8. QUALITY ASSURANCE PROGRAM

Here following the list of the operation required to maintain the continued proper functioning of the unit:

Frequency	Type of check	Done by	Reference
Daily	Functioning of the indicator lights	User	Paragraph 8.2
Daily	Laser alignment check	User	Paragraph 8.3
Monthly	Panoramic image quality check	User	Paragraph 8.4.1
Monthly	Cephalometric image quality check	User	Paragraph 8.4.2
Six-month	3D image quality check	User	Paragraph 8.5
Yearly	Dosimetry test	Authorized personnel	Paragraph 8.6

Note

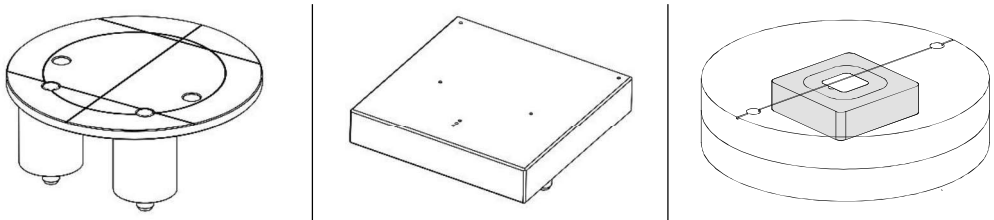
It is recommended to perform the quality assurance procedures either with the suggested frequency or with the frequency required by local regulations if higher.

8.1 Quality control tools

The following tools[1] are required to perform the quality check:

- Support plate: used to check laser alignment and to hold the centering tool
- Centering tool: used to check Panoramic image quality
- 3D quality phantom compliant with DIN 6868-161: used to check 3D image quality
- QuickVision software: used to acquire image and perform measurements
- PhD_C_Test software: used to perform exposure without arm rotation. The PhD_C_Test.exe is located at C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C
- "QC Tool" software: used to assess 3D image quality. The software can be installed from the QuickVision installation media: a shortcut on the desktop will be created
- kV meter (NOT provided by Owandy Radiology SAS): used to measure exposure parameters.

All the tools are provided with the unit, except kV meter. The 3D quality phantom is provided as standard with 110-120V units. For 220-240V the tool is optional and has to be ordered separately.



Support plate | *Centering tool* | *3D Quality phantom*

Figure 7

[1] For removable parts and accessories order codes please refer to the document *I-MAX Spare Parts Guide*

8.2 Functioning of the indicator lights

Power ON the unit, verify that the "Machine Ready" (1), "X-Ray Emission" (2) and "Computer connection" (3) LEDs blink twice.

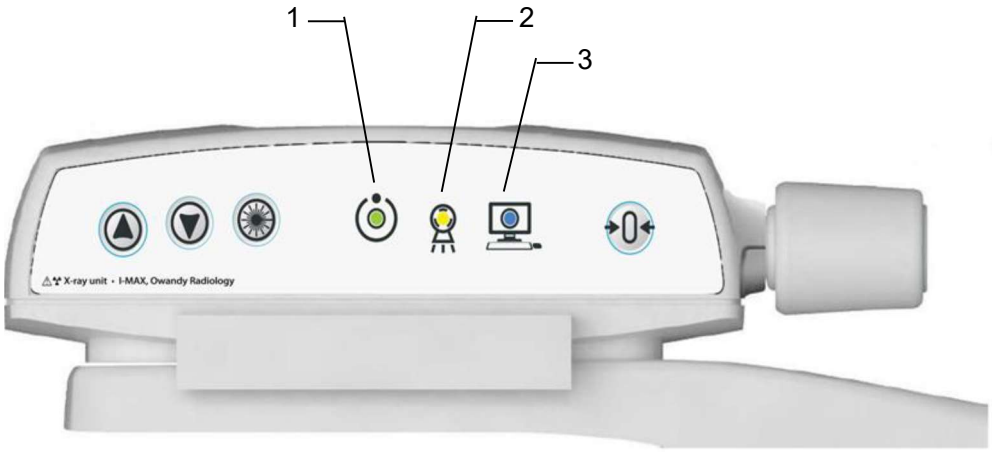


Figure 8

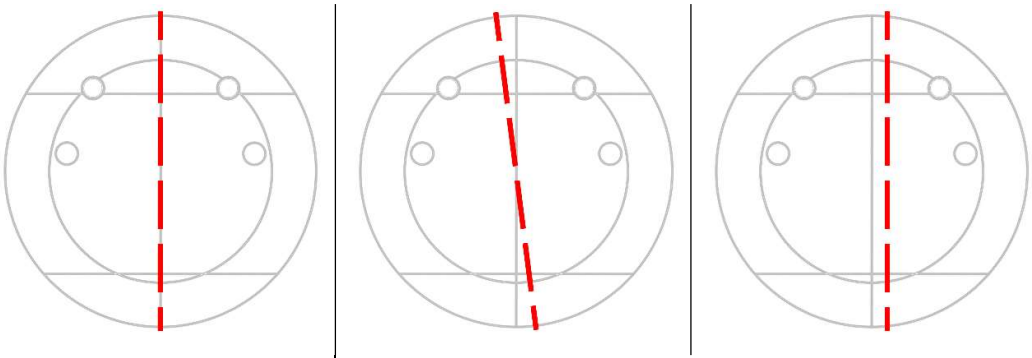
In case the test fails, verify that the main power supply is present in the room. If the case, call technical assistance.

8.3 Laser alignment check

Power ON the unit and perform the axis reset by pressing the >O< button.

At the end of the axis positioning, select standard Panoramic exam (see paragraph 12.1) and press >O<. Place the support plate (Figure 10) on the chin rest support and power ON the laser. Check that the mid-sagittal laser beam is aligned to the reference line of the support plate (± 3mm).

At the end of the check, switch OFF the unit.



Laser correctly aligned *Laser misaligned*

Figure 9

In case the test fails, repeat it checking that there is no mechanical interference. If misalignment is still present, call technical assistance.

8.4 Panoramic and CEPH image quality check

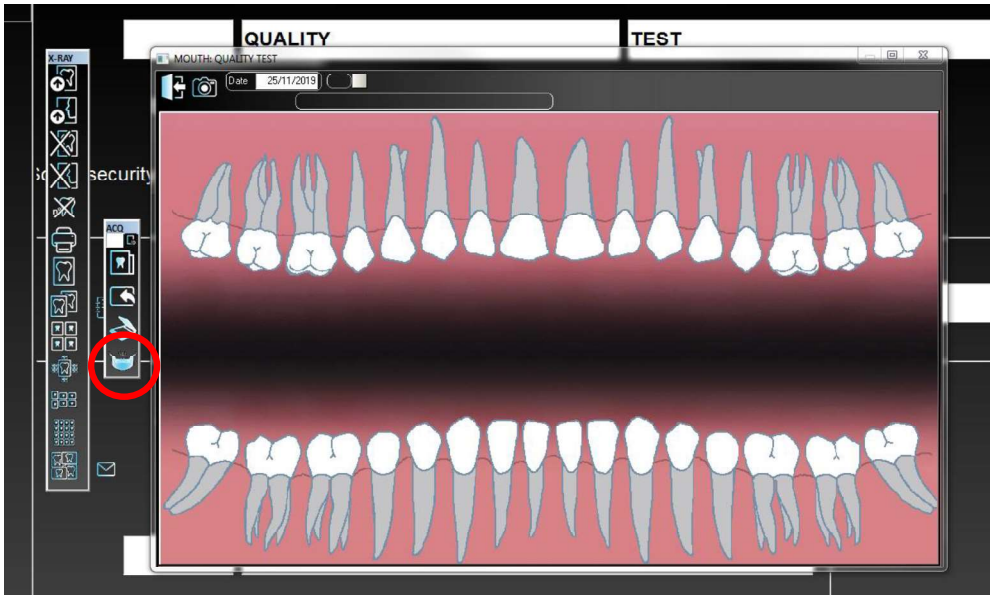
Warning

X-rays will be emitted during the following operations. It is recommended to use the greatest caution and to comply with local safety regulations and laws.

8.4.1 Panoramic image quality check

1. Switch ON the unit (see paragraph 9.1.1).
2. Open QuickVision software and open the patient "Quality Test". If not present, create a new patient (Name: "Quality"; Family name: "Test").
3. Select the "Mouth" icon.

4. From the "ACQ" toolbar, click on the highlighted button to open the virtual keyboard.



5. Mount the centering tool on the support plate and place it on the chin rest support.

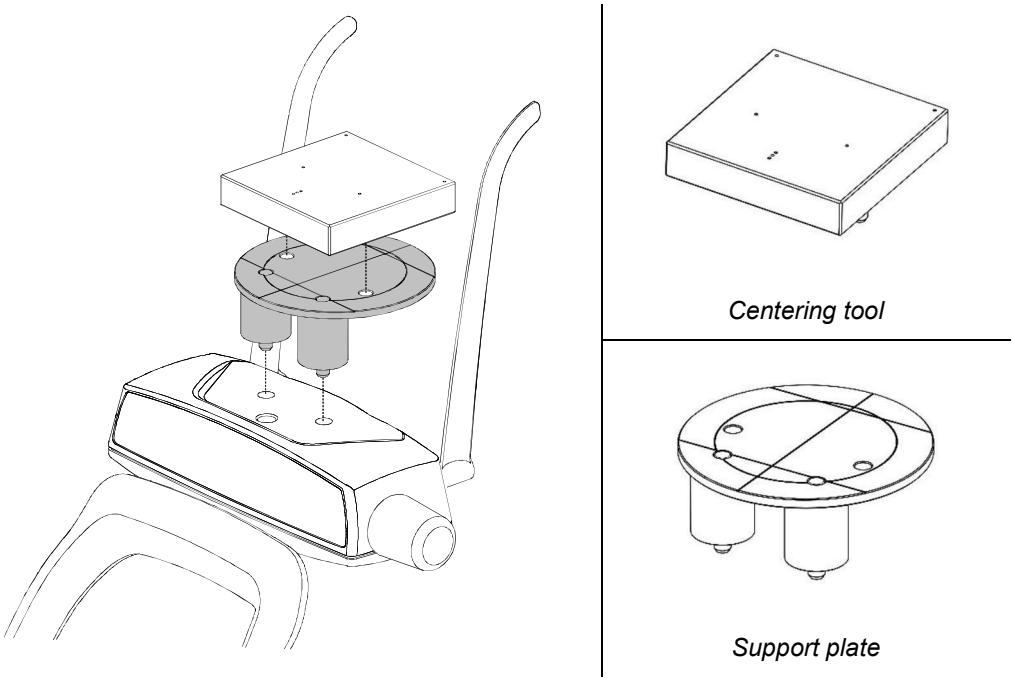
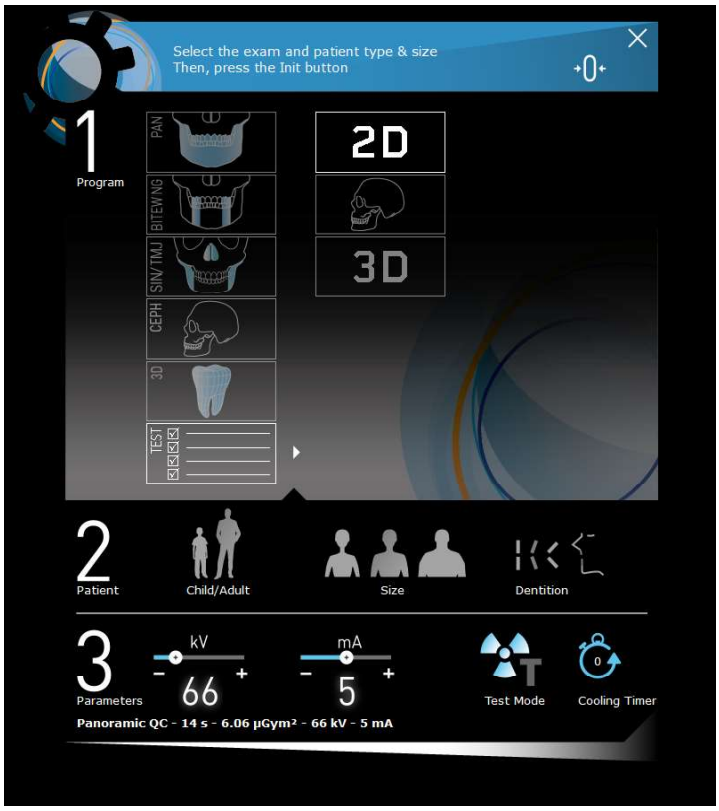
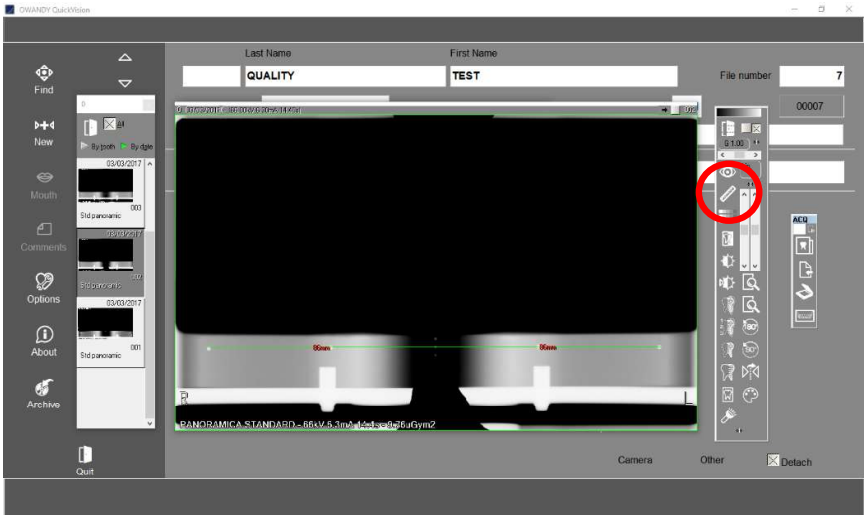


Figure 10: Support plate and centering tool positioning

6. On the main menu of the virtual interface, select "Test" exam, the following image will be displayed:



7. Select "2D" exam.
8. Make an exposure at 66 kV, 6.3 mA (see chapter 10).
9. Select the "Ruler" icon and measure the distance between the two external spheres; this value must be 170 mm ± 2 mm.



In case the test fails, call technical assistance.

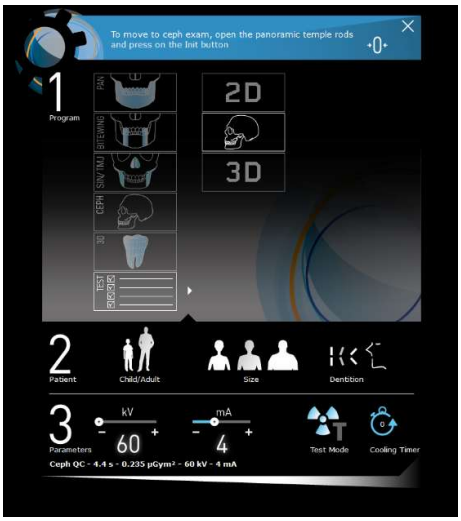
10. Measure the distance between the left external sphere and the central one and the distance between the right external sphere and the central one: the difference of these values must be maximum 2mm.

    In case the test fails, call technical assistance.

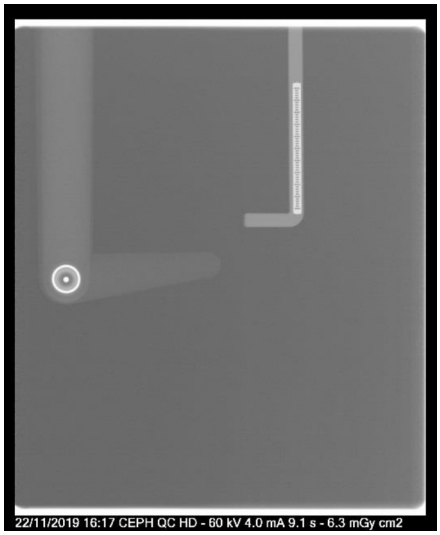
11. Record the tests results in the log book at paragraph 8.4.3.

8.4.2 Cephalometric image quality check

1. Follow steps 1 to 4 of the paragraph 8.4.1 (panoramic image quality check).
2. Remove the centering tool from the chin rest (see step 4 of the panoramic image quality check).
3. On the main menu of the virtual interface, select "Test" exam, the following image will be displayed:



4. Select "CEPH" exam.
5. Prepare the machine to take a CEPH exam (refer to paragraph 0 put the reference to the par making a CEPH exam), rotate the CEPH head support to the latero lateral position.
6. Make an exposure at 60 kV, 4 mA.
7. Verify that the image of the small sphere of the ear pin far away from the detector is inside the circle of the ear pin close to the detector.



8. Record the tests results in the log book at paragraph 8.4.3.