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DOSE-X

Instructions for Use

DOSIMETRY

DOSE-X Instructions for Use

Notice

This document is an integral part of the DOSE-X and should always be kept at hand. Observance of the instructions is required for proper performance and correct operation of the DOSE-X.

The DOSE-X and its accessories must not be used for any other purpose than described in the accompanying documentation (intended use). Violation will result in loss of warranty.

IBA Dosimetry does not accept liability for injury to personnel or damage to equipment that may result from misuse of this equipment, failure to observe the hazard notices contained in this document, or failure to observe local health and safety regulations.

IBA Dosimetry shall under no circumstances be liable for incidental or coincidental damage arising from use of the equipment described in this document.

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Table of Contents

1. Introduction

1.1. Intended Use

The DOSE-X electrometer is intended for reference dose and dose rate measurements in radiation therapy.

Non-Intended Use

The DOSE-X is not intended to be used for applications where the detector or the dosimeter is in contact with the patient.

The DOSE-X is not intended to be used for applications related to radio-diagnostics (medical imaging).

1.2. Intended Users

The DOSE-X is to be used by the personnel with the following expertise:

Area	Expertise
Installation	IT Administrators
Operation	Medical Physicists / Dosimetrists and Dosimetric Assistants
Maintenance and Troubleshooting	Medical Physicists / Dosimetrists

Medical Physicists / Dosimetrists:

Users having the main responsibility for the treatment safety in the radiotherapy department. This includes the definition of the QA tasks to be carried out, their frequency and the acceptance criteria. The medical physicist is responsible for commissioning all dosimetry related QA devices and may override individual pass/fail results at his own discretion.

Dosimetric Assistants:

Users responsible for carrying out the recurring quality assurance tasks. The dosimetric assistants will not define QA tasks and their acceptance criteria. The dosimetric assistants do not have discretion in judging the results of QA measurements.

Intended Patient Population

The intended patient population is anyone undergoing a prescribed radiation therapy.

1.3. Expected Lifetime of Hardware

The expected lifetime of the hardware is at least five years.

1.4. Product Description

The DOSE-X is a high-end, reference class electrometer with added detector and machine libraries, voltage requirements, readout capability (dose & dose rate) and triggered (threshold) detection. Control of the DOSE-X is handled by a large, color LCD touchscreen for fast and easy operation, as well as convenient display of many measurement parameters simultaneously.

Certified initial and yearly calibrations of the DOSE-X may be provided by an accredited dosimetry calibration laboratory (ADCL).

DOSE-X Dosimeter

Note: These instructions refer to version 2.0 of the DOSE-X firmware (FW). Please contact IBA Dosimetry about receiving the latest DOSE-X FW or Instructions for Use for your version. The DOSE-X **Device info** *page displays the currently installed FW version number.*

About Health and Safety Information

NOTICE

IMPORTANT NOTICE

HEALTH AND SAFETY INFORMATION

Device health and safety information is described in Chapter 7, including safety precautions, device labeling, electromagnetic compatibility, environmental requirements, and regulatory requirements. Users are required to read this chapter before using the device.

1.5. About this Document

This document contains health and safety information, description, technical specification, and maintenance of the device.

NOTICE

IMPORTANT NOTICE

ALWAYS KEEP THE INSTRUCTIONS FOR USE AVAILABLE

Always store this document near the system and ensure it is easily accessible.

Contact the manufacturer immediately if this document is missing. A copy of this document is always available from IBA Dosimetry.

Reference Guide

Additional information is available in the *DOSE-X Reference Guide*:

- Algorithms
- Troubleshooting
- Country specific RF symbols

Conventions

- The functions of the devices and the names of the dialogs are indicated by bold font.

  Examples: **Calibration, Save**.
- References to chapter and section headings and captions of tables and figures in this manual are indicated by italic font.

  Examples: *Equipment Setup, Technical Specifications*
- A green arrow bullet [➤] list is used for a list of actions in a procedure; other lists use orange square bullets [■].
- All numbers and selections displayed in images are examples. Values and settings cannot be regarded as references.
- Throughout this manual, hazardous situations or operations are identified by WARNING, CAUTION, and NOTICE. They are indicated by specific signs and colors, and described below:

Sign	Meaning
⚠ WARNING	WARNING indicates a hazardous situation, which, if not avoided, could result in death or serious injury of the operator or patient.
⚠ CAUTION	CAUTION, used with a safety alert symbol, indicates a hazardous situation, which, if not avoided, could result in minor or moderate injury of the operator or patient.
CAUTION	CAUTION without the safety alert symbol, used to address issues related to possible hardware damage.
NOTICE	IMPORTANT NOTICE used to address operational issues not related to personal injury or hardware damages.

2. Equipment Description

2.1. Standard Delivered Items

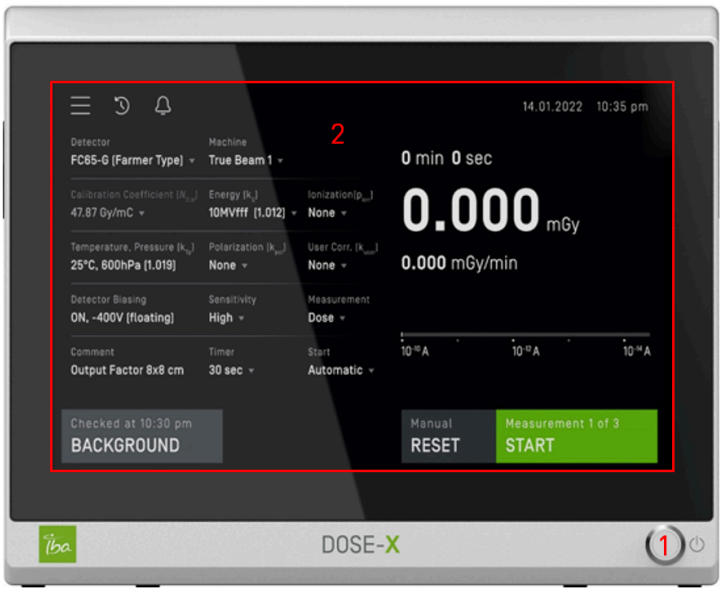
- DOSE-X Electrometer
  - DX00-000 (Device with TNC triaxial connector)
  - DX00-100 (Device with BNC triaxial conenctor)
- DOSE-X Instructions for Use
- DOSE-X Power cord set

Optional:

- DOSE-X Carrying case

2.2. DOSE-X

Front Panel



DOSE-X Front Panel

Power button [1]: Short press the **Power** button to turn **ON/OFF** the device.

Note: If the device is unresponsive, long press the **Power** *button (for at least 6 seconds) to perform a hard shutdown. See Troubleshooting in the DOSE-X Reference Guide for more information.*

LED ring:

- Red: Device is powered on but not ready
- Green: Device is done booting and ready for use
- After the device is ready, if the **LED** ring turns **Red**, this indicates that there is an error.

Touch Screen [2]: The DOSE-X features a large LCD touch screen through which the device is controlled.

The DOSE-X comes with a pre-installed screen protector to help reduce screen wear. Replacement screen protectors can be ordered from IBA Dosimetry.

Back Panel

DOSE-X Back Panel

1: **Power** switch for turning ON/OFF the power supply. After turning off the device with the **Power** button (front panel), it is recommended to turn off the power supply before disconnecting the power cable.

2: Main power supply input.

3: Ethernet port.

4: Bias Voltage Output (4mm bunch plug) used to optionally provide bias voltage to detectors (see Floated vs. Grounded Input).

5: Triaxial Connector connects an ion chamber or other compatible measurement device to the channel (see Section 5.3 for TNC and BNC accessories).

6: The USB port allows the user to:

- Export Measurements, Libraries, and Configuration data
- Import Libraries and Configuration data
- Install FW upgrades

NOTICE

IMPORTANT NOTICE

USB PORT USAGE

The USB socket is intended to be used with commercially available, self-powered, standard USB 3.0 flash drives without a USB cable (not requiring additional power). USB 2.0 flash drives may not be recognized by the DOSE-X, it is therefore advised to only use a USB 3.0.

The usage of any USB device other than what is described above is regarded as non-intended use. In particular, the use of a USB hub (where USB end devices are not directly connected to the DOSE-X) is not supported.

Detectors

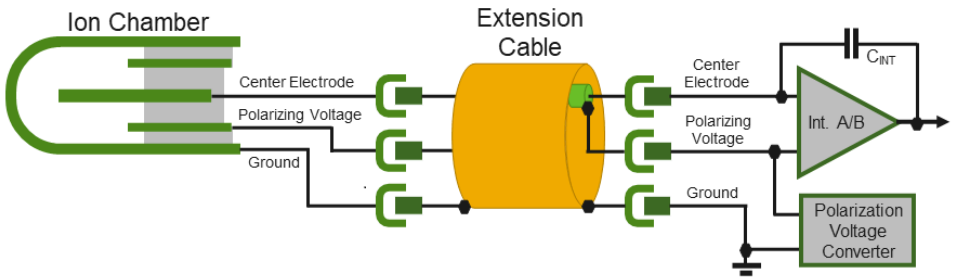
The recommended IBA detectors (ionization chambers and semiconductor detectors) for the DOSE-X system are listed in Section 5.3.

Floated vs. Grounded Input

The DOSE-X has two different methods for connecting ionization chambers to an electrometer: **Floated** and **Grounded** input technology. The main difference between the two systems is the way in which the polarization voltage is supplied to the ionization chamber.

Floated: The floated input clamps the outer chamber wall on ground potential, and provides the polarization voltage through the inner (collecting) electrode. Therefore, the electrometer amplifier is on polarization potential, and needs an isolating amplifier to provide analogue output. The extremely low current, initiated inside the chamber by radiation, forces the use of high sophisticated guarding techniques, in order to make the entire system (chamber, cable, connectors and amplifier) usable in clinical routine.

Floated input technology allows a consistent triaxial conception of electrometer input, cable, and detector. The chamber wall is on ground, and therefore the entire chamber and cable system is properly shielded. No protective sleeve is needed. This consequent shielding system provides extremely low noise operation. The outer shield of the triaxial cable is on ground. Standard triaxial connectors (either bayonet or threaded) can be used.

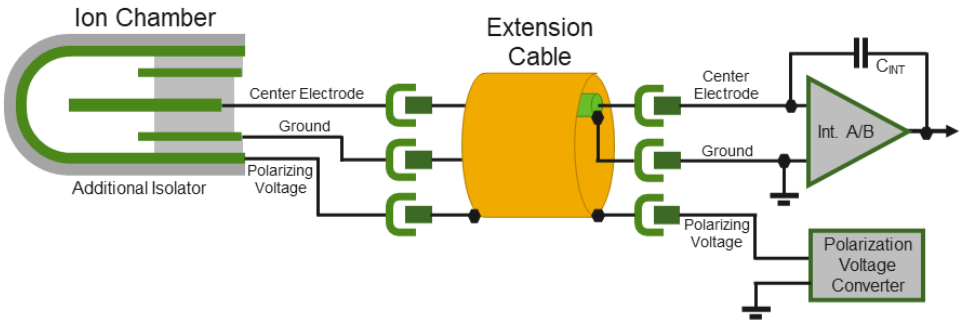


Floated Input Technology

Grounded: The grounded input clamps the electrometer amplifier on ground potential and provides the polarization voltage to the outer chamber wall.

With grounded input technology, typically all electrical components inside the electrometer are on ground potential. With grounded input, the construction of cables and sensors is more demanding, for the following reasons:

- The chamber wall is on polarization voltage, and an additional isolating sleeve is necessary to protect from electrical hazard and leakage current, especially when used in water.
- As the chamber wall is not grounded, RF noise may enter into the chamber and cause problems under all RF operated particle accelerators.
- If a triaxial cable is used, the connectors become complicated, because at the inside the connector's inner and outer shielding must be crossed to get the outer shell of the connector on ground level. The same occurs inside the chamber, if a conductive (metal) chamber body has to be grounded.



Grounded Input Technology

3. Setting up the Device

The following chapter describes the user interface for the DOSE-X and its different functionalities and features. For information on taking measurements, please see Chapter 4.

Password Protected Access

The DOSE-X requires a password for **Admin** access to certain settings and features. This password is set the first time that protected functionalities (such as network settings or editing of the detector library) are used.

⚠ CAUTION

CAUTION

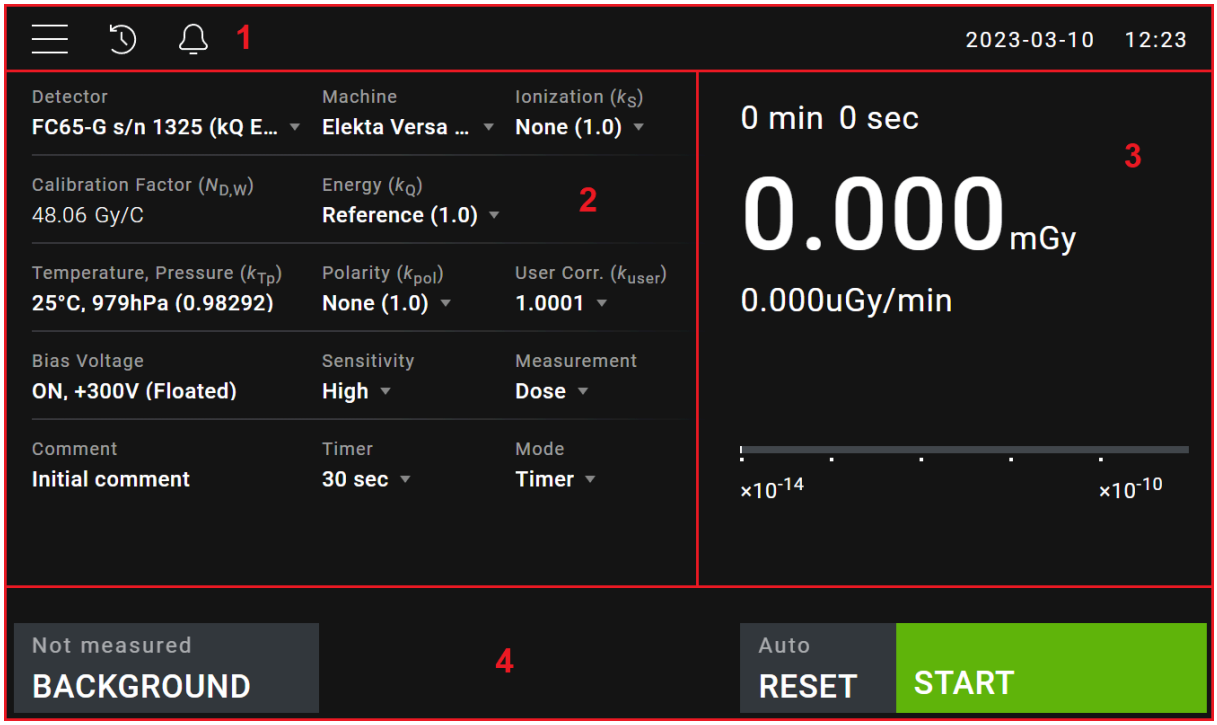
RECOVERY OF A LOST ADMINISTRATOR PASSWORD

In case the ***Admin*** password is lost, access to the DOSE-X can be regained by entering the reset-token provided with the certificate of compliance and calibration at the admin password prompt. You will then be able to choose a new admin-password.

As the password reset-token grants access to protected functionality of the DOSE-X, please store the reset-token in a safe place so that it is not accidentally disclosed.

3.1. Main screen

From the main screen of the DOSE-X the user can see the current detector, settings, and measurement, as well as take new measurements.



On the **Navigation** bar [1], the user can:

- Access the system settings, admin login, and detector / machine libraries via the **Main Menu** icon
- See the **Measurement History** [], **Notifications** [], and current **date and time**
- A **green** figure indicates that the user is logged in as an Admin

The currently selected detector [2] and measurement parameters are displayed. Here certain parameters can be changed before performing the next measurement. The measurement results [3] are displayed on the right side of the screen.

At the bottom of the screen [4] the user can:

- Check the Background
- Reset to take a new measurement
- Start / Stop a measurement

See Chapter 4 for more information on measurements.

⚠ CAUTION

CAUTION

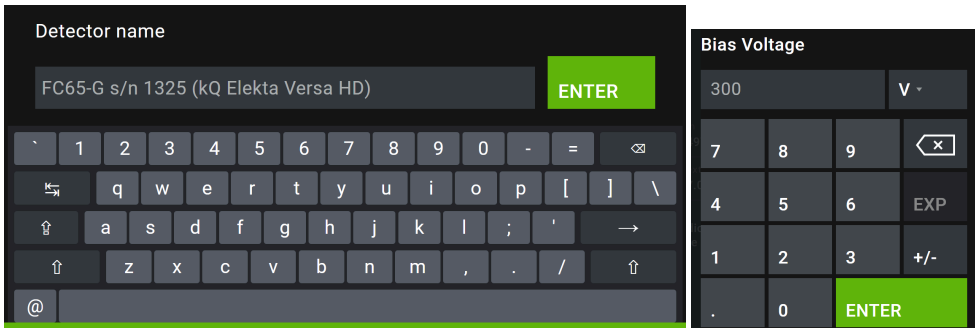
VERIFY DATE AND TIME

Always verify that the date and time displayed on the DOSE-X are correct and correspond with the real date and time at your location. See Section 3.2 for information on setting the date and time.

Entering Information

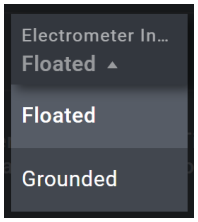
The DOSE-X has an on-screen keyboard and number pad for easy text and value entry.

To enter information, simply tap on a field and the keyboard / number pad will open. Tap **ENTER** when you have finished.



DOSE-X keyboard and number pad

Some fields have dropdown options. Simply tap on the field to open the dropdown menu and select the correct value.



3.2. System Settings

To access system information and change device and measurement settings, tap the **Menu** button and select **System settings**.

Please note that some items and actions are only available to users with **Admin** access.

Item	Description
Device info	Shows device information including, device names, serial number, production date, and hardware and FW versions. Please note, this information is not editable.
Display	■ Screen brightness ■ Display mode: Dark or Light ■ Screensaver timeout: select a time from the dropdown menu
Audio	■ Alarm volume (alarm cannot be switched off and the minimum volume is 40%). The alarm is used to notify the user about: • Errors (see Section 3.8) • Bias Voltage ranges / overcurrent • Board temperature • Leakage Test failure during self-tests ■ End of measurement notification ■ Audible touch feedback
Diagnostic functions	■ Self-test Functions ■ System Monitoring See Section 3.2.1.
Export log files	Select a log type and tap the **Export** button (see Section 3.2.2). Available log types: ■ System log ■ System log since last boot ■ Measurement log ■ Measurement log since last boot

System Settings for users with Admin access only

Item	Description
Time & date	■ Time format: select a 12 or 24 hour format ■ Time zone ■ Date format: switch between 'yyyy-MM-dd', 'MM/dd/yyyy', or 'dd.MM.yyyy' ■ Use time from network: Sets the device time using the connected network. Click **SET** to save the changes.
Language	Select the display language. The FW currently supports English (US), German, Spanish, French, Italian, Portuguese, Russian, Japanese, Korean, and Chinese.

Item	Description
Units	■ °C, °F, and K for temperature (default °C) ■ hPa and Pa for pressure (default hPa) Click **RESET TO DEFAULT** button to reset the units. Before starting a measurement, ensure the k_{Tp} correction units are correct.
Trigger Mode	Set the desired values for **Trigger Mode** (see Trigger mode settings): ■ Beam on time (default 1 s) ■ Beam off time (default 2 s) ■ Pre trigger time (default 500 ms) ■ Post trigger time (default 500 ms)
User calibration	Click on **High**, **Medium**, or **Low** to enter the desired sensitivity. Sensitivity ranges: ■ High: 400fA – 600pA ■ Medium: 6pA – 60nA ■ Low: 2.4nA – 24µA **User calibration factors applied** can be switched on/off.
Network configuration	■ Connect the DOSE-X to a network (WLAN or Ethernet) ■ Allow remote control ■ Import TLS certificate See Section 3.3.
Admin settings	■ Select the time of inactivity before the system logs out • Example: if **5 min** is selected the **Admin** will be logged out approximately **5 min** after there has been no active use of the device. ■ Select the amount of time before control is automatically released. • Example: if **60 sec** is selected, active control of the device is released approximately **60 sec** after there has been no active control actions performed. See Section 3.3.3 for more information on active control. ■ Change the password
Update firmware	Update firmware via USB flash drive or remote access. See Section 6.2.1.
Configuration backup	■ **Import**: Import a backup of the device settings ■ **Export**: Export all configuration, libraries, and measurement history ■ **Reset to Factory Defaults**: Deletes all user settings and restores the device to factory default See Section 3.4.

3.2.1. Diagnostic Functions

Self-Test Functionalities

Self-tests are performed automatically during device warm-up and can be performed manually at any time by pressing the **Perform Test** button on the **Diagnostic Functions** page.

When manually performing self-tests, please ensure that the protective cover has been placed over the Triaxial Connector before tapping the **Perform Tests** button.

The **Self-Test Functions** tab displays the results of the **Leakage**, **Bias**, and **Electrical Sensitivity** tests.

- **Bias Test**: Checks the insulation resistance between the center electrode and GND of the entire sensor, extension cable, and dosimeter system.
- **Leakage Test** (Isolation Collection electrode to Guard): Checks the insulation resistance between the center electrode and the guard of the entire sensor, extension cable, and dosimeter system.
- **Electrical Stability Test**: During the test, a highly stable, bipolar reference charge source is used to check the proper function and the long-term stability of the charge input amplifier circuit. The results of these tests are displayed, as absolute values (nominal and measured value) and relative deviation (in percent of nominal value).

System Monitoring

The **System Monitoring** tab displays the following system status information:

- Power Supply Voltage
- Real Time Clock Battery
- Internal System Voltages
- System Temperature

3.2.2. Export Log Files

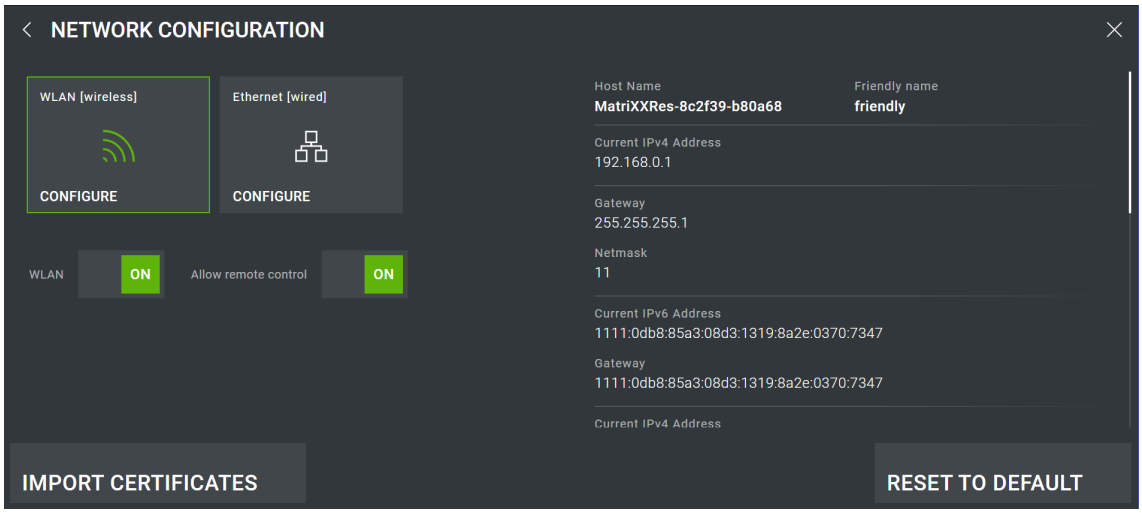
Tapping **EXPORT LOG FILES** in the system settings menu to open the Export log files screen. Select one of four options to export:

- **System log**: Contains log entries of all FW components, inclusive Kernel. The complete system log may have many entries, resulting in a big export file size. The export file size may be reduced by selecting one of the other three options.
- **System log since last boot**: Same as above but reduced to the log entries since the last power on/off.
- **Measurement log**: A filtered system log which contains the log entries from the measurement components only.
- **Measurement log since last boot**: Same as above but reduced to the log entries since the last power on/off.

DOSE-X data is exported as plain text files which can easily be opened in most text editors and word processors.

3.3. Network Configuration

- To open the **Network Configuration** page, tap the **Main menu** button and go to **System settings** > **Network configuration**.



Network Configuration page

3.3.1. WLAN (wireless) Connection

- Tap the **WLAN [wireless] CONFIGURE** button and select the correct network from the list.
- Click on the  icon to edit an available network, or if the desired network is not listed, tap **ADD NEW**.
- Enter the necessary information and tap **SAVE**.

3.3.2. Ethernet (wired) Connection

- Tap the **Ethernet [wired] CONFIGURE** button.
- Select **DHCP/Autoconf** to automatically connect to the detected network, or select **Static** to maually enter the **IPv4/IPv6** addresses.
- Tap **SAVE**.

3.3.3. Remote Control

The DOSE-X can be controlled remotely via a web browser if it is connected to a network. The following browsers are permitted for remote control:

- Google Chrome (version 109.0.5414.120 or later)
- Microsoft Edge (version 109.0.1518.7 or later)

⚠ CAUTION

CAUTION

USE ONLY PERMITTED WEB BROWSERS

Using the DOSE-X remotely from a web browser other than specified may introduce risks related to the product safety, usability, or cybersecurity.

- Ensure that the device is connected to a network.
- Switch on **Allow remote access**.
- Using a remote device (computer, tablet, etc.), open a web browser (Microsoft Edge, Firefox, or Safari).

- Type the device IP address in the web browser to connect to the DOSE-X.
  Please note, the device IP address can be found under the **DEVICE INFO** page.
- To avoid the risk of multiple users changing a setting at the same time and possibly interrupting a measurement, only one user can have active control at a time.

⚠ CAUTION

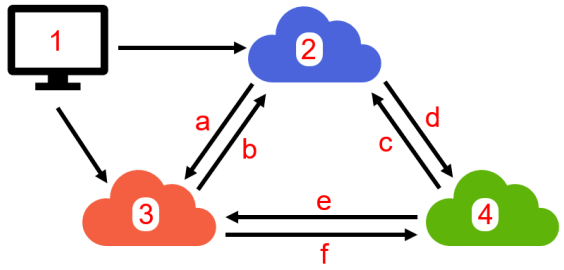
CAUTION

DOUBLE CHECK BEFORE ENABLING THE HV OR CHANGING FACTORS

If you are controlling the DOSE-X remotely, and another user is connected to the DOSE-X (despite not having active control at the moment) double check with this user before enabling the HV or changing any factors.

Concurrent access for remote users

A user has connected to the DOSE-X remotely (1). If one or more users are connected to the device, the status of the remote connection will be shown with a colored frame around the display and a cloud icon. Please see below to understand how the connection status can transition during remote contol.

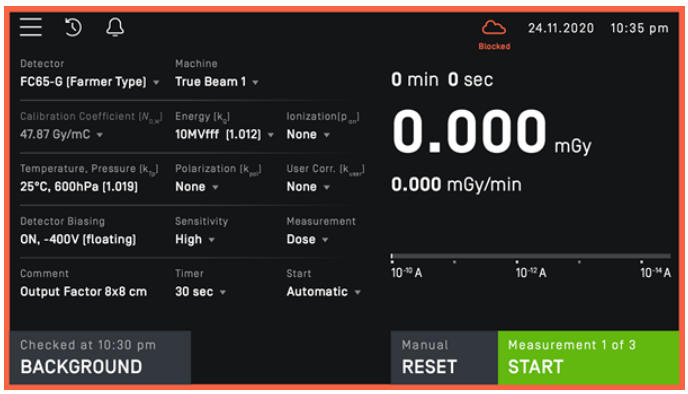


State transitions diagram for remote control of the DOSE-X

Control status of the DOSE-X:

- **Blue**: There is no active control (2) of the device.

- **Orange**: Someone else has active control (3) of the device. The **Admin** may takeover active control.



- **Green**: You currently have active control [4] of the device:

  Only in this state can the user perform *active control* actions. No other use can perform measurements or change settings.

  Note: A remote user signed in as an **Admin** *can take away active control of the device from a non-Admin user.*

A user has active control when they:

- Change a setting
- Start a measurement
- Tap the blue cloud icon

Control status transitions:

- If the color changes from blue to orange [a], someone else has taken control of the device.
- If the color changes from orange to blue [b], someone else has released control of the device.
- If the color changes from green to blue [c], you no longer have active control of the device due to:
  - The device being disconnected
  - The device timing out
  - You have released active control by clicking the cloud icon
- If the color changes from blue to green [d], you have performed an *active control* action and taken control of the device.
- If the color changes from green to orange [e], an **Admin** has taken over active control of the device.
- If the color changes from orange to green [f], you [as an **Admin**] have taken over active control of the device.

⚠ CAUTION

CAUTION

USAGE OF HTTP:// OR HTTPS:// WITH A SELF-SIGNED CERTIFICATE MAY CAUSE SECURITY RISKS

In order to provide out-of-the-box functionality, the DOSE-X is delivered with the option to either use http:// or https:// with a self-signed certificate for the remote connection.

Please note, neither option provides the full level of cybersecurity and may thus cause security risks. It is strongly recommended to secure the remote connection with TLS, using your own valid TLS certificate from your trusted certification provider.

3.3.4. Import Certificates

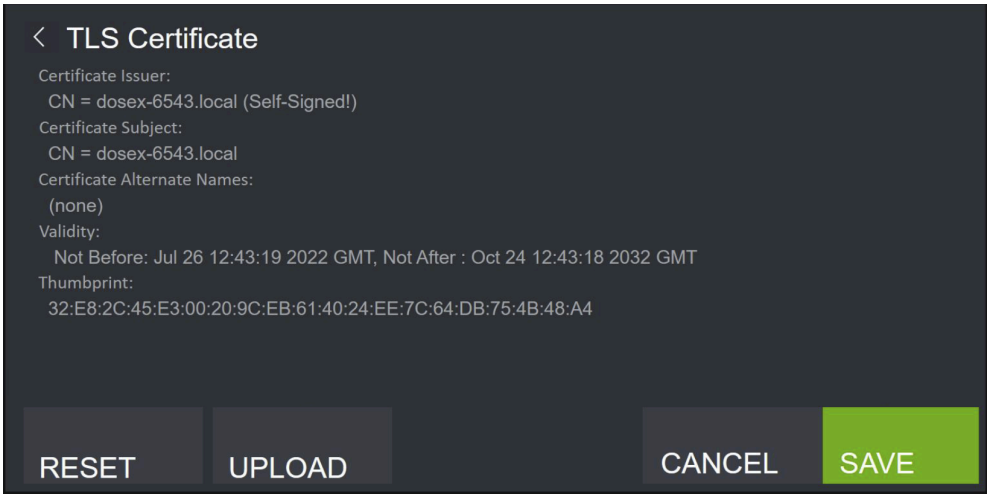
To ensure a secure and encrypted network connection the user can import a TLS Certificate.

- Acquire the TLS key and host certificate for the DOSE-X from your IT department (intermediate certificates are optional).

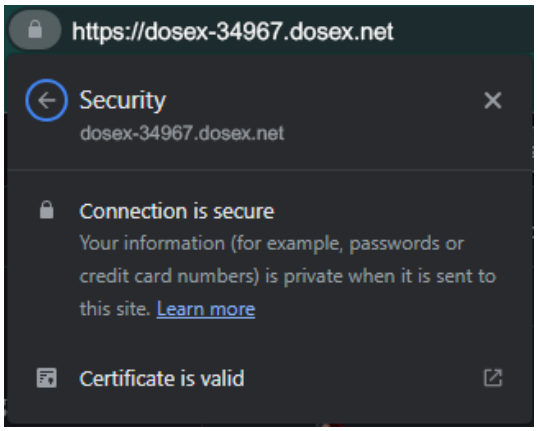
  The intermediate certificates (if any), the host certificate, and the key (host key) for the DOSE-X need to be concatenated to a single file, in **.pem* format.

Example TLS certificate

- Tap the **Import Certificates** button to open the **TLS Certificate** page.



- Tap the **Upload** button to upload the certificate file.
- Tap **Save** to confirm the upload.
- Once the file has been uploaded to the DOSE-X, please check that the correct certificate is being used by accessing the DOSE-X remotely. To check the certificate validity, in the browser, simply click on the lock icon next to the device address.



Example of a secure connection with a valid certificate

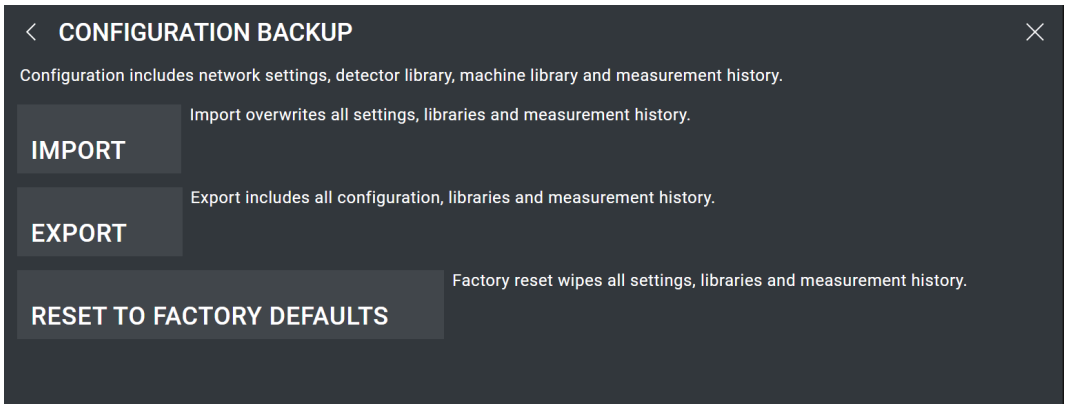
Reset or change the certificate:

- Tap the **Reset** button to remove the previously imported certificate.

  Please note, if a new certificate is not uploaded, the device will reset to the self-signed certificate it came with from the factory.
- Tap **Save** to confirm the reset.
- Repeat the certificate upload procedure with the new certificate.

3.4. Configuration Backup

The **Configuration Backup** page allows the user to **Import** previously saved configuration data, **Export** the current device configuration, or **Reset** the device to the factory default.



Import

- To import the previously saved configuration data, first plug in the USB flash drive or connect to the remote PC with the correct file.
- Tap the **IMPORT** button. The **IMPORT DEVICE CONFIGURATION** page opens.
- If a flash drive is connected, navigate to the correct file and select it.
- If the device is connected to a PC, click the **BROWSE** button to select the correct file.
- Tap the **UPLOAD** button.
- Confirm the upload by tapping **YES**.

Export

- Before exporting the configuration data, please ensure that a USB flash drive is plugged into the device, or the device is connect to a remote PC.
- To create a backup of device settings, detector and machine libraries, and measurement history, tap the **EXPORT** button.

  The **Export device configuration** dialog opens.
- Tap the **EXPORT** button to export the configuration data.
- Save the file on the connected flash drive or PC.

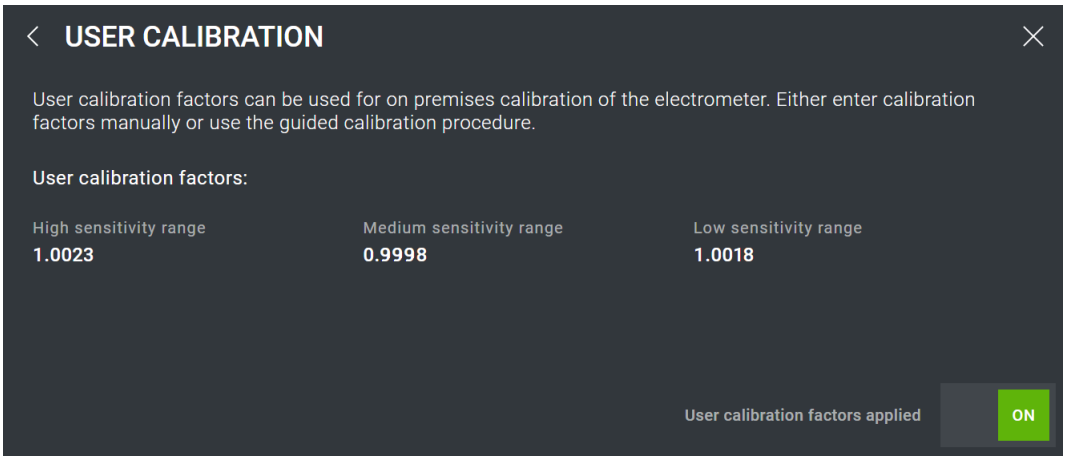
Reset to Factory Default

- To restore the device to the factory default, click the **RESET TO FACTORY DEFAULTS** button.
- The **Reset device to factory defaults?** dialog opens. Click **YES** to confirm.
- All configuration data set by the user, including device and machine libraries, and measurement history, will be erased and the factory defaults will be restored.

3.5. User Calibration

User calibration factors will be applied to measured current / dose rate when displaying the measurement result on the screen.

- Tap **User Calibration** in the **System Settings** menu to open the **User Calibration** page.



- Select the **High**, **Medium**, or **Low** sensitivity range to modify the calibration factor
- Tap **ENTER** to confirm the new calibration factor.

⚠ CAUTION

CAUTION

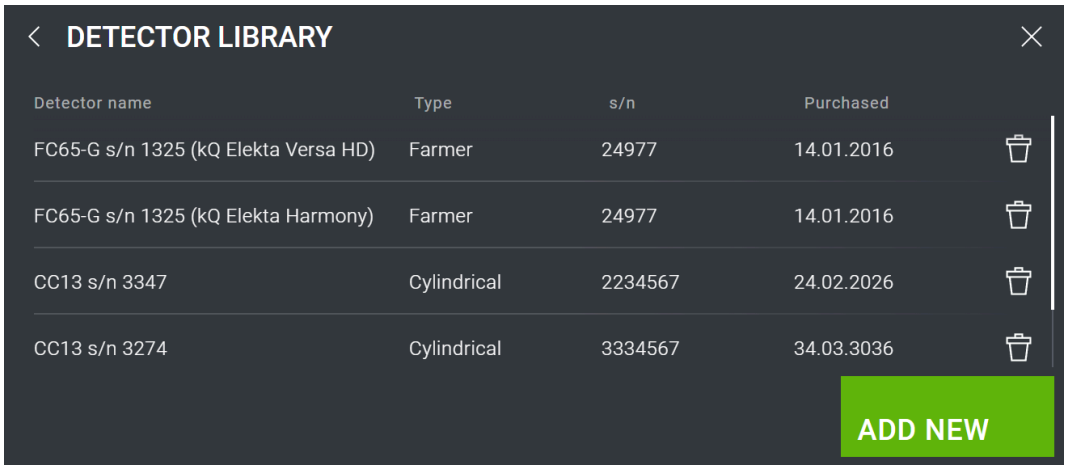
DOUBLE CHECK USER CALIBRATION FACTORS

Before making changes to the calibration factors, please ensure the value entered in the library is identical to the one which is stated on the ADCL calibration certificate. Double-check detector type and serial number. Incorrect values will put the device out of calibraiton.

For information on Electrical and Dosimetric Calibration, please see Section 6.1 for more information.

3.6. Detector Library

The Detector Library page list all the saved detectors.



Tap on a specific device to see: **Basic info**, **Corrections**, **Dose rates**, and k_Q **corrections**.

If no detectors are listed, they will need to be added by an Admin.

3.6.1. Add, Edit, or Delete a Detector

For both detectors and machines, the procedure for adding, editing, and deleting a device from the respective library is the same.

Please note, that only Admin can make changes to the **Detector** and **Machine Libraries**.

Add a New Detector

- On the Detector page, tap **ADD NEW**.
- Enter the necessary information and tap **SAVE**.

Edit a Detector

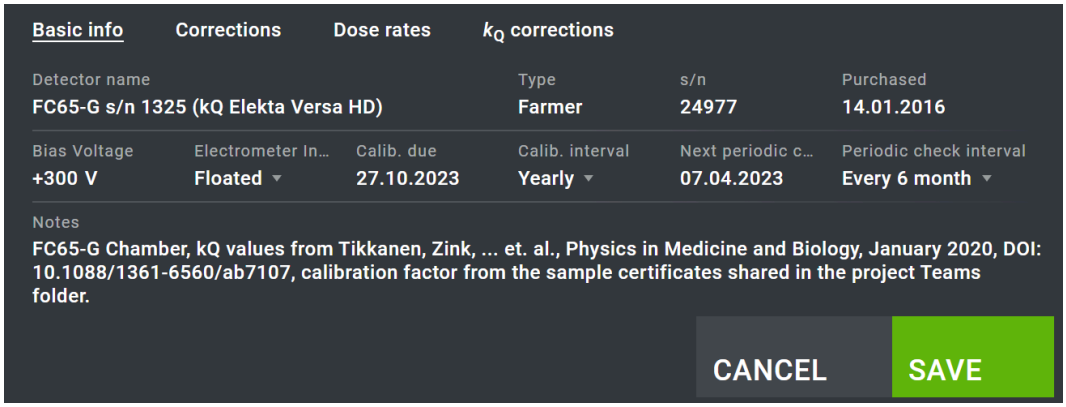
- Tap on a detector to select it from the list
- Change the necessary information and tap **SAVE**

Delete a Detector

- Tap the trash icon .
- A dialog opens showing the name of the item to be deleted.
- Tap **OK** to confirm the deletion or tap **CANCEL** to return to the library overview.

3.6.2. Basic Info

General information about the selected detector is listed under the **Basic info** tab:



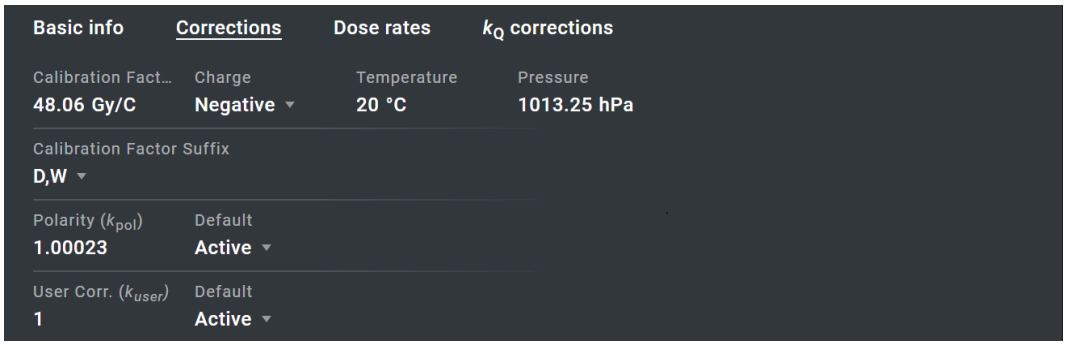
- **Detector information**: enter or change the **Detector name**, **Type**, Serial number (**s/n**), and date **Purchased** for the selected detector.
- **Bias Voltage**
  - **Bias Voltage**: define the high voltage value.

    Note: Please refer to the detector manual for the maximum allowed voltage for each chamber.
  - **Electrometer Input**: select **Floated** or **Grounded** from the dropdown menu. See Floated vs. Grounded Input for clarification on input.
- **Calibration schedule**: set the next calibration due date and the calibration interval.
- **Next periodic check**: set the next periodic check date, and the periodic check interval.
- Click on the **Notes** section to add or edit any notes or comments about the detector.

Tap **SAVE** to save the settings or **CANCEL** to exit the dialog without making any changes.

3.6.3. Corrections

All correction factors for each saved detector is stored under the **Corrections** tab.

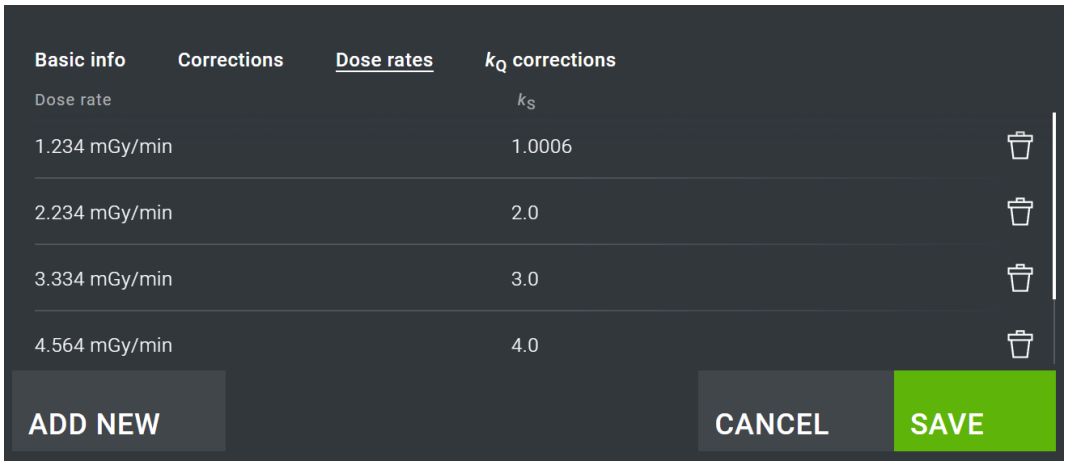


- **Calibration Factor**
  - **Calibration Factor**: enter the calibration factor for the detector.
  - **Charge**: select the polarity of the charge output of the detector.
  - **Calibration Factor Suffix**: select the correct suffix from the dropdown list.
    - D,W: absorbed dose to water
    - X: absorbed dose to air
- **Temperature and Pressure**: enter the reference conditions for the calibration factor. Please note, incorrect temperature and pressure can result in a mis-applied calibration.
- **Polarity Correction** (k_{pol}): enter a value for the polarity correction factor, and choose whether or not this correction is to be applied when the detector is selected on the main screen (**Active / Inactive**).
- **User Correction** (k_{user}): enter a value for any additional user-defined correction value to be applied, and whether or not this correction is to applied when the detector is selected on the main screen (**Active / Inactive**).

Tap **SAVE** to save the settings or **CANCEL** to exit the **CORRECTIONS** page.

3.6.4. Dose Rates

In order to be able to select k_S corrections for the effect of dose-rate dependent charge loss on the main screen, different dose rates can be entered in the **Dose rates** tab.

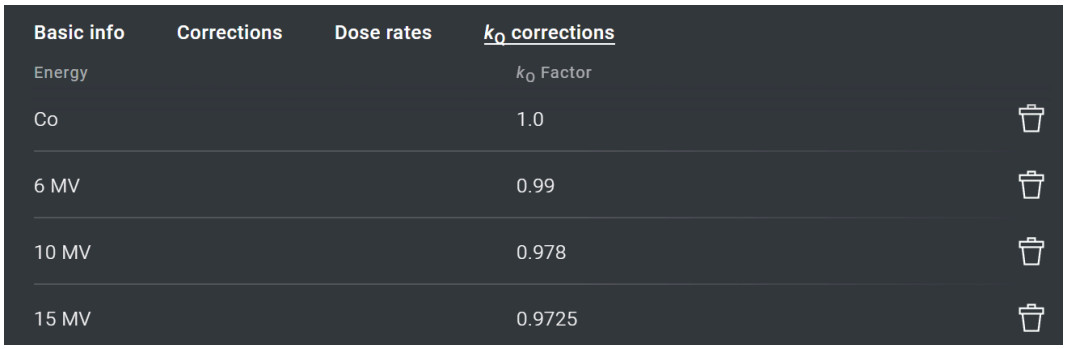


Add, edit, or delete a dose rate:

- **ADD**: Tap **ADD NEW**. Enter the **Dose rate** and **Ionization** (k_S) values and tap **SAVE**.
- **EDIT**: Select a **Dose** from the list to edit the name and/or k_S value.
- **DELETE**: Press the trash icon for the specific dose rate. Tap **OK** to confirm the deletion or tap **CANCEL** to exit the dialog.

3.6.5. k_Q Corrections

In order to be able to select different k_Q corrections for the effect of beam quality dependence on the main-screen, different **Energies** can be entered under the k_Q **corrections** tab.



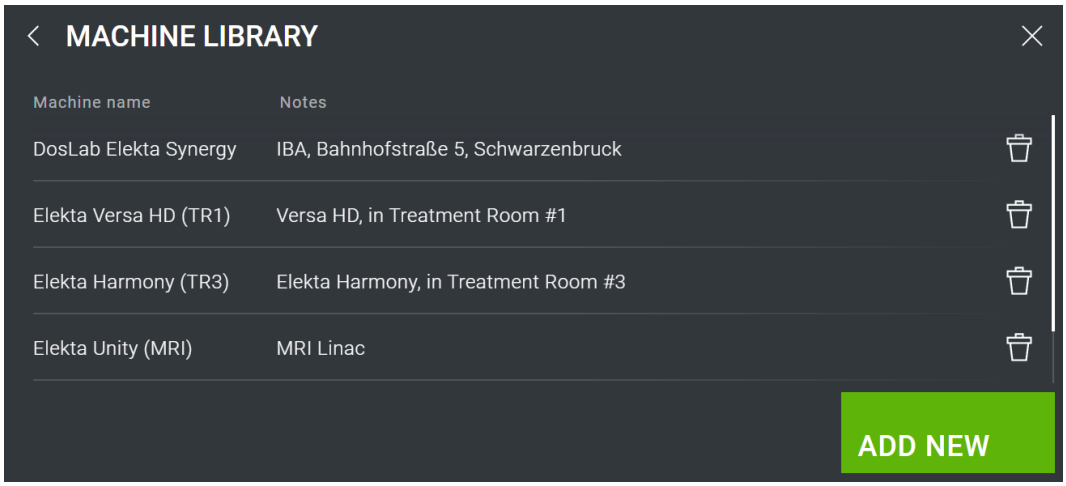
Add, edit, or delete an energy:

- **ADD**: Tap **ADD NEW**. Enter the **Energy** name and value [k_Q **Factor**] and tap **SAVE**.
- **EDIT**: Select an **Energy** from the list to edit the name and/or value.
- **DELETE**: Press the trash icon for the specific energy. Tap **OK** to confirm the deletion or tap **CANCEL** to exit the dialog.

3.7. Machine Library

To select a **Machine** on the main screen, it can be configured in the **Machine Library**. The **Machine Library** shows an overview of the machines saved in the library. Tap on a machine from the list to see more detailed information.

Edit a **Machine name** or add **Notes** by selecting the respective field and tapping **SAVE** to save any changes.



3.8. Common System Notifications

Description	Recommended Action
Internal power supply error The supply voltage provided by the internal power-supply to the DOSE-X electronics is out of the allowed range.	Power-cycle the device (turn it off, disconnect and reconnect the power source, and then turn it back on). If the error persists, contact IBA Dosimetry Service.
Internal system voltage out of range. An internal system voltage has been detected to be out of range.	
Checksum error in non volatile Baseboard memory Memory corruption has been detected.	
Checksum error in non volatile Electrometer memory Memory corruption has been detected.	
System fan malfunction The system fan does no longer rotates, turn off the DOSE-X to avoid overheating!	
Internal system voltage out of range An internal system voltage has been detected to be out of range.	Turn off the device and wait for 5 minutes before turning it back on. If the error persists, contact IBA Dosimetry Service.
Admin authentificaiton failed	Ensure that the password is correct. In the event of a lost admin password, user can reset the admin password by enter admin password reset token in the admin setting menu.
Admin password has been reset	Contact your system admin for the new admin password.
Detector Bias Voltage out of range. The detector bias voltage could not be to the required level, this may be caused ■ by insufficient isolation (or short) of a guarded detector ■ when trying to apply bias voltage to a detector using a grounded biasing scheme (link to the section with the description) by insufficient isolation (or short) of the Bias Voltage connection ■ when trying to apply bias in guarded mode, and at the same time using a Triax to Coax BNC adapter	Check if the detector guard (when grounded), or Bias Voltage input is properly isolated, not shorted, and that the detector is suitable for use with bias (and no coax BNC adapter is used).
Detector k_{Tp} values out of range	Please check the entered values for k_{Tp}.

Description	Recommended Action
System temperature out of range	Only operate the DOSE-X within the given environmental range conditions (see Section 7.8). If the local conditions have been verified to fall within the correct range, a fault of the internal sensor is likely. Contact IBA Dosimetry Service.
System humidity out of range	
System air pressure out of range	
Error in data from Analog to Digital Converter In the event of a surge phenomenon (crosstalk caused by switching very large loads on the DOSE-X supply cable/power grid or a lightning strike in the power grid), the current measurement is aborted for safety reasons.	Before restarting the measurement, check the Diagnostic Functions of the device to ensure the system status is stable. If there are any issues with the device after the surge phenomenon, please contact IBA Dosimetry Service.
Overcurrent on electrometer input The current into the electrometer input exceeds the maximum rated input current for the range selected.	Select a range with lower sensitivity. If the problem persists, and it has been verified that the input current does NOT exceed the value specified in the Instructions for Use, a defect of the electrometer input is possible, contact IBA Dosimetry Service.
Power-on self tests failed The power-on self-test may fail if an external detector is connected.	To verify correct operation, place the protective cover on the electrometer input connector, then start the self-test in the menu. If the message persists, even with the protective cover placed on the electrometer input, contact IBA Dosimetry Service.
Real time clock battery voltage low The voltage of the internal real-time clock battery is low and probably needs to be re-charged.	Leave the DOSE-X turned on for a few hours. If the message persists, contact IBA Dosimetry Service.
An empty dose rate name is not allowed	The **Dose rate** field in the **Detector Library** must have a name (*i.e.*, entered value).
Dose rate name already in use	Each **Dose rate** entered into the **Detector Library** must have a unique name (*i.e.*, entered value).
Empty k_Q correction name is not allowed	Each k_Q correction in the **Detector Library** must have a name (*i.e.*, entered value). Please ensure that both the **Energy** type and k_Q **Factor** have been entered.
k_Q correction name is already in use	Each k_Q entered into the **Detector Library** must have a unique name (*i.e.*, entered value).
An empty library name is not allowed	Each **Detector** or **Machine** in their respective libraries must have a name.
Library name already in use	Each **Detector** or **Machine** in their respective libraries must have a unique name.

4. Measurement

General Measurement Procedure

A typical use case can be described as follows (depending on the particular installation, some of the steps may be skipped):

- Take the DOSE-X out of storage.
- Connect mains power cable, detector cable.
- Turn on the DOSE-X and wait for warm-up of the device.
- On the Main screen:
  - select a detector from the detector library. If no detector has been configured, see Section 3.6
  - set all applicable corrections
  - set **Measurement Type** to **Dose**
  - set **Sensitivity** to **High**
  - turn on the **Bias Voltage**
- Pre-irradiate the detector.
- Perform a background (zero) measurement.
- Start a measurement.
- Irradiate the detector.
- Stop the measurement.
- Write down the measurement value shown on the Main screen, or export the measurement history.
- When all measurements have been completed, turn off the device, remove cables, bring the DOSE-X back into storage.

4.1. Device Warm-up

In order to achieve the stated measurement performance, it is necessary for the DOSE-X to warm-up and perform self-tests after it is powered on; the self-tests run automatically after starting the device.

The warm-up time can vary depending on the environmental conditions of the location of the device:

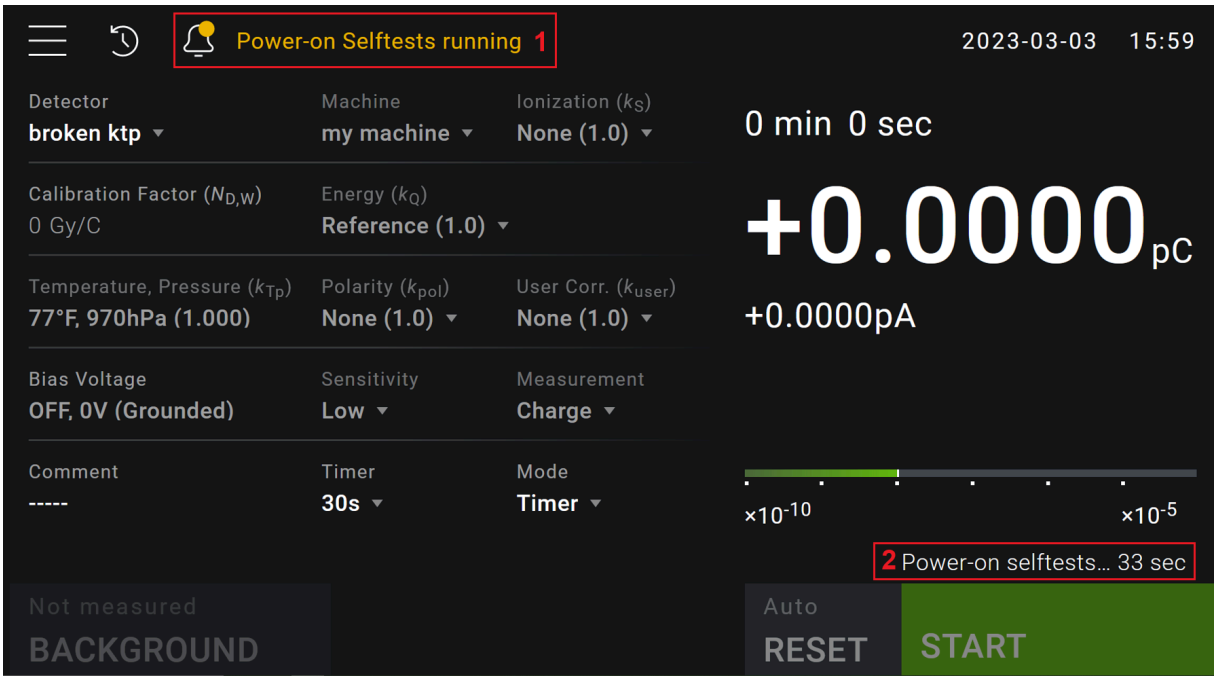
- **10 minutes** after powering the device, provided that:
  - The device has been kept under the required operating conditions (see Section 7.8)
  - The temperature and humidity where it was kept does not differ by more than ± 2°C and ± 2% relative humidity from the conditions at the measurement location.
- **1 minute** after powering the device, provided that it was already sufficiently acclimatized to the conditions at the measurement location and the power was interrupted only for maximum 5 minutes.
- **In all other cases**, the warm-up time may be longer than indicated above:
  - It is recommended to verify with a series of background measurements whether the electrometer is sufficiently stable.
  - If moisture has developed on the device as a result of temperature and / or humidity changes, please do not power the device until it is completely dry. See Section 7.8 for more information.

Please note, a measurement cannot be started until the device is fully warmed up.

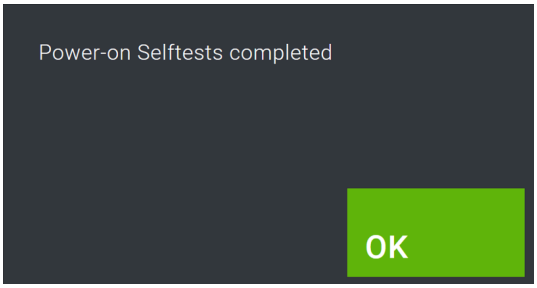
Power-on Selftests

➤ During warm-up the **Power-on Selftests running** notification [1] is shown.

Just above the **START** button, the screen will show how long the selftests have been running [2].



➤ A pop-up will appear informing the user that the **Power-on Selftests** have finished. Tap **OK**.



*Note: The power button's change of color from red to green indicates the completion of the **Power-on Selftests**, but is not related to warm-up times. The Power-on Selftests completed pop-up must appear before measurements can start.*

4.2. Setup for Measurements

To prepare the DOSE-X for measurements, select or enter the correct factors for the following. Please note, if performing a charge measurement, certain detector settings cannot be selected / edited and will be greyed out.

- **Detector**: select a detector from the dropdown list.

⚠ CAUTION

CAUTION

CHECK THE DETECTOR TYPE AND SERIAL NUMBER

Ensure that the detector selected from the library is identical to the one which is physically connected to the DOSE-X. Double-check detector type and serial number.

- **Machine**: select a machine from the dropdown list.
- **Ionization** [k_S]: if k_S correction factors have been configured, and should be applied, select the applicable Dose rate [k_S] factor from the Ionization [k_S] menu.

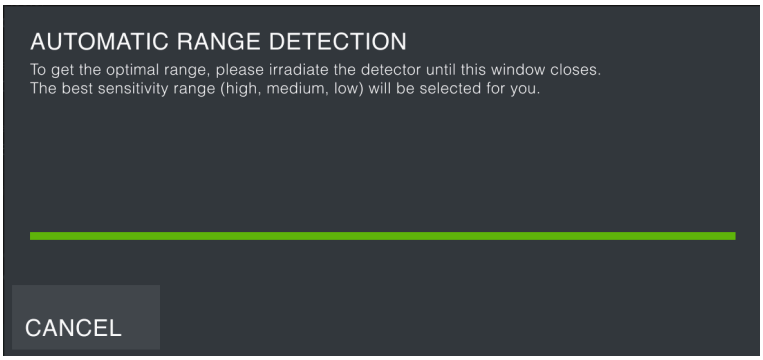
- **Energy** [k_Q]: if Energy [k_Q] correction factors have been configured, and should be applied, select the applicable k_S factor from the k_Q menu .
- **Temperature, Pressure** [k_{Tp}]: To apply k_{Tp} correction, configure temperature and pressure in the Temperature, Pressure k_{Tp} menu. The correction factor can be turned **ON/OFF**.

  Note: To confirm turning the correciton factor **ON/OFF***, tap the* **Enter** *button.*
- **Polarity Correction** [k_{pol}] and **User Correction** [k_{user}]:
  - Activate (or deactivate) application of a **Polarity correction** [k_{pol}] in the Polarity [k_{pol}] menu, the default is configured in the detector settings.
  - Activate (or deactivate) application of a user-specific additional correction [k_{user}] in the User Corr [k_{user}] menu, the default is configured in the detector settings.
- **Bias Voltage**: tap the **Bias Voltage** field to turn **ON/OFF** the **High Voltage**, change the **Bias** value, and select **Floated** or **Grounded**. See Floated vs. Grounded Input for clarification on input.

  Note: When turning the Bias Voltage **ON/OFF** *or selecting* **Floated/Grounded***, tap the* **Enter** *button to confirm the action.*
- **Sensitivity**: select **High**, **Medium**, **Low**, or **Auto** from the dropdown list. See Chapter 5 for sensitivity range.

  Note: For best performance, select the lowest range possible for the intended measurement while avoiding the saturation of the electrometer. Please see the respective detector manuals to determine the appropriate ranges and senitivities.

  If **Auto** is selected, the **Automatic Range Detection** dialog will open to determine the best sensitivity range for the selected detector and parameters.



- **Measurement Type**: select between **Dose** or **Charge**.

  To perform a purely electrical measurement (charge and current), select **Charge** from the menu. In this measurement mode, dose calibration and correction factors will be applied, and the display will be in electrical units.
- **Mode**: select the type of Measurement mode: **Manual**, **Trigger**, or **Timer**.
  - **Manual** mode: the measurement can be started / stopped manually by pressing the **START/STOP** button.
  - **Trigger** mode: the measurement is activated / deactivated by pressing the **START/STOP** button. Please see Trigger mode settings for additional information.
  - **Timer** mode: the measurement will run for the selected amount of time. See Timer mode for more information.

Trigger mode settings

Before activating **Trigger** mode, the user will need to:

- Define the value for the high, medium, and low ranges. See Chapter 5 for sensitivity range.
- Ensure that the **Beam on / off times** and **Pre / post trigger times** have been defined in the **Trigger Mode** settings.
  - **Beam on / off times**: To avoid spurious starts and stops of measurements, it is required that the signal stays above for at least 1 s, or below the threshold for at least 2 s.
  - **Pre / post trigger time**: To not loose any charge in the event of a slowly increasing signal, the charge collection time is artificially extended by at least 500 ms before the measured current has exceeded, and by at least 500 ms after the current has fallen below the threshold.

After activating **Trigger** mode, the measurement will automatically start once the measured current has exceeded the **Beam on Threshold** value, and the measurement will end once the current falls below the threshold value.

The **Beam on Threshold** value can be found in the **Background Settings** page (see Section 4.4). See Chapter 5 for information on how the **Beam on Threshold** is determined.

Comment

On the main screen tap **Comment** to open the comment dialog. Here the user can enter comments for the specific measurement.

Tap **Return** to close the comment dialog.

4.3. Connect a Detector

When connecting a detector, it is recommended to first select the detector from the detector library in the DOSE-X. If using a new detector, please add it before continuing with the connection procedure (see Section 3.6.1).

Note: Never connect or disconnect a chamber cable or adapter cable to or from the DOSE-X unless the Bias Voltage is switched OFF (or set to 0 V).

- Carefully remove the detector from its carrying case. Do not touch the sensitive area of the detector and ensure the dust cap is on the connector when the detector is not in use.
- Position the detector in the desired measurement geometry. Use alginment markings on the detector to ensure consistent orientation between measurements.

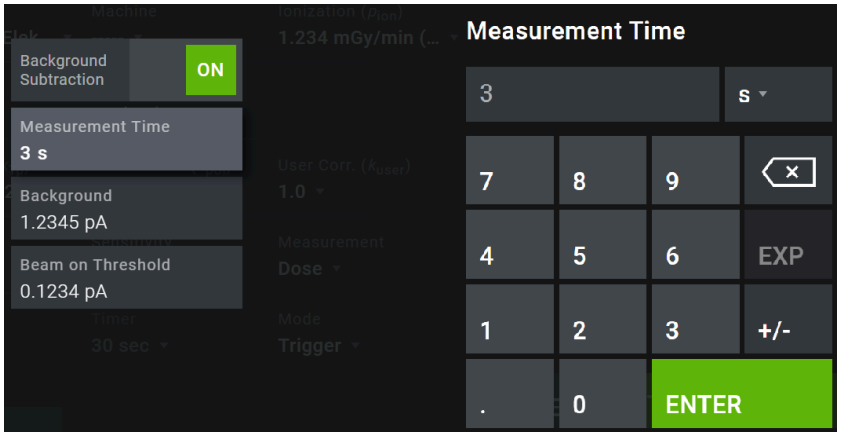
  Please note that if you are working with a linear accelerator, any uncertainties in the alignment and position of the mechanical components can influence the detector alignment and have an impact on subsequent measurements; it is strongly recommended to verify the leveling and alignment of the detector to the reference coordinate system.
- Ensure that the Bias Voltage at the electrometer is switched OFF (or set to 0 V).
- Remove dust cap from detector cable and connect an extension cable. It is advised to close the protection caps by screwing them together.
- Ensure the extension cable is in good condition and confirm any induced triboelectric effects (common in a recently unwound cable) have dissipated before taking measurements. Secure the cable so that no sharp bends can be created in it, especially if the detector will be moving.
- Remove dust cap from the connector and connect it to the extension cable, being careful not to touch either connectors internal components. It is advised to close the protection caps by screwing them together.
- Turn ON the Bias Voltage, set it to the desired value, and check the device system before proceeding, see Section 3.2.1.

4.4. Background

The **BACKGROUND** button shows the time of the last background measurement. Please note, before performing a measurement, it is recommended to perform a background measurement.

- Ensure that radiation is switched off before the background is measured.
- Click **RESET** to return measurement values to zero.
- Tap the **BACKGROUND** button to take a new background measurement.
- When the background has been applied the button is activated and shows **Checked at (time of day)**.

To open the background settings page:



- Press and hold the **BACKGROUND** button.
- Type in the desired measurement time and tap **ENTER** (default value is 60 s).
- Turn on/off the **Background Subtraction**.

  Please note, when background subtraction is active (**ON**), the **BACKGROUND** button will be activated (white text), if the background is not subtracted (**OFF**), the button will be shown inactive (grey text).
- View the **Beam on Threshold** (see Trigger mode settings for more information).
- Tap the icon to exit to return to the main screen.

4.5. Start a Measurement

There are three **Modes** available for starting a measurement:

- Manual
- Trigger
- Timer

See below for information on taking measurements with each mode type.

The finished measurement is displayed on the main screen. See Section 4.6 for more information on understanding measurements.

Completed measurements will be added to the Measurement History (see Section 4.7).

Manual mode

- Select **Manual** under **Mode**.
- Tap the **START** button.
- The DOSE-X begins the mesaurement.
- Tap the **STOP** button when the measurment is complete.

Trigger mode

- Check that the **Trigger Mode** parameters have been set to the correct values. See Trigger mode settings.
- Select **Trigger** under **Mode**.
- Tap the **START** button. This activates **Trigger** mode.
- When the input signal is above the **Beam On Threshold** for longer than **Beam On Time** duration, the DOSE-X will recognize the beam on point and start the integration of charge/dose measurement.
- The DOSE-X will continue to take measurements in the defined beam on/off interval.
- Tap the **STOP** button when the measurement is complete.

Timer mode

- Select the desired measurement time via the dropdown menu:
  - 1, 2, 3, 5, 10, or 30 seconds
  - 1, 1.5, 2, 3, 5, 10, 15, 30, or 60 minutes
- Select **Timer** under **Mode**.
- Tap the **START** button.
- The DOSE-X begins the mesaurement.
- The measurement will run for the selected time.
- The finished measurement is displayed on the main screen. See Section 4.6 for more information on understanding measurements.

When the measurement is complete it will appear in the Measurement History (see Section 4.7)

Reset

- Tap the **Reset** button to clear the previous measurement.
- Tap and hold the **Reset** button to select **Auto** or **Manual** reset.

4.6. Understanding Measurements

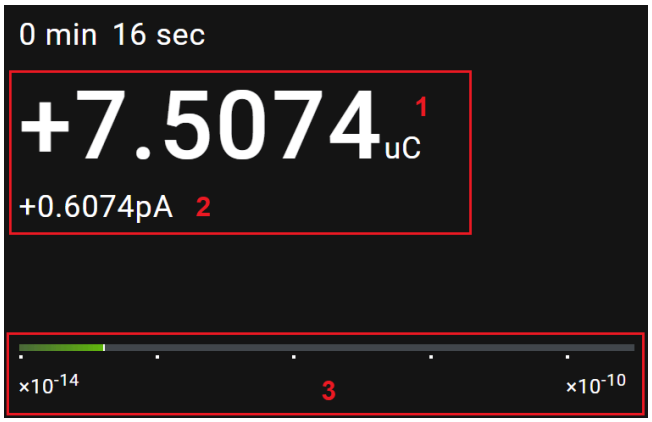
The display on the main screen provides two elements showing the measurement value:

- The larger number (1) shows the absolute charge or dose value (depending on the measurement type).
- The smaller number (2) shows the average electric current or dose (depending on the measurement type).

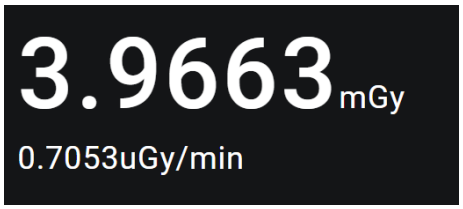
Please note, the current displayed after a measurement is finished is integrated charge to total measurement time. For **Manual** and **Trigger** modes, the measurement time displayed is rounded to the nearest second.

During a measurement:

- A sliding average of current / dose rate is displayed [2] and after the measurement the average over the complete measurement is shown
- The measurement value is refreshed every 0.5 seconds.



Charge measurement



Dose measurement

Range Bar

The logarithmically scaled bargraph [3] below the main display can be used to quickly assess whether the input current from the connected detector is within the effective input current range of the DOSE-X electrometer input. It is refreshed every 200 ms, independent from a running measurement, and shows the peak value of the input current.

The bar will change color when the current measurement value gets closer to the maximum boundary of the current sensitivity:

- **Blue**: Indicates that the input current from the detector is below the rated minimum value for the selected range.

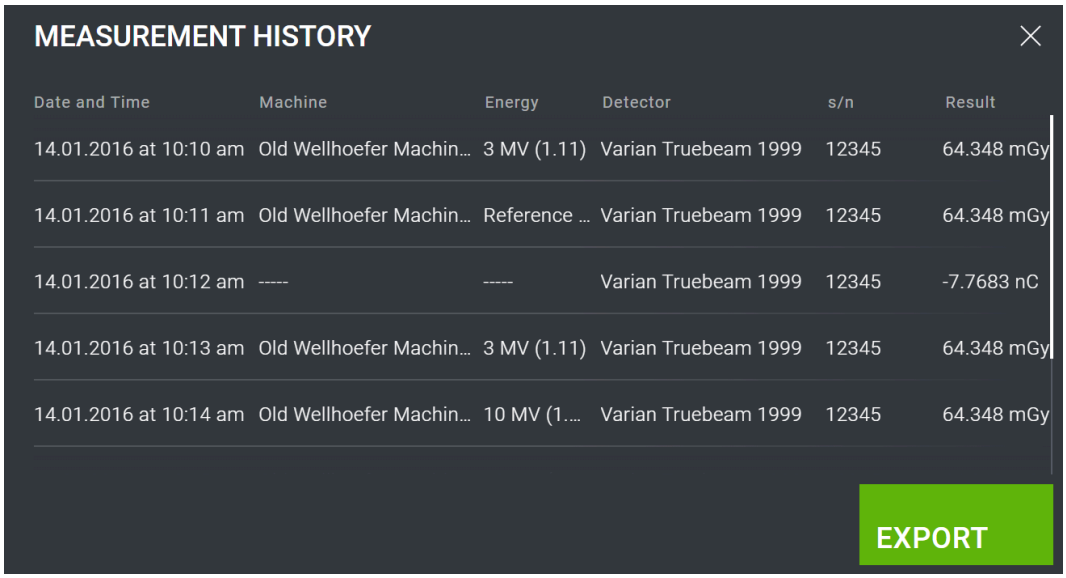
- **Green**: < 80% of maximum value. This indicates that the desirable range for the detector has been selected.

- **Yellow**: ≥ 80% and < 95% of maximum value. It is recommended to choose a lower sensitivity as further increases of the current may exceed the rated range of the chosen sensitivity.

- **Red**: ≥ 95% of maximum value. This indicates an imminent overrange condition. Once the input current reaches the maximum rated value, a warning symbol will be shown. The symbol will be visible for five seconds.

4.7. Measurement History

Tap on the Measurement History icon to view the measurement history. The list is displayed in chronological order, starting with the most recent measurement.



Tap on a measurement from the list to see detailed information about the selected measurement.

5. Technical Specifications

5.1. DOSE-X

Dimensions (mm)	123.4 (D) × 201.9 (H) × 249.7 (W)
Display	10" HD Touchscreen
Weight	4.6 kg
Connectivity	Ethernet LAN 1 Gbit/s, Wi-Fi (802.11ac/b/g/n) (Release for FW 2.0), USB 3.0 Host
Power supply	100-240V, 50/60Hz
Fuses	T2A, 250V
Mains Voltage	Input voltage range: 90 - 264V
Insulation of External Circuits	50 Ohm
Measurement Modes	Manual, Trigger (beam triggered), and Timed
Measurement Types	Dose and Charge
Correction Factors	k_{user}, k_{pol}, k_Q, k_{Tp}, k_S
Bias Voltage	± 50 V ... ± 500 V, ± 2 %
Range (current)	High Sensitivity: 400 fA to 600 pA Medium Sensitivity: 6 pA to 60 nA Low Sensitivity: 2.4 nA to 24 µA
Range (charge)	Minimum charge: 24 pC. Maximum charge: per pulse is limited to 65 nC at a pulse repetition frequency ≤ 400Hz. The total charge is not limited.
Display Resolution	5-digits, 0.1 fA (current) and 0.1 fC (charge) in high sensitivity range
Repeatability	< ± 0.25 % (≤ ± 0.25 % IEC 60731)
Long-term Stability	≤ ± 0.2 % (≤ ± 0.5 % over one year, IEC 60731)
Response Time	< 1.5 s
Non-linearity	≤ ± 0.25 % (≤ ± 0.5 %, IEC 67031)
Zero Drift	≤ ± 0.25 % (≤ ± 0.5 %, IEC 60731)
Zeroing	60 s (default)

Beam on Threshold	± 1.5 × (I_{max} - I_{min}) where I_{max}, I_{min} are the maximum and minimum current value during the background measurement.
Configurations	TNC Triax, BNC Triax
Use	Reference class 60731

5.2. Dose-X Electromagnetic Compatibility

Electromagnetic Emission

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The DOSE-X is intended for use in the electromagnetic environment specified below. The customers or the users should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions (CISPR 11)	Group 1	The DOSE-X uses RF energy only for its internal function. Therefore, its RF emissions are very low, and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class A	
Harmonic emissions (IEC 61000-3-2)	Not applicable	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Voltage fluctuations / flicker emissions (IEC 61000-3-3)	Not applicable	

Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter (see the column **Electromagnetic environment - guidance**			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 6100046	3 V_{rms} 150 kHz to 80 MHz	3 V	$d = 1{,}2\sqrt{P}$ 150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz

Guidance and manufacturer's declaration - electromagnetic immunity			
Radiated RF IEC 6100043	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2{,}3\sqrt{P}$ 800 MHz to 2.5 GHz
Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The DOSE-X is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 6100042	±6 kV contact ±8 kV air	±6 kV ±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 6100044	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100045	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000411	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % UT (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of device requires continued operation during power mains interruptions, it is recommended that device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 6100048	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

5.3. Accessories

NOTICE

IMPORTANT NOTICE

ACCESSORIES AND SPARE PARTS

No other accessories and spare parts than those provided or approved by IBA Dosimetry must be used, otherwise operator safety, specified measurement accuracy, and interference free operation cannot be guaranteed. Violation of this prescription will result in loss of warranty. IBA Dosimetry cannot be held liable for any damages resulting from the use of accessories or consumables that are not provided or approved by IBA Dosimetry.

TNC and BNC Accessories

Item Number	Description
TNC Accessories	
EB908000	Adapter TNC triaxial – BNC triaxial
DS10-005	Triaxial ion chamber/diode detector cable (low noise), 5m on cable reel, TNC triax connector

Item Number	Description
DS13-005	Triaxial ion chamber/diode detector cable (low noise), 5m without cable reel, TNC triax connector
DS10-205	Thick version of triaxial ion chamber/diode detector cable (low noise), 5m on cable reel, TNC triax connector, thick version (Ø 5.3mm)
DS13-205	Thick version of triaxial ion chamber/diode detector cable (low noise), 5m without cable reel, TNC triax connector, thick version (Ø 5.3mm)
DS10-118	Triaxial ion chamber cable (low noise), 18 m on cable reel, TNC triax connector
DS13-018	Triaxial ion chamber cable without cable reel, 18 m, TNC triax connector
DS10-218	Thick version of triaxial ion chamber/diode detector cable (low noise), 18m on cable reel, TNC triax connector, thick version (Ø 5.3mm)
DS13-218	Thick version of triaxial ion chamber/diode detector cable (low noise), 18m without cable reel, TNC triax connector, thick (Ø 5.3mm)
SVC-0004	Adapter cable for connection of PTW detectors (M-type connector) to IBA controller (TNC triax connector), 5m without cable reel
SVC-004A	Adapter cable for connection of PTW detectors (M-type connector) to IBA controller (TNC triax connector), 18m without cable reel
SVC-0006	Adapter cable for connection of PTW detectors (PTW-TNC connector) to IBA controller (TNC triax connector), 5m without cable reel
SVC006A	Adapter cable for connection of PTW detectors (PTW-TNC connector) to IBA controller (TNC triax connector), 18m without cable reel
BNC Accessories	
DS10-105	Triaxial ion chamber/diode detector cable (low noise), 5m on cable reel, BNC triax connector
DS13-105	Triaxial ion chamber/diode detector cable (low noise), 5m without cable reel, BNC triax connector
DS10-305	Thick version of triaxial ion chamber/diode detector cable (low noise), 5m on cable reel, BNC triax connector, thick version (Ø 5.3mm)
DS13-305	Thick version of triaxial ion chamber/diode detector cable (low noise), 5m without cable reel, BNC triax connector, thick (Ø 5.3mm)
DS10-118	Triaxial ion chamber cable (low noise), 18 m on cable reel, BNC triax connector
DS13-118	Triaxial ion chamber cable without cable reel, 18 m, BNC triax connector
DS10-318	Thick version of triaxial ion chamber/diode detector cable (low noise), 18m on cable reel, BNC triax connector, thick version (Ø 5.3mm)
DS13-318	Thick version of triaxial ion chamber/diode detector cable (low noise), 18m without cable reel, BNC triax connector, thick (Ø 5.3mm)

Item Number	Description
SVC-0008	Adapter cable for connection of PTW detectors (PTW-TNC connector) to IBA controller (BNC triax connector), 30m, thick cable, without cable reel

Detectors

The following detectors have been tested in combination with the DOSE-X. Please note, the use of detectors outside of the device range is not recommended (see Section 5.1 for more information on ranges).

More detailed information about the detectors listed below can be found in the dedicated *Instructions for Use*.

Type	Detector	Nominal sensitivity [nC/Gy]	Inner diameter [mm]	Active volume [mm^3]
Graphite, Pinpoint Chamber	RAZOR Nano Chamber	0.11	2.0	0.003
	RAZOR Chamber	0.3	2.0	0.01
Compact Thimble Ion-Chamber	CC01	0.4	2.0	0.01
	CC04	1.1	4.0	0.04
	CC08	2.7	6.0	0.08
	CC13	3.8	6.0	0.13
	CC13-S	3.8	6.0	0.13
	CC25	8	6.0	6
Plane Parallel Ion-Chamber	NACP	2	10.0	0.16
	PPC05	6	9.9	0.046
	PPC40	12	16.0	0.40
Diode Detectors	RAZOR Diode	4.1	0.6	~0.05
	PFD	100	2.0	~1.6
	EFD	100	2.0	~1.6
	RFD	100	2.5	~2.0
Farmer Chamber	FC23-C	7	6.2	0.23
	FC65-P	21	6.2	0.65
	FC65-G	21	6.2	0.65

6. Maintenance

There are no user serviceable parts in the DOSE-X. Please note, opening of the DOSE-X housing introduces a risk to the correct function of the device and voids the warranty.

6.1. Calibration

The DOSE-X has been calibrated in the factory, before delivery.

⚠ CAUTION

CAUTION

OBSERVE THE PROPER MAINTENANCE INTERVALS

Ensure that electrometer channels and detectors are recalibrated according to the stated (or legally required) maintenance / ADCL recalibration intervals. Otherwise, drifts and instabilities in the measurement chain may not be recognized, leading to wrong measurement values.

Electrical Calibration

Electrical calibration can be performed by the user with an external electrical check source / circuit by measuring different points of all current / dose rate ranges of the DOSE-X electrometer or in the factory of IBA Dosimetry.

Please note, an electrical calibration performed by a user is not the same as a factory calibration.

Dosimetric Calibration

As is standard practice for other electrometers, it is recommended that the DOSE-X be calibrated yearly, or at least every 2 years. This calibration should be performed by an accredited dosimetry calibration laboratory (ADCL). Contact IBA Dosimetry for calibration information, see Chapter 8.

6.2. Updating Firmware

The latest FW can be obtained from IBA Dosimetry, please see contact details in Chapter 8.

⚠ CAUTION

CAUTION

DO NOT USE OLD FIRMWARE

The installation of an older firmware version may reduce the security or safety of the device.

⚠ CAUTION

CAUTION

VERIFY THE CHECKSUM

Before the installation of a new firmware version, verify the checksum of the downloaded file with the checksum for this file provided by IBA Dosimetry along with the firmware version, to ensure the authenticity and integrity of the received firmware file. Contact your IT Administrator for more information on verifying checksums or the support of IBA Dosimetry (Chapter 8).

6.2.1. Updating via USB flash drive

Please note, the FW can only be updated via flash drive when using the touchscreen of the DOSE-X.

If the user tries to update the FW without a flash drive plugged into the device, a dialog will appear prompting the user to insert a USB.

- Upload the FW onto a secure flash drive.
- Insert the flash drive into the DOSE-X.
- Go to the **Update Firmware** page in **System Settings**.
- Open the flash drive and navigate to the folder containing the latest FW.
- Tap the **UPLOAD** button.
- Confirm the installation by tapping **YES**.

6.2.2. Updating via Web Browser

- Save the FW on your local PC.
- Open a web browser and access the DOSE-X remotely.
- Go to the **Update Firmware** page in **System Settings**.
- Click the **BROWSE** button and select the correct FW file.
- Click the **UPLOAD** button
- Confirm the installation by clicking **YES**

If the DOSE-X is operated remotely, the browser will open a file dialog, allowing the user to select a file from the remote client.

CAUTION

CAUTION

USE THE CORRECT WEB BROWSER

Accessing the firmware UI with a web browser other than specified may introduce risks related to the product safety, usability, or cybersecurity.

6.3. Cleaning

CAUTION

CAUTION

CLEANING

This device should never be submerged in water or a solvent, or scrubbed with an abrasive cleaner as it is not protected against liquid ingress. Observe the stated cleaning instructions.

Sterilization of the DOSE-X is not required. Exterior cleaning of the device can be done with a soft brush and a cloth:

- Gently brush all surfaces to remove dirt and dust.
- Remove any remaining dirt with a cloth slightly dampened with a solution of mild detergent and water or a liquid disinfecting agent.
- Do not use water or liquid on the triaxial connector.
- Do not permit any liquid to seep into the DOSE-X in any manner during cleaning.
- It is not recommended to clean the LCD display with anything other than a mild detergent and a very soft cloth. Failure to do so may result in a scratched screen, and this may impair the visibility of the display.

Triaxial Connector Cleaning

Dust can collect on the inside of a triaxial connector. Often dirty connectors are responsible for drifts or leakage of detectors and electrometers. Periodic cleaning of a connector can reduce the need for servicing of these parts.

Prior to cleaning a connector, ensure:

- The detector is disconnected from the electrometer.
- There is no water or moisture visible in the connector.

To clean a dirty connector:

- Remove the connector cap (if applicable).
- Use only a dry and oil free compressed air source, such as Chemtronics® Ultra Jet.
- Gently blow dirt and contaminants from the inside of the connector, moving the air source in a circular manner a few inches from the connector.

To reduce dust collection, always ensure that the connector cap is placed over the triaxial connector when not in use (if applicable).

DO NOT:

- Use sharp objects to attempt to clean a dirty connector.
- Use a compressed gas other than air, or a compressed gas source that may have moisture or oil in the source or lines.
- Use your mouth to blow on the connector.
- Disassemble the connector.
- Touch the internal parts of the connector with your finger.

If there are any questions or comments regarding this information, or if this procedure does not resolve the drift or leakage issues, please contact IBA Dosimetry Customer Service (see Chapter 8).

6.4. Disposal

If assistance is desired in the proper disposal or recycling of this product (including accessories and components), after its useful life, please return the device to IBA Dosimetry.

7. Health and Safety Information

7.1. General

The purpose of this chapter is to identify the hazards associated with the equipment. This information is presented by displaying all safety and rating labels, which are attached to the equipment, and by providing instructions to avoid the associated hazards.

NOTICE

IMPORTANT NOTICE

ALL PERSONNEL MUST READ THIS CHAPTER

All personnel must read this chapter and be fully aware of its contents before commencing installation, and before operating or servicing the device. If the DOSE-X is used in a way not specified in this document, the protection provided by the equipment may be reduced.

NOTICE

IMPORTANT NOTICE

GENERAL CONDITIONS

IBA Dosimetry accepts responsibility for the safety, reliability, and performance of DOSE-X and the supported equipment under the following conditions only:

- Only personnel authorized by IBA Dosimetry are allowed to carry out assembly operations, extensions, or repairs
- The electrical installations of the relevant rooms comply with IEC recommendations [see Section 5.2]
- The DOSE-X system is used in accordance with this document

NOTICE

IMPORTANT NOTICE

CHAMBER INFORMATION

Chamber type, calibration coefficients, and chamber serial number are imprinted in the chamber ventilation sleeve.

7.2. Prescription only

The DOSE-X system is available on prescription only.

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

7.3. Safety and Rating Labels

7.3.1. Rating Label

50-60 HZ
100-240 V ~
30 W
Fuse T2A, 250 V

⚠ WARNING

WARNING

HAZARDOUS VOLTAGE

Pay attention to the voltage ratings on the rating labels. These determine the safety hazards for components connected to the supply voltages. Do not open covers.

7.3.2. Labels on the Device

Bias Voltage	Voltage type: bias
Data	Ethernet for data communication
Detector	Connector for ionization chamber or detector

7.3.3. Symbols Used with the Device

Note: Some symbols present on the DOSE-X are country specific and not listed below. See the DOSE-X Reference Guide for country specific symbols.

	Consult the Instructions for Use before using the device.
CE 0123	The device meets the essential requirements of Medical Device Regulation (EU) 2017/745 concerning medical device.
	Important! Observe the warnings and safety precautions given in the accompanying documents.
	Manufacturer This symbol is accompanied by the name and the address of the manufacturer.
REF	Device Part Number
SN	Serial number. This symbol is accompanied by the manufacturer's serial number adjacent to it.
MD	Medical Device An indication that the device is a medical device
Rx only	Caution: US Federal law restricts this device to sale by or on the order of a physician.
	Separate collection of electrical and electronic devices in accordance with EC Directive 2002/96/EC: Do not dispose of the device with normal domestic waste. Keep separate from domestic waste and dispose in an environmentally safe way in compliance with local regulations.

7.4. Responsibility

The DOSE-X should only be used by people who:

- are aware of, and understand, the limitations of the device in measurement of radiation output,
- have knowledge about safety procedures to be observed when working with radiation sources such as Cobalt-60 machines or linear accelerators,
- are aware of safety precautions required to avoid possible injury when using electrical / electronic equipment.

CAUTION

CAUTION

QUALIFIED PERSONNEL REQUIRED

Before performing measurements, the operator must verify the general functionality, safety, and duly condition of the device and the dosimetry system. The device must not be used if any damage is noticed, and IBA Dosimetry should be notified.

Measurement of high activity radioactive sources is potentially hazardous and should be performed by qualified personnel.

Obligations

The following incidents may increase the hazard potential of the equipment:

- Loss of important equipment functions
- Failure of defined methods for maintenance and servicing
- Danger to personnel through exposure to electronics and mechanics

Device Owner

The equipment must be kept and used in a safe condition to ensure safe operation. The owner of the equipment must therefore ensure that the following points are followed:

- Instruct the operating and maintenance personnel in the proper use of the DOSE-X system.
- Check that safety precautions are being observed.
- Clearly define areas of responsibility for each area (operation, maintenance, etc.).
- Operating and maintenance personnel are obliged to report any safety issues or faults to their supervisors immediately.
- Ensure that the system cannot be used by unauthorized personnel.
- Observe the local regulations and conditions when connecting the equipment to the mains.

7.5. Safety Precautions

General

⚠ CAUTION

CAUTION

DO NOT USE A DAMAGED OR DEFECTIVE DEVICE

Do not use a DOSE-X with damaged or defective components. Regularly verify the correct function of the DOSE-X (especially by using the built-in self test function) and its accessories (such as detectors, extension cables, connectors).

NOTICE

IMPORTANT NOTICE

NO TEMPERATURE/PRESSURE CORRECTION ON THE ELECTRICAL UNITS

Temperature/pressure correction is only applied to radiological units. It is not applied to electrical units.

NOTICE

IMPORTANT NOTICE

USE THE HIGHEST SENSITIVITY FOR MEASUREMENTS

For best performance, select the range with the highest sensitivity possible for the intended measurement.

CAUTION

CAUTION

DO NOT EXCEED THE SPECIFIED CURRENT LIMITS

Do not attempt to measure or inject currents larger than the specified limits of the range being used or incorrect charge measurements may occur.

⚠ CAUTION

CAUTION

DO NOT USE THE DEVICE ON A PATIENT

The DOSE-X measurement assembly is not intended to be used for applications where the detector / the dosimeter is in contact with the patient.

⚠ CAUTION

CAUTION

CAUTION DO NOT USE FOR MEDICAL IMAGING

The DOSE-X measurement assembly is not intended to be used for applications in the field of medical imaging.

⚠ CAUTION

CAUTION

STRAY RADIATION

Do not place the DOSE-X in an area affected by (stray) radiation.

⚠ CAUTION

CAUTION

DO NOT USE A USB HUB WITH A USB FLASH DRIVE OR START/STOP BUTTON

Do not use a USB hub when connecting a USB flash drive or a USB start/stop button to the DOSE-X. The use of a configuration where peripherals are not plugged directly into the DOSE-X is not supported.

NOTICE

IMPORTANT NOTICE

CHAMBER INFORMATION

Chamber type, calibration coefficients and chamber serial number are imprinted in chamber ventilation sleeve.

⚠ CAUTION

CAUTION

DO NOT USE A LONG CABLE

Do not use a chamber extension cable longer than 30 meters. This may lead to a considerable increase of the noise level, thus compromising measurement accuracy.

⚠ CAUTION

CAUTION

RECOVERY OF DETECTOR LIBRARY CONTENT

In case of an incident where the detector library content has been affected, you will need to restore the library content manually from the calibration certificates. Please store the certificates in a safe place.

⚠ CAUTION

CAUTION

CONFIGURE EXCEL TO PREVENT AUTOMATIC UPDATE OF EXTERNAL LINKS

To prevent unintended execution of embedded commands when opening a CSV file in Excel, do not activate the automatic update of external links. It is strongly recommended to configure Excel accordingly and to pay attention to warning messages displayed when opening a CSV file.

⚠ WARNING

WARNING

DO NOT STACK THE DEVICE

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ CAUTION

CAUTION

THE USER IS RESPONSIBLE FOR ADEQUATE BRIGHTNESS SETTING

The user is responsible for an adequate brightness setting of the DOSE-X display, in order to be able to recognize error messages and error conditions.

⚠ CAUTION

CAUTION

CAUTION WHEN USING WITH OTHER DEVICES

Where applicable, IBA Dosimetry products are designed to be used with the versions of common radiation delivery devices, treatment planning systems and other products or systems used in the delivery of ionizing radiation, available at the time the IBA Dosimetry product is released. IBA Dosimetry does not assume responsibility, liability and/or warrant against, problems with the use, reliability, safety, or effectiveness that arise due to the evolution, updates or changes to these products or systems in the future. It is the responsibility of the customer or user to determine if the IBA Dosimetry product can be properly used with these products or systems.

Handling the Device

CAUTION

CAUTION

DO NOT DROP OR MISHANDLE UNIT

Do not drop or mishandle unit. Calibration factor changes may result.

CAUTION

CAUTION

DO NOT USE SHARP OBJECTS

Do not use sharp objects on the touch screen or speaker holes.

CAUTION

CAUTION

DO NOT DISASSEMBLE UNIT

Do not disassemble unit since it may result in change of calibration factor. Refer servicing to qualified individuals.

CAUTION

CAUTION

DO NOT USE DAMAGED CABLES

Damaged or kinked ionization chamber cables or extension cables should not be used.

⚠ CAUTION

CAUTION

FIRE HAZARD

The DOSE-X is not intended to be used in flammable mixture atmospheres.

Do not use with flammable anesthetic mixture with air, with oxygen, or nitrous oxide.

NOTICE

IMPORTANT NOTICE

DO NOT OPEN COVERS

Do not open covers while the DOSE-X is switched on.

⚠ CAUTION

CAUTION

DO NOT COVER THE VENTILATION SLITS OF THE DOSE-X

To prevent baseboard over-heating, do not cover the ventilation slits. Always ensure proper air ventilation around the DOSE-X. Do not place the powered device in a closed cabinet or drawer (not permitting air flow).

CAUTION

CAUTION

CORRECT PLACEMENT OF THE DOSE-X

Make sure that the device is not in a position where it is difficult to operate the device.

Electrical Installations

⚠ WARNING

WARNING

PROTECTIVE EARTH

To avoid the risk of electric shock, this equipment must only be connected to a mains outlet with a protective earth contact.

NOTICE

IMPORTANT NOTICE

GROUNDING PIN

All equipment must be connected to mains outlets with protective earth contacts. For the mains connection of the device and associated equipment, use a power cord and multi-outlet power strip with a grounding pin.

CAUTION

CAUTION

MAINS POWER SUPPLY FLUCTUATION

The output of the mains power may fluctuate due to the environmental influence. Ensure that the output of the power supply is within the range stated in technical specifications of the products in Chapter 5.

⚠ WARNING

WARNING

ENSURE THE BIAS VOLTAGE IS SWITCHED OFF

To prevent from electrical shock, switch off the Bias Voltage before connecting or disconnecting a detector or extension cable.

CAUTION

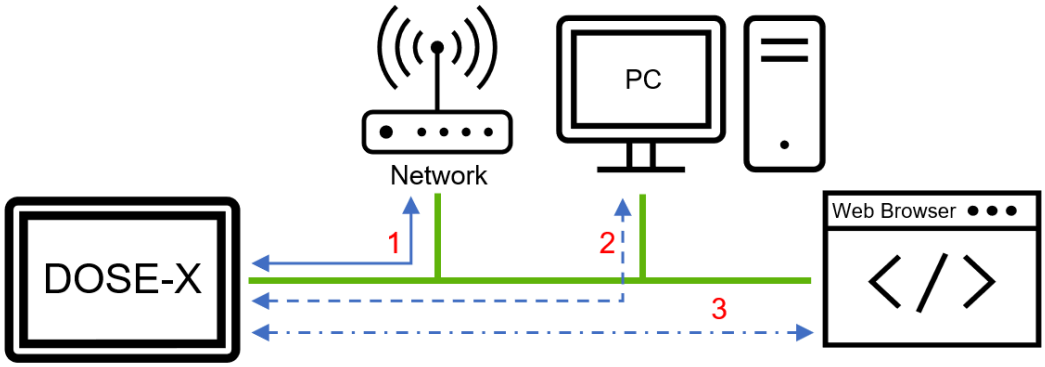
CAUTION

USE ONLY PROVIDED POWER CABLE

Using alternates other than the provided power cord can degrade minimum safety. The proper replacements from IBA Dosimetry are required for compliance with the requirements of IEC 60601-1. In the event of damaged, missing, or wrong plug type, please contact IBA Dosimetry, see Chapter 8.

7.6. Information Related to Cybersecurity

The diagram below illustrates the DOSE-X network connectivity:



1: The DOSE-X is connected to the local network

2: The DOSE-X can be connected to a remote PC via an automated script which can directly access API functionality

3: The DOSE-X can be remotely controlled via an approved web browser on a Tablet or PC (see Section 3.3.3)

⚠ WARNING

WARNING

It is recommended to install a firewall to prevent unintended traffic or any unauthorized traffic between unidentified hosts and the DOSE-X software.

⚠ CAUTION

CAUTION

RECOMMEMDED TO USE WPA2 ENCRYPTION

It is recommended to use WPA2 encryption for the WLAN connection. It must be set up by the user (customer) on the WLAN access point.

⚠ CAUTION

CAUTION

USE SECURE USB DEVICES

Always ensure that connected USB devices do not contain viruses or other malware. Check the devices regularly with an up-to-date virus scanner and follow your local IT policy. Remove any files which are unknown or susceptible before connecting them to the DOSE-X.

General Assumptions on User's IT Network Infrastructure

The location of use of the DOSE-X is within the premises of a radiotherapy department, near a radiation treatment machine, but not in a publicly accessible space. It is assumed that a high level of physical / electronical access control to this area is implemented by the healthcare provider. Consequently, the DOSE-X does not implement any particular user authentication; any user who has (physical or remote) access to the instrument is free to use it. However, changes related to critical functionality are subject to permission control (authorization) through an **Admin** password (see System Settings for users with Admin access only).

The DOSE-X is controlled locally (using the touchscreen), or over the clinical IT-network via a web-application on a Tablet or PC, or via an automated script which can directly access API functionality.

Data Confidentiality

Because the measurements taken with the DOSE-X are related to a treatment machine rather than to an individual patient, the DOSE-X does not handle or store any personal health information (PHI) or other kind of personally identifiable information (PII). The **Admin** role and password are not directly attributable to a

specific person, since several users can assume this role. There is no other confidential data handled or stored on the instrument.

Data Integrity

Integrity of data (such as measured dose values, calibration and correction factors, firmware code) at rest and in transit is the main security objective. This includes the following provisions:

- Secure firmware updates (via a hash value determined with SHA-256, enabling the user to verify the authenticity and integrity of the firmware file received).
- Changes to critical functionality (including firmware updates) are protected by a strong password. The password is stored on the device as salted hash.
- Critical data on the instrument (such as calibration or correction factors) are secured with a checksum.
- The user is able to further hardening the device by uploading their own valid TLS certificate; thus securing the communication and data transfer between the device and the PC or tablet.
- Control of the USB interface: only firmware files and exported libraries / configuration data can be imported, any executables on the USB device are blocked.
- Auto-Logoff for Admin sessions after a configurable time of inactivity.

Those provisions are also intended to reduce the likelihood of an intrusion of an attacker into the instrument and ultimately into the clinical network.

Data Availability

Non-availability of data (or of the whole instrument) does not have a direct effect on patient safety, nor does it cause a security risk. Thus, no particular measures are implemented to prevent denial-of-service attacks. However, patient treatment may be delayed in some situations. It is recommended to the healthcare provider to include non-availability of the device in their risk management for the patient treatment process, *e.g.*, by planning for a backup device or taking other precautions.

Cybersecurity Tips

The use of the DOSE-X (especially via remote control) on an IT network could result in previously unidentified risks to patients, users, and third parties. It is therefore recommended to the customer's risk management team, to identify, analyze, evaluate, and control such risks, especially in case of changes to the IT network, *e.g.*:

- Changes in the IT network configuration,
- Addition of items such as hardware and / or software platforms or software applications to the IT network,
- Removal of items from the IT network,
- Upgrades of hardware and / or software platforms or software applications on the IT network.

A cybersecurity attack presents a possible security risk to your patients and their personal data. To minimize the risk of a cybersecurity attack we recommend the following:

- Ensure that the Admin password is secure
- Keep the FW updated
- Restrict access by only allowing authorized users to access your network
- Encrypt your patients' data
- Protect your Service Set Identifier (SSID)
- Ensure you have a firewall installed and running
- Maintain up-to-date anti-virus software
- Use file sharing with caution and avoid sharing over public networks
- Ensure your access point software is patched and up to date
- Connect to your network using a Virtual Private Network (VPN)

Please contact your IT Department to ensure that all necessary and recommended security measures are being taken.

7.7. Warranty

The General Terms and Conditions of IBA Dosimetry GmbH apply. The user is provided with these at the time of the contract acceptance. IBA Dosimetry GmbH accepts no warranty or liability claims in the event of personal injury or damage to equipment if this was caused by any of the following:

- Improper use of the measurement device and its accessories.
- Improper installation, start-up, operation, and maintenance of the devices.
- Failure to observe the instructions in this document.
- Changes to the hardware carried out by the user.
- Incorrect maintenance, repairs, and service work.
- Damage caused by accidents or contamination.

7.8. Environmental Requirements

The DOSE-X:

- Is a sensitive measuring device, and must be stored in a clean, dry, preferably air-conditioned area, and at room temperature. Protect the device from mechanical and thermal stress, and unnecessary moisture.
- Has pollution degree 2 (operating and storage conditions) according to IEC 61010-1 Amd.1.
- Is designed for extended environmental conditions according IEC 61010-1:2010 + Amd.1:2016/Cor.1:2019.
- Has no hazardous sound emission. The noise produced by the device is less than 80 dB during operation.
- Should be used only inside a building and at less than 2000 m attitude.

Table 7.4. Environmental conditions for the DOSE-X electrometer

Condition	Operation	Storage	Transportation
Temperature	+15°C - +35°C	+5°C - +40°C	-20°C - +50°C
Pressure	70 kPa - 106 kPa	70 kPa - 106 kPa	50 kPa - 106 kPa
Relative humidity	20% - 80%	5 % - 85 %	10% - 90%

⚠ CAUTION

CAUTION

OBSERVE THE STATED OPERATION, TRANSPORTATION, AND STORAGE CONDITIONS

Observe the stated operation, transportation, and storage conditions.

Ensure correct environmental conditions according to the specifications for temperature, pressure, and relative humidity.

Operation or storage of the DOSE-X under conditions other than specified may have an adverse effect on measurement accuracy.

⚠ CAUTION

CAUTION

LOCATION OF USE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTICE

IMPORTANT NOTICE

PROTECT AGAINST MOISTURE

The DOSE-X is not sealed against humidity. Devices on which moisture has developed because of temperature changes (*i.e.*, moving the device from a colder storage location) must not be used unless they have been completely dried.

7.9. Regulatory Requirements

The DOSE-X fulfills the requirements of the Medical Device Regulation (EU) 2017/745 and is a medical device class IIb according to annex VIII, classification rule 10.

The DOSE-X is in conformity to the Radio Equipment Directive 2014-53-EU.

The DOSE-X is in compliance with:

- IEC 60731:2011 + Amd.1:2016.
- IEC 61326-1:2012 and is suitable for industrial electromagnetic environments.
- IEC 60601-1-2:2014 (without *chapter 4.1* and *5*) and is suitable for professional healthcare facility management. It also complies with IEC 60731:2011, *chapters 5.2.12* and *6.2.6*.

The quality management system at IBA Dosimetry is certified according to EN ISO 13485:2016.

This device is manufactured by:

IBA Dosimetry GmbH

Bahnhofstrasse 5

DE-90592 Schwarzenbruck

Germany

http://www.iba-dosimetry.com

8. Technical Support

8.1. Contacts for Technical Support

If you need technical support, please contact the local IBA Dosimetry GmbH representative first. If you need any further assistance, please contact:

USA, Canada, Latin America	Europe, Middle East, Africa	Asia Pacific
Phone: +1 786 288 0369	Phone: +49 9128 607 38	Phone: +65 3129 2472
service-usa@iba-group.com	service-emea@iba-group.com	service-apac@iba-group.com

8.2. Reporting Complaints and Incidents

Reporting Complaints

The Quality Management System of IBA Dosimetry GmbH includes a routine to handle any reported complaints.

All complaints about the product should be reported to any representative of IBA Dosimetry GmbH or directly to the technical support, see the contact information in the above section.

Reporting Serious Incidents

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

8.3. Returning Device for Repair

Procedure for shipping the device to the factory for repair:

- Contact your local IBA Dosimetry GmbH representative first to get support for the shipment.
- The Service personnel will generate an RMA (Return Material Authorization) number. You will receive an *RMA Form* with the RMA number and provided information by e-mail.
- Place the *RMA Form* into the package and ship the device to the address below:

  Service Department, IBA Dosimetry GmbH

  Bahnhofstrasse 5

  DE-90592 Schwarzenbruck

  Germany