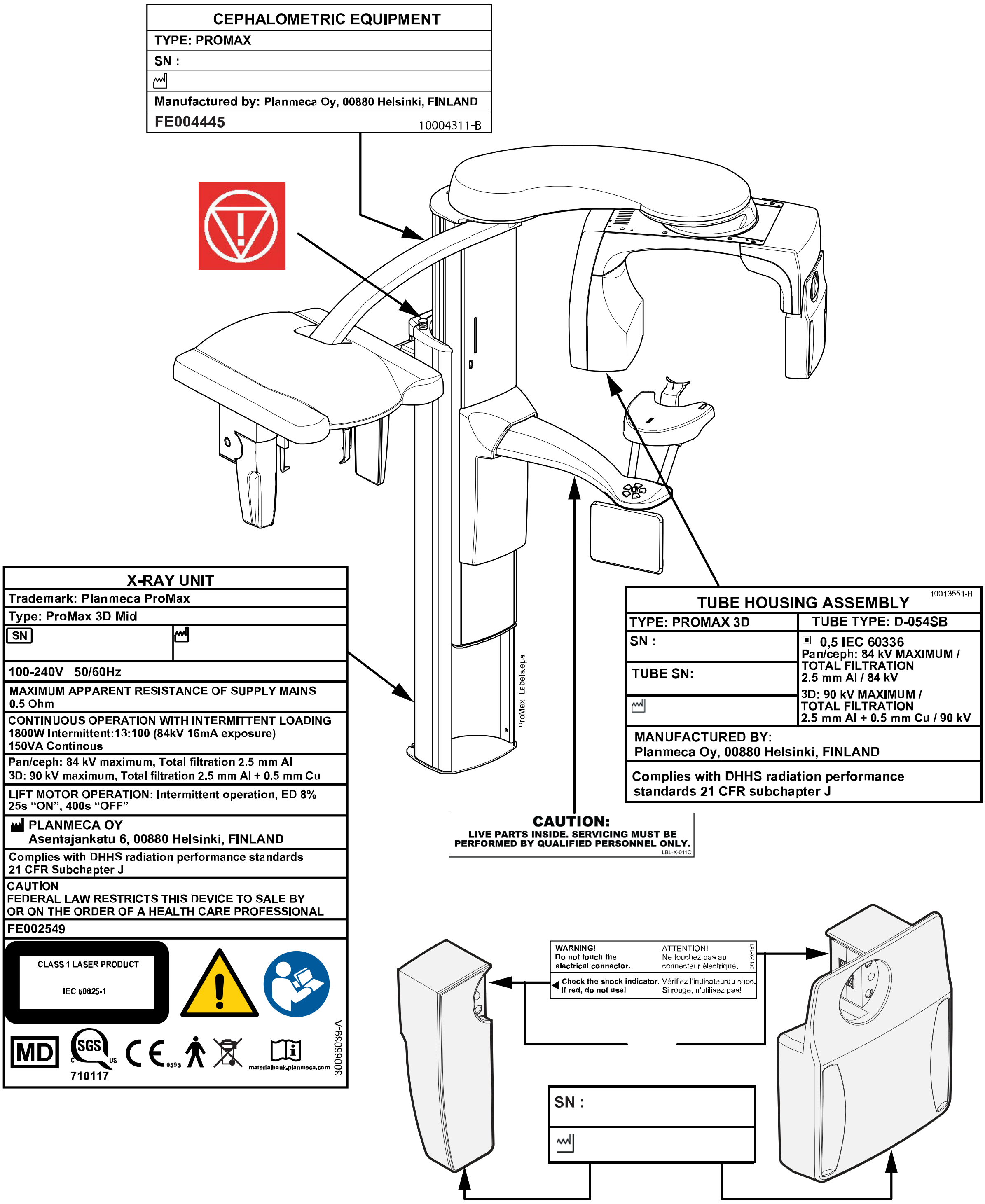
11 Preventive maintenance

To guarantee user and patient safety and to ensure consistent image quality, the X-ray unit must be checked and recalibrated by a qualified service technician once a year or after every 10 000 exposures, if this is sooner.

Perform the maintenance checks and calibrations described in the following sections (in the order listed) and complete the maintenance check list in the appendix "Maintenance check list" on page 314.

11.1 Check product labels

Check that no labels are detached or worn and that they are all legible, see the figure below, showing the location of the labels.



11.2 Check X-ray unit's wall mounting

Check that the X-ray unit's wall mounting is in good condition and is able to resist the required pull-out force.

For more information on the wall strength and mounting requirements, see *Planmeca ProMax installation manual*.

11.3 Check lubrication

- Visually check for the amount of lubricant in the linear actuator and threaded rods of the linear actuator, collimator and the temple support mechanism.

  If necessary, lubricate the parts with Shell Gadus S3 A1300C 2 grease, or a grease with the same specifications.
- If performing maintenance for ProMax 3D Plus or 3D Mid, visually check for the amount of lubricant in the patient support axle and threaded rod.

  If necessary, lubricate the parts with Shell Gadus S3 A1300C 2 grease, or a grease with the same specifications.

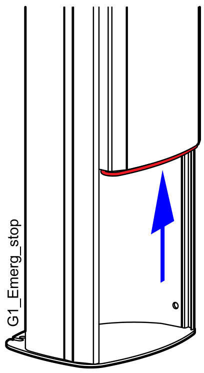
11.4 Check emergency stop button

Confirm that activating the emergency stop button will stop the X-ray unit operating.

Pressing the emergency stop button should block all movements of the X-ray unit, disable radiation and produce a help message.

11.5 Check emergency stop plate

Confirm that activating the emergency stop plate will stop the X-ray unit column movement.



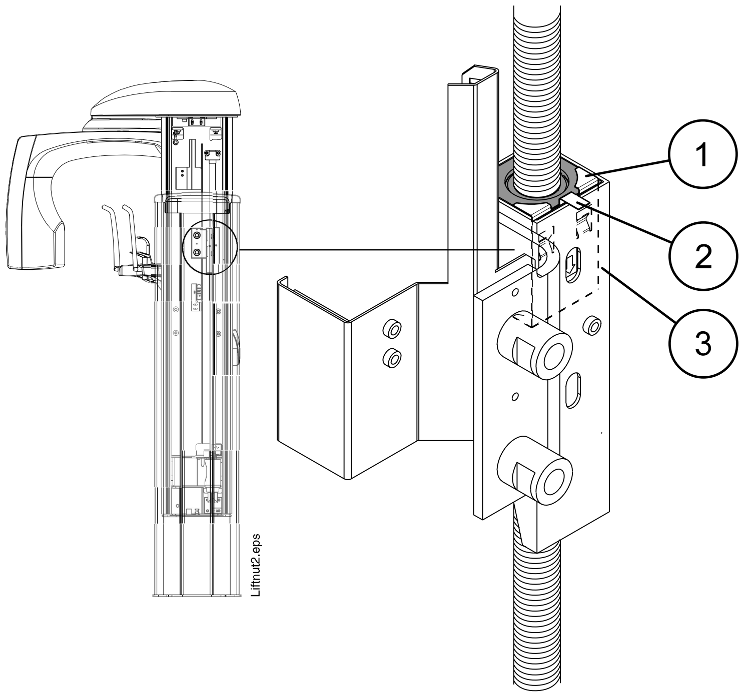
The column movement stops automatically if the emergency stop plate at the bottom is pressed upward.

11.6 Check column motor safety nut

The column motor is equipped with double motor nut assembly consisting of lower, solid nut (primary), and upper, floating nut (secondary). In case the primary nut fails, the secondary nut becomes active. The visual check of the column motor nut assembly must be performed once a year as follows.

1. Switch the unit off.
2. Remove the two rear cover plates of the telescopic column as described in section **Parts replacement and repair** > **Removing and replacing covers**.

   The column motor nut assembly is attached to the stationary column and can be seen from the opening on the stationary column top.
3. Check, if the lug of the indicator sheet **(2)** is bent and the top surface of the secondary motor nut is level with the edge of the column nut frame **(3)**, or a little higher (see the figure below).



1 Upper motor nut

2 Lug of the indicator sheet

3 Column nut frame

4. If the secondary nut is clearly inside the column nut frame **(3)** and the lug of the indicator sheet **(2)** is straightened, the column motor nut assembly must be replaced.

11.7 Check exposure switch and indicators

The following sections describe the operating checks have to be performed on a regular basis.

Exposure warning signal

Confirm that the units buzzer comes on for the length of the exposure.

The exposure switch also contains a buzzer. However, this buzzer can be disabled or enabled (from within the exposure switch assembly) depending on local regulations. Check that this buzzer also comes on for the length of the exposure if it is enabled.

Exposure switch

Confirm that the exposure switch requires continuous activation to maintain the exposure.

Releasing the exposure switch during the radiation should stop the exposure and produce an error message.

Make a visual check and check for possible wear or damage of the exposure switch spiral, and replace if necessary.

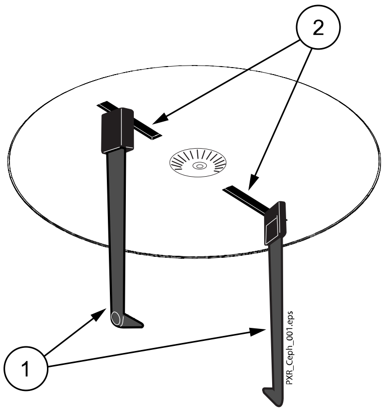
Exposure indicators

Confirm that the exposure indicator lights turn on in the control panel and in the exposure switch for the length of the exposure.

Additionally, check also the (optional) external exposure indicator, if the unit is equipped with such.

11.8 Cephalostat ear posts fluent motion

If the X-ray unit is equipped with cephalostat, check the fluent movement of the cephalostat ear posts **(1)**.



If the ear posts are not easily sliding wide after patient positioning, add some teflon spray to the ear post attachment rails **(2)**.

11.9 Clean X-ray unit and Reconstruction PC

CAUTION

When disinfecting the unit surfaces, the unit should be switched off. The unit must not be exposed to gaseous disinfectants or explosive anesthetics. Never spill any liquids into the unit. If that happens, make sure that the liquid did not come into con- tact with any of the internal electronic parts (cables/ sensors/PCBs) before switching on the unit.

X-ray unit

For cleaning instructions, refer to the X-ray unit’s user’s manual.

Reconstruction PC (3D X-ray units)

Vacuum clean dust inside Reconstruction PC case and clean the filters.

11.10 Update imaging system software

X-ray unit

To get the new features and improvements, it is recommended to update the imaging system software according to the instructions provided in the *Imaging System Updater* manual.

Reconstruction PC (3D X-ray units)

Install all updates recommended by the Reconstruction PC hardware manufacturer.

These updates might include e.g. important cyber security updates.

11.11 Perform filament definition

Perform the filament definition, see instructions in section "Performing filament definition" on page 40.

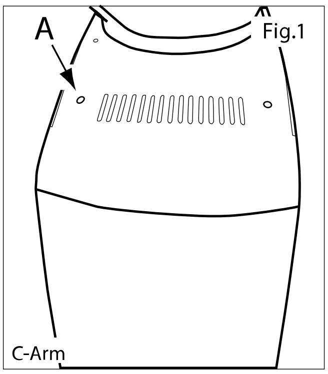
11.12 Calibrate and perform QA tests with Device Tool

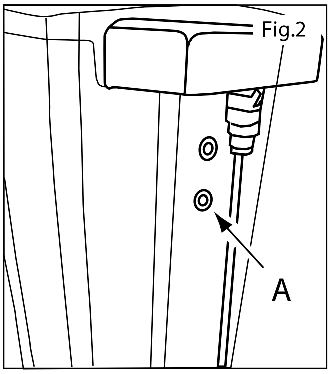
Calibrate the X-ray unit and perform the QA tests with the Device Tool, see *Planmeca ProMax Device Tool* manual.

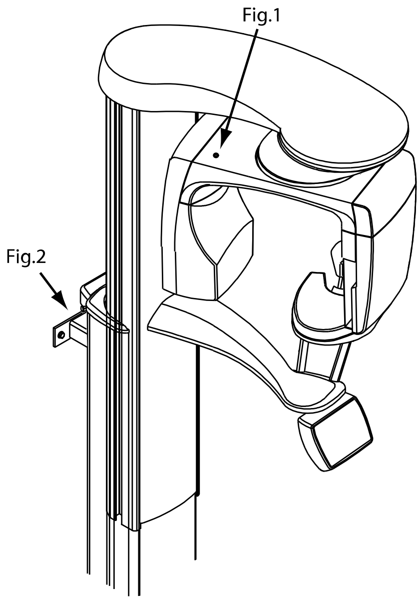
11.13 Perform electrical safety measurements

All the measurements shall be performed using an IEC62353-compliant measurement device. The unit shall be separated from the supply main (live, neutral and protective earth) during the measurements.

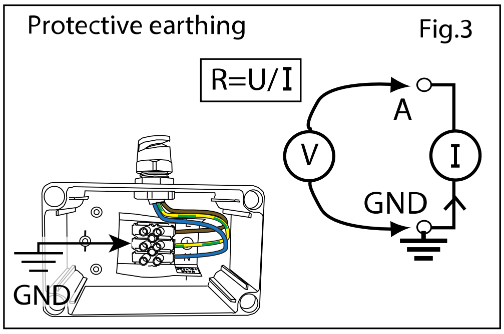
Protective earthing







Measurement between main ground point and A (Fig.1 , Fig2 , Fig.3)

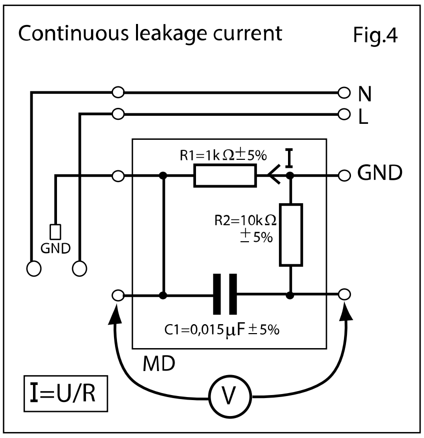


For equipment with a non detachable power supply cord the impedance between the protective contact in the mains and any accessible metal part, which is protectively earthed, shall not exceed 300 mΩ.

Measurements shall be performed using a measuring device able to deliver a current of at least 200 mA into 500 mΩ. The open circuit voltage shall not exceed 24 V.

Continuous leakage current

Measurement from protective earth with MD (Fig.4)



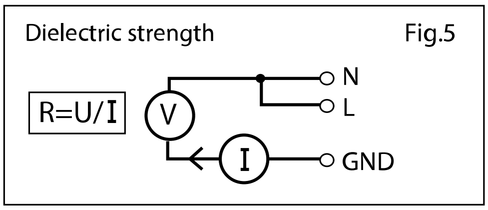
The electrical insulation providing protection against electric shock shall be of a quality that current flowing through it is limited to the specified values.

The specified limit value of the continuous earth leakage current is in normal condition (N.C) 0,5 mA tested in stand -by condition and in full operation with the mains in any position.

The continuous earth leakage current shall be measured from a protective earth conductor with a measuring device (MD).

Dielectric strength

The dielectric strength shall be tested between live parts with accessible metal parts, which are protectively earthed , and the enclosure not protectively earthed.



This insulation shall be basic insulation and the test voltage for measuring shall be 500 V for 1 min, when the equipment’s mains is connected off from the line.

During the measurement main switch of the MAINS PART shall be in operating position (ON), to include, as far as it is practicable , all insulations of the MAINS PART during measurement.

During the test, no flashover or breakdown shall occur and the insulation resistance should be least 2 MΩ.

11.14 X-ray tube feedback system

The unit performs a complete check on the feedback system before every exposure. Any found errors or deviations are reported as error messages (exposure is prevented).

Therefore the actual need for this annual test is dictated by the local authorities and respective regulations. Be sure to perform all tests required by the authorities.

There are two ways of doing most of the tests, either non-invasively (from the radiation beam) or invasively (from the units feedback signals). Both are presented here. Note that not all tests can be performed both ways.

CAUTION

Radiation is emitted during all these tests. Proper protection against unnecessary exposure to radiation must be considered.

11.14.1 Non-invasive testing (directly from radiation)

A non-invasive method can be used for checking the kVp, radiation quality (half-value layer) and the exposure time. This method is efficient since no covers need to be opened, and it gives a “second” opinion on the measured parameters. However, care must be taken when selecting the appropriate non-invasive X-ray meter; older meters calculate the kVp avg based on the assumption that the kV waveform is AC. The X-ray unit has DC high voltage with very small high frequency ripple, so the accurate measurement of kV waveform can be impossible if, for an example, the meter’s sampling frequency isn’t high enough. If in any doubt whether or not the meter is suitable for the X-ray unit, please consult the meter manufacturer for additional information. Otherwise, please refer to the radiation meter manufacturers user manual of how to use the meter.

Peak tube potential (kVp) measurement

When a non-invasive meter is used for kVp measurement, following things should be noted:

1. The sensor should be placed exactly in the middle of the X-ray field in both horizontal and vertical directions (very important especially if the measurements are made in the panoramic mode!), use a fluorescent screen to determine the X-ray field area if you are not totally sure about it.
2. The sensor distance from the focal spot should be as short as possible to maximise the signal / noise ratio.
3. The whole sensor area must be within the radiation field.
4. The meter must be properly calibrated and, when necessary, appropriate calibration/ correction factors must be used when interpreting the results.

The measured kVp must be within ±5% of the value displayed on the user interface.

Half-value layer measurement

There are several methods for measuring the HVL. The HVL is defined as the thickness of a specified material (generally expressed in mm Al) which attenuates X-rays of a specified spectrum to such an extent that the value of the air kerma rate (or exposure or absorbed dose) is reduced to half the value measured without the material.

The simplest way to ensure that the X-ray unit meets the requirement is to first measure the air kerma rate without any additional material in the radiation field, then add 3.0 mm Al to the radiation field, measure the air kerma rate again, as follows.

1. Measure the air kerma rate without any additional material in the radiation field, using 84 kV exposure.
2. Add additional 3.0 mm Al material in the radiation field.

NOTE

No additional Al filtration equipment is supplied with the X-ray unit.

3. Measure the air kerma rate using 84 kV exposure.
4. Use the following formula to check that the air kerma rate with the addition of 3.0 mm Al material is **more** than half the air kerma measured without the additional material.

$$\frac{\text{Dose rate with added 3.0 mm Al eq filtration}}{\text{Dose rate without added filtration}} > 0.5$$

This is sufficient to ensure that the HVL is at least 3.0 mm Al. Depending on the type of radiation meter used, it may be necessary to apply a correction factor to the result measured with added material in the radiation field.

Exposure time measurement

The exposure time is controlled by the X-ray unit. The exposure time is defined automatically based on the selected program and is displayed in the X-ray unit's user interface.

Attach a non-invasive sensor to the front of the X-ray unit sensor. In panoramic mode, select 70 kV / 8 mA and take an exposure and record the measured exposure time. The measured exposure time must be within ±10% of the exposure time displayed in the user interface.

11.14.2 Invasive testing (directly from unit's own feedback signals)

NOTE

The manufacturer does not require the invasive testing. The invasive test must only be performed if the local authorities require it.

An invasive method should be used for checking the tube current (mA), and can be used for checking the kVp and exposure time. This method requires that the covers around the tube head assembly are removed, and a special measurement adapter cable (part number 10008320) is connected to the connector J2 in the FBK PCB. The FBK PCB is permanently fastened to the front side of the tube head assembly. The analog feedback voltage signals can be measured with a calibrated multimeter from the adapter cable connectors (labelled kVpos, kVneg, mApos and mAneg). An oscilloscope is required if kV and mA waveforms need to be observed, for an example when determining the exposure time.

NOTE

The feedback signals are differential, so measuring only one polarity signal (e.g. kVpos with respect to the X-ray units ground potential) will give false results. The feedback signals must always be measured differentially, kV feedback voltage = (kVpos – kVneg) and mA feedback voltage = (mApos – mAneg).

Peak tube potential (kVp) measurement

Connect the kVpos plug of the measurement adapter to the positive terminal of the multimeter and the kVneg plug to the negative (ground) terminal of the multimeter.

Select the appropriate DC voltage measurement range for 1 to 5 V signal level. Take an exposure with desired kV setting (selected mA value has no effect, however low mA should be used to minimise the amount of unnecessary radiation) and when the voltage reading has stabilized, record it. The actual tube voltage relates to the measured feedback signal as follows:

Actual tube voltage = 27 000 * measured feedback voltage (in volts)

The resulting tube voltage should be within ±5% of the voltage indicated in the user interface.

Tube current (mA) measurement

Connect the mApos plug of the measurement adapter to the positive terminal of the multimeter and the mAneg plug to the negative (ground) terminal of the multimeter.

Select the appropriate DC voltage measurement range for 100 mV to 5 V signal levels. Take an exposure with desired mA setting (selected kV value has no effect, but lowest possible kV is recommended to minimise the amount of unnecessary radiation) and when the voltage reading has stabilized, record it. The actual tube current relates to the measured feedback signal as follows:

Actual tube current (in mA) = 5.06 * measured feedback voltage (in volts)

The resulting tube current should be within ±10% of the current indicated in the user interface.

Exposure time measurement

A calibrated oscilloscope is needed for invasive exposure time measurement. Connect oscilloscope channel 1 to kVpos, channel 2 to kVneg and oscilloscope ground to the tube head ground. Select differential signal (Ch1 – Ch2) from the oscilloscope math menu and take an exposure with desired values. The exposure time can be defined from the oscilloscope screen as the time interval during which the tube potential exceeds 70% of the peak tube potential. The exposure time must be within ±10% of the value displayed in the user interface.

Feedback signal offset measurement

The feedback signals have a small offset voltage that is used for internal self-testing of the equipment. In some cases, it can be useful to measure these offsets for troubleshooting purposes etc. The offset of all feedback signals (kVpos, kVneg, mApos and mAneg) should be 49 ± 2 mV with respect to the unit ground potential. The offsets should be measured in idle state (before exposure).