ORTHOPANTOMOGRAPH™ OP 3D

3D Image Quality Control with QUART

ENGLISH

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1. Introduction

1.1 ORTHOPANTOMOGRAPH™ OP 3D Quality Control

These instructions describe how to check and monitor 3D image quality of the **ORTHOPANTOMOGRAPH OP 3D** (CBCT) 3D dental imaging device (the device) in accordance with:

- DIN 6868-161 3D device acceptance test and

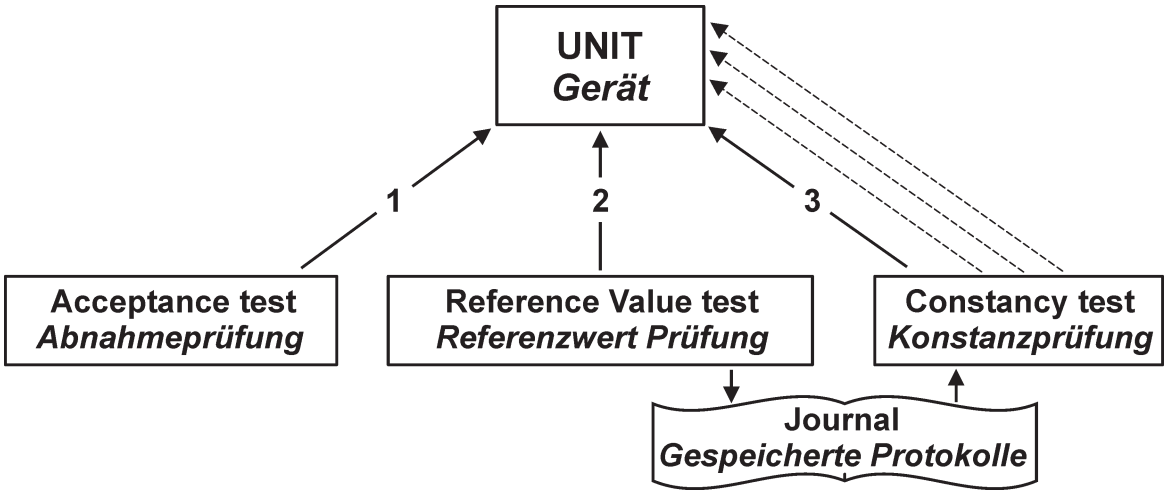
- DIN 6868-15 3D device constancy test.

1.2 Overview of the 3D Quality Assurance procedure

For the device to meet the 3D image quality standards (QUALITY ASSURANCE) described in DIN 6868-161 and DIN 6868-15 3D, three tests must be carried out by the service technician:

1. **Acceptance test**
2. **Reference Value test**
3. **Constancy test**

NOTICE!
The user of the device must regularly carry out the Constancy test to monitor the 3D image quality of the device (DIN 6868-15).



1.3 The 3D quality assurance tests

Acceptance test

Why is the Acceptance test carried out?

The Acceptance test is carried out to check the 3D image quality of the device. In some countries or states the Acceptance test must be carried out as part of the device installation procedure and the device cannot be approved for use until this test has been completed.

In addition, if the image quality is acceptable it indicates that the 3D device is functioning correctly and is operating in accordance with the manufacturer's specifications.

The test must be carried out in accordance with DIN 6868-161 3D device acceptance test

When is the Acceptance test carried out?

- When the device is installed for the first time
- If the device is moved and reinstalled to a new location.
- After replacing the tubehead
- After carrying out any repairs/upgrades where the device needs to be recalibrated. Examples of these are:
  - Sensor replacement
  - Generator board replacement
  - Collimator replacement
  - Software / Firmware changes

Who carries out the Acceptance test?

The Acceptance test must be carried out by the service technician.

The equipment and software needed for the Acceptance test

- QUART_ap test phantom
- QUART_tec software.
- QUART phantom base
- Dose meter

Reference Value test

Why is this Reference value test carried out?

The Reference Value test is carried out to obtain 3D image quality values that are used as a reference for the Constancy test.

After the Reference Value test has been carried out, the test software enables the Constancy test series creation.

The test must be carried out in accordance with DIN 6868-15 3D device constancy test.

When is the Reference value test carried out?

- After the Acceptance test has been carried out.
- When new reference values are required for the constancy test.
  For example:
  - The PC connected the 3D device is replaced.
  - Driver update that affects the imaging chain.
- Whenever national or local regulations concerning the use of 3D dental imaging devices require the test to be carried out.

Who carries out the Reference value test?

The Reference value test must be carried out by the service technician.

The equipment and software needed for the Reference value test

- QUART_kp test phantom
- QUART_pro software.
- QUART phantom base

Constancy test

Why is the Constancy test carried out?

The Constancy test is carried out to ensure that 3D image quality remains consistent throughout the operating life of the device.

In addition, if the image quality is acceptable it indicates that the 3D device is functioning correctly and is operating in accordance with the manufacturers specifications.

The test must be carried out in accordance with DIN 6868-15 3D device constancy test.

When is the Constancy test carried out?

The FIRST Constancy test must be carried out after the Reference value test has been carried out (it is carried out to demonstrate the Constancy test to the user).

When the device is in normal use the Constancy test must be carried out:

- Monthly
- Whenever national or local regulations concerning the use of 3D dental imaging devices require the test to be carried out.

Who carries out the Constancy test?

The FIRST Constancy test must be carried out by the service technician. Subsequent Constancy tests must be carried out by the user.

The equipment and software needed for the Constancy test

- QUART_kp test phantom
- QUART_pro software.
- QUART phantom base

2. The Acceptance test

2.1 General information

To get accurate Acceptance test values **three** (3) 3D images of the QUART_ap test phantom must be taken.
The 3D exposures are then examined using the **QUART_tec** software and average values calculated.

Before the Acceptance test is started all device calibrations, including the 3D collimator calibration must be successfully completed and the X-ray dose measurements must be taken, see chapters ***2.4 Taking the dose measurements*** and ***2.5 3D X-Ray beam alignment verification***.

Refer to **DIN 6868-161** for more information.

NOTICE! *The QUART software related instructions may not be in line if you are using a different software version. In such cases, refer to QUART software manual for accurate information on the software usage.*

2.2 Installing the QUART_tec software

Install the QUART_tec software into the PC connected to the device if it has not yet been installed.

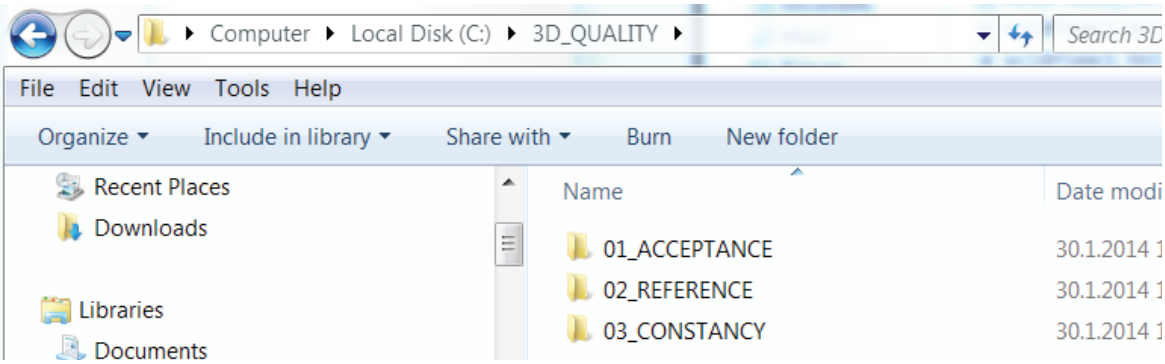
If you install the software for the first time, you must click **SETUP** from the bottom menu, login and then register the software.
Refer to the instructions supplied with the software, and follow the on screen instructions.

2.3 Preparing the device for the Acceptance test

1. Calibrate the device, if it has not already been done. Refer to the ORTHOPANTOMOGRAPH OP 3D user manual for information on how to do this. Also refer to chapter ***2.5 3D X-Ray beam alignment verification*** for more informaiton on the beam size verification, carried out as part of the 3D collimator calibration.

2. Calibrate the display monitor that is used with the device, if it has not already been done. Refer to the monitor/software manuals for information on how to do this.

3. **PC:** In the PC connected to the device create new folders in which all the 3D Quality Assurance images and data from the Acceptance, Reference value and Constancy tests can be saved. Give the folders names that make them easy to identify;
   e.g. **3D_QUALITY\01_ACCEPTANCE**
   \02_REFERENCE
   \03_CONSTANCY



4. **PC:** Start CLINIVIEW™ software and open a **Patient** (patient card) in which the 3D images from the Acceptance test can be stored.
   Give it a name that makes it easy to identify, e.g. **ACCEPTANCE_TEST**

   Refer to the **CLINIVIEW User Manual** for information on how to do this.

2.4 Taking the dose measurements

Three X-ray dose measurements must be taken. The dose measurement results are needed for the Acceptance test.

1. Detach the head support and head support rods from the lower shelf of the device.

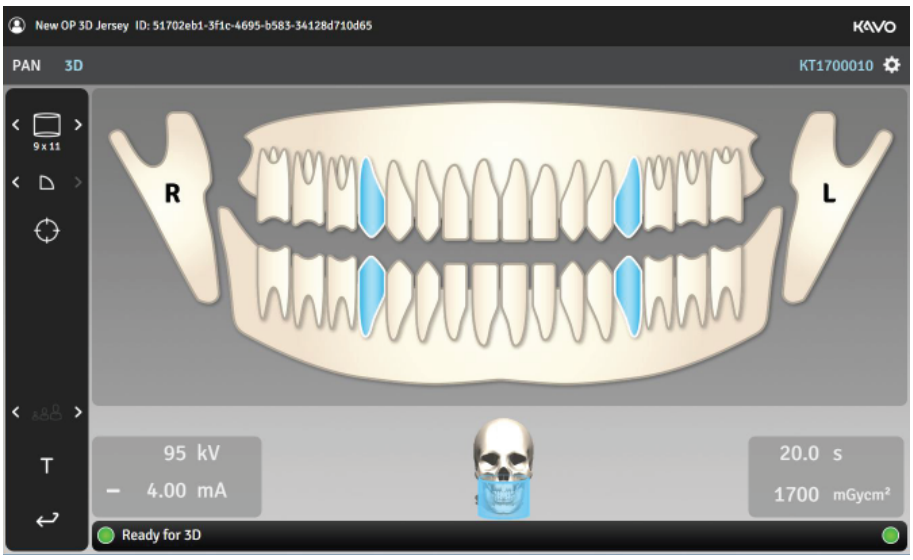
2. Attach the X-ray dose meter, that measures mGy, to the middle of the sensor cover using sticky tape.

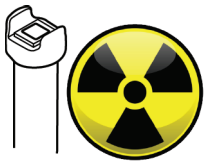
3. Prepare the device for imaging.
   Refer to the OP 3D User and Installation manual for information on how to do this.

4. Attach the chin rest to the lower shelf of the device.

5. **GUI:** Select 3D imaging modality and the following imaging factors:

   • Select the second premolars from dental chart
   • Disable Scout imaging
   • Select high resolution setting
   • Set 4.00 mA





5. **PROTECT YOURSELF FROM RADIATION**
   Take a 3D exposure with the X-ray dose meter attached to the sensor cover to obtain a dose reading (mGy).
   Press and hold down the exposure switch for the duration of the exposure.

   NOTICE! *Half-way through the 3D exposure sequence there is a pause. This may cause the dose meter to stop taking the dose measurement. If the dose meter stops measuring and is unable to measure the total image time, release the exposure button half way though the exposure and then multiply the measured dose by 2. Record the result.*

6. Take TWO (2) more dose readings as described above. Record the results as they will be needed later as described in chapter ***2.7 Carrying out the Acceptance test.***

Reading 1	Reading 2	Reading 3
x2		

   NOTICE! *The three measured dose values must not deviate more than 10% from their mean dose value. This will be calculated by the QUART software during the Acceptance test.*

7. Remove the dose meter from the device.

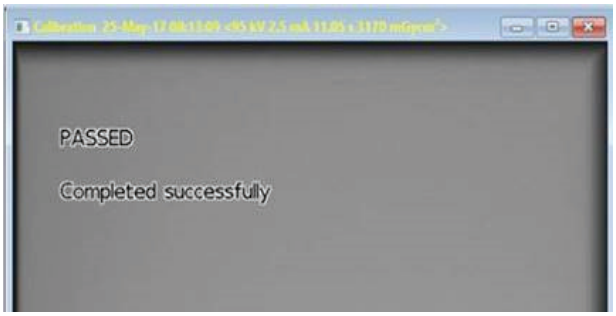
2.5 3D X-Ray beam alignment verification

A radiation field alignment check needs to be carried out to verify that the X-Ray beam hits the active area of the detector with the required accuracy.

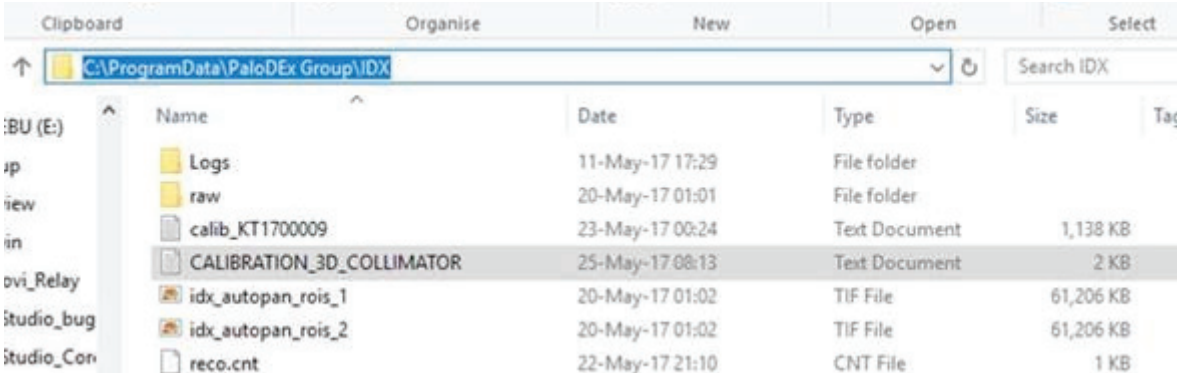
Refer to DIN 6868-161 and IEC 60601-1-3 for more information on the requirements.

With OP 3D device, the 3D X-Ray beam alignment is checked as part of the device Collimator Calibration routine, during which the radiation field size and location of the beam, with respect to the detector, is calibrated. Therefore the X-Ray beam check is automatically performed everytime the device collimator calibration procedure is run.

When the Collimator Calibration routine, including the X-ray beam alignment check, has been successfully completed the ”PASSED” result is displayed on the device GUI and the calibration image with the result of the beam alignment check printed in it is generated.



The numeric values obtained from the beam alignment check are saved into a text file named ”CALIBRATION_3D_COLLIMATOR.txt” which is stored in folder ***C:\ProgramData\PaloDEx Group\IDX*** on the workstation.



The stored file includes the pre-determined acceptance limits (“acceptanceLimit”) in mm for the different edges of the beam with respect to the detector edges individually and also for case of opposite edges combined.

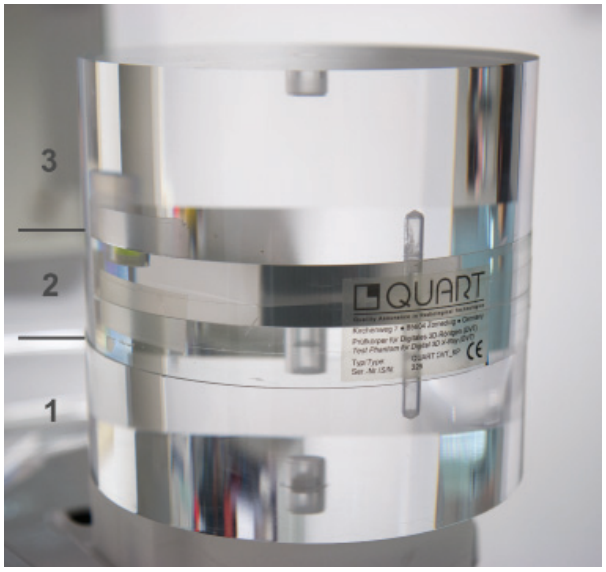
In addition to the limits, the file includes actual measured result (“measuredOverlap”) in mm, which gives the actual difference measured between the location of the beam edge and the edge of the sensor active area. Also the verbal result of the check, shown also in the calibration image, is printed in this file.

NOTICE! *A negative value in actual result* (“measuredOverlap”) *means that the beam does not exceed the detector active area on the direction indicated.*

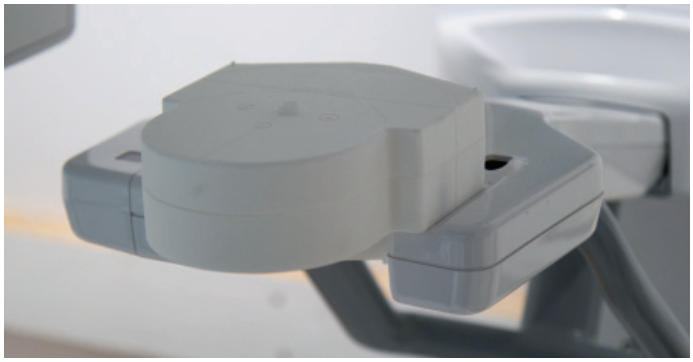
2.6 Taking an exposure of the QUART_ap phantom

The QUART_ap phantom comprises of three parts:

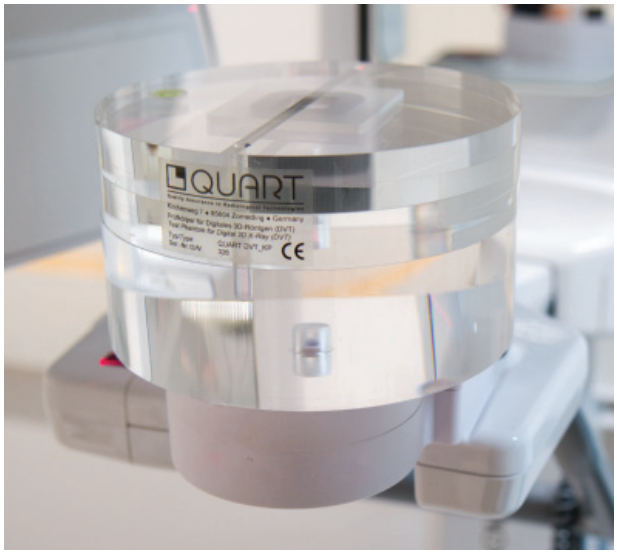
1 Lower part (50mm Homogenous material)
2 Middle part (Resolution test object)
3 Upper part (60mm Homogenous material)



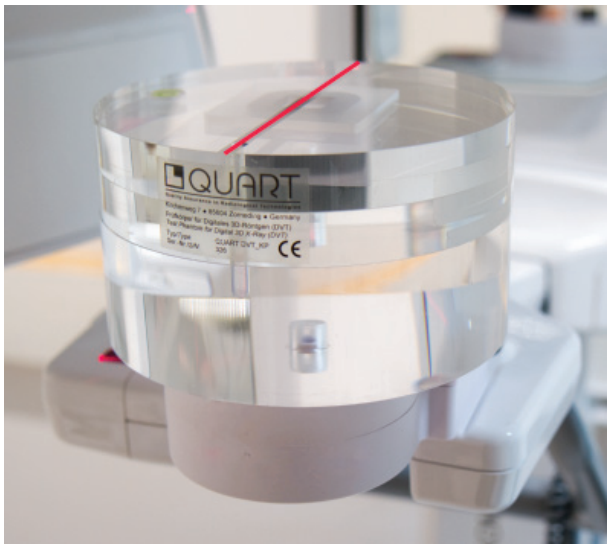
1. Attach the 3D QC phantom holder to the lower shelf of the device.



2. Place the lower (**1**) and middle (**2**) parts of the QUART_ap phantom to the 3D QC phantom holder.



3. Adjust the middle part (**2**) of the QUART_ap phantom so that its center line lines up with the midsagittal light of the device.

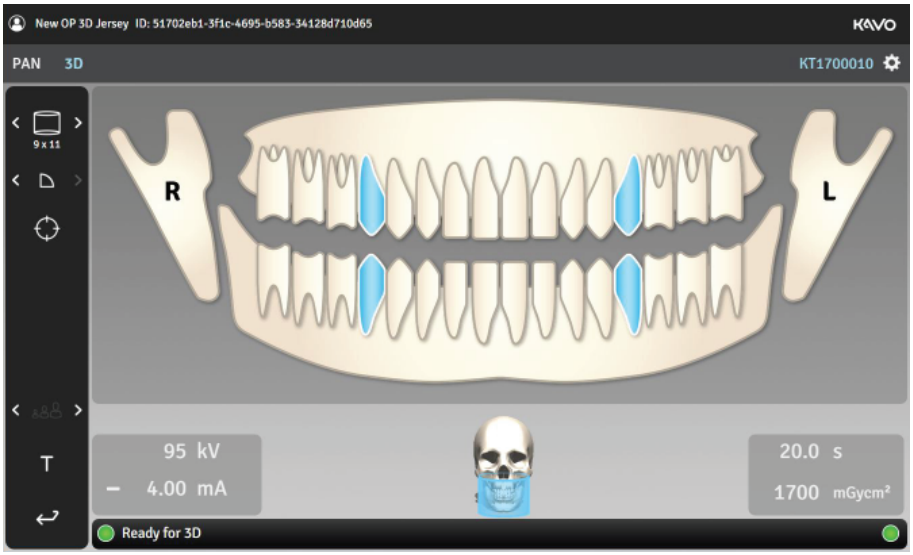


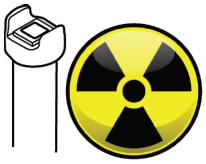
4. Carefully place the upper (**3**) part of the phantom on top of the middle (**2**) phantom. Make sure that the lower parts do not move.

5. Prepare the device for an exposure.
Refer to the OP 3D user manual for information on how to do this.

6. **GUI:** Select 3D imaging modality and the following imaging factors:

   • Select the second premolars from dental chart
   • Disable Scout imaging
   • Select high resolution setting
   • Set 4.00 mA





8. **PROTECT YOURSELF FROM RADIATION**
   Take a 3D exposure of the QUART_ap phantom.
   Press and hold down the exposure switch for the duration of the exposure.

   The 3D image will be saved in Patient (card) previously created, **ACCEPTANCE_TEST**.

9. After the exposure, open the 3D imaging program if it does not automatically open (depends on the program settings).
   Select the **axial view** and scroll through the 3D image and check for any artifacts that could effect 3D image quality.

   Make a note of any artifacts that are present.

ARTIFACT TYPES

- **Hardening artifacts;**
  Stripes in axial files due to beam hardening in the beam path direction when passing hard objects like metal implants

- **Extinction artifacts;**
  Happens when object in the FOV absorbs the full beam so there is no enough signal to the detector. So the whole beam is absorbed in certain areas causing white areas in the CBCT image. Extinction artifacts are typical seen together with hardening artifacts.

- **Partial volume effects and exponential edge gradient effect (EEGE);**
  These artifacts occurs during the reconstruction process. There is light line or dark line type of artifacts in CBCT image.

- **Aliasing artifacts;**
  These artifacts are coming from image reconstruction process. These can been seen as poor pixel or voxel accuracy. These can been seen as less homogenous image.

- **Ring artifacts;**
  Ring artifacts can be seen as light/dark circles in axial views. There artifacts are caused by sensor and image reconstruction process.

- **Motion artifacts;**
  These artifacts can be seen as shadows in the image, eg. there is double anatomical structure seen in the image. These artifacts are due to patient movement during the scan or external movement during the scan (the vibration of ground or walls) or sometimes technical issues with device.

  If there are any noticeable artifacts, check the installation and calibration of the 3D device.

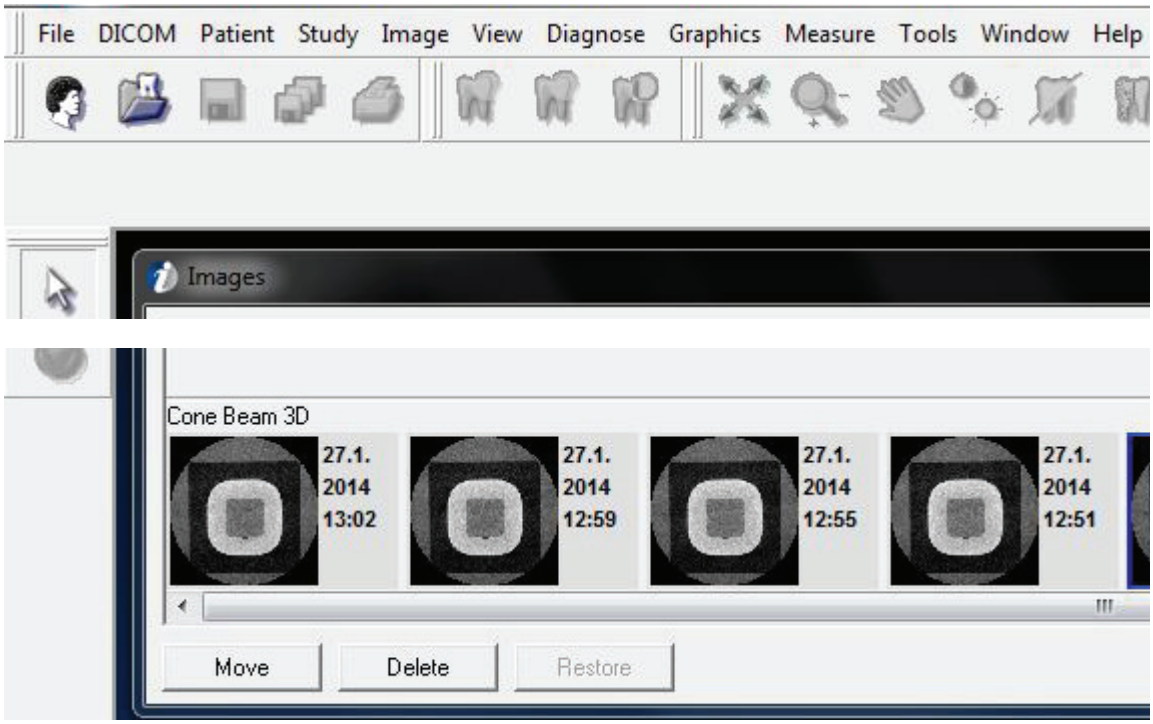
10. Take two (2) additional 3D exposures of the phantom using the same 3D imaging program. They will be saved in the same Patient as the previous image. Check each exposure for artifacts.

11. After the three 3D images have been saved in CLINIVIEW software they must be exported as DICOM format so that the QUART_tec software can process and check the 3D image during the acceptance test.

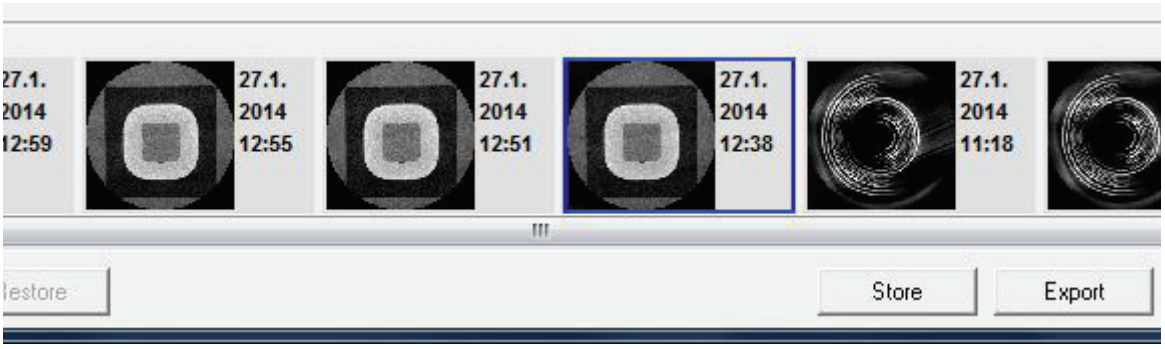
2.7 Export images from CLINIVIEW sw to DICOM format

1. If not already open, open the CLINIVIEW software **Patient** (card) where the Acceptance test 3D images were saved,
   e.g. **ACCEPTANCE_TEST**.

2. Open the **Images** selection window.

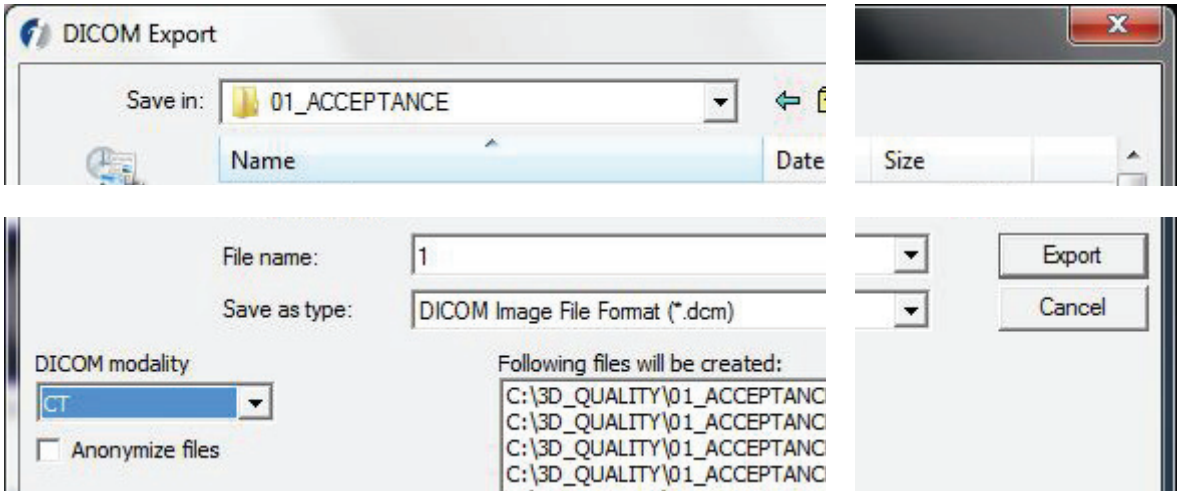


3. Click and select the three thumbnail 3D images of the previously taken QUART_ap phantom.



4. Click **Export**.

5. The DICOM export window will appear. From the **Save in** field select the folder, previously created in the PC connected to the device, in which you wish to save the DICOM files, e.g. **3D_QUALITY \ 01_ACCEPTANCE**.

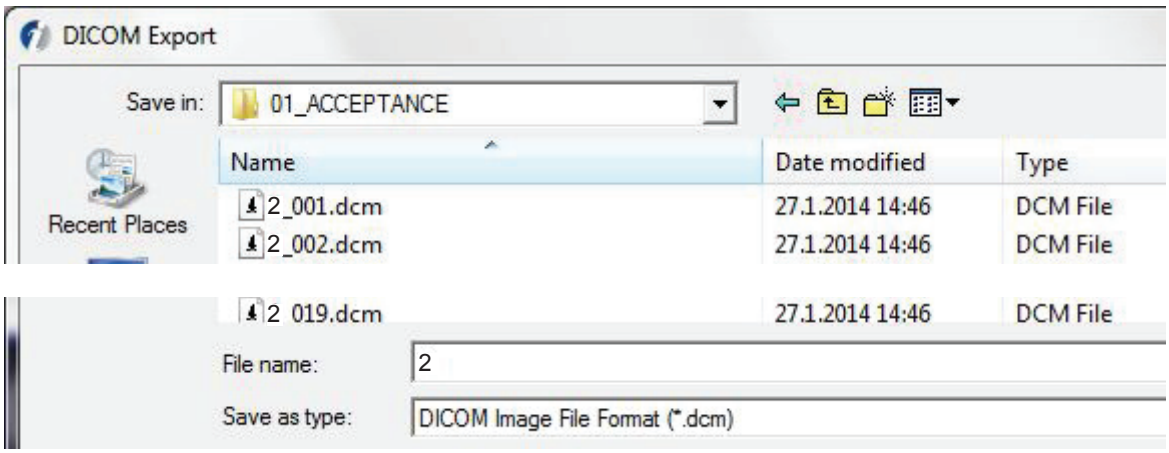


From the **DICOM modality** menu select **CT**.

In the **File name** field key in a name, for example **1**, that will be given to the first set of DICOM files to be exported. Click **Export**.

6. The three 3D phantom images will be exported, one by one, from CLINIVIEW software as DICOM format files.

   As each of the 3D phantom image is exported, messages will appear requesting new **File names** for each set of DICOM files. Give each set a different file name so that they can be easily identified later.
   For example use file names (**1**), **2** and **3**.



   Each horizontal layer will be saved as a separate DICOM format file.

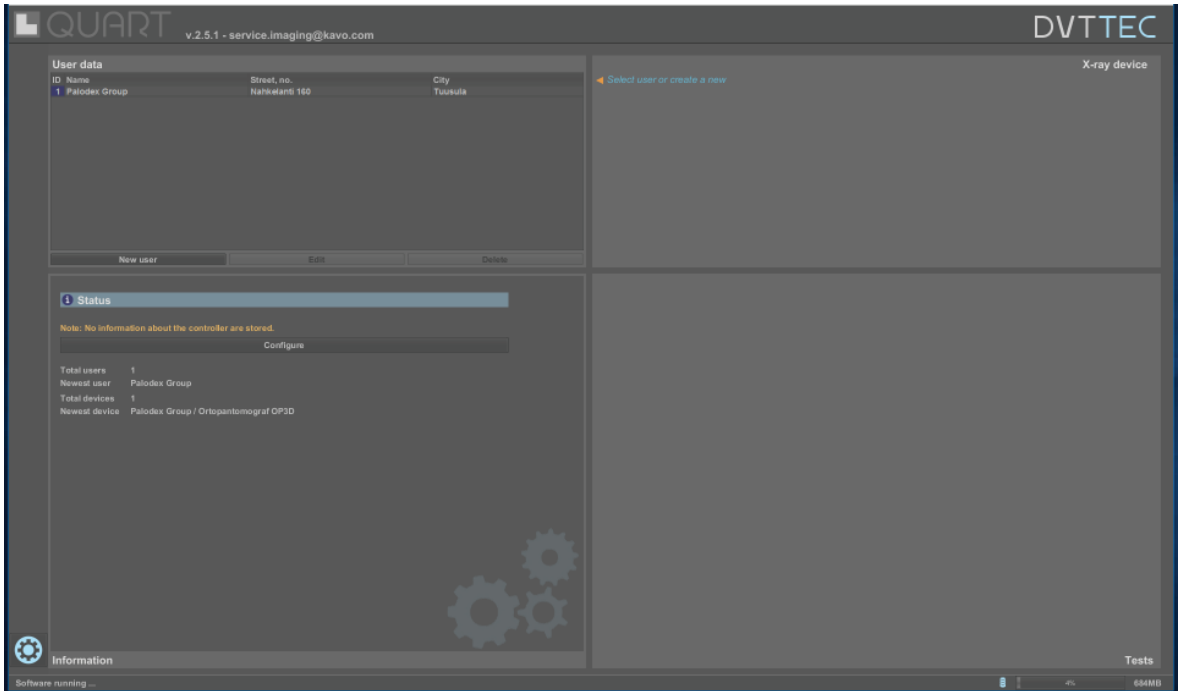
7. The QUART_tec software must now be opened and used to carry out Acceptance tests on the three 3D phantom images.

2.8 Carrying out the Acceptance test

The Acceptance test must be carried out on each of the three (3) 3D phantom exposures.
The QUART_tec software is used to examine the DICOM files to check and evaluate the 3D image quality of the device.

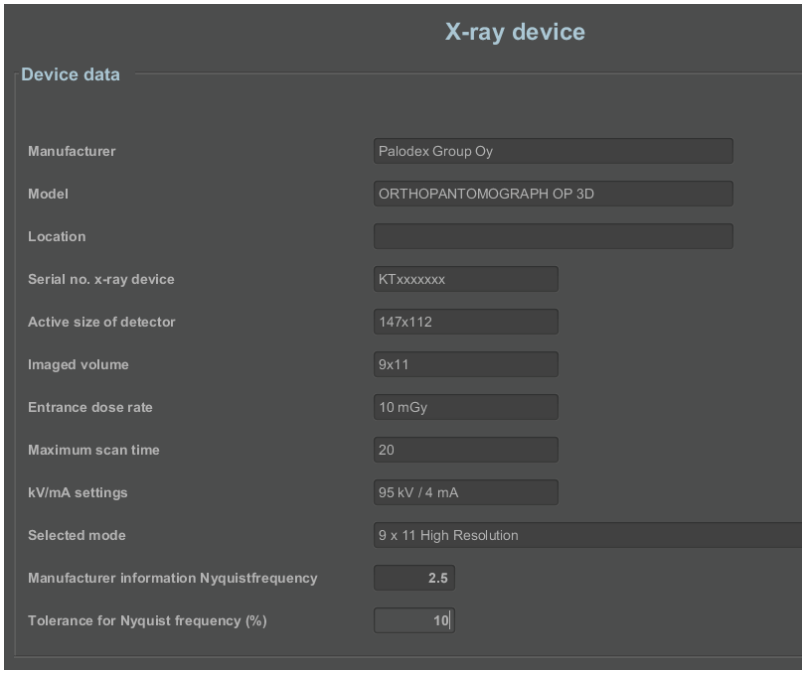
NOTICE! *For more information about the QUART_tec software, refer to the documentation supplied with the software.*

1. **PC:** Open the QUART_tec software.
   The main menu window will appear.



2. Create a new user or select an existing user.

3. Add a new device.

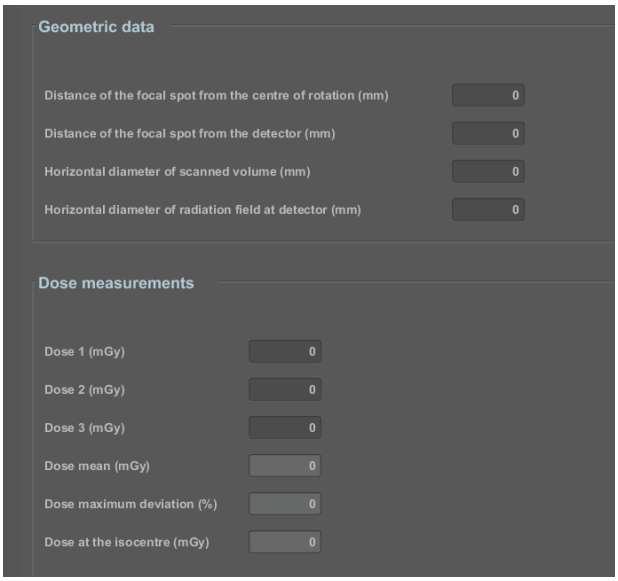


Device data:

Manufacturer: ***Palodex Group Oy***
Model: ***ORTHOPANTOMOGRAPH OP 3D***
Location: ***Installation location***
Serial no. x-ray device: ***KTxxxxxxx***
Active size of detector: ***147 x 112 mm***
Imaged volume: ***9 x 11 cm***
Entrance dose rate: ***10 mGy***
Maximum scan time: ***20 s***
kV/mA settings: ***95 kV / 4 mA***
Selected mode: ***9 x 11 High Resolution***
Manufacturer information Nyquist frequency: ***2.5***
Tolerance for Nyquist frequency (%): ***10***

Click **Save and close.**

4. Select Perform device test and input the geometric data of the device and dose measurements.



Geometric data:

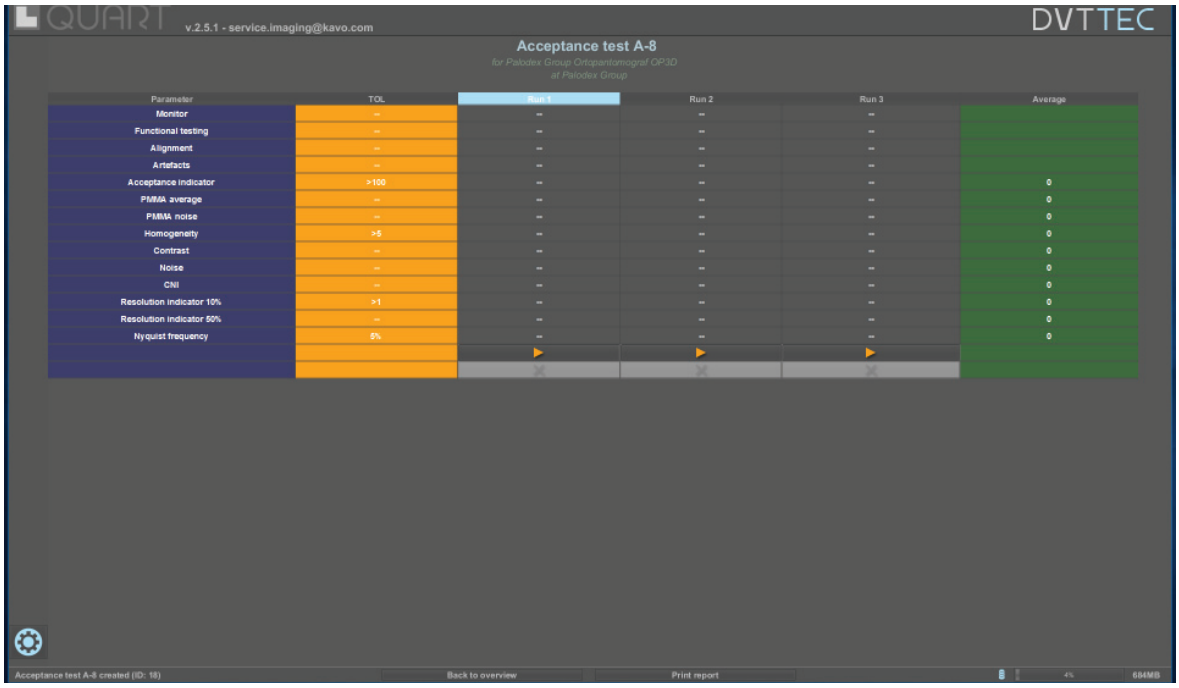
Distance of the focal spot to the center of rotation (mm): ***360***
Distance from the focal spot to the detector (mm): ***580***
Horizontal diameter of scanned volume (mm): ***110***
Horizontal diameter of radiation field at the detector (mm): ***176***

Dose measurements:
Enter the previously recorded dose measure ments into the appropriate fields. The values in the other field will be automatically calculated after the dose measurements have been entered.

Click **Save and close**.

5. Click **Perform acceptance test**.

6. The Acceptance test page will open.

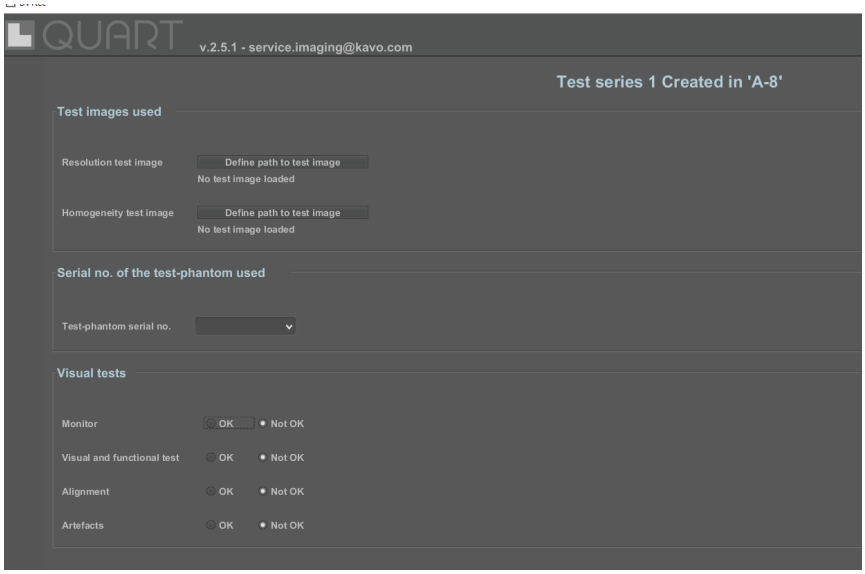


Tests (Run 1, 2 & 3) have to be carried out on the three 3D phantom images (DICOM image sets) so that the QUART_tec software can calculate the average values.

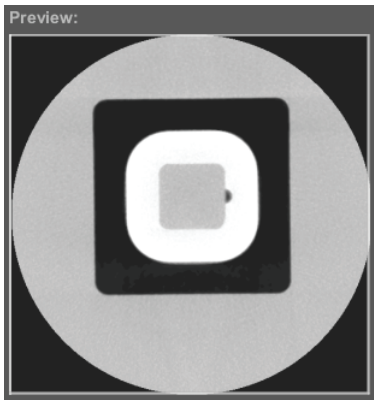
To carry out the tests, follow the information below and the software on screen instructions. Additional information can also be found in the QUART_tec User guide.

Click the ► button in the column 1 to start the first test of the first exposure.

7. Fill the form and load the test images.



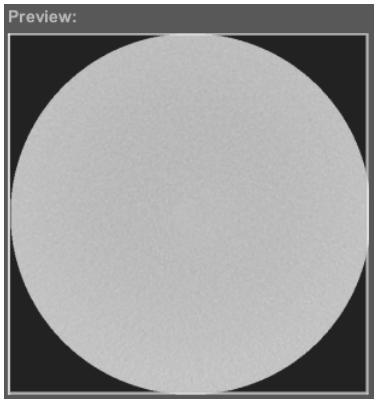
Resolution test image
Define path for the **test phantom image**. This image is one DICOM file (horizontal image) from the first set (**1**) of DICOM files saved in the folder **01_ACCEPTANCE**.
From DICOM file set **1** select file which shows the ***resolution test objects clearly***.



NOTICE! *Use the image Preview to see which layer file is best usable for the resolution test.*

NOTICE! *Write the layer file number down, e.g. 1_85.dcm, as the same layer files must be used for the two additional tests also.*

Homogenity test image
Define path for the **test phantom image**. This image is one DICOM file (horizontal image) from the first set (**1**) of DICOM files saved in the folder **01_ACCEPTANCE**.
From DICOM file set **1** select file which shows the ***acrylic part of the phantom as homogenic as possible***.



NOTICE! *Use the image Preview to see which layer file is best usable for the homogenity test.*

NOTICE! *Write the layer file number down, e.g. 1_300.dcm, as the same layer files must be used for the two additional tests also.*

8. When all required information is entered, the **Start test series** button activates. Click the button to start the test.

9. Carry out the above test for the other two (2) 3D images, columns Run 2 and Run 3 on the Acceptance test page.

   IMPORTANT NOTE! When defining images for the tests, make sure that you select the DICOM file from the correct set of DICOM files saved in the folder **01_ACCEPTANCE,** e.g.:
   - Run 2 - images **2_85.dcm** and **2_300.dcm**
   - Run 3 - images **3_85.dcm** and **3_300.dcm**

10. If the results obtained from the Acceptance tests are NOT within the limits shown in the Acceptance test table, the device must be recalibrated or serviced.

11. When you have completed the Acceptance tests click the **Print report** button to produce a report of the test.

12. Print file and store a hard copy of the Acceptance test report.

3. The Reference value test

3.1 General information

To get accurate Reference values **three** (3) 3D images of the QUART_kp phantom must be taken. The three 3D exposures are then examined using 3D viewing software and average values (the Original Data Set) are calculated by the QUART_ pro software and then showed as reference values in the constancy test series.

Refer to **DIN 6868-15** for more information.

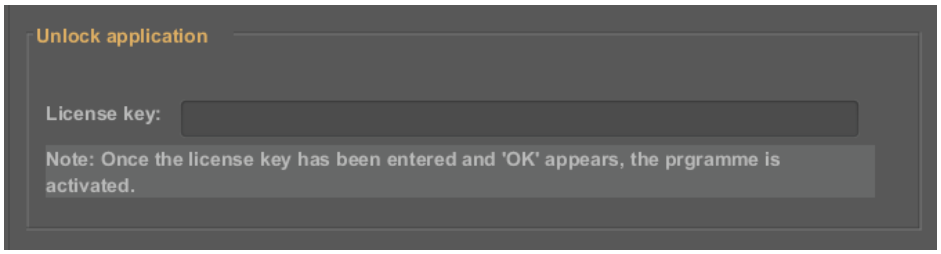
NOTICE! *The QUART software related instructions may not be in line if you are using a different software version. In such cases, refer to QUART software manual for accurate information on the software usage.*

3.2 Installing the QUART_pro software

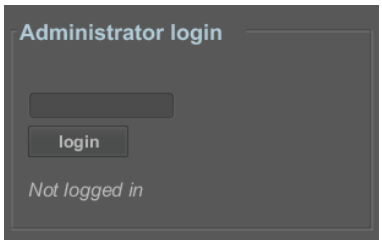
1. Install the QUART_pro software into the PC connected to the device if it has not yet been installed.

2. Start the program and press the setup button in the lower left corner. A new settings window will open.

3. Register the software by entering the licence key into the Licence key field. The software requires separate licences for each device it is used with so make sure that you register it to the correct PC.



NOTICE! *The software and it's functions can be tested without registering the software.*

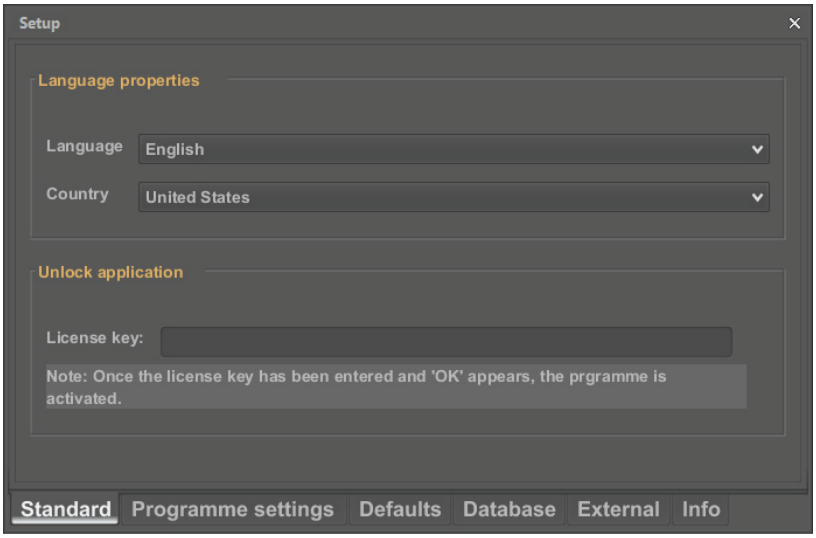


4. Close the setup window and login.

   NOTICE! *The login credentials are supplied with the phantom.*

3.3 Setting up the QUART_pro software

The Quart_pro setup menus can be used to setup the software according to the usage.
The setup window is opened by clicking the setup button in the lower left corner of the main view.



Standard:
The standard view of the settings is used to setup the language and enter your license key. It is adviced to enter the license key before the first use of the software.

NOTICE! *To obtain the license key, see* ***Appendix A****.*

Programme settings: (optional)
This menu is used to choose the decimal places for the display of results, the monitor where you would like to start the program (in case you have multiple monitors connected) and the bit depth of the image.

Defaults: (recommended)
The first panel (test series) is used to choose the default values for the result of the visual test (display system, positioning and artifacts). If the results for these tests are passed in most cases, choose the default to be “yes“. You will be asked to confirm this information before every test series.

In the panel below (test sequence), you can choose between manually positioning the ROIs (USER) for the image quality evaluation or automatically positioning of the ROIs by the software (AUTO). It is recommended to use the AUTO mode only after the user has become familiar with the software.

The menu also allows to turn the Nyquist ROI position test on or off. It is recommended to leave this setting ”on” because this will alert the user when the ROI for calculation of the Nyquist frequency is misplaced.

Database: (optional)
You can specify the path for a folder where your database should be stored.

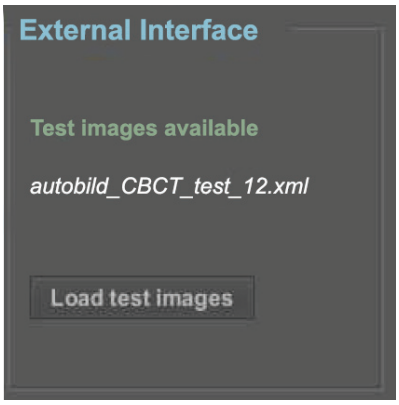
External: (optional)
You can choose an XML file to upload specific images into the software. If you use this feature together with the AUTO mode, results for many scans can be obtained in an extremely quick and organized fashion.

1. Modify the XML template, found in QUART documentation, to contain the path to your DICOM files (the homogenity image and the contrast/MTF image).

2. Save the XML file in your hard drive.

3. Set “turn on script” to YES.

4. Click on the file panel to browse your computer and select the XML file.



When you start a test, the external interface will display the message “Test images available“ and the name of your XML file.

Click **Load test images** button and proceed with the test.

For more information on the XML script option, contact QUART for support.

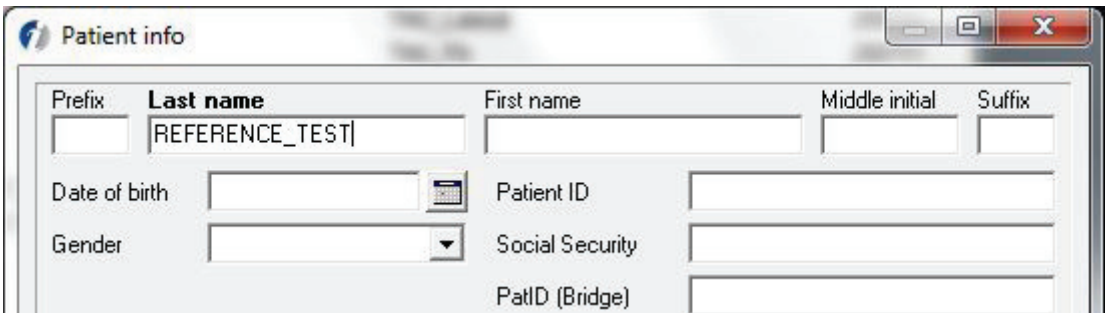
3.4 Preparing the device for the Reference value test

1. Calibrate the 3D device, if it has not already been done.
   Refer to the device manuals for information on how to do this.

2. Calibrate the display monitor that is used with the 3D device if that has not already been done.
   Refer to the monitor/software manuals for information on how to do this.

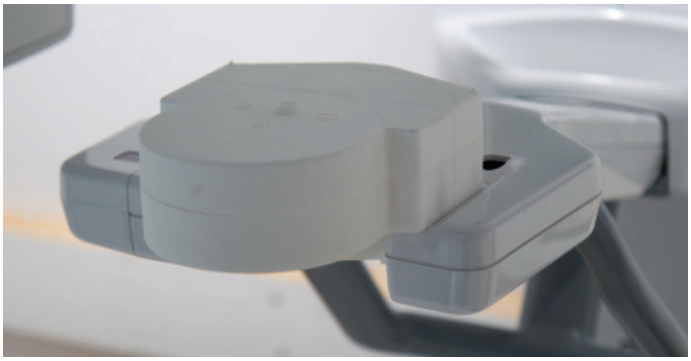
3. Start CLINIVIEW software and create a **Patient** (patient card) where the 3D images from the Reference test can be stored.
   Give it a name that makes it easy to identify, e.g. **REFERENCE_TEST**

   Refer to the **CLINIVIEW User Manual** for information on how to do this.

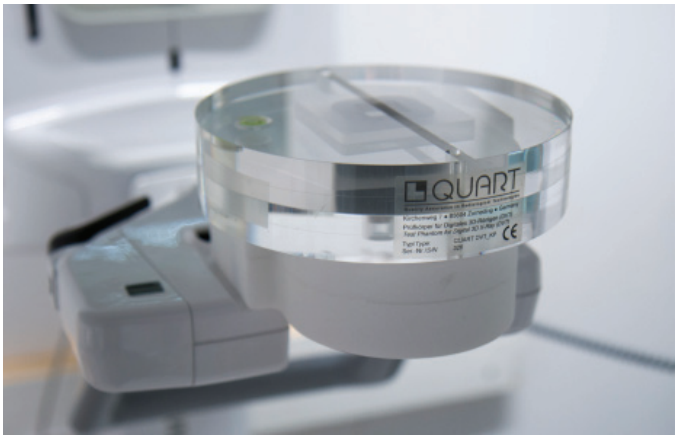


3.5 Taking an exposure of the QUART_kp phantom

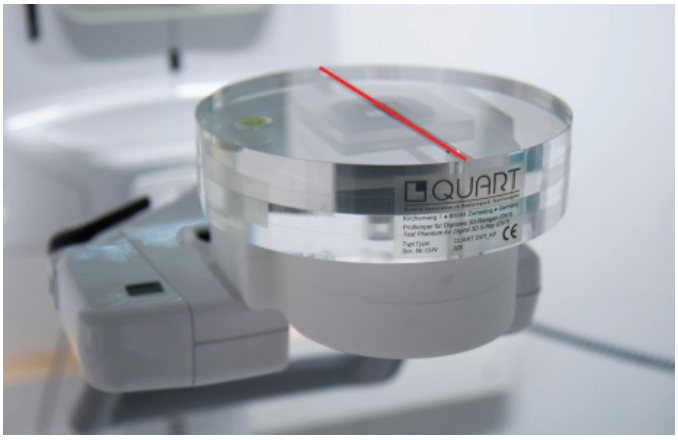
1. Attach the 3D QC phantom holder to the lower shelf of the device.



2. Place the QUART_kp phantom to the 3D QC phantom holder.



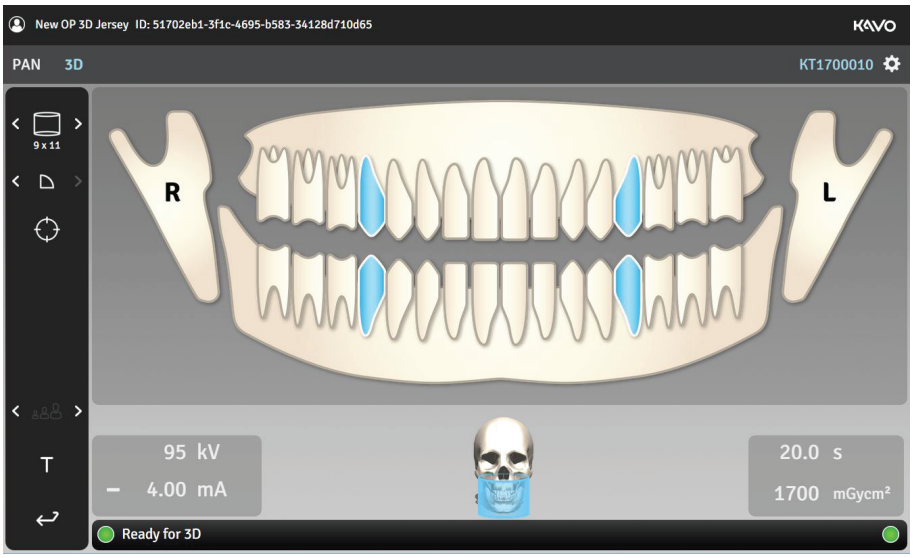
3. Adjust the phantom so that its center line lines up with the midsagittal light of the device.

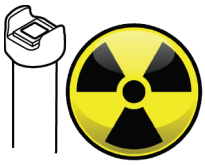


4. Prepare the device for imaging.
   Refer to the OP 3D User and Installation manual for information on how to do this.

5. **GUI:** Select 3D imaging modality and the following imaging factors:

   • Select the second premolars from dental chart
   • Disable Scout imaging
   • Select high resolution setting
   • Set 4.00 mA





5. **PROTECT YOURSELF FROM RADIATION**
   Take a 3D exposure of the phantom.
   Press and hold down the exposure switch for the duration of the exposure.

   The 3D image will be saved in Patient (card) previously created, **REFERENCE_TEST**.

6. After the exposure, open the 3D imaging program if it does not automatically open (depends on the program settings).
   Select the axial view and scroll through the 3D volume to see if there are any artifacts that could effect 3D image quality.
   Make a note of any artifacts that are present.

For a description of artifacts, refer to the Acceptance test **2.5 Taking an exposure of the QUART_ap phantom**.

If there are any noticeable artifacts check the installation and calibration of the 3D device.

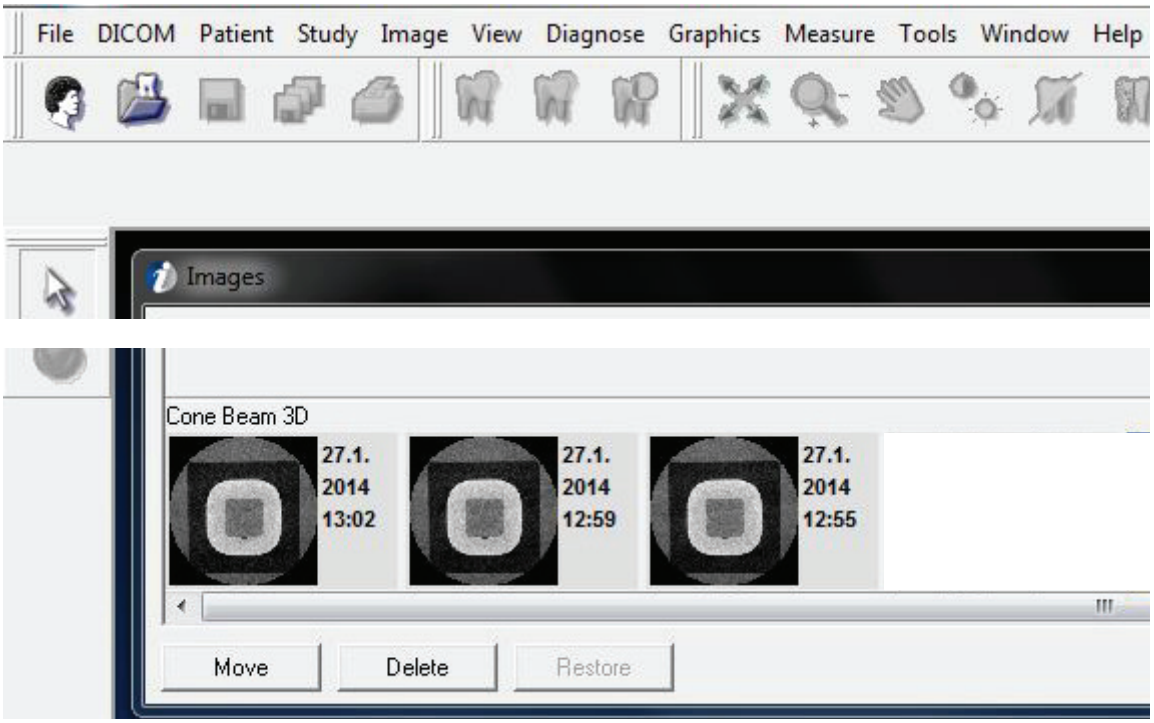
7. Take two (2) additional 3D exposures of the phantom using the same exposure values. They will be saved in the same Patient as the first image.
   Check each exposure for artifacts.

8. After the three 3D images have been acquired they must be exported from CLINIVIEW software and saved as DICOM format so that the QUART_pro software can process and check the 3D images and produce Reference values for the Constancy test.

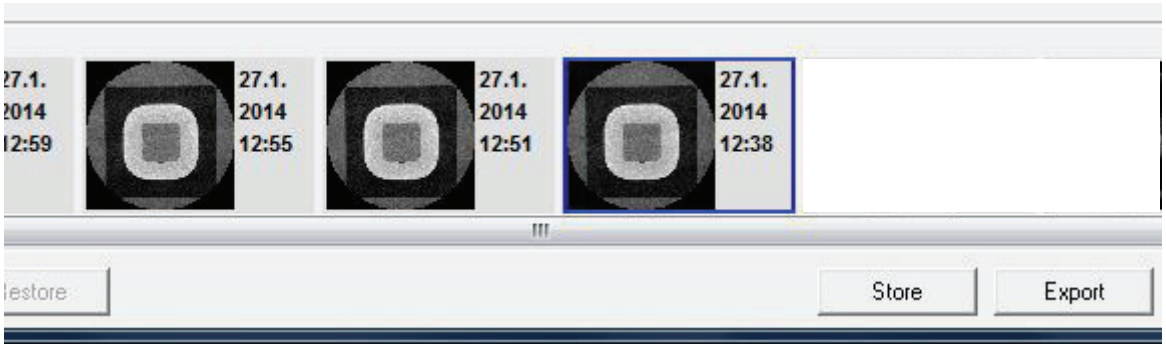
3.6 Export images from CLINIVIEW sw to DICOM format

1. If not already open, open the CLINIVIEW software **Patient** (patient card) where the three Reference test 3D images were saved, e.g. **REFERENCE_TEST**.

2. Open the **Images** selection window.

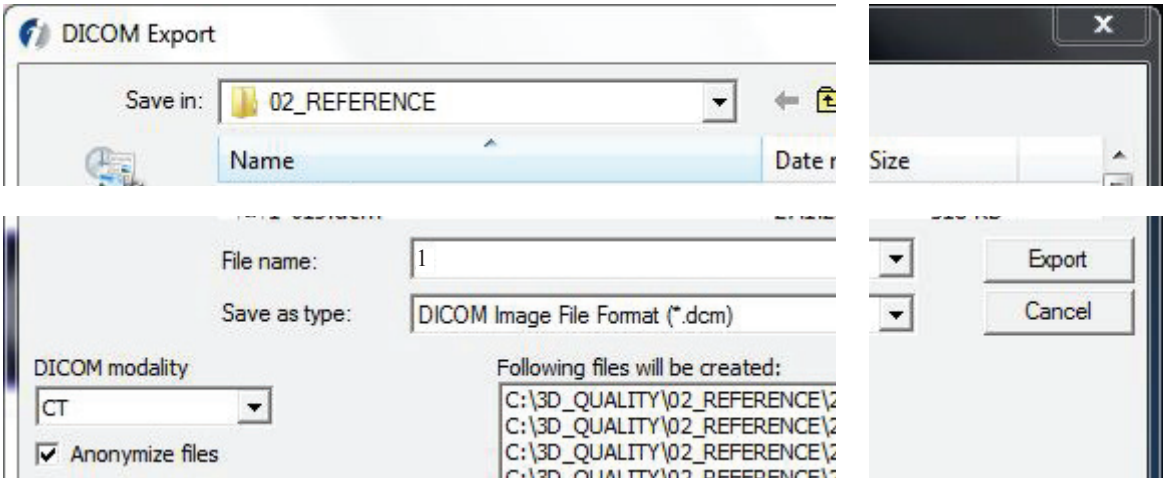


3. Click and select the three thumbnail 3D images of the previously taken QUART_kp phantom.



Click **Export**.

4. The DICOM export window will appear. From the **Save in** field select the folder, previously created in the PC connected to the device, in which you wish to save the DICOM files, e.g. **3D_QUALITY \ 02_REFERENCE**.

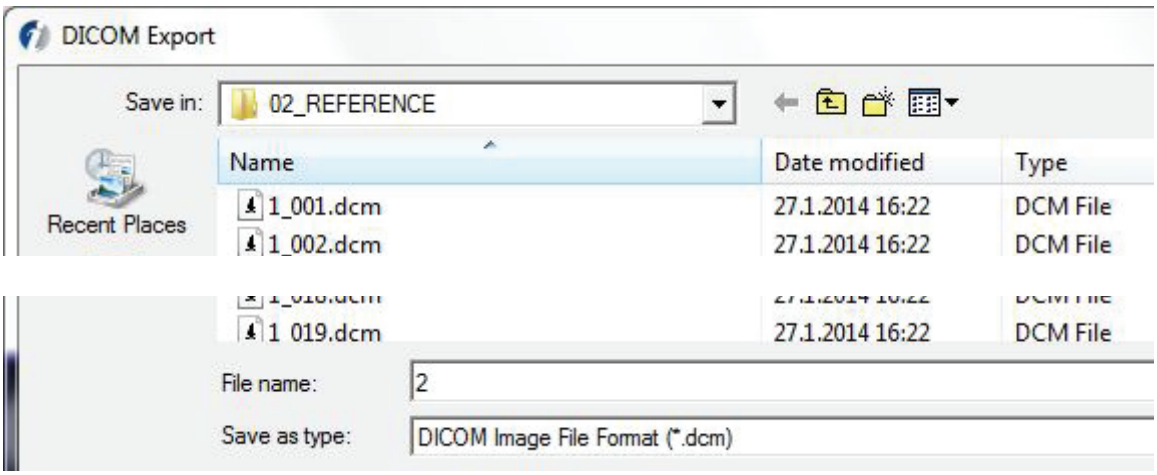


From the **DICOM modality** menu list select **CT**.

In the **File name** field key in a name, for example **1**, that will be given to the first set of DICOM files to be exported. Click **Export**.

5. The three 3D phantom images will be exported, one by one, from CLINIVIEW software as DICOM format files.

   As each of the three 3D phantom image is exported, messages will appear requesting new **File names** for each set of DICOM files. Give each set a different file name so that they can be easily identified later.
   For example use file names (**1**), **2**, **3**.



   Each horizontal layer will be saved as a separate DICOM format file.

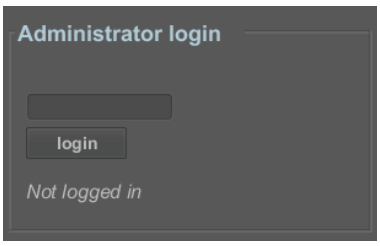
6. The QUART_pro software must now be opened and used to carry out Reference value tests on the three 3D phantom images.

3.7 Carrying out the Reference Value test

The Reference value test must be carried out on each of the three (3) 3D phantom exposures.
The QUART_pro software is used to examine the DICOM files and calculate Reference values for the Constancy test.

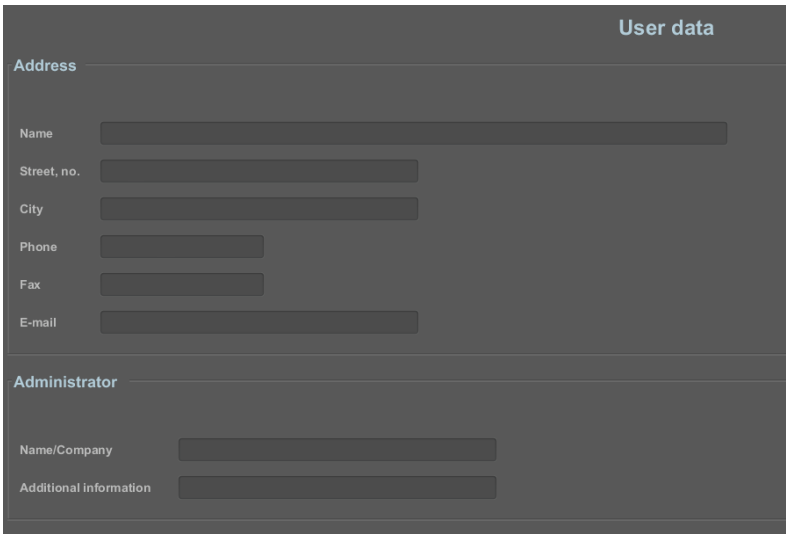
NOTICE! *For more information about the QUART_ pro software, refer to the documentation supplied with the software.*

1. Open the QUART_pro software and login.



2. Create a new user by clicking the **Create new user** button.

3. The User Data view will appear.

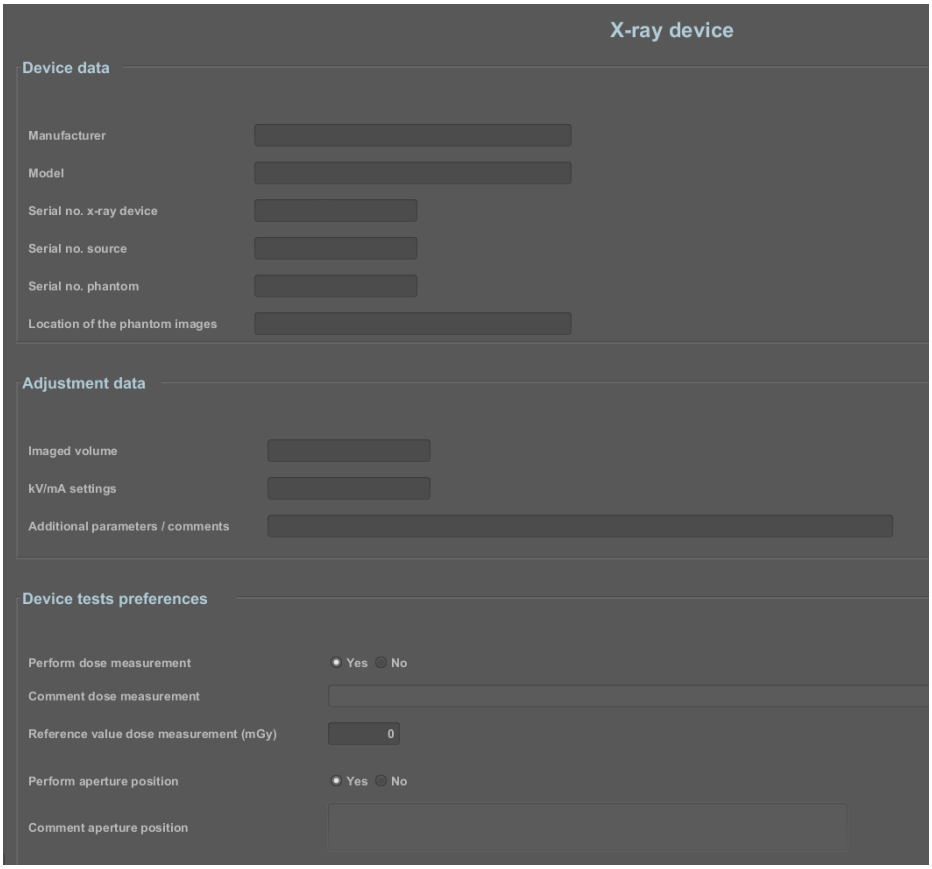


Enter the information about the user or clinic where the device is installed.

4. Click **Save & Close** to save the information.

5. Create a new device data by clicking the **Create new device data** button.

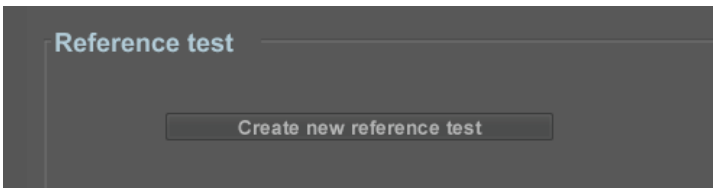
6. The X-ray device view will appear.



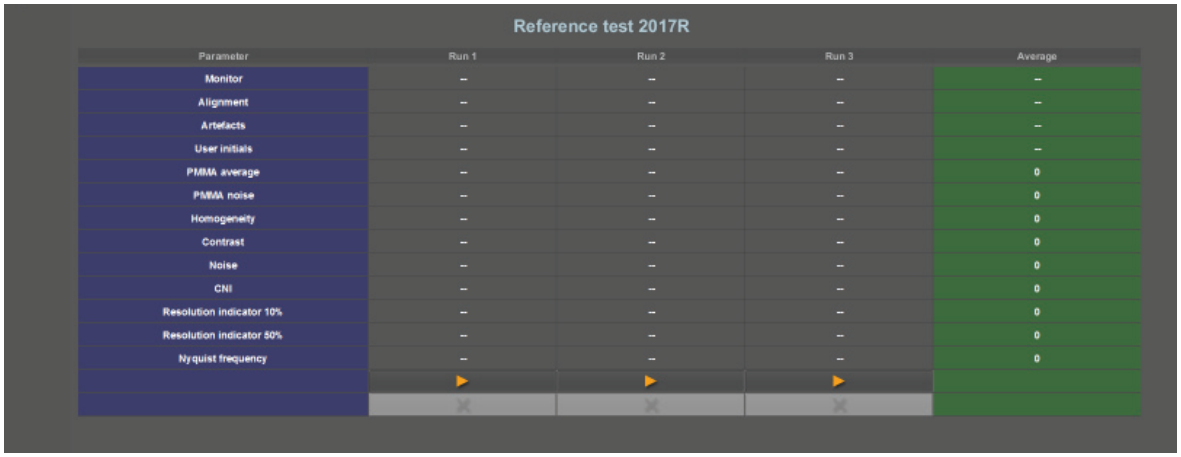
Enter the same device information as you entered in the Acceptance test user and device page. See **2.7 Carrying out the Acceptance test.**

7. Click **Save & Close** to save the information.

8. The reference value test can now be performed. Click **Create new reference test** button.



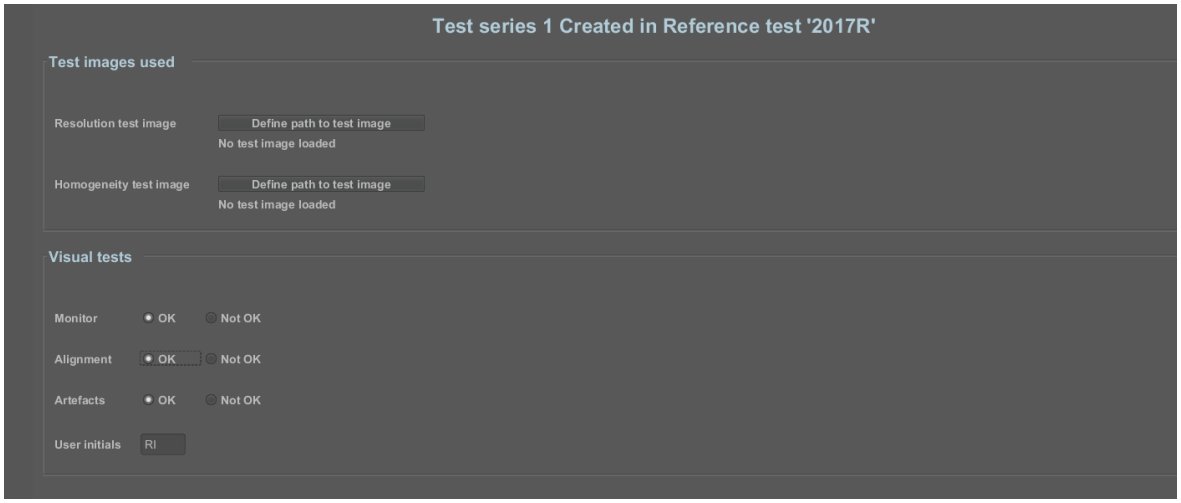
9. The Reference value test view will appear.



10. The list of test parameters is shown on the left column and must be obtained using three different image series from the X-ray device.

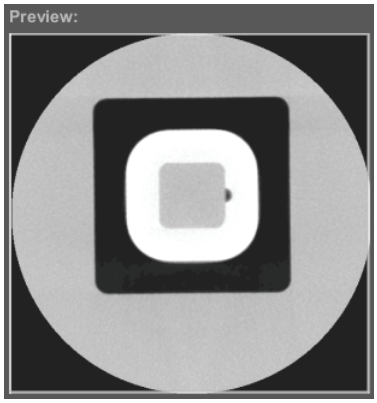
    To perform the first test, click the ► button in the Run 1 column.

11. The Test series 1 view will appear.



12. Load phantom images by clicking the **Define path to test image** buttons in the “Test images used” menu.

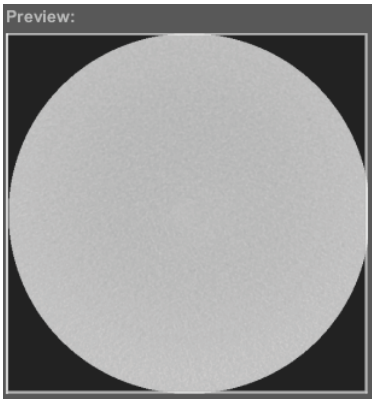
    Resolution test image
    Define path for the **test phantom image**. This image is one DICOM file (horizontal image) from the first set (**1**) of DICOM files saved in the folder **02_REFERENCE**.
    From DICOM file set **1** select file which shows the ***resolution test objects clearly***.



NOTICE! *Use the image Preview to see which layer file is best usable for the resolution test.*

NOTICE! *Write the layer file number down, e.g. 1_330.dcm, as the same layer files must be used for the two additional tests also.*

Homogenity test image
Define path for the **test phantom image**. This image is one DICOM file (horizontal image) from the first set (**1**) of DICOM files saved in the folder **02_REFERENCE**.
From DICOM file set **1** select file which shows the ***acrylic part of the phantom as homogenic as possible***.



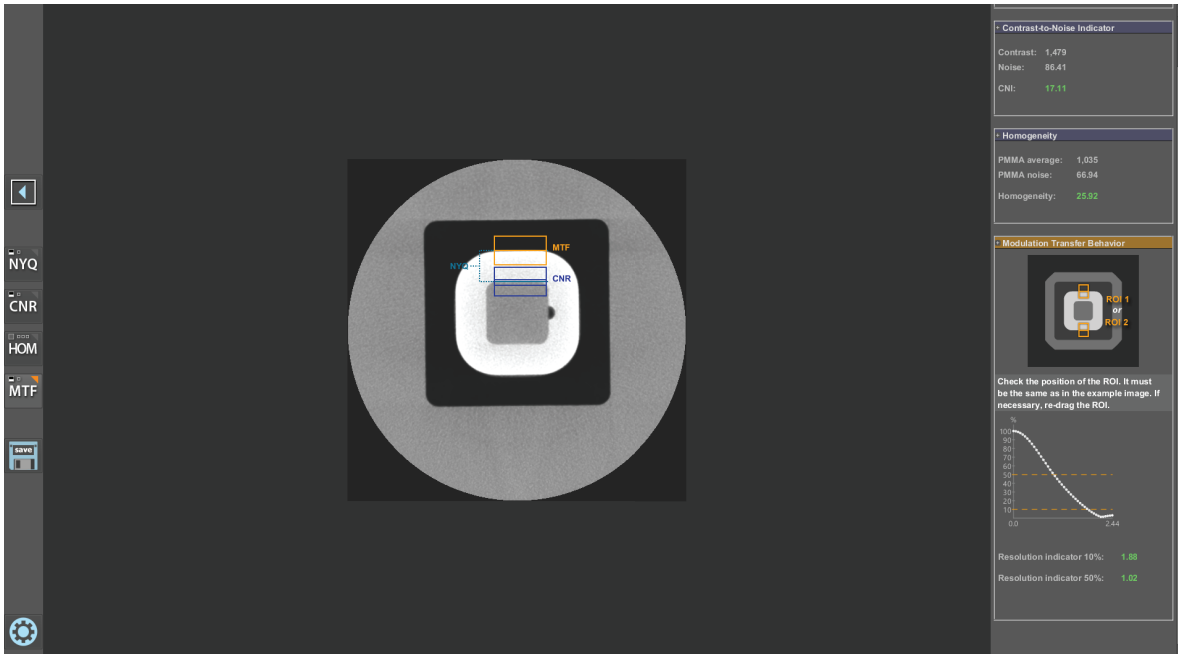
NOTICE! *Use the image Preview to see which layer file is best usable for the homogenity test.*

NOTICE! *Write the layer file number down, e.g. 1_420.dcm, as the same layer files must be used for the two additional tests also.*

13. Before starting the actual software assisted image quality evaluation, check the Monitor, Alignment and Artifacts sections as OK or Not OK, based on the monitor calibration, phantom alignment and artifact inspection procedures described in sections **3.4 Preparing the device for the Reference value test** and **3.5 Taking an exposure of the QUART_kp phantom**. If the DICOM slice images were taken performing the required steps, select OK and enter your initials to guarantee that the visual tests are performed.

14. Click **Start test series** button.

15. The Reference test view will appear.



Perform the tests by following the instructions on the right side of the screen and select different test programs using the buttons on the left side of the screen.

16. After you have performed all of the tests and gained the test values from them, click the **Save** button to go back to the protocol view and see the results in the corresponding column.

17. Now carry out the above tests on the remaining two 3D images, Run 2 and 3 on the Reference value test view.

IMPORTANT NOTE! When defining images for the tests, make sure that you select the DICOM file from the correct set of DICOM files saved in the folder **02_REFERENCE,** e.g.:
- Run 2 - images **2_330.dcm** and **2_420.dcm**
- Run 3 - images **3_330.dcm** and **3_420.dcm**

18. When you have completed the three Reference value tests you can click **Back** to return to the main view or click the **Print report** button to produce a report of the test.

    NOTICE! *It's recommendable to print a hard copy of the test report for archiving.*

19. After the Reference tests, carry out a Constancy test to demonstrate the test to the user.

4. The Constancy test

4.1 General information

The Constancy test is carried out regularly to ensure that 3D image quality remains consistent throughout the operating life of the device.

The values obtained from the Constancy test are saved in the Constancy test tables.
The values obtained from the Constancy test must be compared to the values obtained from the Reference value test.

Refer to **DIN 6868-15** for more information.

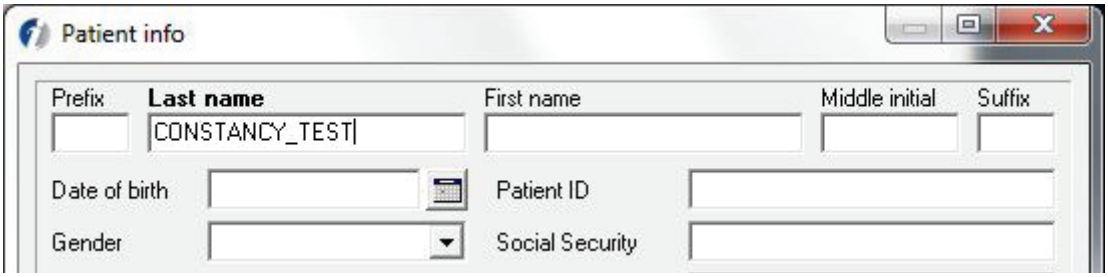
NOTICE! *The QUART software related instructions may not be in line if you are using a different software version. In such cases, refer to QUART software manual for accurate information on the software usage.*

4.2 Preparing the device for the Constancy test

1. Calibrate the display monitor that is used with the PC connected to the 3D device, if that has not already been done.
   Refer to the monitor/software manuals for information on how to do this.

2. Start CLINIVIEW software and create a **Patient** (patient card) where the 3D images from the Constancy test can be stored.
   Give it a name that makes it easy to identify, e.g. **CONSTANCY_TEST**

   Refer to the **CLINIVIEW User Manual** for information on how to do this.



4.3 Taking an exposure of the QUART_kp phantom

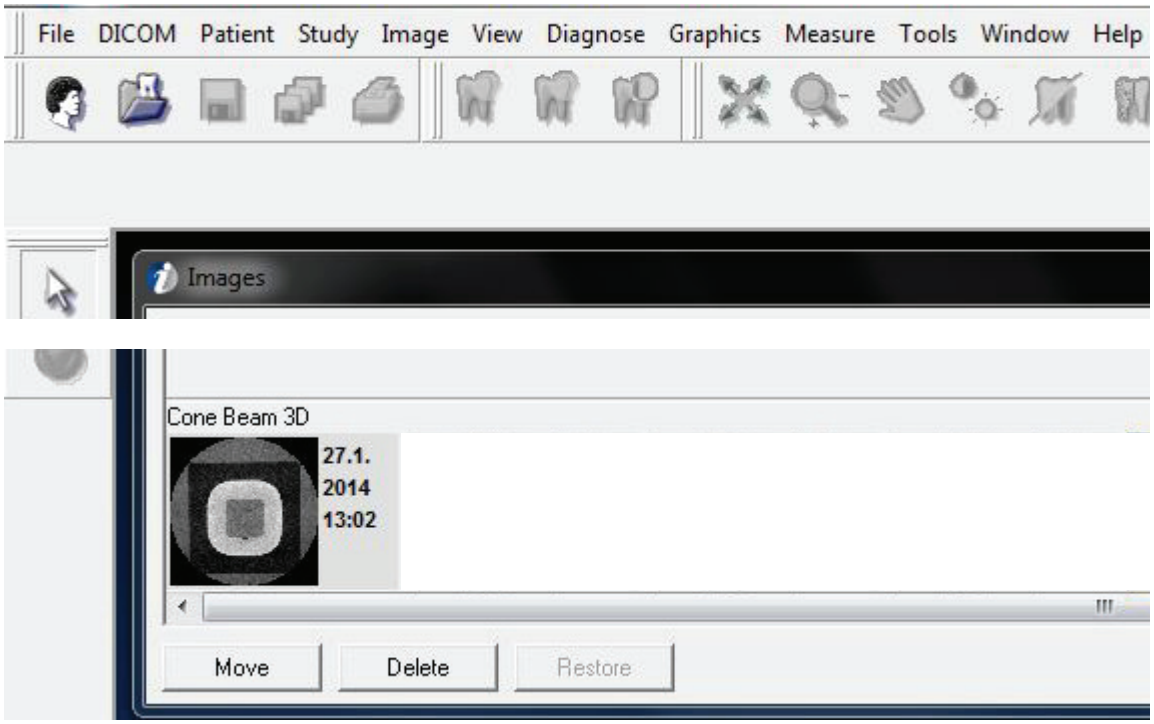
Take a single (1) exposure of the phantom in the same way as described in the Reference value test, see chapter **3.5 Taking an exposure of the QUART_kp phantom**.
Use the same positioning and the same exposure values.

Check the image for artifacts. For a description of artifacts, refer to chapter ***2.6 Taking an exposure of the QUART_ap phantom*.**

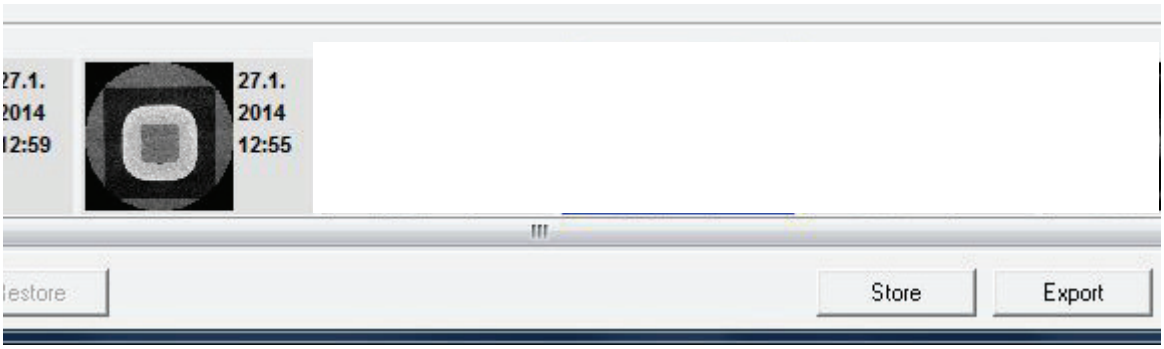
4.4 Export images from CLINIVIEW sw to DICOM format

1. If not already open, open the CLINIVIEW software **Patient** (patient card) in where the Constancy **test** 3D image was saved e.g. **CONSTANCY_TEST**.

2. Open the **Images** selection window.

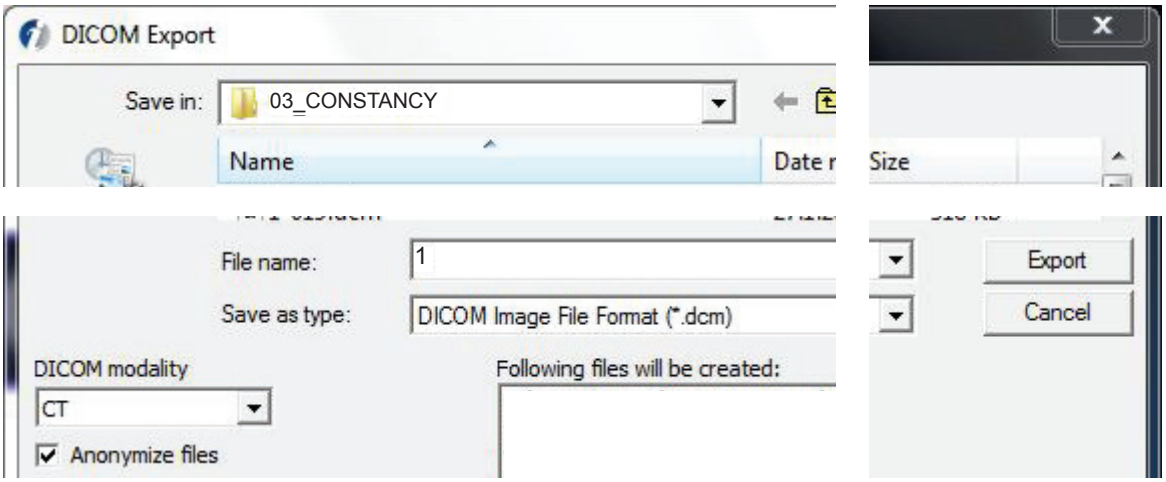


3. Click and select the thumbnail 3D image of the previously taken QUART_kp phantom.



Click **Export**.

4. The **DICOM export** window will appear. From the **Save in** field, select the folder previously created in the PC connected to the 3D device, in which you wish to save the DICOM files, e.g. *3D_QUALITY/03_CONSTANCY*.



From the **DICOM modality** menu list select **CT**.

In the **File name** field key in a name, for example **1**, that will be given to the set of DICOM files to be exported. Click **Export**.

NOTICE! *It's a good practice to name the set as per month/week. For example 1 for January/ Week 1 etc.*

5. The 3D phantom image will be exported from CLINIVIEW software and saved as DICOM format files.

   Each horizontal layer will be saved as a separate DICOM format file.

   NOTICE! *If there is a previously exported set of DICOM images there will be a prompt to overwrite them.*

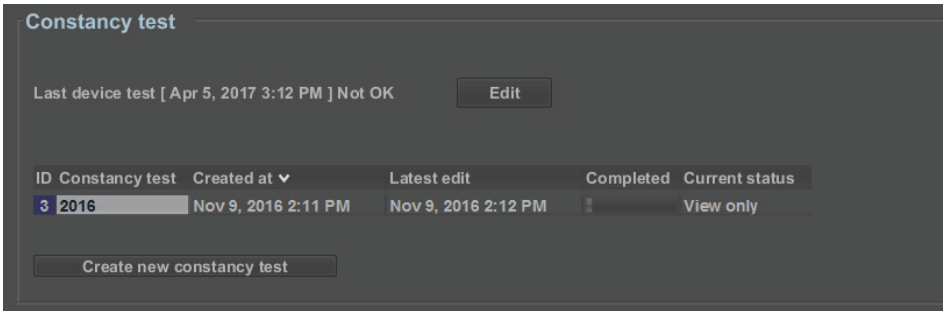
6. The QUART_pro software must now be opened and used to carry out a Constancy test on the 3D phantom image.

4.5 Carrying out the Constancy test

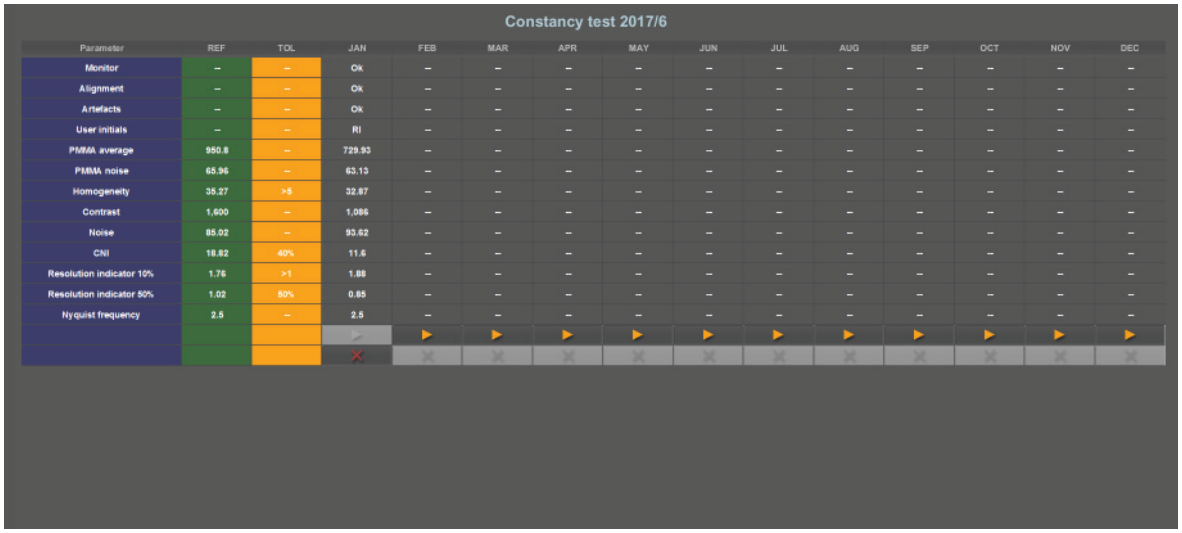
The Constancy test must be carried out on the 3D exposure of the QUART_kp phantom.

NOTICE! *For additional information on the QUART_pro software, refer to the documentation supplied with the software.*

1. Open the QUART_pro software and click **Create new constancy test** button to start a new constancy test or click on an existing constancy test to continue it.



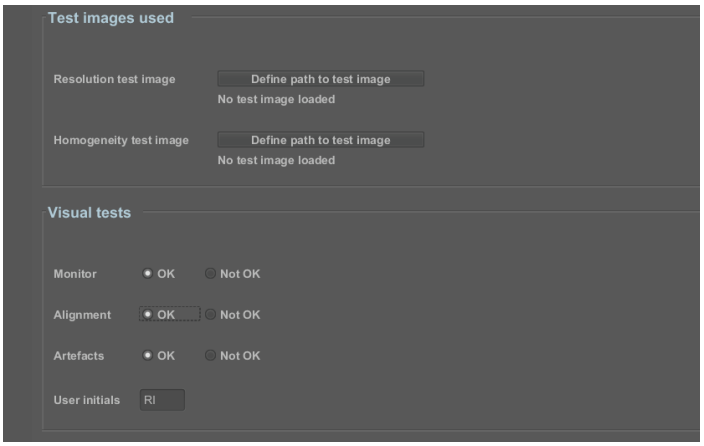
2. The **Constancy test** view appears



The REF column shows the values for each test based on the Reference test performed earlied. The empty columns are reserved for test data of each month, when the constancy test should be performed, to ensure that 3D image quality remains consistent.

3. Select the column of the current month and press the ► button to start the constancy test.

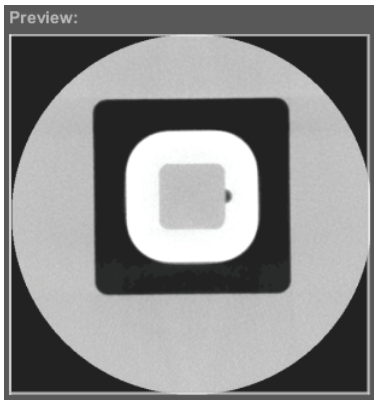
4. The **Test series** view will appear.



5. Load phantom images by clicking the **Define path to test image** buttons in the “Test images used” menu.

Resolution test image
Define path for the previously taken **test phantom image** saved in the folder **03_ CONSTANCY**, refer to chapter *4.4 Export images from CLINIVIEW sw to DICOM format*.

From the DICOM file, select the **same layer** which was used in the reference test, e.g. *330. dcm*. The file should show the **resolution test objects** clearly.



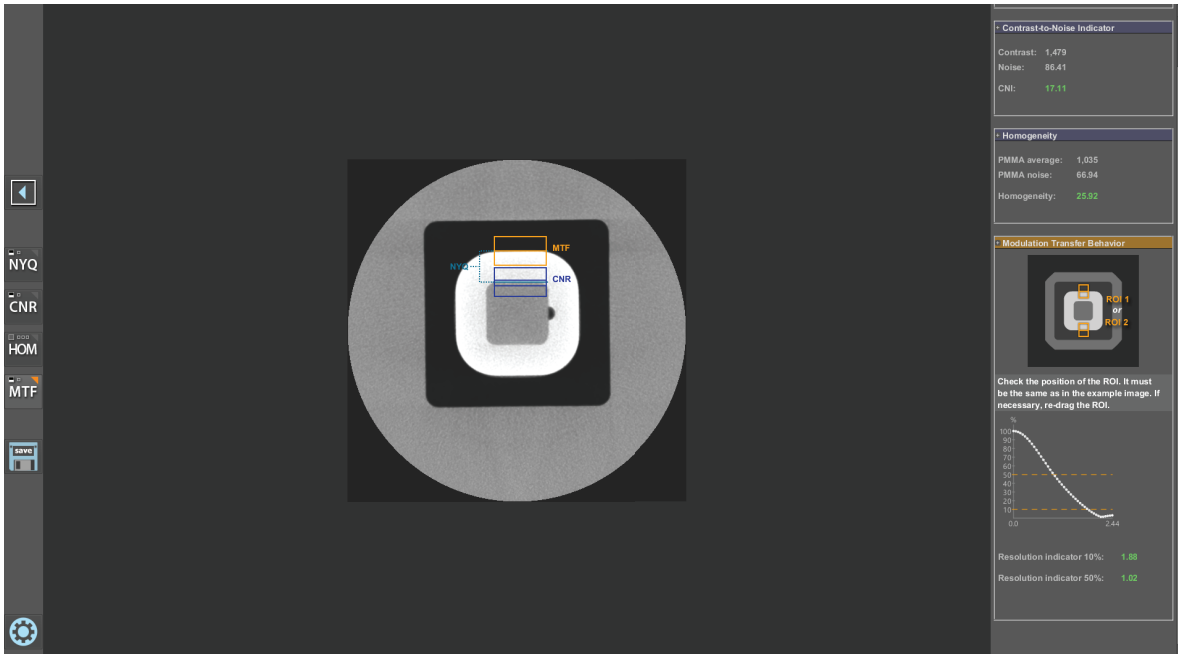
Homogenity test image
Define path for the previously taken **test phantom image** saved in the folder **03_ CONSTANCY**, refer to chapter *4.4 Export images from CLINIVIEW sw to DICOM format*.

From the DICOM file, select the **same layer** which was used in the reference test, e.g. *420. dcm*. The file should show the **acrylic part of the phantom** as homogenic as possible.

6. Before starting the actual software assisted image quality evaluation, check the Monitor, Alignment and Artifacts sections as OK or Not OK, based on the monitor calibration, phantom alignment and artifact inspection procedures described in sections **4.2 Preparing the device for the Constancy test** and **4.3 Taking an exposure of the QUART_kp phantom**. If the DICOM slice images were taken performing the required steps, select OK and enter your initials to guarantee that the visual tests are performed.

7. Click **Starts test series** button.

8. The **Constancy test** view will appear.

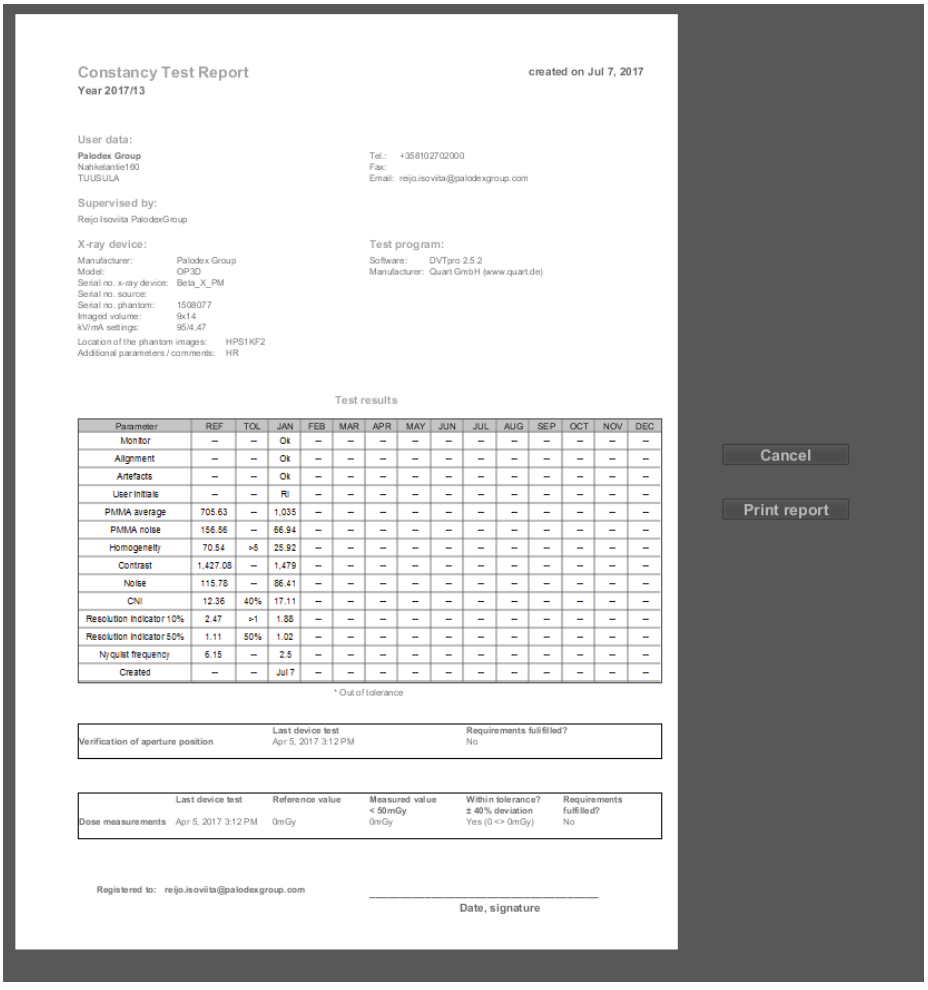


Perform the tests by following the instructions on the right side of the screen and select different test programs using the buttons on the left side of the screen.

16. After you have performed all of the tests and gained the test values from them, click the **Save** button to go back to the protocol view and see the results in the corresponding column.

    NOTICE! *If the result values are displayed in red background, it means that the results are out of the tolerance range. You can clear the test by clicking the* ***X*** *button and redo the measurements.*

17. When you have completed the Constancy test click the **print report** button. The constancy report should always be printed as a hard copy for archiving.



Constancy Test Report
Year 2017/13

created on Jul 7, 2017

User data:

Palodex Group
Nahkelantie160
TUUSULA

Tel.: +358102702000
Fax:
Email: reijo.isovita@palodexgroup.com

Supervised by:
Reijo Isovita PalodexGroup

X-ray device:

Manufacturer: Palodex Group
Model: OP3D
Serial no. x-ray device: Beta_X_PM
Serial no. source:
Serial no. phantom: 1508077
Imaged volume: 9x14
kV/mA settings: 95/4.47
Location of the phantom images: HPS1KF2
Additional parameters / comments: HR

Test program:

Software: DVTpro 2.5.2
Manufacturer: Quart GmbH (www.quart.de)

Test results

Parameter	REF	TOL	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Monitor	–	–	Ok	–	–	–	–	–	–	–	–	–	–	–
Alignment	–	–	Ok	–	–	–	–	–	–	–	–	–	–	–
Artefacts	–	–	Ok	–	–	–	–	–	–	–	–	–	–	–
User initials	–	–	RI	–	–	–	–	–	–	–	–	–	–	–
PMMA average	705.63	–	1,035	–	–	–	–	–	–	–	–	–	–	–
PMMA noise	156.56	–	66.94	–	–	–	–	–	–	–	–	–	–	–
Homogeneity	70.54	>5	25.92	–	–	–	–	–	–	–	–	–	–	–
Contrast	1,427.08	–	1,479	–	–	–	–	–	–	–	–	–	–	–
Noise	115.78	–	86.41	–	–	–	–	–	–	–	–	–	–	–
CNI	12.36	40%	17.11	–	–	–	–	–	–	–	–	–	–	–
Resolution indicator 10%	2.47	>1	1.88	–	–	–	–	–	–	–	–	–	–	–
Resolution indicator 50%	1.11	50%	1.02	–	–	–	–	–	–	–	–	–	–	–
Nyquist frequency	6.15	–	2.5	–	–	–	–	–	–	–	–	–	–	–
Created	–	–	Jul 7	–	–	–	–	–	–	–	–	–	–	–

* Out of tolerance

	Last device test	Requirements fulfilled?
Verification of aperture position	Apr 5, 2017 3:12 PM	No

	Last device test	Reference value	Measured value < 50mGy	Within tolerance? ± 40% deviation	Requirements fulfilled?
Dose measurements	Apr 5, 2017 3:12 PM	0mGy	0mGy	Yes (0 <> 0mGy)	No

Registered to: reijo.isoviita@palodexgroup.com

Date, signature

Cancel

Print report

APPENDIX A. Activating QUART_pro software

To make full use of the purchased QUART_pro software, you need to register your personal copy. To register the program you need the associated **software serial number** to acquire the software licence key.

The software serial number is contained on the **delivery slip** included with the shipment and the **shipment's invoice document**.

1. To activate the software, go to QUART license server: **http://www.quart.de/lizenz/**

2. When on the website of the license server, enter your **Name**, **Organization/Company**, **Email address** and the **Software serial number**.

3. Click "**Request license key**".

4. An automated email will be sent to the entered **email address**, providing your personal license key. The license key should be in format "*email address-serial number-XXX-XXX-XXX*"

5. Enter the license key to the software **Setup** window. If the license key is correct, text OK will appear next to the box.

   NOTICE! *Once registered, the test admin login doesn't work anymore. The correct login password for the specific license should be provided by QUART.*