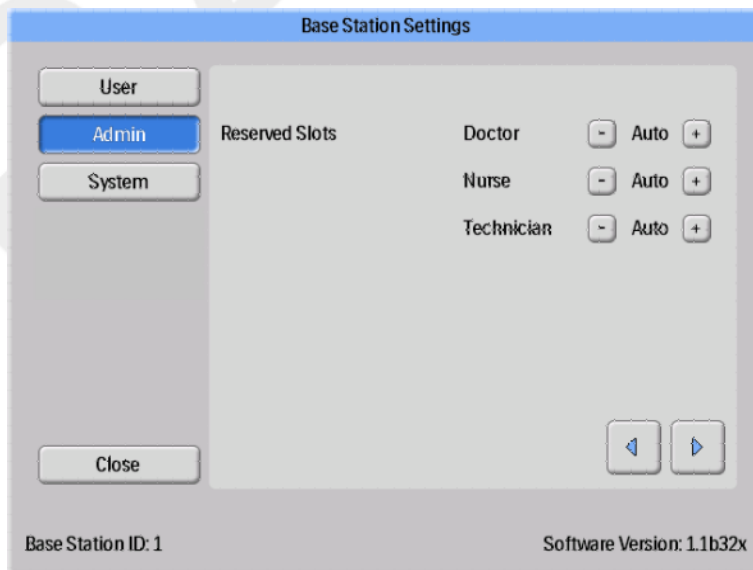


Figure 3.9 The Reserved Slots menu

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 (see figure above).

If you, for example, have reserved three slots for Doctors but the Base Station 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 PDMs will appear on the screen in the order the Base Station detects them, sorted after their clinical role. This is the recommended setting.

Network Setup menu

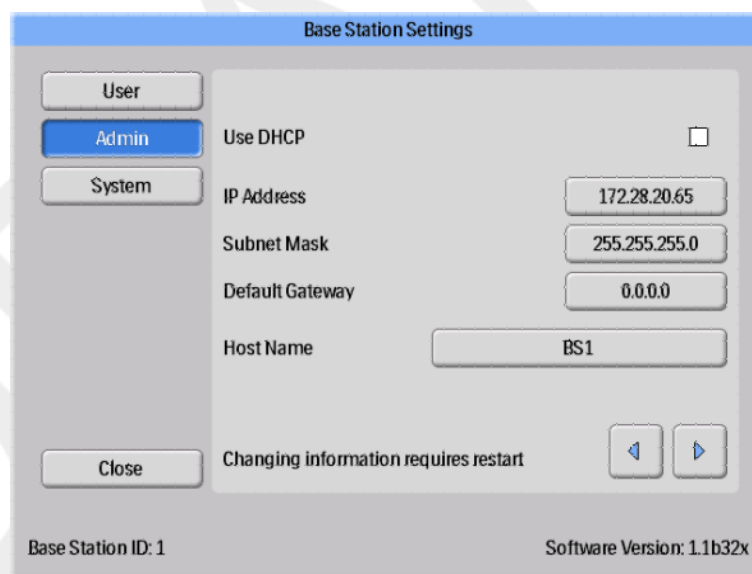


Figure 3.10 The Network setup menu

Configure the network connection between the Base Station and the Dose Manager (see figure above). You might have to contact the local IT department to receive the IP address.

If you change this information, the Base Station requires a restart.

NOTE

Network setup is only applicable if you are using Dose Manager.

Time and Date menu

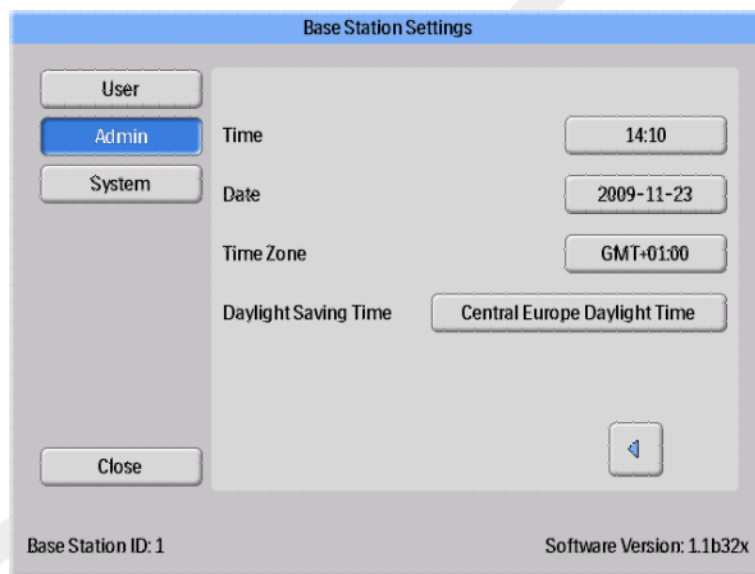


Figure 3.11 The Time and Date menu

Set time, date, time zone and manage daylight saving time for the Base Station (see figure above).

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

This menu is intended for service and is described in a separate service manual.

9
10 **3.4 Shutting down the Base Station**

11
12
13 **3.4.1 Shutting down a wall mounted Base Station**

- 14
15
 - Unplug the power adaptor.

16
17 **3.4.2 Shutting down an MCS mounted Base Station**

- 18
19
 - Switch off the X-ray system and the Base Station will be switched off.

DRAFT

4 Using DoseView

4.1 Introduction to DoseView

The DoseView application lets you, for one PDM at a time:

- View the PDM's dose history.
- Change the PDM options, for example full name and displayed name.

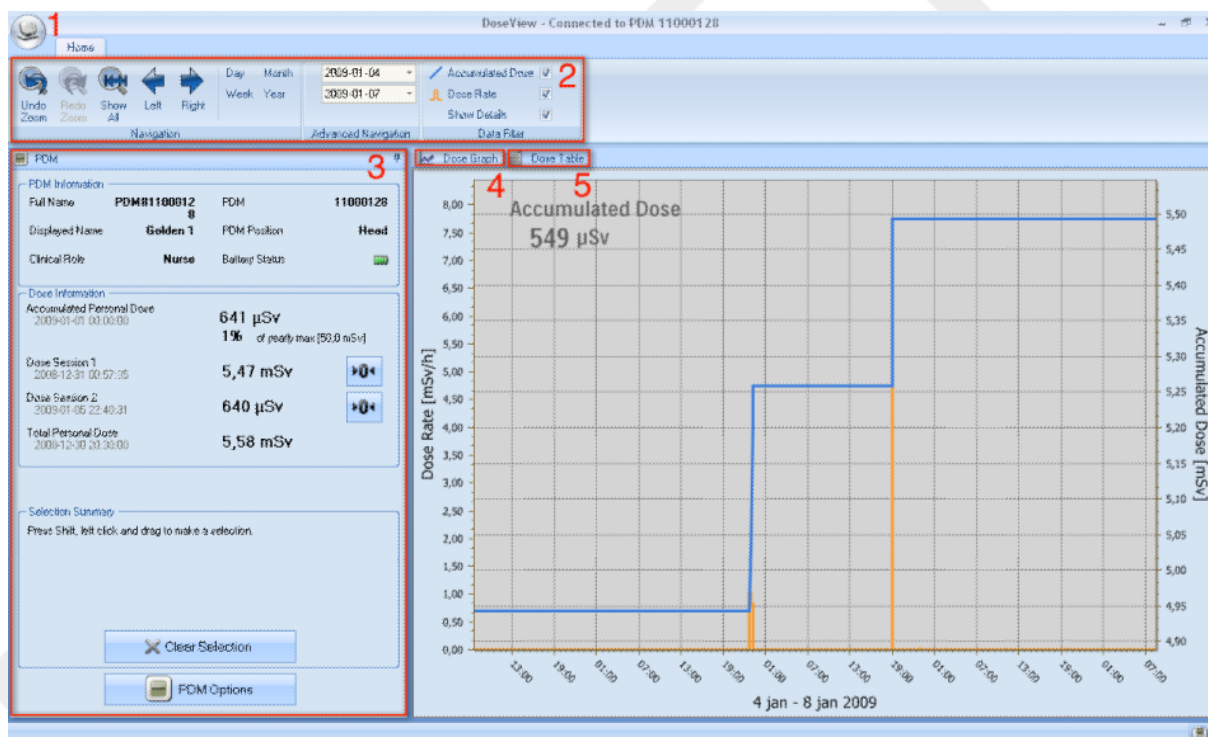


Figure 4.1 DoseView overview

Philipp's Healthcare 002.16623

The following items are available when you start DoseView:

Table 4.1 DoseView information

Item	Description
Application menu	Access the DoseView options dialog, see section “Specify password and language” on page 4-15.
Home toolbar	Access tools to navigate in dose graphs and dose tables, see section “Home Toolbar overview” on page 4-3.
PDM panel	Show and manage options for a PDM that is placed in a Cradle. You can only access and change PDM options when the PDM is in a Cradle, see section “PDM panel” on page 4-5.
Dose graph	View the dose history as a graph, see section “View dose graph” on page 4-12.
Dose table	View the dose history as a table, see section “View dose table” on page 4-14.

4.2 Getting started with DoseView

NOTE

Do not connect the Cradle to the computer unless DoseView and the Cradle driver are installed on the computer.

Follow the steps below to get started with DoseView:

- 1 Start the DoseView application.
- 2 Connect a Cradle to your computer’s USB port.
- 3 Put a PDM in the Cradle.

Within a few seconds, DoseView will detect the PDM. This is indicated at the top of the DoseView window by a note “Connected to PDM 100001158”, where PDM 100001158 is an example of a PDM ID.

DoseView will start loading the PDM dose history. This may take up to a few minutes. You can follow the progress on the progress bar at the bottom of the DoseView window.

4.3 Home Toolbar overview

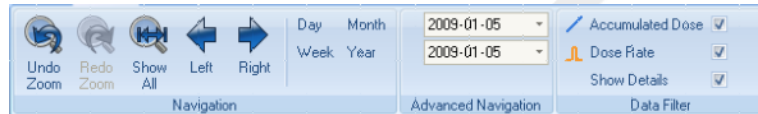


Figure 4.2 Home toolbar

The home toolbar is where you find tools to navigate in dose graphs and dose tables.

The following items are available in the home toolbar:

Table 4.2 Navigation Group — access tools for dose history navigation

Function	Description
Undo zoom button	Move one step back in a sequence of zoom actions, showing the last selected time range.
Redo zoom button	Move one step forward in a sequence of zoom actions, showing the time range that was selected before the last undo zoom action.
Show all button	Show all available data for the selected PDM. The time range will start the first date any PDM begun to measure dose and stop the last date any PDM was synchronized.
Left button	Shift the time range one step backward. If you have selected year/month/week/day, the time range will move one year/month/week/day backward. If you have selected another time range, the time range will move approximately 10% backward.
Right button	Shift the time range one step forward. If you have selected year/month/week/day, the time range will move one year/month/week/day forward. If you have selected another time range, the time range will move approximately 10% forward.
Day button	View dose history for the current day.
Week button	View dose history for the current week.

Function	Description
Month button	View dose history for the current month.
Year button	View dose history for the current year.

Table 4.3 Advanced Navigation Group

Function	Description
Start time button	The viewed time range start day.
End time button	The viewed time range end day.

Table 4.4 Data Filter Group — select which information is visible in the graph

Function	Description
Accumulated dose check box	Show/hide the accumulated dose in the graph.
Dose rate check box	Show/hide the dose rate in the dose graph.
Show details check box	Checked: The graphs will display dose rate samples for every second, where such data is available. Unchecked: the graphs will display mean dose rate values per hour.

4.4 PDM panel

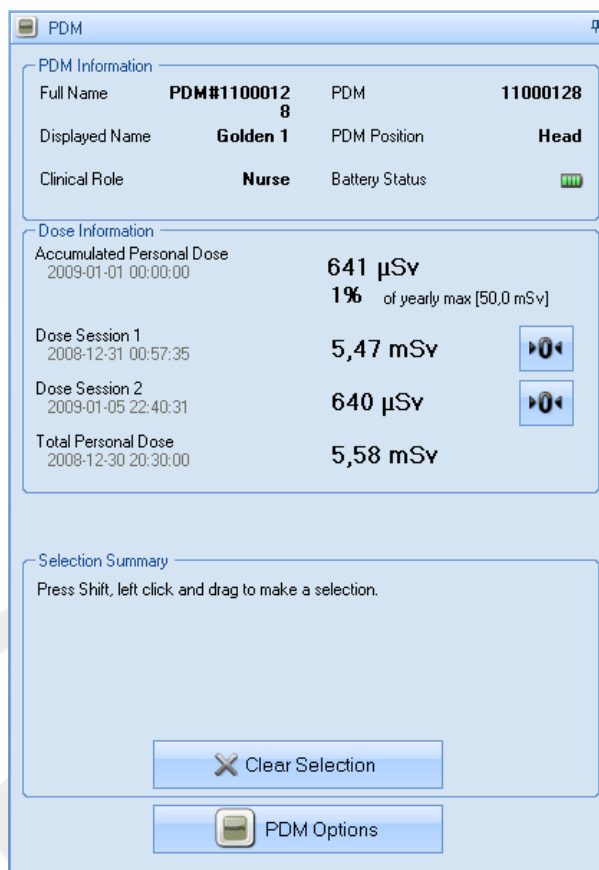


Figure 4.3 PDM panel

4.4.1 PDM information

The following information is visible when a PDM is placed in the Cradle:

Table 4.5 PDM information

Item	Description
Full name	Full name of the person using the PDM.
Displayed name	The name that is displayed in the Base Station Online View.

Item	Description
Clinical role	One of Doctor, Nurse, Technician or Other.
PDM	A unique PDM serial number.
PDM position	One of Head, Torso, Hand, Belly, Leg or Other.
Battery status	The PDM's battery status: <ul style="list-style-type: none"> • Green: normal use. • Yellow: normal use. • Red: the PDM need to be replaced in 4-6 months at normal use. • Crossed battery: there is no battery left. The PDM does not measure radiation and will not communicate with Base Stations.

4.4.2 Dose information

Table 4.6 Dose information

Item	Description
Accumulated personal dose	The PDM's total dose measured this year or since last reset, measured in Sv.
Percentage of annual dose	The PDM's accumulated annual dose measured this year or since last manual reset, measured in Sv.
Dose Session 1 and 2	Trip meter for dose values. The accumulated dose for a session since last Dose Session reset, measured in Sv. You can also reset these values. See NOTE below.
Total personal dose	The total dose exposure for a PDM since last dose history reset.

NOTE

Dose session reset done in DoseView will not appear as an event in Dose Manager.

4.4.3 Selection summary

View a summary of the dose data selection you might have done either in the dose table or in the dose graph (see section “View dose graph” on page 4-12 and section “View dose table” on page 4-14). You can also clear the contents of the selection summary field by tapping clear selection.

4.4.4 Change PDM options

The screenshot shows a dialog box titled "PDM Options" with a close button (X) in the top right corner. The dialog is split into two panes. The left pane has two sections: "Information" (with a person icon) and "Settings" (with a gear icon). The right pane contains the following fields:

- Full Name: PDM#11000128
- Displayed Name: Golden 1
- PDM Position: Head (dropdown menu)
- Clinical Role: Nurse (dropdown menu)
- Displayed Symbol: [Person icon] (dropdown menu)
- Annual Dose Limit (mSv): 50.00 (spin control)

At the bottom of the dialog are two buttons: "Save" (with a green checkmark icon) and "Cancel" (with a red X icon).

Figure 4.4 PDM options dialog box 1

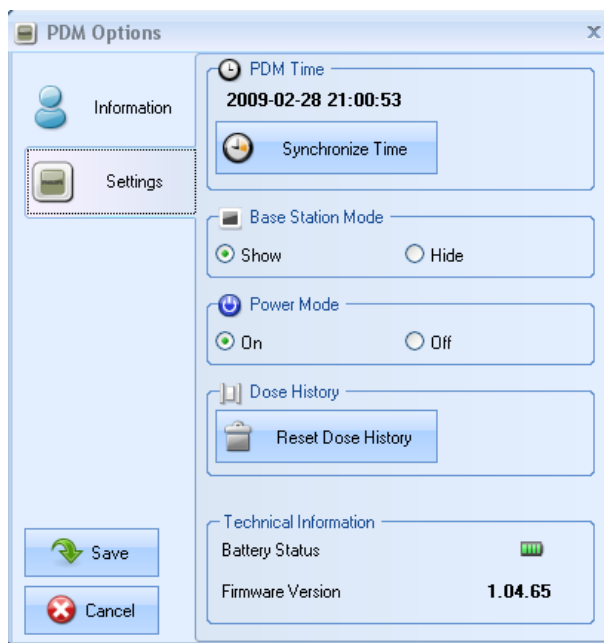


Figure 4.5 PDM options dialog box 2

Follow the instructions below to change PDM options:

- 1 Make sure that a Cradle is connected to your computer's USB port.
- 2 Insert a PDM in the Cradle.

The computer will detect the PDM automatically and the PDM information will appear in DoseView.

- 3 Access the PDM options dialog by clicking the | PDM options| (see figure above).

The PDM options dialog consists of two tabs as shown below.

NOTE

If a password has been set (see section "Specify password and language" on page 4-15), access to the PDM options dialog box will be password protected.

PDM options

The screenshot shows a dialog box titled "PDM Options" with a close button (X) in the top right corner. On the left side, there are two tabs: "Information" (selected) and "Settings". The "Information" tab contains the following fields:

- Full Name: PDM#11000128
- Displayed Name: Golden 1
- PDM Position: Head (dropdown menu)
- Clinical Role: Nurse (dropdown menu)
- Displayed Symbol: A small icon of a person wearing a hard hat and safety vest.
- Annual Dose Limit (mSv): 50.00 (spin box)

At the bottom left of the dialog, there are two buttons: "Save" (with a green checkmark icon) and "Cancel" (with a red X icon).

Figure 4.6 PDM Options Dialog Box — Information

In the Information tab you can:

- Edit PDM information (full name, displayed name, PDM position, clinical role, and annual dose limit value, see section “Walk-Up view – view detailed dose data ” on page 3-7) and select a displayed symbol, which is displayed in the Base Station interface. The displayed name is used to identify a PDM in the Base Station. The name is limited to 16 characters. However, in the Base Station’s online view, the displayed name may be truncated.

NOTE

The dose measurement for a PDM depends on factors such as where on the body the PDM is positioned and if x-ray protection devices (for example a lead apron) that shield the PDM measurements are used. These factors need to be considered for the annual dose limit.

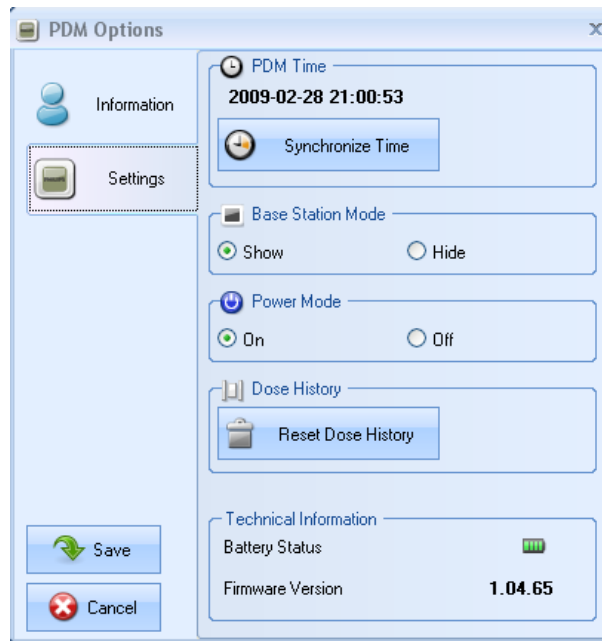


Figure 4.7 PDM Options dialog box — Settings

In the Settings tab you can:

- Set Base Station Mode to Show/Hide, which makes the PDM to be shown/not shown on a Base Station.
- Turn Power Mode On/Off, which puts the PDM in operating or power saving mode. In operating mode, communication with Base Stations will take place and registration of dose data will occur. In power saving mode no communication with Base Stations will take place and no registration of dose data will occur.
- Reset the PDM's Dose History — **This will permanently delete the PDM's entire dose data.**
- View Battery Status and Firmware Version.
- View and synchronize the PDM's clock with the computer's clock.

WARNING



Make sure that the computer's clock is correct, otherwise the dose history data will be shifted in time and therefore not accurate anymore.

NOTES

- *If you need to change hour-portion of time, the dose history will have to be reset. This is done automatically; you just need to confirm the action. When you synchronize PDM's time the internal clock will be synchronized to the same time as the host PC, including the Windows time zone settings. If you are using multiple PDMs, it is important to synchronize time for the PDMs with the same PC, because they will have the same time reference.*
- *If you need to change the time backwards to where there is dose history stored, the dose history will have to be reset. This is done automatically; you just need to confirm the action*
- *The synchronization takes immediate effect and you do not need to press the |Save| button.*

4.5 View dose graph

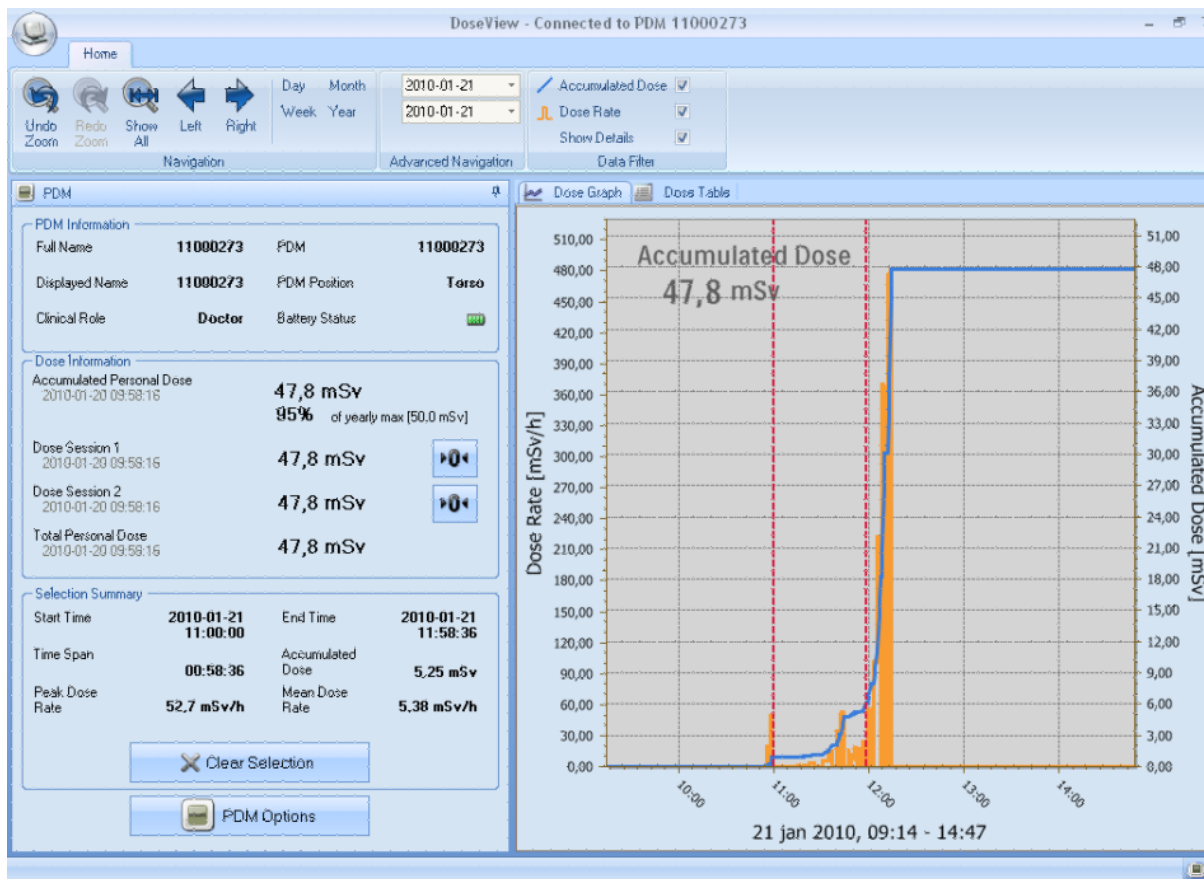


Figure 4.8 Dose graph with selection (vertical red dotted lines)

Use the data filter panel in the home menu toolbar to select which information to be visible in the graph:

- Accumulated Dose graph – blue graph
- Dose Rate graph – orange graph, displays dose rate samples for every second, where such data is available
- Show details
 - Checked: The graphs will display dose rate samples for every second, where such data is available.
 - Unchecked: the graphs will display mean dose rate values per hour

The graphs are covering a time span that you choose, either:

- From the Advanced Navigation panel.
- From the Navigation panel.
- Or by left-clicking and dragging in the graph (zooming).

You can also select a time span to be summarized in the Selection Summary field of the PDM panel. Make a selection by shift-left-clicking and dragging in the graph. Two red, dotted vertical lines in the graph will indicate the selected time span. The Selection Summary field will provide information about start time, end time, time span, accumulated dose, peak dose rate and mean dose rate.

4.6 View dose table

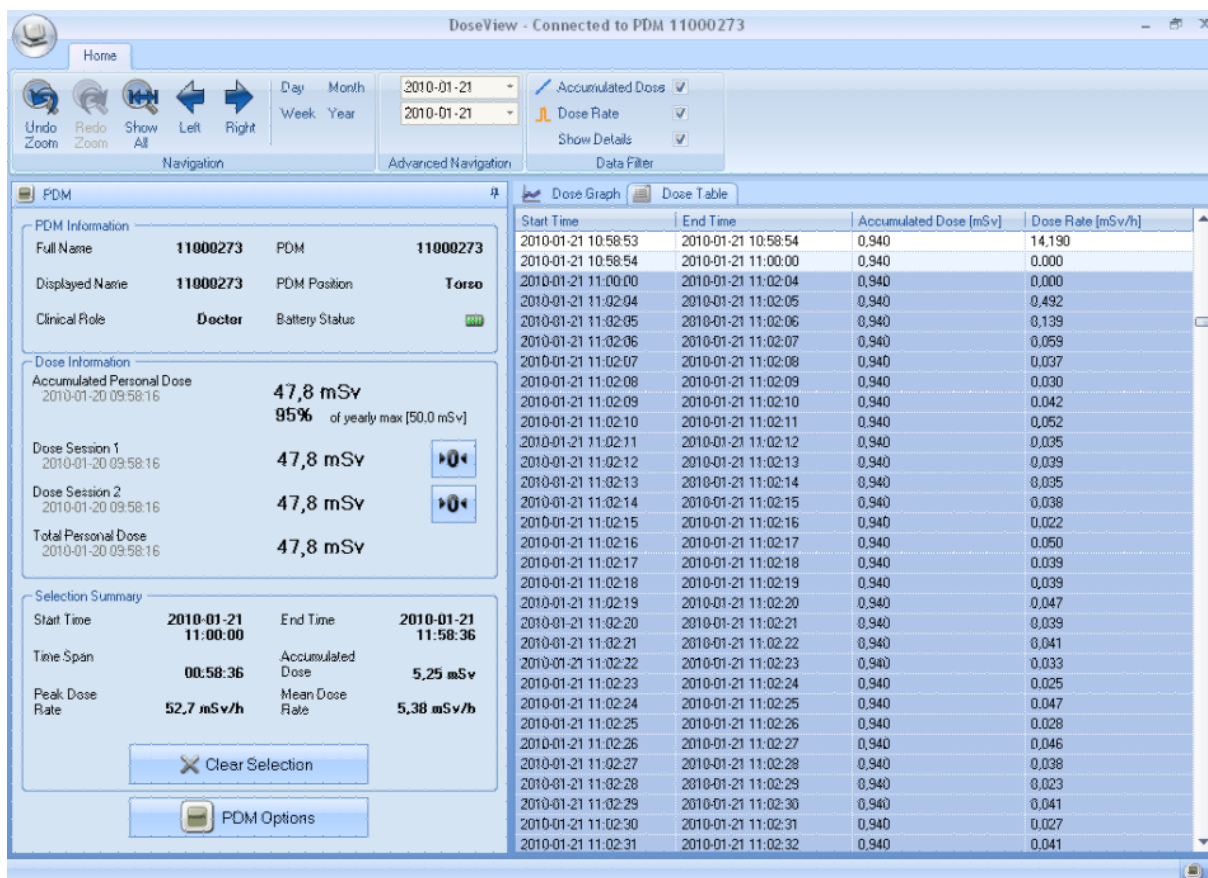


Figure 4.9 Dose table with selection

In the Dose Table tab (see figure above) you can view a table of:

- Accumulated Dose values.
- Dose Rate values.

The tables are covering a time span that you choose either from the:

- Navigation panel.
- Or the Advanced Navigation panel.

You can also select one or several rows to be summarized in the Selection Summary field of the PDM panel. The Selection Summary field will provide information about start time, end time, time span, accumulated dose and mean dose rate.

With the Show details check box checked, the table will list second data, where such data is available.

4.7 Specify password and language

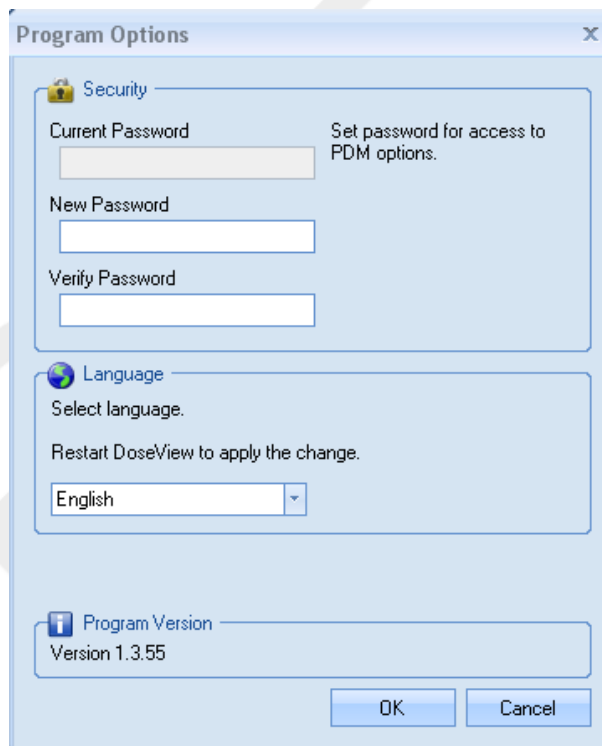


Figure 4.10 Program Options dialog box

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10 In the Application Menu -> Program Options dialog box (see figure above)
11 you can:

- 12 • Specify a password to protect the access to the PDM options dialog. The
13 password is only used when you are making PDM options changes.
14 Others can still view the PDM data.
- 15 • Change application language.
- 16 • View the DoseView program version.

17
18
19 **NOTES**

- 20 • **Contact your local administrator for password guidelines.**
- 21 • **If you have lost your password, contact your local administrator, who will have to re-**
22 **install the software**

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5 Using the PDM

5.1 Introduction



Figure 5.1 The PDM

The PDM is an active dose meter designed for maintenance-free usage throughout its lifetime.

You can personalize the PDM's appearance by attaching one of the 8 inlays of different color, which are delivered together with the PDM (see the PDM Quick Guide).

The PDM measures staff dose. The optimal usage for the PDM to measure dose is to use it unshielded from any X-ray protection devices.

5.2 Getting started

Follow the instructions below to start using your PDM:

- 1 Make sure that the PDM's power mode is set to section "Change PDM options" on page 4-7.
- 2 Attach the PDM on your clothes using the metallic clip, which is located on the back of the PDM, or the lanyard holder that is provided with the PDM.

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10 The PDM now records dose values and transmits them to Base Stations
11 within range. You can also read out the recorded dose values
12 by using DoseView via the Cradle (see section “Getting started with
13 DoseView” on page 4-2).
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15 See the “Technical Data” chapter to learn more about PDM
16 memory and data transfer between PDM and Base Stations.
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6 Using the Cradle

6.1 Introduction



Figure 6.1 The Cradle

The Cradle is a dock station that lets you connect a PDM to a computer for data read out as well as PDM Options writing into the PDM. Use the Cradle in combination with the DoseView and/or Dose Manager applications.

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10 **6.2 Getting started**11
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13 **NOTE**

Do not connect the Cradle to the computer unless DoseView and the Cradle driver are installed on the computer.

- 1 Start the DoseView application.
- 2 Connect a Cradle to your computer's USB port.
- 3 Put a PDM in the Cradle.

Within a few seconds, DoseView will detect the PDM. This is indicated at the top of the DoseView window by a note "Connected to PDM 100001158", where PDM 100001158 is an example of a PDM ID.

DoseView will start loading the PDM dose history. This may take up to a few minutes. You can follow the progress on the progress bar at the bottom of the DoseView window.

7 Maintenance

7.1 Calibrating the Base Station screen

If the touch screen does not respond correctly to user interaction, a touch screen re-calibration may be needed.

Follow the instructions below to perform a re-calibration:

- 1 Tap and hold on the Philips start up screen that appears during Base Station startup until the Setup view appears.
- 2 Follow the instruction on the bottom of the screen and the subsequent instructions in the next views.

7.2 Cleaning and disinfection

Cleaning and disinfection of this product is required periodically. Guidelines for each are given below.



WARNING

Always isolate the equipment from the mains electrical supply before cleaning, disinfecting or sterilizing to prevent electric shocks.

CAUTION

Never allow water or other liquids to leak into the equipment as this may cause electrical short-circuits or metal corrosion.

Cleaning and disinfection techniques for both the product and the room must comply with all applicable local laws and regulations.

7.2.1 Cleaning

Enameled parts and aluminum surfaces should only be wiped clean with a damp cloth and a mild detergent, and then rubbed down with a dry woolen cloth. Never use corrosive cleaning agents, solvents, abrasive detergents or abrasive polishes. If you are not sure about the properties of a cleaning agent, do not use it.

Chrome parts should only be cleaned by rubbing down with a dry woolen cloth. Do not use abrasive polishes. To preserve the finish, use non-abrasive wax.

7.2.2 Disinfection

Those parts of the product that are suitable for such treatment, including accessories and connecting cables, can be disinfected by wiping with a cloth dampened with a suitable agent. Never use corrosive or solvent disinfectants or sterilizing agents. If you are not sure about the properties of a disinfectant or sterilizing agent, do not use it.



WARNING

Do not use flammable or potentially explosive disinfecting sprays. Such sprays create vapors, which can ignite, causing fatal or other serious personal injury.

CAUTION

Disinfecting a medical product room by means of sprays is not recommended, since the vapor could penetrate the product, causing electrical short-circuits, metal corrosion or other damage to the product.

If non-flammable, non-explosive spray disinfectants are to be used, the equipment must first be switched off and allowed to cool. This prevents convection currents from drawing spray mist into the product. Plastic sheeting must be used to cover the product thoroughly, after which spraying can begin.

Once all traces of the disinfectant vapor have dispersed, the plastic sheeting can be removed and the equipment itself can be disinfected in the recommended way.

If a spray was used, you must be satisfied that all traces of the vapor have dispersed before switching the product on again.

8 Troubleshooting

8.1 Base Station

Table 8.1 Base Station troubleshooting

Problem	Solution
The PDM does not appear in the Online View.	Use DoseView or Dose Manager to check that the PDM's: <ul style="list-style-type: none">• Battery Status is OK (see section “Change PDM options” on page 4-7).• Power Mode is set to ‘On’ (see section “Change PDM options” on page 4-7).• Base Station Mode is set to ‘Show’ (see section “Change PDM options” on page 4-7).

8.2 DoseView and Cradle

Table 8.2 DoseView and Cradle troubleshooting

Problem	Solution
The PDM does not appear in DoseView	Check that the PDM is correctly fitted into the Cradle
DoseView does not detect the Cradle	<ul style="list-style-type: none">• Check the USB connection between the Cradle and the computer.• Install the Cradle driver 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 DoseView 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.
I have forgotten my password	Contact your local administrator, who will have to re-install the software

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DoseView and Cradle

Troubleshooting

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9 Product disposal

9.1 Introduction

Philips Medical Systems is concerned to help protect the natural environment, and to help ensure continued safe and effective use of this product, through proper support, maintenance and training.

Therefore Philips products are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the product is properly operated and maintained, it presents no environmental risks. However, the product may contain material, which could be harmful to the environment if disposed of incorrectly. Use of such material is essential to performing the functions of the product, and to meeting statutory and other requirements.

This section of these Instructions for Use is directed mainly at the user/owner of the product.

9.2 Passing the system on to another user

If this product passes to another user, it must be in its complete state, including all product support documentation.

Make the new user aware of the support services that Philips Medical Systems provides for installing, commissioning and maintaining the product.

Before passing on the product or taking it out of service, all data must be (backed up elsewhere if necessary, and) unrecoverable be deleted on the product.

It must be remembered by all existing users that passing on electrical products to new users may create serious technical, medical and legal (e.g. on privacy) risks. Such risks can arise even if the product is given away.

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10 Existing users are strongly advised to seek advice from their local Philips
11 Medical Systems representative before committing themselves to passing on
12 any product. Alternatively, contact the manufacturer.

13
14 Once the product has been passed on to a new user, a previous user may still
15 receive important safety-related information, such as bulletins and field
16 change orders. In many jurisdictions, there is a clear duty on the previous
17 user to communicate such safety-related information to new users. Previous
18 users who are not able or prepared to do this should inform Philips Medical
19 Systems about the new user, so that Philips Medical Systems can provide the
20 new user with safety-related information.
21

22 23 24 **9.3 Final disposal of the system**

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26 Final disposal is when the user disposes of the product in such a way that it
27 can no longer be used for its intended purpose(s).
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30 In the European Union (the WEEE directive), this label indicates that this
31 product should not be disposed of with household waste.
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44 This product should be disposed of at an appropriate facility to enable
45 recovery and recycling.
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47 Philips supports users in:

- 48 • Recovering reusable parts.
 - 49 • Recycling of useful materials by competent disposal companies.
 - 50 • Safe and effective disposal of product.
- 51
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For advice and information, contact your Philips Service Organization first, or otherwise the manufacturer.

9.4 Fitting, removing, and disposing of batteries

NOTE

Batteries harm the environment; dispose of the old batteries in an environmentally sound way.

For information about disposal of the product, batteries, and hazardous materials, see the Philips Medical Systems product sustainability website at:

<http://www.healthcare.philips.com/main/about/Sustainability/Recycling/>

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9.4 Fitting, removing, and disposing of batteries

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Technical data

10.1 PDM radiology

Table 10.1 PDM radiology technical data

Characteristic	Measure
Operational Quantity*	Hp(10)
Reproducibility	10% or 1 μ Sv, whatever is greatest
Dose Rate Range	40 μ Sv/h – 500 mSv/h
Energy dependence X-/g-rays	+/- 30% within N40 – N120
Angular dependence	+/- 5% within +/- 5° +/- 30% within +/- 50° +200%/-100% within +/- 90°
Temperature dependence	+/- 5% within 20-26°C +/- 25% within 15-35°C
Battery voltage dependence	+/- 2% from fully charged until low battery shutdown
Response time	Less than 1s above 100 μ Sv/h, less than 5s otherwise
Position on body**	On torso outside lead apron

*) Hp(10): Personal dose equivalent at a depth of 10 mm according to ISO 4037.
**) Position on body: The Hp(10) measurement is only valid for a position on the torso outside any lead apron or other protection. (To estimate effective dose to a user, one must use other means to estimate things like the environmental radiation situation and the effectiveness of protection.)

10.2 PDM memory

The PDM has two dose data memories:

- The accumulated dose memory, where the PDM stores *accumulated dose values* every hour for the entire lifetime of the PDM.
- The dose rate memory, where the PDM stores *dose rate samples*. When the radiation exceeds 40 $\mu\text{Sv/h}$, the PDM stores one sample per second. This memory is limited to 3600 second-samples.

NOTE When the dose rate memory is full, the oldest data will be overwritten with newer data.

10.3 Base Station memory

The Base Station stores dose information and PDM Info for PDMs that have been connected to it.

As the Base Station does not have a limitation of 3600 s for the dose rate memory, the information transmitted from the PDM will be more detailed. When a PDM is connected to a Base Station, it continuously transmits its measured dose exposures.

NOTE When the Base Station memory is full, the oldest data will be overwritten.

The capacity of the Base Station depends on the number of PDMs that have been On-Line and the number of dose rate samples. Storage capacity example:

- 290 hours of dose exposure for 50 PDMs each.

10.4 Dose data transfer from PDM to Base Station

When a PDM gets within range of a Base Station, it will transfer data to the Base Station (the *accumulated dose values* the PDM has collected since last time it was within range). If a PDM is within range of a Base Station when it is exposed to radiation, the PDM will also start sending *dose rate samples* to the Base Station each second.

10.5 PDM and Base Station/DoseView memories

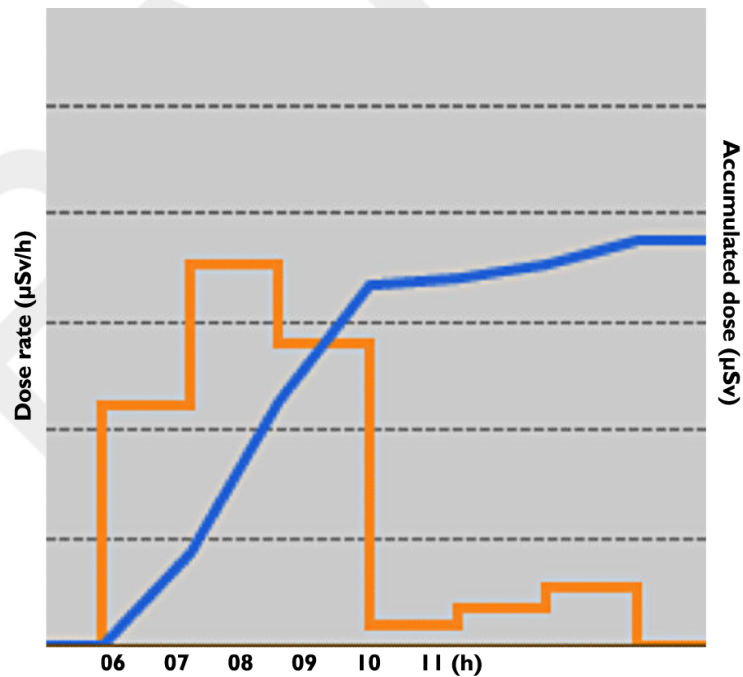
Dose rate samples that have been overwritten in the PDM's dose rate memory may still be available in the Base Station.

If there are no dose rate samples neither in the Base Station, nor in the PDM dose rate memory, the Base Station and DoseView will instead display mean dose rate values based on accumulated dose values (see figure below).

Lack of dose rate samples in the Base Station and/or DoseView memories occurs when the:

- PDM is not within range of the Base Station when it is exposed to radiation.
- Dose rate samples in the PDM dose rate memory are overwritten.

Figure 10.1 DoseView chart. In lack of dose rate samples, the yellow curve displays mean dose rate values per hour calculated from the accumulated dose (blue curve).



NOTE

The same effect as illustrated in the figure above is also obtained by un-checking the Show details check box in the Data filter panel (see section "View dose graph" on page 4-12).

10.6 Time management

The PDM logs dose history in local time with no daylight saving time adjustments. Daylight saving time adjustment is done in the Base Station, DoseView or Dose Manager when the dose history is presented.

The following happens when the daylight saving time is changed:

- When going to summertime, one extra hour with no dose data will be added to the dose log.
- When going to wintertime, two hours of dose data will be merged into one hour. This hour contains no dose rate details. When changing from summertime to wintertime, dose data details in the two merged hours will not be displayed.

10.7 Technical Specifications

10.7.1 Radio communication

- The communication range between a PDM facing a Base Station and the Base Station 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.

10.7.2 Base Station

Table 10.2 Base Station technical specifications

Characteristic	Measure
Weight	1.45 kg (3,2 lb)
Dimensions	297x243x51 mm (WxHxD)
Display	10.4" touch screen, 640x480 pixels, 65 000 colors
Power supply	12 V, 2 A
Memory	512 Mb
Storage	Approximately 290 hours of dose history for each of 50 PDMs

10.7.3

PDM

Characteristic	Measure
Backlight life time	Approximately 50000 hours
Maximum heat dissipation	25 W
Network	Ethernet 10/100
USB	1.1 host for USB Mass Storage Device

Table 10.3 PDM technical specifications

Characteristic	Measure
Weight	30 g (1 oz)
Dimensions	44x45x10 mm (WxHxD)
Fastening	Metallic clip and lanyard holder
Log memory 1	5 years Accumulated Dose with 1 hour resolution, cyclically overridden
Log memory 2	3600 Dose Rate samples with one-second resolution, cyclically overridden. Dose Rate is only measured above a 40 μ Sv/h threshold limit
Time resolution	1 second
Time accuracy	Maximum error 2 seconds/24 hrs
Power supply	via the Cradle when connected to a computer via USB
Expected battery life	At least 4 years based on “normal use”, which is defined as the operating conditions under normal use are 8 hours per day, 5 days a week and 52 weeks per year at an ambient temperature of 20°C.

10.7.4

Cradle

Table 10.4 Cradle technical specifications

Characteristic	Measure
Weight	50 g
Dimensions	64x61x59 mm (WxHxD)
Cable length	1,5 M

Characteristic	Measure
Power	via USB
Communication with computer	USB 2.0

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15 **10.8**

Security and privacy requirements

Antivirus

An AVS solution is not installed on this Windows CE device because of the security measures taken to reduce the attack surface.

Network ports

The following ports and protocols are open on the Base Station for communication with the Dose Manager:

TCP/UDP	Port number	Protocol	Additional note
TCP	8070	gSOAP httpd 2.7	Used for regular (bidirectional) communication between Base Station and Dose Manager
UDP	8060	Proprietary discovery protocol	Protocol (bidirectional) used for Base Station discovery

Encryption

DoseAware data is encrypted during transmission, at rest on the Base Station and is stored in an encrypted Dose Manager database.