X MIND trium

QUALITY ASSESSMENT MANUAL



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1. INTRODUCTION

Depending on local and national requirements, a Quality Check has to be done using the Quality Check phantoms supplied, as explained here following.

PLEASE NOTE

The Quality Assessment procedure must be carried out at the end of the installation and following servicing interventions.

It is highly recommended to perform the Quality Assessment procedure at least once per year and keep the filled in Quality Assessment Checklists together with the device records.

2. QUALITY CHECK PHANTOMS

In the following paragraphs are listed the quality check phantoms used for each quality test.

2.1 Panoramic/CEPH Quality Check Phantom

For the Panoramic and Cephalographic Quality Checks it is recommended to use the **Dental <u>Test Phantom Digital X-Ray for Intraoral, OPT and CEPH</u> applications**

(see http://quart.de/test-phantoms) (Quart dent/digitest 2D: Art. No 12107)

Description:

- Open bottom segment to easily remove the sensor after the test
- Universal design: sensor slot to accept any intra-oral sensor
- High-Quality Line Pair Test (6 Lp, 45° arrangement)
- Integrated 6mm added aluminium filtration
- Slots for digital storage screen, digital sensor and dosimeter detector
- Low-contrast test objects
- Enhanced centering aid

Furthermore, it is suggested to purchase the proper *phantom holder* for easy positioning at digital dental x-ray equipment featuring CCD or digital storage screen. In particular, the **QUART dent/digi H-Universal Test Phantom Holder** allows the ideal positioning of the dental test phantom in routine quality controls.

2.2 CBCT Quality Check Phantom

For the CBCT Quality Checks it is recommended to use the provided **W0900235** - XMT 3D PHANTOM KIT, the universal test phantom for Critical Testing/acceptance Test at Dental 3d/CBCT equipment

Description:

- Consists of 4 parts; incl. scatter radiation bodies
- Modular and future-proof design
- Positioning: 1 Bubble Level, Central markings (linear + selective)
- Optional holder equipment available
- Test Objects: tissue equivalent, bone equivalent, air
- Size: Ø 160 mm x 150 mm height

For an accurate placement of the CBCT quality check phantom, it is suggested to purchase the manufacturer (2.97.02396 - XMT SEM SUPP FANT 3D QC (ONE LEVEL), showed in the following figure



Furthermore, this quality check phantom is equipped with its proper ALTA-QC software that automatically evaluates all the required parameters contribute to the technical assessment of 3D imaging quality. The test procedure itself is straight-forward and self-explaining. Hence, only a minimum of time is needed to acquire all necessary parameters. In addition, rather a minimum of user interaction is required. The procedure is oriented towards a comprehensive collection and evaluation of computerized data, merely the presence of artefacts is subjects to visual evaluation.

3. PANORAMIC QUALITY CHECK



(a) Turn ON the workstation and launch the AIS. (b) Turn ON the X-MIND trium. (c) Create a new patient "Panoramic Quality Check". (d) Select standard panoramic projection and choose Woman- Medium (75kV -9mA). (e) Make a standard panoramic projection. (a) Open the acquired Image S with AIS 2D Software (b)Remove all default filters, automatically set for the patient by clicking the "double-undo button". Visually evaluate the result. The following aspects have to be evaluated: 9 (a) The exposed area must be Ч Ц smooth and without artifacts. (b) High contrast resolution: minimum 3.1 lp/mm must be distinguishable. (c) Low contrast resolution: all the four holes must be visible.

4. CEPHALOGRAPHIC QUALITY CHECK



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- (a) Turn ON the workstation and launch the AIS.
- (b) Turn ON the X-MIND trium.
- (c) Create a new patient "Ceph Quality Check".
- (d) Select AP projection and choose Woman- Medium (75kV 10mA).
- (e) Make a AP projection.



- (a) Open the acquired Image with AIS 2D Software
- (b) Remove all default filters, automatically set for the patient by clicking the "double-undo button".

Visually evaluate the result. The following aspects have to be evaluated:

- (a) The exposed area must be smooth and without artifacts.
- (b) High contrast resolution: minimum 3.1 lp/mm must be distinguishable.
- (c) Low contrast resolution: all the four holes must be visible.

5. CBCT QUALITY CHECK

5.1 CBCT Quality Check Procedure





- (a) Select DENTAL FOV projection and choose Man - Medium (90kV -8mA).
- (b) Select 80x80 FOV and Medium Quality
- (c) Check that the "Select Filter" trigger is enabled, then click NEXT.

In the exam filtering parameters section, set the VOXEL SIZE at 100µm and leave all the rest as suggested from the AIS software.

STEP 7

- Make the CBCT 80x80exam.
- Then:
- (a) Repeat the STEP 4
- (b) Create a new patient "CBCT 110x80 Quality Check".



- (a) Select DENTAL FOV projection and choose Man - Medium (90kV -8mA).
- **(b)** Select 110x80 FOV and Medium Quality
- (c) Check that the "Select Filter" trigger is enabled, then click NEXT.

In the exam filtering parameters section, set the VOXEL SIZE at 100µm and leave all the rest as suggested from the AIS software.

Make the CBCT 80x80exam

STEP 11

Evaluates results following the instructions described in section 5.2 for both the patients created in the procedure.

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5.2 CBCT Quality Analysis

5.2.1 Slices

- a) For the CBCT Quality Analysis, in the ALTA-QC software it is request to extract two groups of five slices from the images data set, respectively five for the homogeneity analysis and five for edge analysis. For the device X-MIND trium, please choose the following slices ranges:
 - Homogeneity Slices: 520 525
 - Insert (Tissue and Bone equivalents) Slices: 300 305
- b) Export the slice images into a folder reserved for quality control images.
- c) To evaluate the slice images with the ALTA-QC software tool, export and save the images in DICOM format.
- 5.2.2 Contrast to Noise Ratio (CNR)

For the device X-MIND trium in the operative mode CBCT, the noise is evaluated by scanning the technical phantom Quality phantom and analyzing the tomographic images by the ALTA-QC software.

The noise is hereafter considered as the Image Noise defined in the DIN 6868-161.

The Image Noise (N_{DVT}) is the geometrical mean of all standard deviations of the pixel values in PVC and PMMA inside the scanned phantom as follows:

$$N_{DVT} = \sqrt{\frac{1}{2} \left(S_{PVC}^2 + S_{PMMA}^2 \right)},$$

where S_{PVC} and S_{PMMA} are the standard deviations of the pixel values in PVC and PMMA, respectively.

In addition, the following statements also report the Contrast-to-Noise Ratio (CNR), which is defined in the DIN 6868-161 as the ratio between the contrast of PVC and PMMA (C_{DVT}) and the Image Noise:

$$CNR = \frac{C_{DVT}}{N_{DVT}}$$
,

In turn, the $C_{\mbox{\scriptsize DVT}}$ is obtained by:

$$C_{DVT} = \left| P_{PVC} - P_{PMMA} \right|,$$

where P_{PVC} and P_{PMMA} are the mean values of the pixel in PVC and PMMA, respectively. In the following table are reported examples of CNR.

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Operative conditions	Tube Voltage [kV]	Exposure [mAs]	N _{DVT} [HU]	CNR []
FOV 80x80 - Man Medium - Medium	90	57.6	120,93	5.82
FOV 110x80 - Man Medium - Medium	90	57.6	115.41	6.10

5.2.3 Homogeneity

For the device X-MIND trium in the operative mode CBCT, the Homogeneity is automatically evaluated analyzing the tomographic images by the ALTA-QC software.

5.2.4 Modular Transfer Function (MTF)

For the device X-MIND trium in the operative mode CBCT, the Modulation Transfer Function (MTF) is evaluated by scanning the technical phantom Quality phantom and analyzing the tomographic images by the software ALTA-QC software.

The MTF is defined as a measure of how the CBCT scanner reproduces the details of an object to the tomographic image.

For each operative conditions used for the statements of noise, a graphical presentation of the MTF is provided below along with the following resolution indicators defined in the DIN 6868-161:

- $v_{50\%}$: is the spatial frequency transferred in the reconstructed tomographic images with the 50% of the maximum modulation;
- $v_{10\%}$: is the spatial frequency transferred in the reconstructed tomographic images with the 10% of the maximum modulation.



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5.2.5 Nominal Tomographic Section Thickness

Since the device X-MIND trium is a CBCT scanner, the reconstruction is isotropic, that is the size of the reconstructed voxels is the same along the three orthogonal directions. In this condition, the nominal tomographic section thickness is equivalent to the voxel size and can be set within the range [75µm - 500µm].

5.3 CBCT Quality Acceptance Ranges

5.3.1 Man-Medium, Medium Quality, 80x80 FOV

In the following table are listed the acceptance ranges for each evaluated quality indicator.

Test Variable	Acceptance Range		
Homogeneity	15.0 ± 5		
CNR	> 5.0		
V _{10%} [LP/mm]	> 1.6		
V _{50%} [LP/mm]	> 0.5		

5.3.2 Man-Medium, Medium Quality, 110x80 FOV

In the following table are listed the acceptance ranges for each evaluated quality indicator.

Test Variable	Acceptance Range
Homogeneity	12.0 ± 5
CNR	> 4.0
V _{10%} [LP/mm]	> 1.5
V _{50%} [LP/mm]	> 0.4

6. QUALITY ASSESSMENT CHECKLIST

<u>X-MIND trium data</u>		
X-MIND trium SN	Model	
Supply voltage	Supply Frequency	
<u>Order data</u>		
Order n°	Dealer contact person	
Order date	Installation Date	
Dealer	Training Date	
Installer (Name and Last Name)	Company	
<u>Facility data</u> Facility name		
Facility address		
State/province	City	
Nation	Zip or postal code	
Facility phone number	E-mail	
Name of repress. of facility		
Repres. phone number	Repres. e-mail	

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PAN Test	Passed	Failed	Description
PAN Quality Check			Verify that the exposed area is smooth
\rightarrow Absence of artifacts	Р	F	and without artifacts
PAN Quality Check			Verify that the High Contrast
→ High Contrast Resolution	Р	F	resolution is at least 3.1 Lp/mm
PAN Quality Check			Verify the Low Contrast resolution,
→ Low Contrast Resolution	Р	F	visible.

CEPH Test	Passed	Failed	Description
CEPH Quality Check			Verify that the exposed area is smooth
\rightarrow Absence of artifacts	Р	F	and without artifacts
CEPH Quality Check			Verify that the High Contrast
→ High Contrast Resolution	Р	F	resolution is at least 3.1 Lp/mm
CEPH Quality Check			Verify the Low Contrast resolution,
\rightarrow Low Contrast Resolution	Р	F	visible.

CBCT Test	Passed	Failed	Description	
CBCT 80x80 Quality Check → Homogeneity	P	F	Verify that the Homogeneity of the 80x80 FOV Test is in the acceptance	
			range	
CBCI 80X80 Quality Check			Verify that the CNR of the 80x80 FOV	
→ CNR	Р	F	rest is in the acceptance range	
CBCT 80x80 Quality Check			Verify that the $V_{\rm 10\%}$ of the 80x80 FOV	
$\rightarrow V_{10\%}$	Р	F	Test is in the acceptance range	
CBCT 80x80 Quality Check			Verify that the $V_{50\%}$ of the 80x80 FOV	
$\rightarrow V_{50\%}$	Р	F	Test is in the acceptance range	
CBCT 110x80 Quality Check			Verify that the Homogeneity of the	
→ Homogeneity	Р	F	range	
CBCT 110x80 Quality Check			Verify that the CNR of the 110x80 FOV	
→ CNR	Р	F	Test is in the acceptance range	
CBCT 110x80 Quality Check			Verify that the $V_{10\%}$ of the 110x80 FOV	
$\rightarrow V_{10\%}$	Р	F	Test is in the acceptance range	
CBCT 110x80 Quality Check			Verify that the $V_{50\%}$ of the 110x80 FOV	
$\rightarrow V_{50\%}$	Р	F	Test is in the acceptance range	