EURATOM

Project Deliverable

Project number:	Project Acronym:	Project title:
212246	SEDENTEXCT	Safety and Efficacy of a New and Emerging Dental X-ray Modality

Instrument:	Activity code:
Collaborative Project (Small or medium-scale focused research project)	Fission-2007-3.2-01

Start date of project:	Duration:
1 January 2008	42 months

Title:
D3.3 Phantom delivered and QA software validated

Contractual Delivery date:	Actual Delivery date:
30 September 2010	16 January 2011

Organisation name of lead beneficiary for this Deliverable:	Document version:
NKUA (National Kapodistrian University of Athens)	V1.0

Dissemination level:		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission)	
RE	Restricted to a group defined by the consortium (including the Commission)	
CO	Confidential, only for members of the consortium (including the Commission)	

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Abstract:

In order to develop tools for Quality Assurance on CBCT in terms of image quality evaluation, successive prototype phantoms were constructed and tested using specifically designed software for the evaluation of image quality, in three rounds during the project. In the third round, results from the prototype phantoms and versions of software were taken into account for the construction of the final QA phantom and the accompanying software for semi-automatic image evaluation of the phantom images. While earlier work is summarised, this deliverable primarily concerns the third and final round.

The definitive phantom consists of a cylindrical Poly (methyl methacrylate) (PMMA) holder (16cm diameter) and a number of inserts (3.5cm diameter) for evaluating different physical properties of the CBCT technique, employing several CBCT units. For the semi-automatic evaluation of phantom images, a specific software program was developed. Images from the definitive phantom scanned on several CBCT units were used for the validation of the software.

Results were obtained during the validation of the software, including compatibility with the DICOM datasets of the various CBCT units, usability of the graphical user interface, and consistency of the analysis results.

The results lead to the conclusion that SEDENTEXCT has met the WP3 objective, to develop a phantom and software for CBCT QA analysis. The evaluation procedures carried out on the definitive phantom and the results obtained by the software validation (Deliverable D3.3) will be used to inform the writing of the QA Procedure (QA Protocol) as part of the final deliverable (D3.4).

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1. The Context

1.1 SEDENTEXCT aims and objectives

The aim of this project is the acquisition of the key information necessary for sound and scientifically based clinical use of dental Cone Beam Computed Tomography (CBCT). In order that safety and efficacy are assured and enhanced in the 'real world', the parallel aim is to use the information to develop evidence-based guidelines dealing with justification, optimisation and referral criteria and to provide a means of dissemination and training for users of CBCT. The objectives and methodology of the collaborative project are:

1. To develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies. Guideline development will use systematic review and established methodology, involving stakeholder input.
2. To determine the level of patient dose in dental CBCT, paying special attention to paediatric dosimetry, and personnel dose.
3. To perform diagnostic accuracy studies for CBCT for key clinical applications in dentistry by use of in vitro and clinical studies.
4. To develop a quality assurance (QA) programme, including a tool/tools for QA work (including a marketable quality assurance phantom) and to define exposure protocols for specific clinical applications.
5. To measure cost-effectiveness of important clinical uses of CBCT compared with traditional methods.
6. To conduct valorisation, including dissemination and training, activities via an 'open access' website.

At all points, stakeholder involvement will be intrinsic to study design.

1.2 Work package 3 (WP3) objectives

The Quality Assurance (QA) process is vital in order to provide confidence in the suitability of an imaging technique for its intended purpose and to ensure its safe use in clinical use. It is usually performed by using a test phantom in conjunction with software routines that help in the interpretation of the results.

Preliminary tests before the start of this project on the NewTom 3G CBCT unit showed that using a phantom designed for Quality Assurance on medical CT equipment results in images with worse low-contrast resolution than the medical CT scan. Furthermore, discrimination between objects with different density was not always successful. It is speculated that this is due to the fact that NewTom 3G - and possibly all other dental CBCT units – are optimized for imaging of hard tissues. This is also related to the low dose delivered compared with medical CT. Therefore, the development of a specifically designed phantom, with a size and densities

resembling those of dental interest is necessary. A variety of test objects would be included in the phantom body (as inserts) for the testing of the imaging performance characteristics. Software tools would be developed for the interpretation of the results and the evaluation of image quality.

The objectives of WP3 are the following:

- to develop, design and test a phantom for QA tests on dental CBCT equipment.
- to develop software tools for the evaluation of image quality and for routine QA testing
- to form an Image Quality testing protocol and determine its implementation on CBCT units
- to form and implement a routine QA protocol, for periodic QA tests in daily clinical practice
- to investigate dose reduction techniques for patients and staff (thyroid shields; field of view limitation)

1.3 Deliverable 3.3

The purposes of Deliverable 3.3 are:

- to provide the definitive phantom together with inserts for the testing of the imaging performance characteristics
- to validate the readiness of the associated software, including that:
  (1) the software is able to open datasets from all available CBCT devices;
  (2) the software allows for the measurement of all image quality parameters that are relevant for quality control;
  (3) there is a sufficient agreement between repeated measurements (by different observers or by the same observer).

The contractual date for the deliverable was 30th September 2010 (M33), while the actual date of submission to the UNIMAN Project Coordinator was 21st December 2010. The reason was that the definitive phantom construction was delayed for two months, due to late delivery of overdue parts by the supplier of LTO. The delivery of the definitive phantom took place on the first week of November (M35). An additional month was therefore required for the software validation by the partners KUL, NKUA, UNIMAN, VU and CLUJ. The delay may have an impact on the D3.4 date (final deliverable) that is now expected at the end of January 2011 (contractual date 31st December 2010). The delay does not affect WP1.

2. The Methodology

2.1 Phantom design (by partners NKUA, KUL, LTO)

The development of the definitive phantom was started right after the analysis of the results in Deliverable 3.2 (D3.2). All improvements on the design of the phantom that were reported as necessary by NKUA and KUL in D3.2 were implemented by LTO in the final phantom as part of this deliverable (D3.3).

More specifically, during the development of the definitive phantom, LTO implemented the following in the design of the final QA phantom:

Phantom housing
The phantom consists of a cylindrical PMMA holder (16cm diameter) and a number of inserts (3.5cm diameter) for different evaluation purposes. The PMMA cylinder houses 7 columns for the accommodation of the different test inserts.

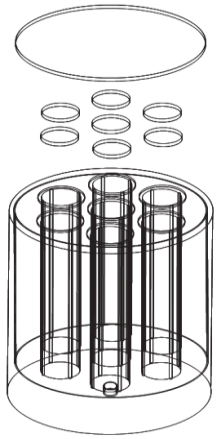


Figure 1. *Phantom body with 7 columns for test insert accommodation*

White markings on the outer surface of the phantom indicate the exact position of each insert facilitating the exact positioning and alignment of the phantom in the dental CBCT units.

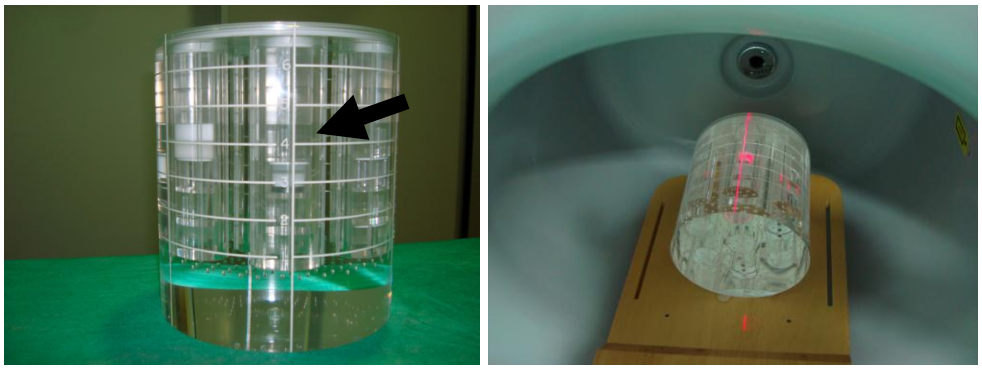


Figure 2. *White engraved lines (arrow) for accurate positioning / alignment*

The PMMA cylinder includes four rails in each column so that the test inserts are reproducibly oriented when put into the phantom. The cylinder also includes a series of voids under the insert columns which are intended for testing geometric distortion. Each column within the cylinder includes a separate threaded cap which allows the user to fill and empty a single column of inserts without disturbing the other columns.

Figure 3. *The lettered threaded caps and the orientation rails(arrow)*

A 20mm deep section at the bottom of the phantom is included which is used for homogeneity and noise measurements. A threaded hole at the bottom of the phantom means it can be securely attached to a support (e.g. a tripod or table).

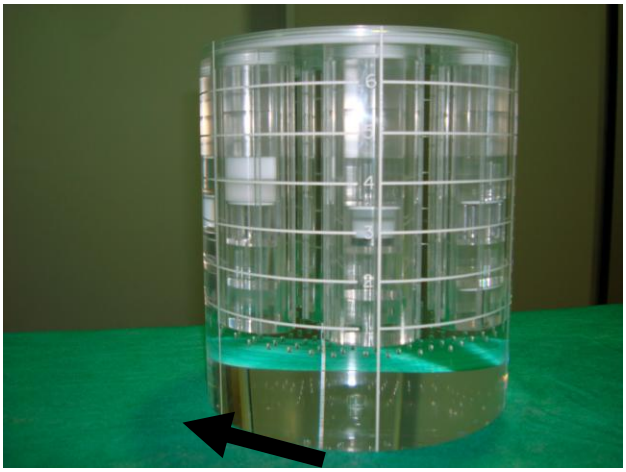


Figure 4. *The homogeneity 20mm deep section (arrow) with the threaded hole at the bottom*

Test Inserts

General

Each insert includes four notches to allow them to slide on the rails in the columns of the phantom housing, thus positioning the inserts in a reproducible manner.

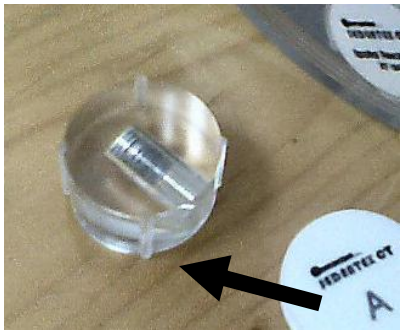


Figure 5. *The notches on the inserts (arrow)*

Contrast Resolution insert

Figure 6. *The Contrast Resolution insert*

Five inserts with contrast details of different material (Al,PTFE, Delrin, LDPE and air) of size varying between 5mm and 1mm are used for the Contrast Resolution tests.

Pixel Intensity insert

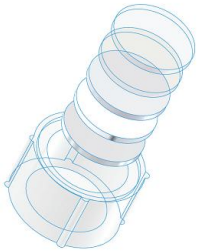


Figure 7. *The Pixel Intensity insert*

An insert accommodating stack of disks made of different material (Al,PTFE, Delrin, LDPE and air) is used for the Pixel Intensity measurements tests.

Spatial Resolution insert

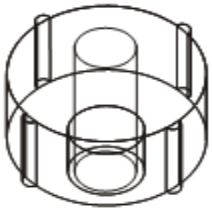


Figure 8. *The LP/mm test insert*

Two inserts with alternating discs of Aluminium and Polymer, one along the z-axis and the other along the XY-axis are used for the LP/mm spatial resolution tests. The range of line pairs frequency is between 1.0 and 5.0 LP/mm.

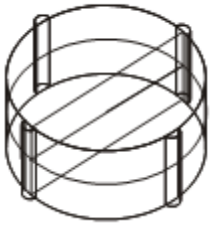


Figure 9. *The line spread function (LSF) insert*

The Line Spread Function (LSF) insert comprises 'a chequerboard' of PTFE and PMMA quarters bonded together.

Figure 10. *The point spread function (PSF) insert*

The Point Spread Function (PSF) insert comprises a stainless steel wire (0.25mm dia.) in an air gap of sufficient size.

Artefacts inserts

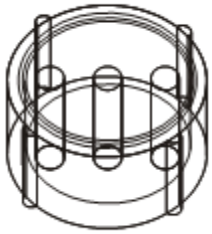


Figure 11. *The artefacts inserts*

Inserts with three rods of Titanium are used for artefacts tolerance testing.

A detailed specification sheet with drawings of the definitive phantom and inserts is included within the draft User Manual in Appendix 1[1].

2.2 Software development (by partners KUL, LTO)

Along with the final phantom, an updated software package was delivered by LTO and KUL. Several improvements were made to the design of the software and measurements to allow for image quality analysis of the final phantom for the available range of CBCT devices.

This section provided an overview of the software package and its functionality. In a first subsection, a brief description of the software is provided. Next, the improvements to the previous software version are described by following the consecutive steps in the software analysis protocol and describing for each step which improvements have been performed. In the final subsection, the validation of this software is described.

Overview of software design

The overall shape of the software remained the same. The general idea behind the software is that the user imports a CBCT dataset of the phantom into the software, performs the analysis of certain image quality parameters and enters these results into a QC report. These image quality parameters are either assessed through visual analysis or user-interactive measurements.

There are two different parts to the software: (1) the graphic user interface (GUI) which allows the user to import and visualise CBCT datasets and allows for the visual analysis of spatial resolution and contrast resolution as well as the measurement of geometric accuracy; (2) different executables (i.e. a set of instructions in a specific computer language) that allow the user to extract certain regions of interest from the dataset for automated measurement of all other image quality parameters. The first part is coded by LTO, the second part by KUL. The two parts are merged into one package which allows for a full

[1] Please note that the User Manual is part of the next deliverable (D3.4) so is not complete.

assessment of all phantom-related QC parameters. The following subsection provide more detailed descriptions of the two software parts, and give an idea on the workflow followed by the user.

First part – user interface and insert selection

The user is able to open datasets by selecting 'File, Open set of images' in the software, then browsing to the folder containing the dataset and selecting any slice in that folder. Opening the dataset is done in different steps. First, the software recognises all DICOM files in the selected folder and converts them to bitmap images (BMP). Subsequently, coronal and sagittal reformatting is achieved using the stack of axial slices (note: this requires that the dataset is in fact a stack of axial slices, exported at the lowest possible slice thickness and interval).

The interface of the software contains four windows. On the left side, three small windows show the axial, coronal and sagittal slices. The main window can display one of these small windows in full size. After importing a dataset, by default, the axial slices are shown in the main window. The user can switch to the other slices by selecting one of the other small windows on the left side.

By scrolling through the slices, there is a possibility for: (1) visual analysis of certain image quality parameters, (2) linear measurements to assess geometric accuracy, (3) the selection of regions of interest for automated image quality analysis. For this third step, an 'insert selection tool' is implemented, which enables the free selection of certain parts of the phantom for automated analysis. This selection tool will be described in more detail.

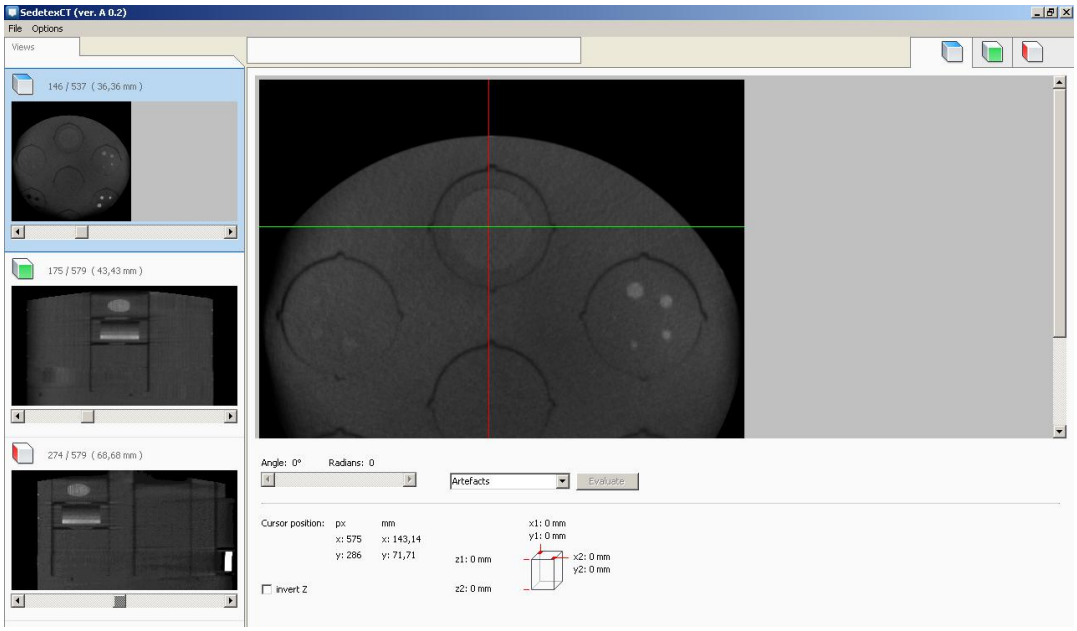


Figure 12. *Software with main (right) and side (left) windows.*

Second part – region extraction and automated analysis

To start using the selection tool, the user has to click and drag to create a selection box while using the axial view, after which the borders of the selection can be adjusted in every direction and using all three slice windows. The toolbar in the bottom of the interface shows the coordinates of the selection, which are used as input for the executables which extract the selection and perform the measurement.

After the appropriate selection of a region of interest (which can be either an insert or the PMMA portion of the phantom), the measurement of a certain image quality parameter is performed in two steps. In the first step, the program performs the extraction of the region of interest from the imported dataset. Next, the measurement is performed using insert-specific measurement coordinates and parameters. This second step is fully automated and requires no user interaction; the only requirement for the user is that he accurately places the region of interest (selection box). The measurement results are displayed in a pop-up window. Further details regarding the measurement of the different image quality parameters are provided in the 'Validation' subsection.

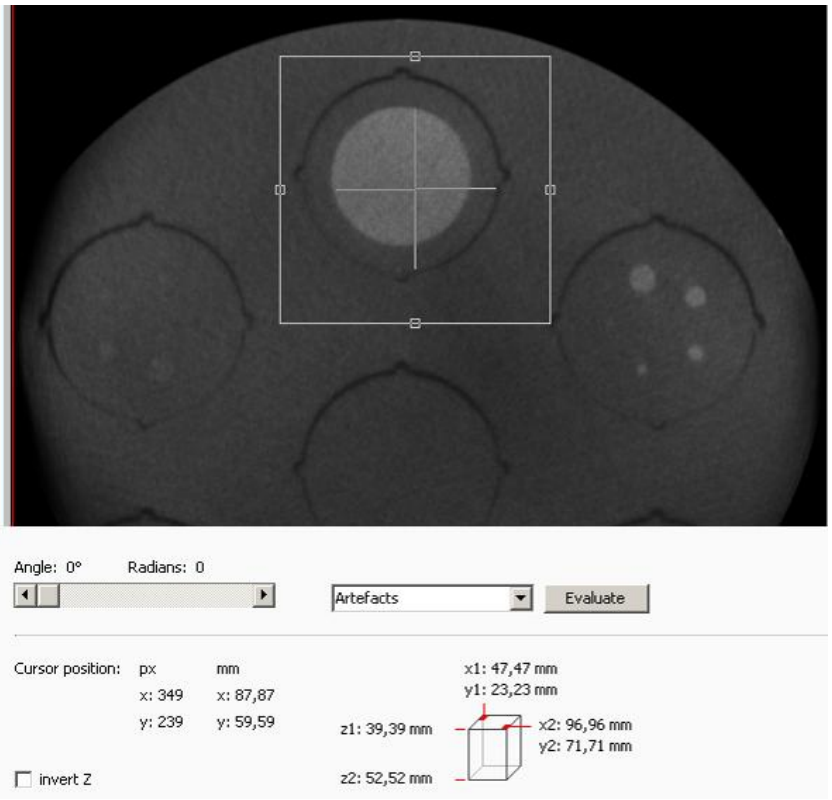


Figure 13. *insert selection tool and toolbar.*

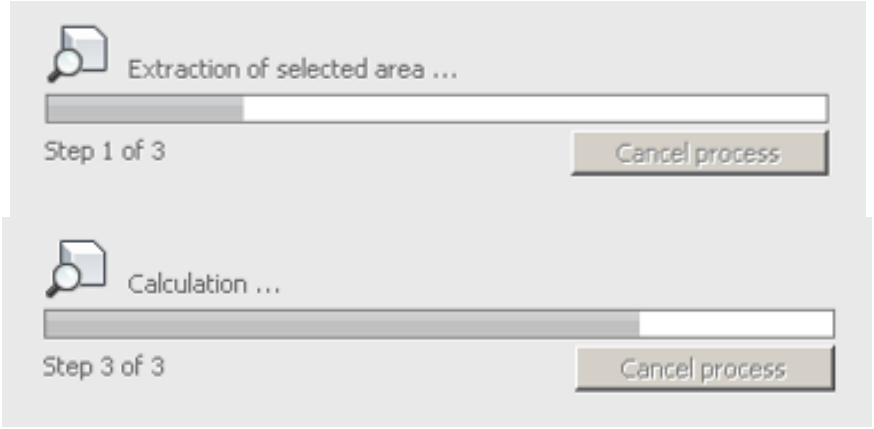


Figure 14. *Two steps for image analysis. Note that the original step 2 of 3 (registration of extracted region with geometric model) is skipped in the final software, as described in the 'Improvements – Extraction' subsection.*

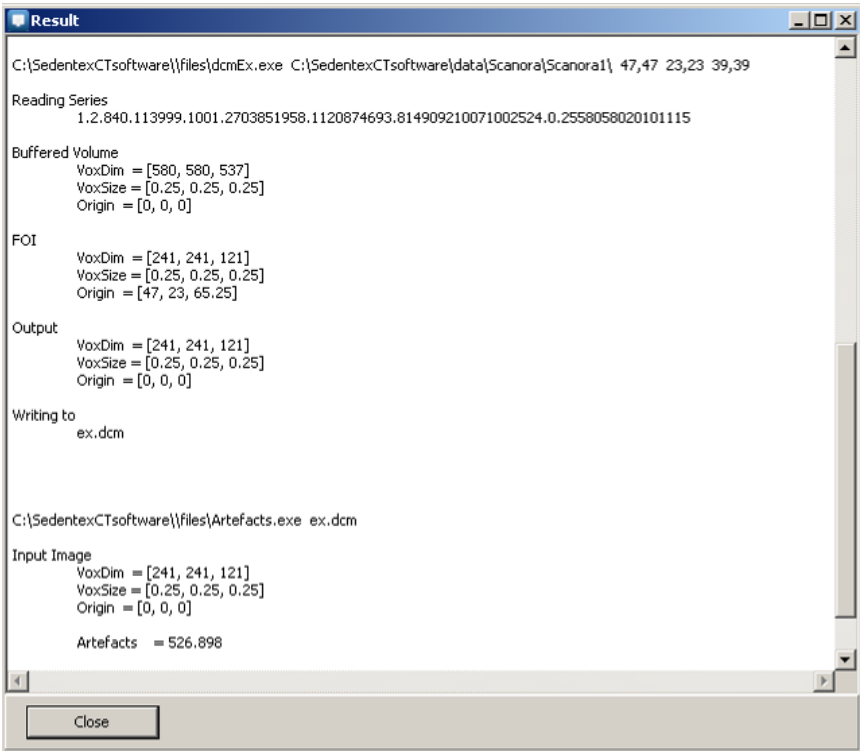


Figure 15. *Pop-up window with image analysis results.*

Improvements to software design in this development round

Import of datasets

The previous software versions experienced a number of different problems when trying to open datasets from different CBCT devices. However, the goal is that the software should be compatible with datasets from all CBCT devices, when exported in the DICOM (Digital Imaging and Communications in Medicine) format. This is not straightforward, because this standard format is still used in

different ways by different manufacturers. A few problems resulting include the use of compressed DICOM (which is JPEG-like) by some devices, large differences in bit depth and actual grey scaling, and different slice orientations.

The software needs to take care of these different issues by enabling three functional elements: the import of the dataset itself should be successful, the dataset should be visualised using the correct image orientation and the display of the dataset (window or level of the displayed grey scale, i.e. which part of the total grey scale is displayed, allowing for optimal brightness and contrast) should be optimal for visual analysis as well as manual insert selection. All of these issues were taken in consideration for the update to the 'import' part of the software.

Regarding the orientation of the dataset, it was found that, depending on the manufacturer, the slices are ordered from bottom to top or vice versa. This resulted in some datasets showing a flipped (upside down) coronal and sagittal view. This issue has been adressed by enabling a 'z-axis flip' which transforms the latter dataset to a proper coordinate system.

Finally, concerning the display of the datasets, it was found that most datasets appeared with a suboptimal grey level display (generally appearing much too dark). This has been solved by implemented 'presets' for grey levels. Using these presets, all datasets can be opened using their specific, optimal preset for window and level of grey values.

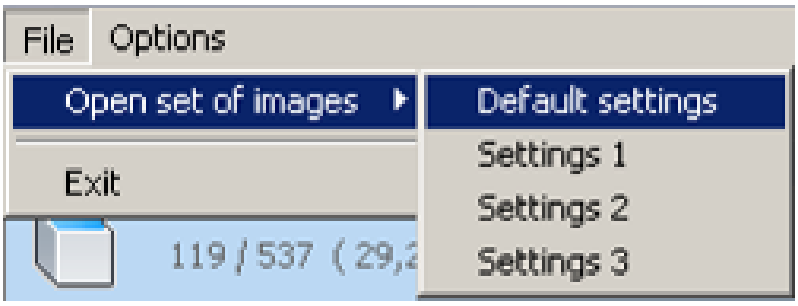


Figure 16. *Preset settings (Default and Settings 1-3) for grey levels*

Insert selection tool

There have been a few improvements to the insert selection tool. In the initial software, a registration algorithm was used to align the insert selection with a geometric model of the insert, after which measurements at specific coordinates could be performed. As described below, it was found that this approach was suboptimal, and that a semi-automated measurement can be equally accurate and reproducible. Therefore, a few changes were made to the insert selection tool which should enable an accurate depiction of regions of interest.

First of all, the size of the insert selection can be changed freely. This enables the selection of individual inserts, as well as different parts of the homogeneous PMMA portion of the phantom. For individual inserts, the extracted region is fixed and independent of the actual size of the selection. This means that a fixed

cuboid region is extracted based on the x1,y1,z1 coordinates defined by the user. From a user point of view, this means that the left and top borders in the axial view (x1 and y1) as well as the top border in the coronal and sagittal view (z1) are crucial and need to be positioned accurately at the insert border. The other borders of the selection can aid in this positioning. For the PMMA portion, different sized regions can be extracted based on the field of view size. The available size of PMMA can range from 4x4cm to 16x16cm.

Furthermore, the selection can be rotated for inserts that are not symmetrical. A crosshair is added which enables the determination of the correct rotation angle. The angle can be defined in the bottom toolbar. The rotational factor is further explained in the following subsection.

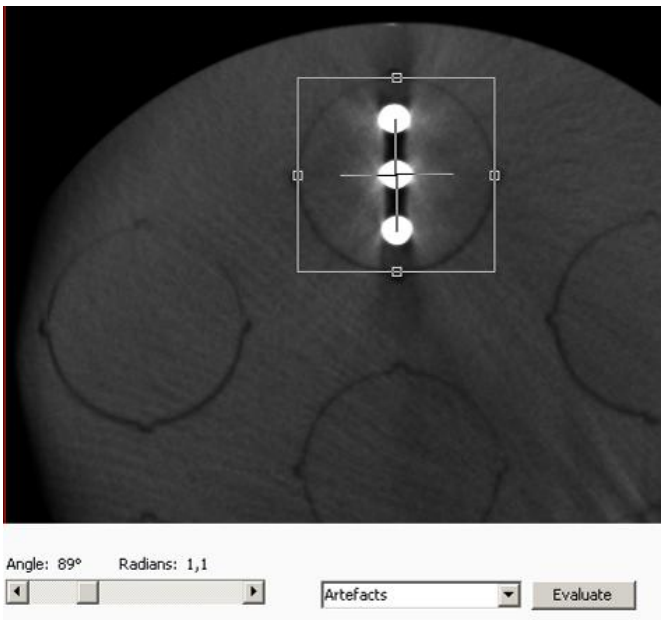


Figure 17. *Rotation of insert selection. In the current case, the selection was rotated approximately 90° because the artefacts measurement assumes the three titanium rods (white spots) to be aligned left-to-right, not front-to-back.*

Extraction of selection

The extraction tool has gone through extensive changes. As mentioned before, for the previous software version a registration tool was used which iteratively matches the extracted region with a geometric drawing of the insert using the Maximization of Mutual Information (MMI) registration algorithm. However, it was found that due to the relatively high computational power needed for this registration, the time needed for a full assessment of the phantom becomes unacceptable. Furthermore, a registration with sub-voxel accuracy is not required for the SEDENTEXCT phantom, as it was found for the second prototype that manual selection of regions of interest can be equally accurate. This led to the conclusion that the registration step is not needed.

The extraction tool was adapted because the registration tool implied a few restrictions to the extraction which were now no longer applicable. This allowed

for the extraction tool to skip a few image manipulation steps, resulting in further speeding up of the measurement process.

As mentioned before, different extraction tools have been defined using different sizes of the extracted regions, making them suitable for insert analysis or PMMA analysis for various field of view sizes.

Measurement of image quality parameters

Each image quality parameter which uses the selection-extraction tool has been re-coded based on the image analysis results from the second prototype phantom. Based on the coordinates of the extracted dataset, different regions are defined and different parameters are measured or calculated.

For all parameters, there is a certain margin of error because the selected coordinates for measurement are not placed close to an edge (e.g. edge between contrast material and PMMA) or an area of high variability in grey values (e.g. direct vicinity of titanium rods). Although it is important that the user defines the selection as accurately as possible, a small shift of the selection along the x-, y- or z-axis does not hamper the analysis results significantly.

2.3 Validation of software (by NKUA, KUL, UNIMAN, CLUJ, VU)

The specific objectives for software validation were to investigate if (1) the software is able to open datasets from all available CBCT devices; (2) the software allows for the measurement of all image quality parameters that are relevant for quality control; (3) there is a sufficient agreement between repeated measurements (by different observers or by the same observer). If these three conditions are met, the software is ready for implementation in QC practice, providing that there is a clear QA protocol which provides the different steps needed for the measurements and clear instructions on how to interpret the results.

No multi-user testing was required to investigate if the software is able to open datasets from all available CBCT devices. Datasets from 10 different manufacturers (16 device types in total) were tested by KUL with the updated software version. For 8 out of 10 manufacturers, the datasets could be opened without any error. For 2 manufacturers, there was still an error in opening, which is currently under investigation.

For a validation of user functionality and measurement accuracy, the software package was distributed to all involved partners (KUL, NKUA, UNIMAN, CLUJ, VU) along with a detailed and richly illustrated measurement protocol. An adapted version of this software protocol will be implemented into the phantom's user manual as well as the QA protocol (Deliverable 3.4).

For a proper validation of measurement accuracy, it was imperative that all users performed the evaluation in similar conditions. Therefore, datasets from the Scanora 3D CBCT were provided to allow for comparative measurements. Three

different datasets were provided which encompass all parts of the phantom that are used for visual analysis or user-interactive image analysis (PMMA, contrast resolution, pixel intensity value, artefacts, spatial resolution, geometric accuracy).

The evaluation was performed independently by seven users from all partners mentioned above. From these seven users, five had no previous experience with the phantom or software. They can be considered as 'new' users, and were asked to provide feedback regarding their experiences while performing the measurements. In the group of observers, two types of stakeholders were represented: 4 observers were dentists/radiologists (routine QA testing) and 3 were medical physicists (for advanced imaging performance tests).

The measurement task can be divided into two parts. First, a number of visual analyses are performed which serve as a straightforward, quick evaluation of the CBCT's performance in terms of spatial and contrast resolution. Subsequently, the software is used to perform a number of user-interactive analyses involving linear measurements as well as the use of the selection tool described above.

It was ensured that the selected measurements were all relevant for actual quality control for CBCT. For example, for the 'pixel intensity value' insert the contrast-to-noise ratio was measured, as this is an important parameter for quality control. Another optional parameter for this insert, the correlation with CT numbers (Hounsfield Units) was not selected because measurements on the second prototype phantom have shown that this is not a parameter for which CBCT devices are expected to have a stable, reproducible value.

The inter-observer agreement between the measurements was assessed. Also, four users performed the entire measurement task twice or more with a time interval between the measurements to assess intra-observer agreement.

Overview of analyses

For visual analysis of contrast resolution, the user was asked to determine the number of visible rods for the five contrast resolution inserts. A number from 0 to 5 (i.e. number of distinguishable rods) is determined for each of the five materials used (air, LDPE, Delrin, PTFE, aluminium).

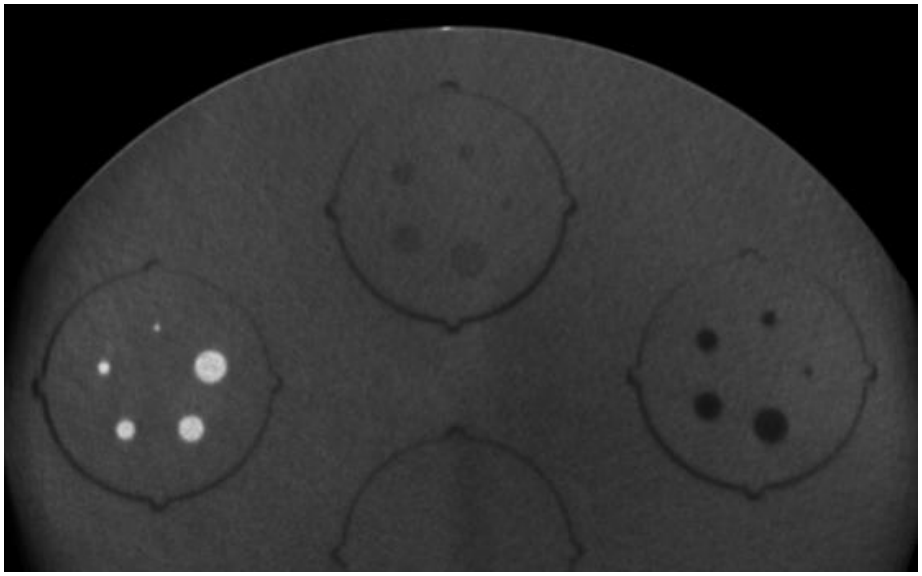


Figure 18. *Three out of five contrast resolution inserts for visual analysis (rod counting). Left: aluminium, middle: LDPE, right: air.*

Next, visual analysis is performed for the spatial resolution insert. As mentioned before, this insert contains slices of aluminium alternated with polymer using a range of slice thicknesses, corresponding to spatial resolutions ranging from 1.0 to 5.0 line pairs per millimetre. The user needs to count the number of distinguishable lines by zooming into the pattern.

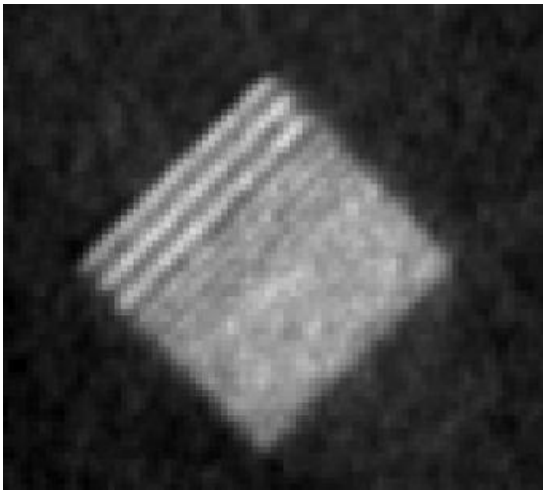


Figure 19. *Spatial resolution pattern for visual analysis (line counting)*

For geometric accuracy, the hole pattern that separates the PMMA portion of the phantom from the insert portion is used. This is also a quick test to ensure that the system allows for accurate linear measurements in the sub-millimetre range. The user measures the distance between two of the holes (selected by the user, based on the size of the field of view) using a linear measurement tool, and compares this measurement to the actual distance (which is 1 cm for adjacent holes). This measurement is repeated a few times to allow for geometric evaluation in all directions, and the average deviation from the actual distance is reported.

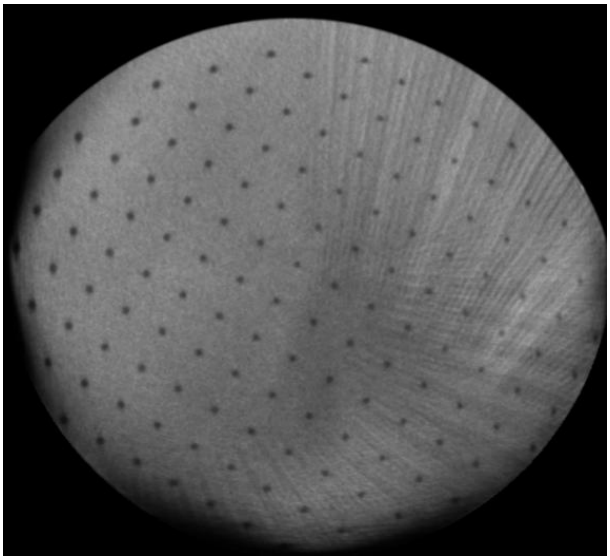


Figure 20. *Hole pattern for geometric accuracy measurement*

For the following measurements, the software selection, extraction and evaluation tools are used. Two types of selections are performed: for contrast-to-noise ratio and artifact evaluation, the insert needed for this analysis is selected and extracted from the dataset. For noise and uniformity evaluation, part of the PMMA portion of the phantom is selected and extracted.

For contrast-to-noise ratio measurements, the selection box is placed at the 'pixel intensity value' insert, containing slices of 6 different materials (the 5 materials used for visual contrast resolution + PMMA as background material. Next, the user selects 'CNR' from the insert list and clicks the Evaluate button to start the extraction. After a few seconds, the report window pops up, showing the CNR values for all 5 materials.

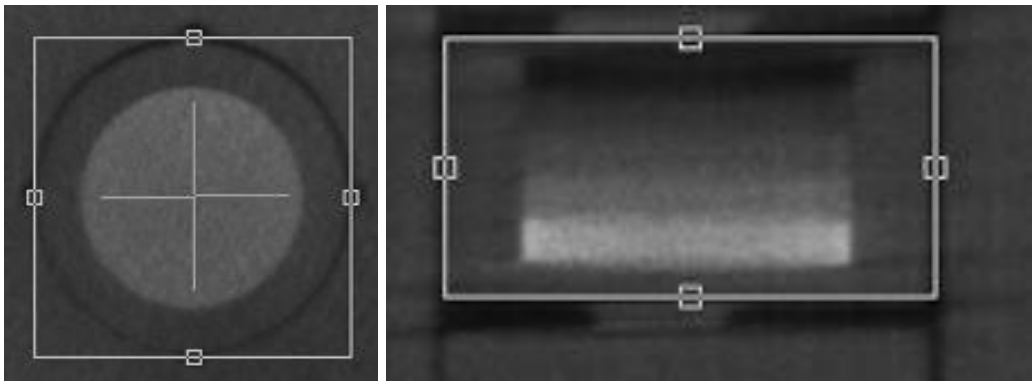


Figure 21. *Positioning of the selection box for contrast-to-noise ratio evaluation. Left: axial view, right: coronal view.*

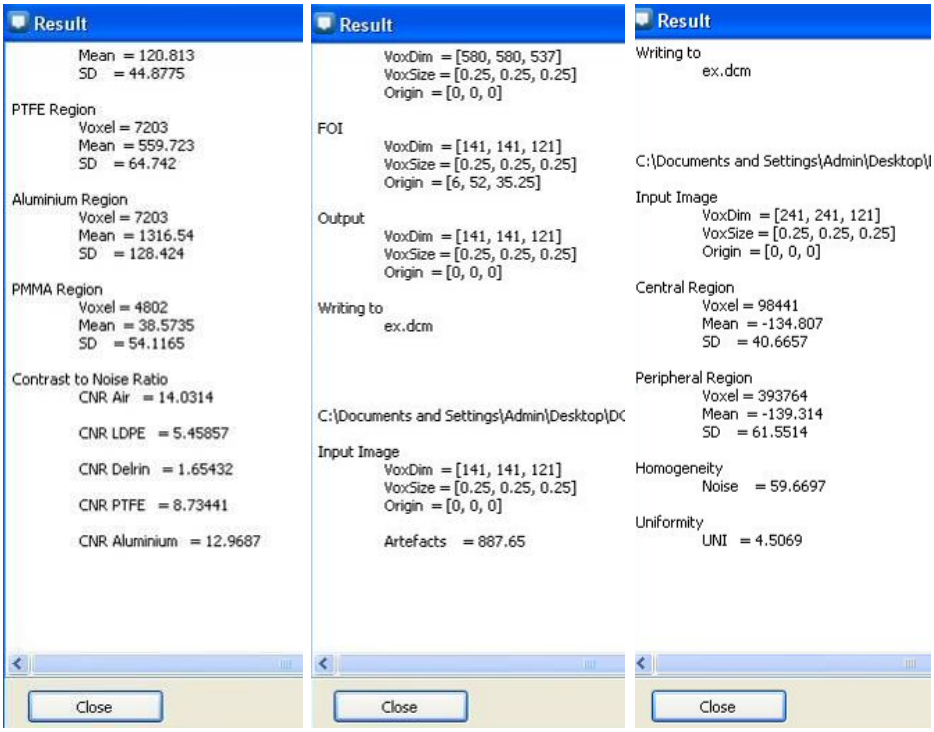


Figure 22. *Example of pop-up report with CNR (left), artefacts (middle) and noise and uniformity (right) measurements*

For the metal artefacts evaluation, the selection method is basically the same, but focusing on the metal artefacts insert. Also, the user has to define the rotation of the rods by using the crosshair and rotation toolbar. After selecting 'Artefacts' from the insert list and clicking the Evaluate button, the results are provided in the same fashion as before.

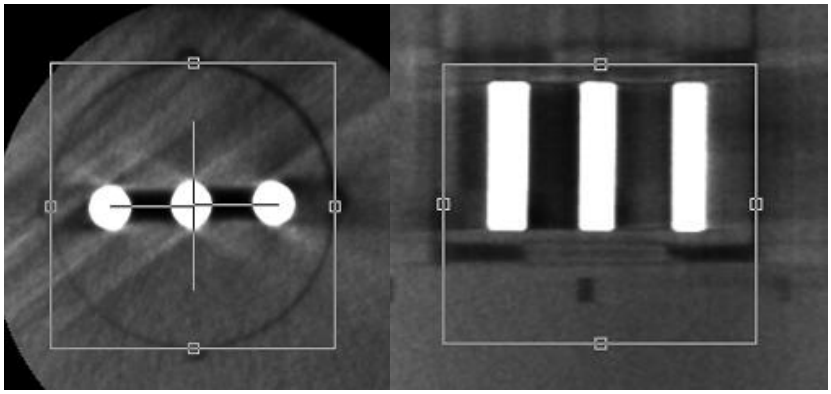


Figure 23. *Positioning of the selection box for metal artefacts evaluation. Left: axial view, right: coronal view.*

For noise and uniformity, a homogeneous portion of PMMA is selected. The position of this selection depends on the size of the field of view; different extraction sizes are provided in the insert list to suit the entire range of CBCT field diameters. The user selects the correct extraction size from the insert list and performs the selection, ensuring that the center of the extracted region corresponds to the center of the field of the original dataset. The top of the selected region is aligned with the bottom of the geometric accuracy pattern,

using the sagittal or coronal view. After pressing the evaluate button, results for noise and uniformity are reported.

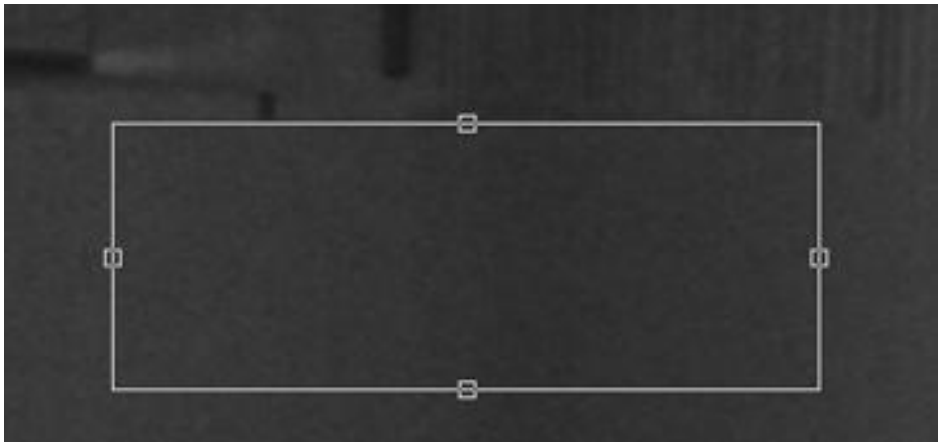


Figure 24. *Selection of PMMA region for noise and uniformity measurement*

3. Results

3.1 Phantom applicability

The definitive phantom and inserts were scanned on a wide range of CBCT devices. Depending on the field of view size, the number of scans needed varied between different devices. Exact positioning of the phantom was facilitated by the white markings on the outer surface of the phantom, especially in the units with small FOV. The design changes that were implemented into the definitive phantom are found appropriate for both the body and the inserts for the different image quality tests.

3.2 Software validation

For the visual analyses of contrast resolution, there was a perfect agreement (all rods visible) between all observers for all materials except Delrin. For this material, 2 observations stated the smallest rod is visible, whereas 10 observations did not find this rod to be sufficiently distinguishable from the background. Most likely, the 2 observers that stated that the rod was visible confused it with a noise speckle.

For spatial resolution, a bit more variability was found between the observers. Although the intra-observer agreement was perfect (i.e. repeated measurements from the same observers showed the same value), it was found that the majority of the observers could distinguish 6 lines, whereas other observers decided that only 3 or 4 lines were visible. This is the typical case of ‘optimistic’ versus ‘pessimistic’ observers.

The results from the visual analysis show that these measurements should be performed by the same observer over time, because there are differences between observers that cannot be accounted for. One way to ensure that the observation is somewhat more objective, and that this analysis is truly relevant to decide whether or not the image quality of the device has deteriorated, is to save an image from the first QC analysis performed on a device after installation, and compare this ‘baseline’ image for each subsequent QC procedure to investigate if there is a significant visible difference regarding spatial and contrast resolution.

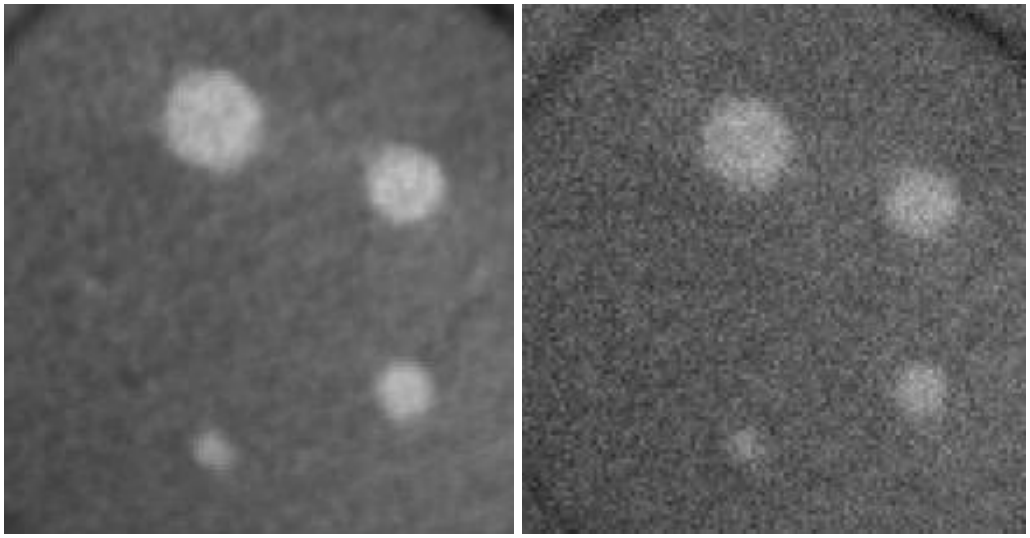


Figure 25. *Visual analysis of the contrast resolution insert using the 'baseline' method. Left: example of how a contrast resolution image could look like after installation of the CBCT device. Right: simulation (by adding noise) of how this image could look like if there is significant image quality deterioration. This deterioration can be easily spotted by the observer by comparing the two images.*

Linear measurements for geometric accuracy were found to be accurate, showing deviations below 0.5 mm for all measurements except one (which was 1.0 mm). As CBCT devices are expected to show sub-millimeter accuracy, the measurements show that it is possible to verify this accuracy using the hole pattern. In QC practice, measurements showing deviations higher than 1 mm would have to be repeated for consistency. If consistent, it should be flagged as a potential problem regarding the geometric calibration of the CBCT device.

Measurements of contrast-to-noise ratio (using the software's insert selection tool) showed some variability, It could easily be spotted that a few observers did not position the selection box correctly, which led to values that were completely inaccurate. When discarding those observers, the measurements for all materials showed an accuracy of 2-6%. Although this accuracy is suitable for QC measurements, it could be further improved. First, further training with the software could help the observers to accurately place the selection box, as it was seen that the user who had more experience with the software showed the best reproducibility. Secondly, the slices of the materials are quite thin, which makes the measurement (especially the 'noise' factor) very sensitive for slight dispositions. For commercialization of the phantom and software it could still be decided to have thicker slices for each material, to avoid this kind of inaccuracy which is caused by a combination of user inaccuracy and undersampling (i.e. analyzing a small amount of data, leading to a larger inaccuracy).

For the measurements of metal artefacts, it was also seen that inaccuracies in positioning of the selection box can lead to rather large differences in the parameter value. It was shown by one observer at VU and one observer at KUL that perfect accuracy (0,0%) can be obtained when positioning the region of interest appropriately.

The ‘Noise’ parameter, measured in the PMMA portion of the phantom, was the most accurate of all measurements, showing 2% accuracy over all observers. Repeated measurements by observers showed perfect consistency (0,0%) if carefully positioning the region of interest. For this parameter, undersampling is not an issue because the extracted region is much larger than for the inserts, the only important factor is consistent user positioning of the region of interest.

The ‘Uniformity’ parameter showed somewhat more variability because of its relatively small absolute value. However, it was once again shown by repeated measurements that a perfect consistency can be obtained.

4. Conclusions

The design changes that were implemented into the definitive phantom are found appropriate for both the body and the inserts for the different image quality tests. Validation of the associated software by five consortium partners was successful. A clear protocol for all measurements was established. It was found that the final software is easy to work with, that the working speed has been significantly increased, and that the measurements can be sufficiently reproducible for QC purposes. The purpose of this work, to produce a marketable QA phantom for dental CBCT with associated software is met, as indicated by the presented marketing plans of the partner LTO, where the acceptance of the final phantom and the associated software for commercial production is demonstrated.

The methodology used in this deliverable (D3.3) for the evaluation procedure carried on the definitive phantom with the use of the validated software will form the basis for the writing of the QA Procedure (QA Protocol) as part of the final deliverable (D3.4). More specifically, knowledge acquired from D3.3 on the phantom handling and positioning, test inserts selection and placing, and using the software for specific image quality tests will be passed to the D3.4 and the final Guidelines (WP1) as part of the QA chapter.

The outcome of the WP3 (QC phantom, software and QA protocol) is expected to have a great impact on several stakeholder groups. Dentists and radiologists will benefit from following frequently the QA protocol and using the phantom and the software, ensuring that their CBCT equipment operates efficiently in terms of output image quality. Medical physicists may use the same phantom and software for advanced imaging performance tests on CBCT units. The research community may use the phantom and the software for further studies on imaging characteristics. Finally, the CBCT unit manufacturers may use the phantom and the software for testing prototypes units, their new equipment before delivery and any new features added to their units.

5. Future actions – project plan

WP Task	***Objective***	***Date due***	***Date expected***
WP3.3	*QA procedure (protocol) ready* ***(D3.4)***	***31 Dec 2010***	***31 Jan 2010***


EUROPEAN COMMISSION
European Research Area

Appendix 1: SEDENTEXCT phantom specification

The phantom specification forms part of the SEDENTEXCT User Manual, which is being prepared as part of the next deliverable, D3.4. The draft User Manual showing the phantom specification is overleaf.

Leeds Test Objects
www.leedstestobjects.com

SEDENTEXCT

user manual

Draft Summary

Medical Imaging Phantoms

DESCRIPTION

Insert Comments Here

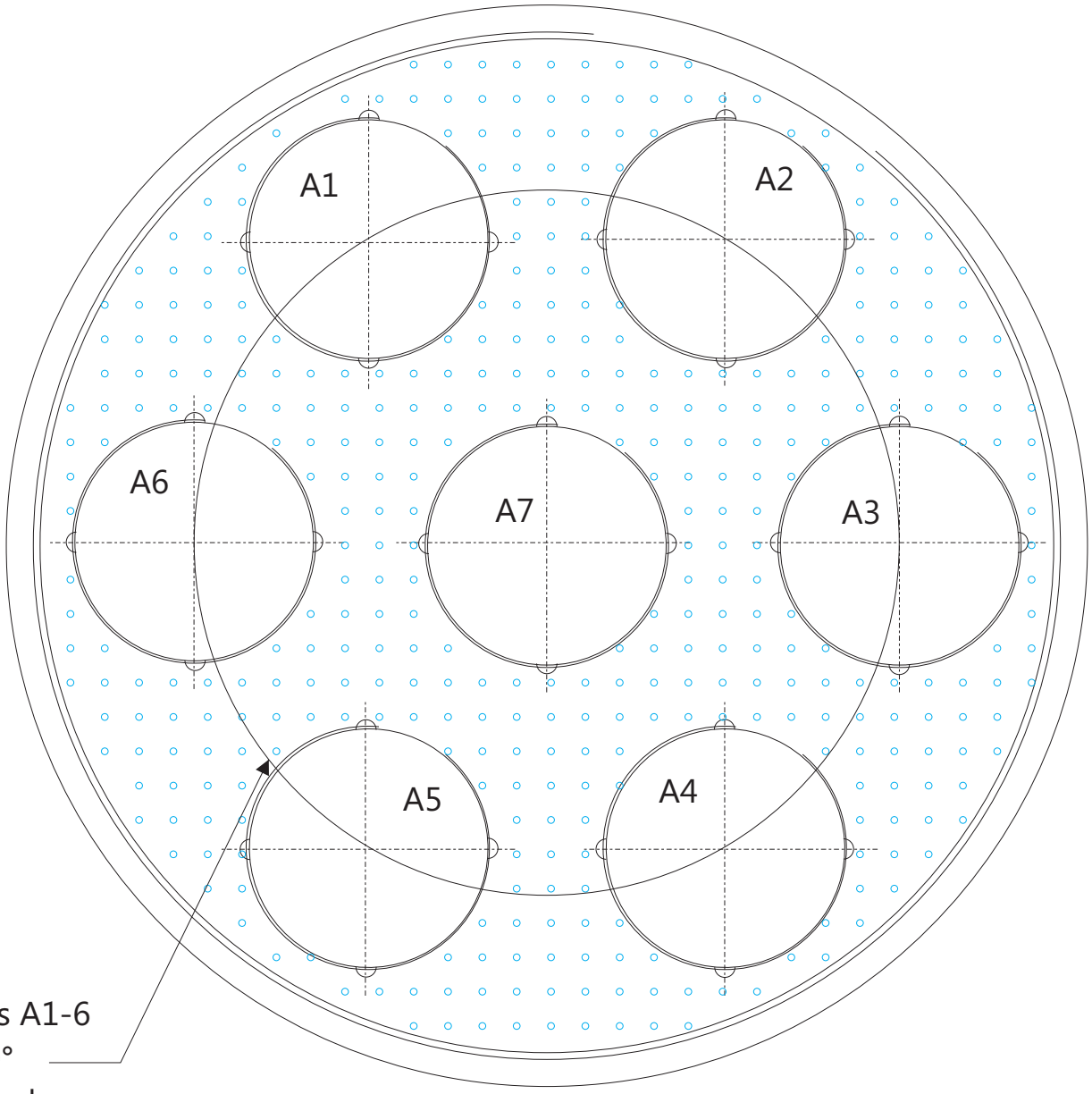
POSITIONING THE TEST OBJECTS

Insert Comments Here

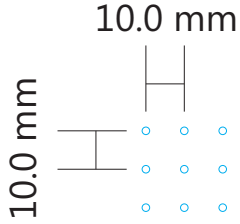
X-RAY BEAM CONDITIONS

Insert Comments Here

PHANTOM HOUSING (PMMA)

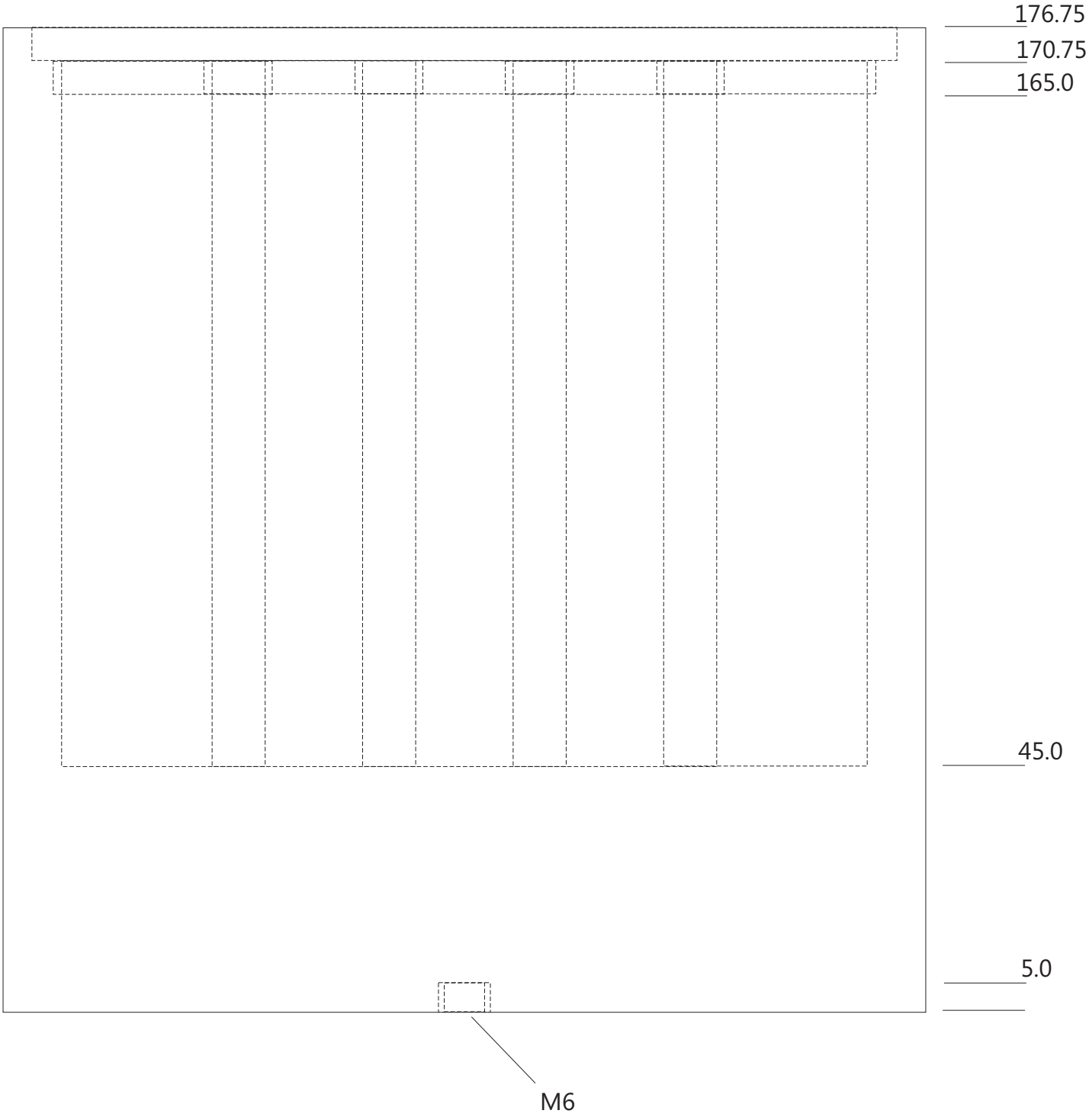


Holes A1-6
at 60°
intervals on
circle Ø 104.8mm

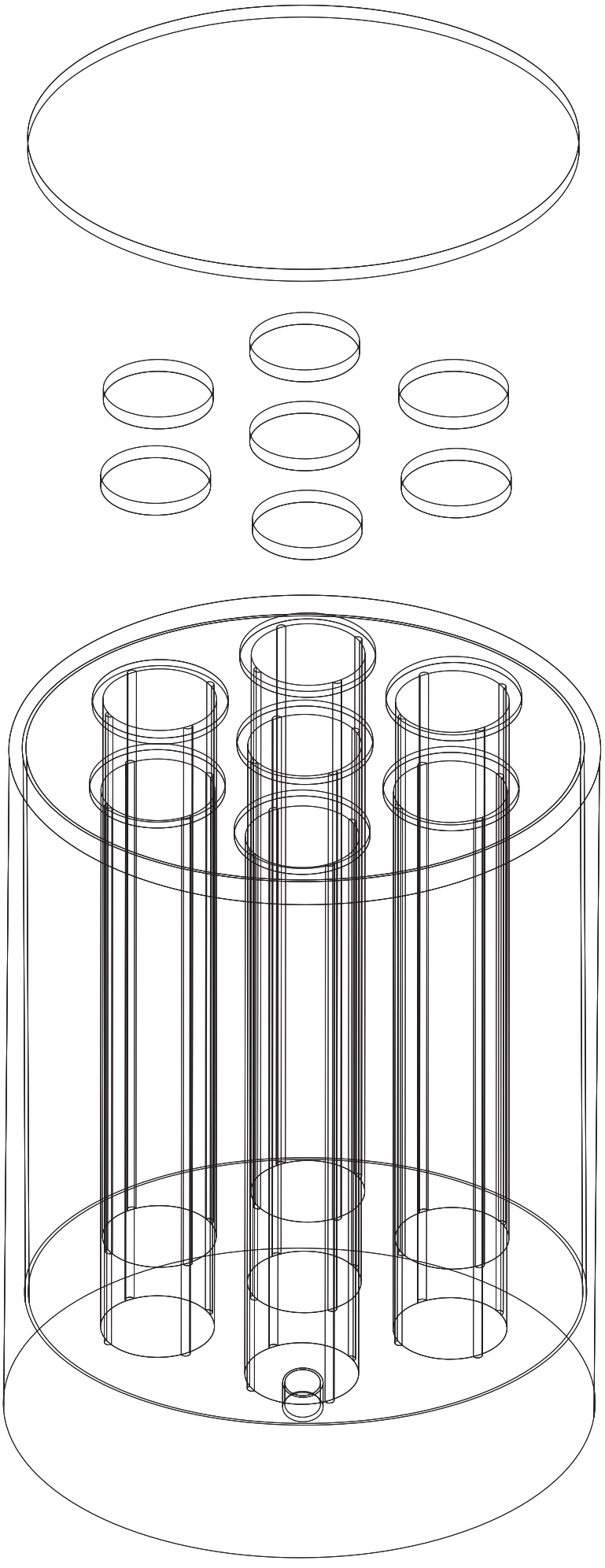


177 x ∅2.0 recesses (3.0mm depth)
in the body of the phantom centred
3.5mm below the base of the 7 holes -
Geometric Distortion.

PHANTOM HOUSING (PMMA)

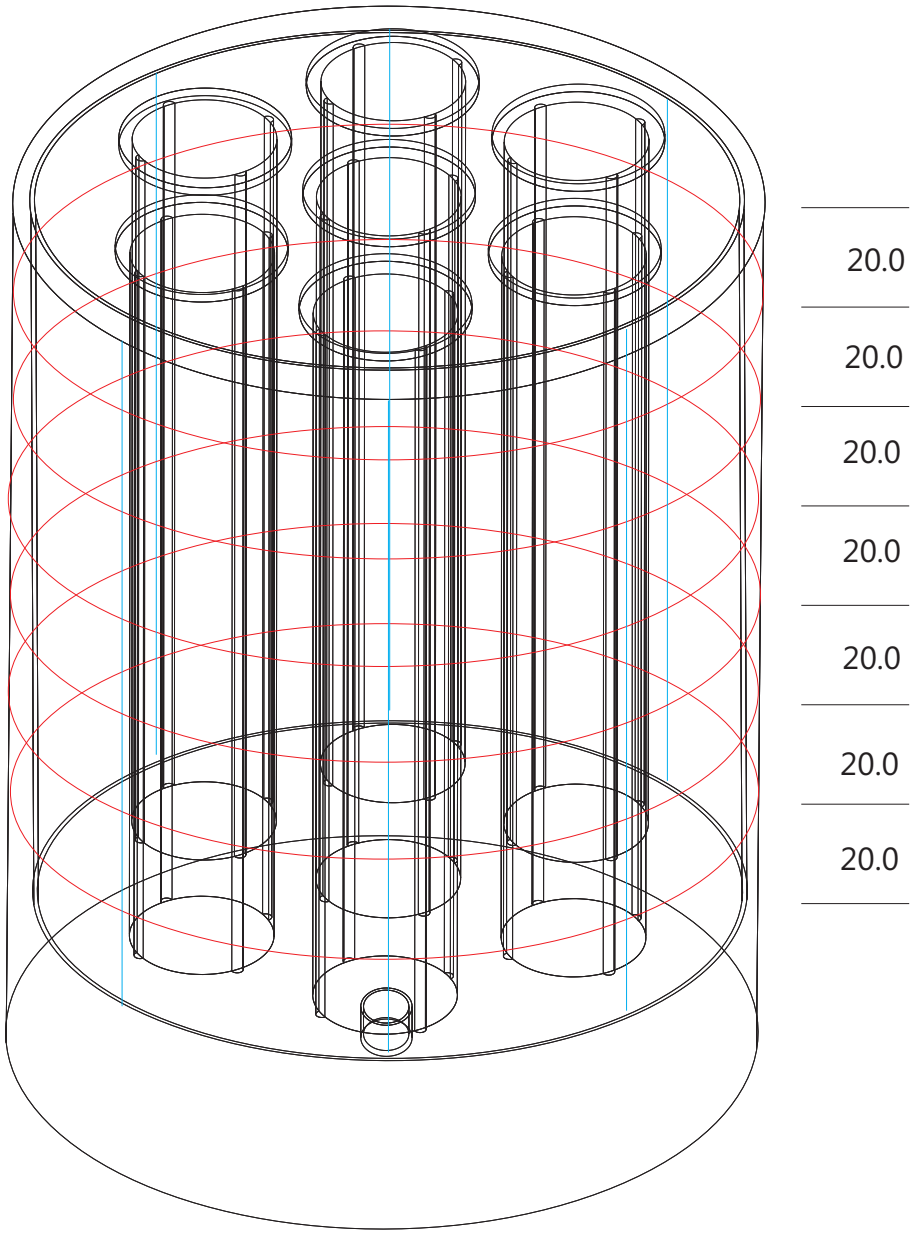


Housing
(1 per set)

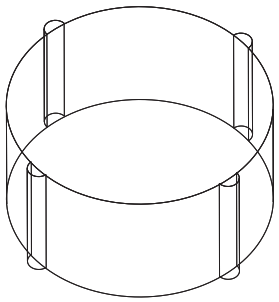


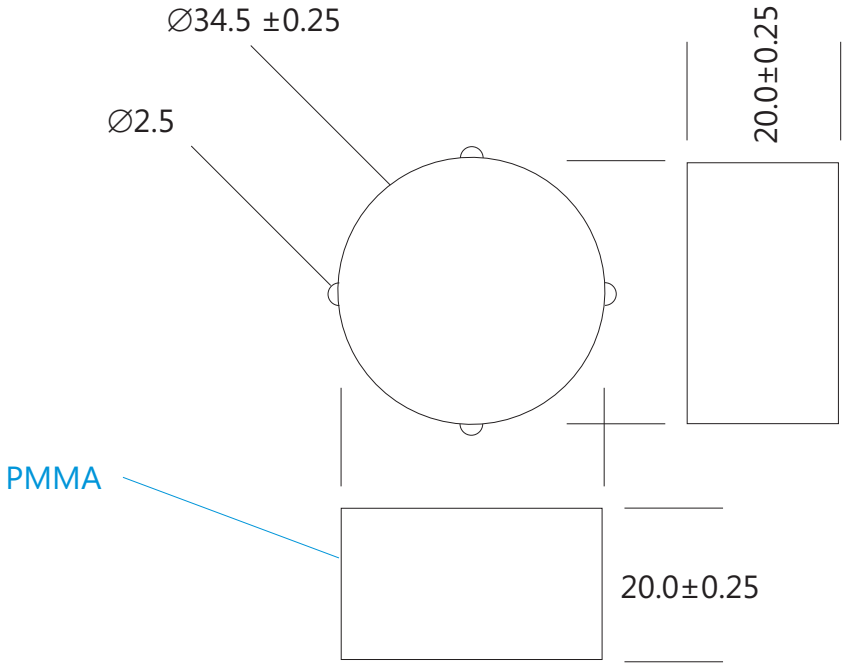
HORIZONTAL ENGRAVED LINE
(6 lines, labelling 6 x 20.0mm intervals through 140.0mm depth of holes)

VERTICAL ENGRAVED LINE
(Centred on each of 6 peripheral holes)

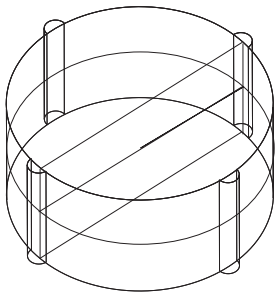


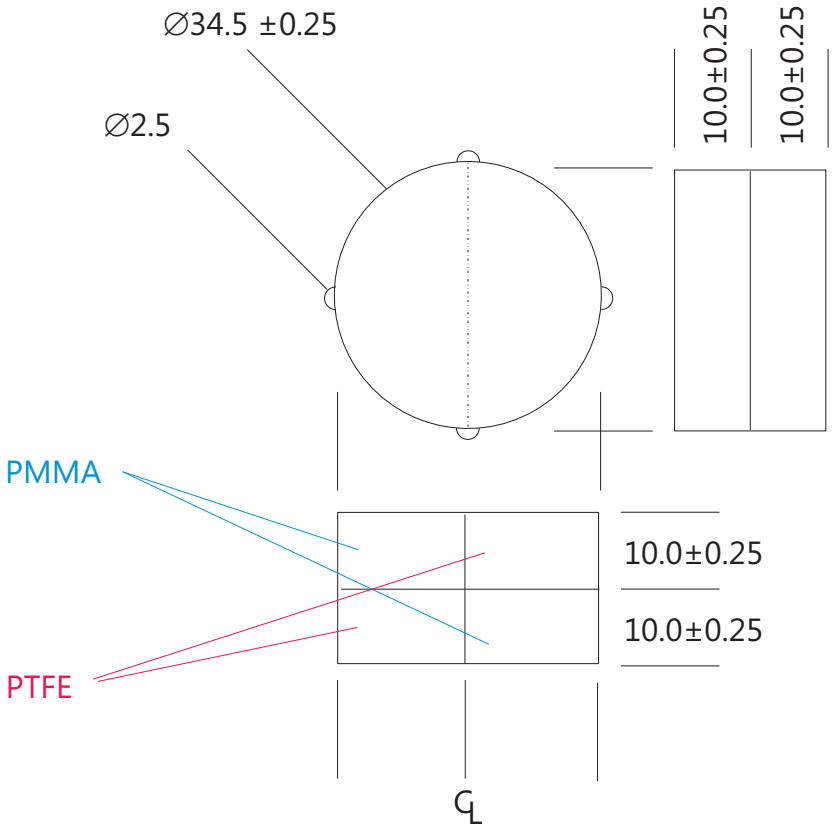
BLANK INSERT (PMMA, 30 PER SET)





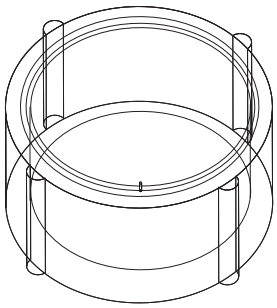
LSF INSERT (1 PER SET)

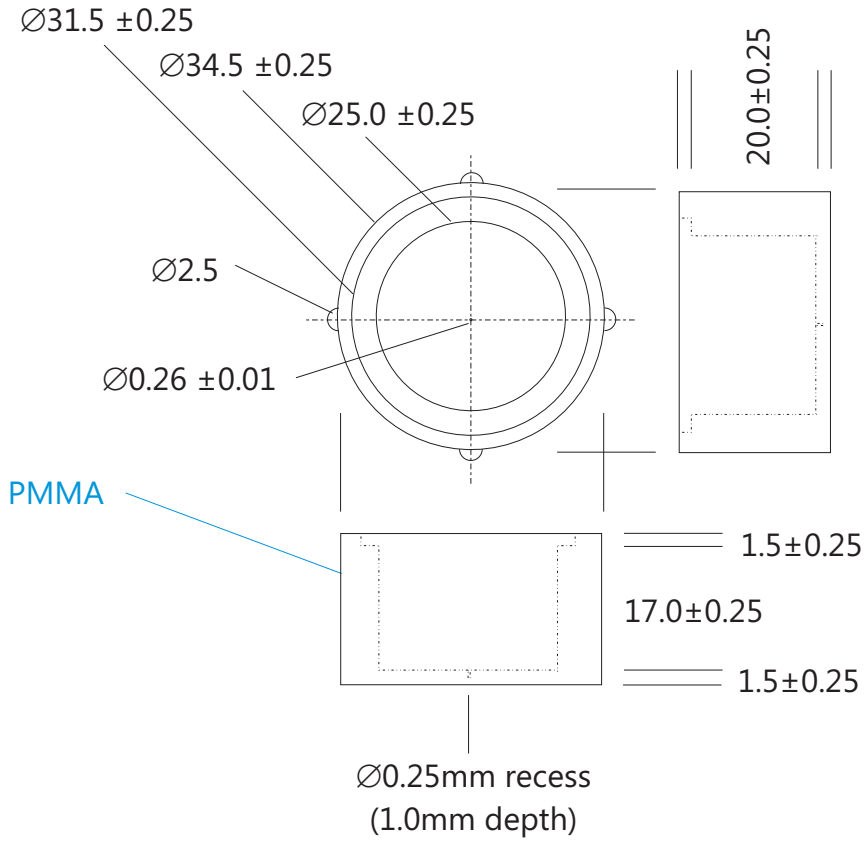


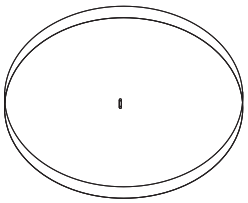


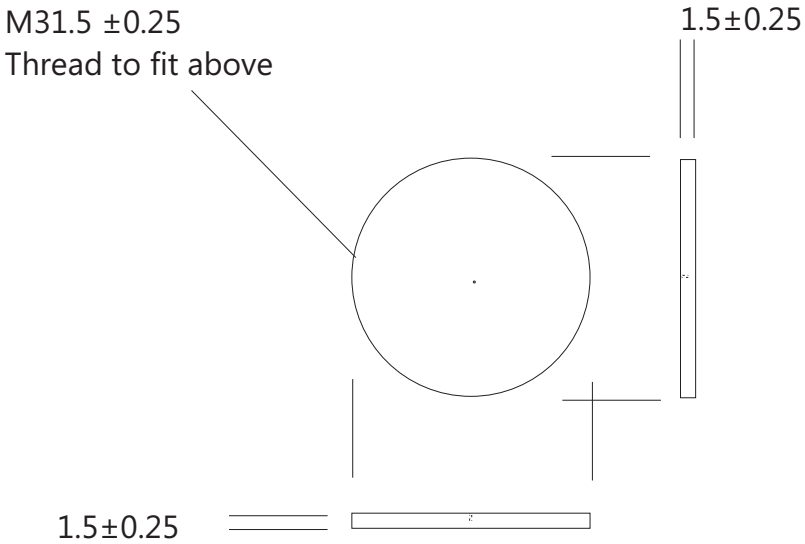
PSF INSERT (1 PER SET)

0.25mm diameter Stainless Steel Wire



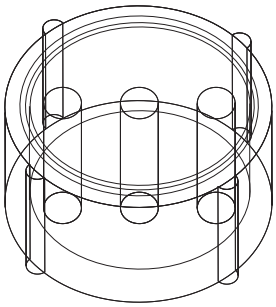


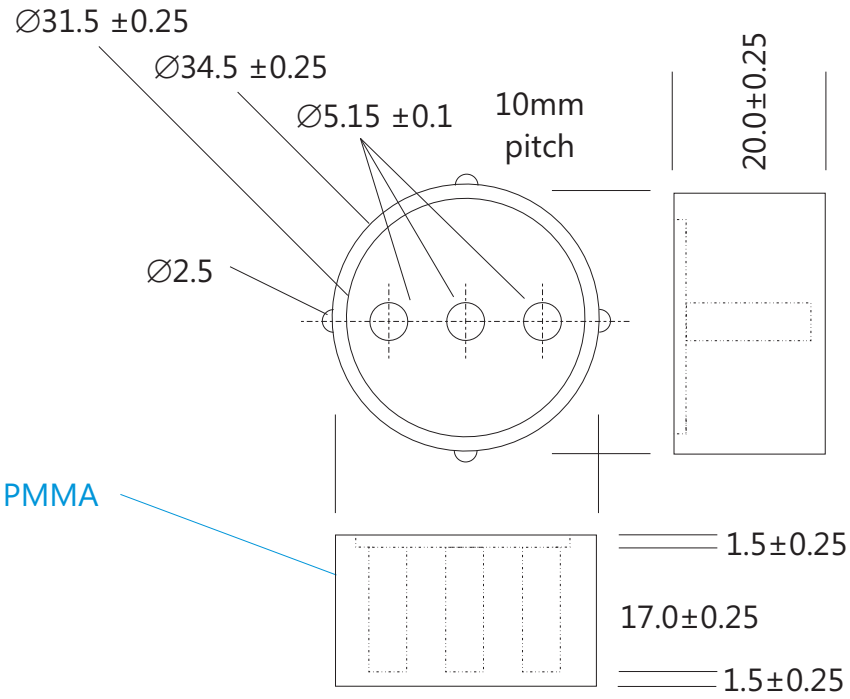


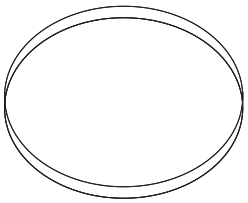


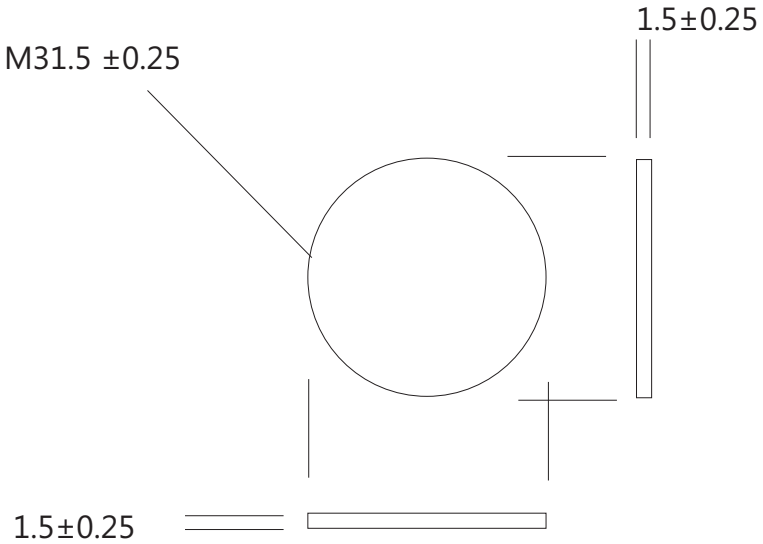
ARTEFACT (BEAM HARDENING) INSERT

2 per set
Titanium inserts



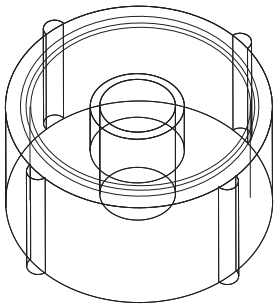


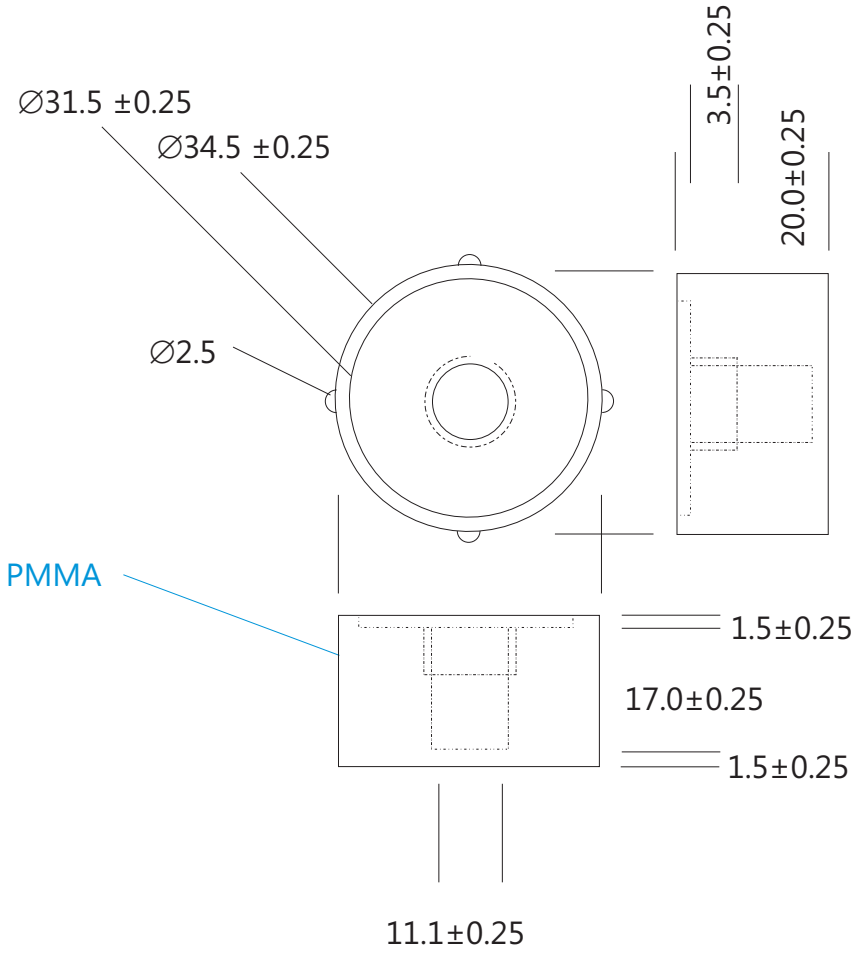


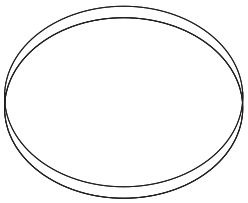


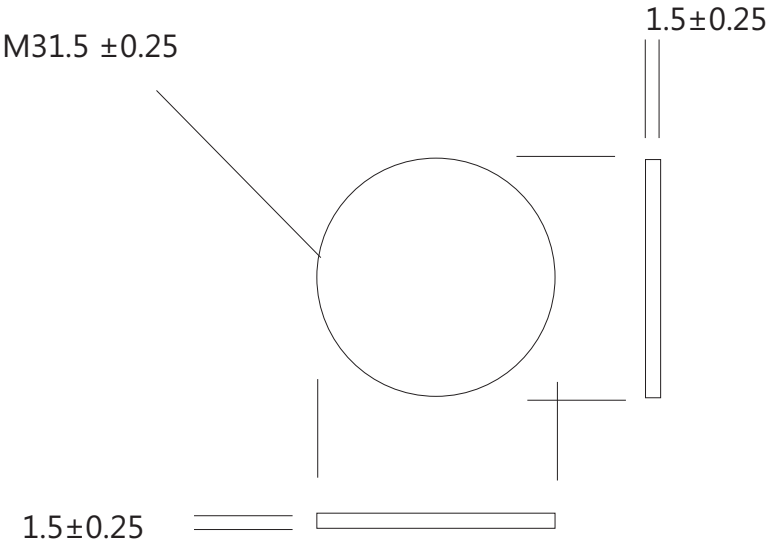
SPATIAL RESOLUITION Z (1 PER SET)

1.0 LP/mm
1.7 LP/mm
2.0 LP/mm
2.5 LP/mm
2.8 LP/mm
4.0 LP/mm
5.0 LP/mm









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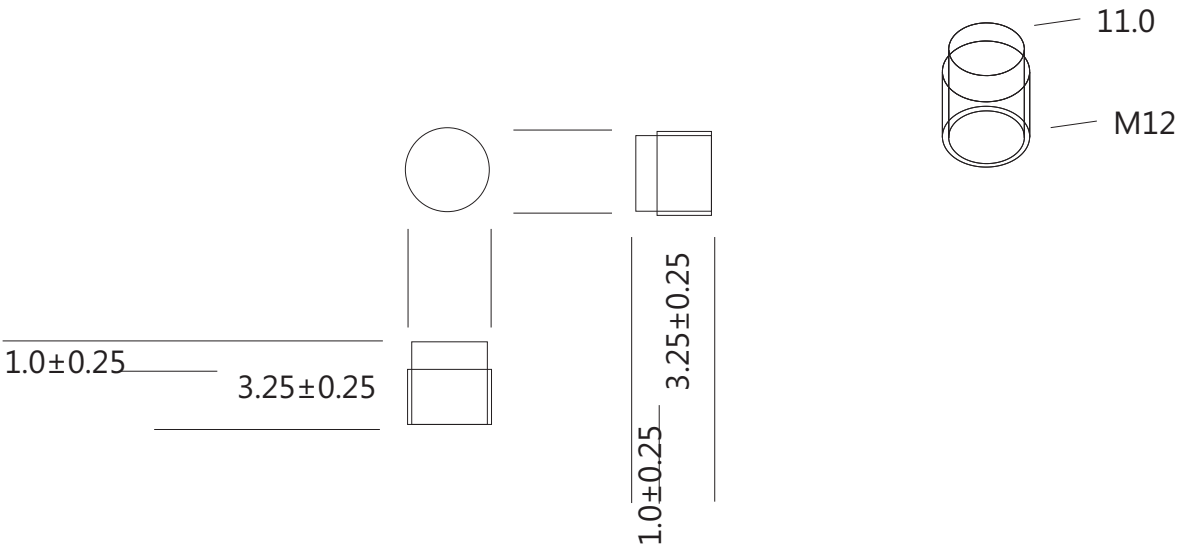
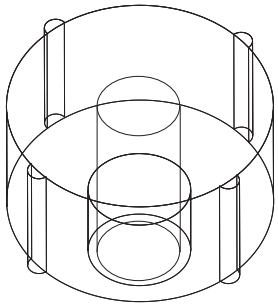
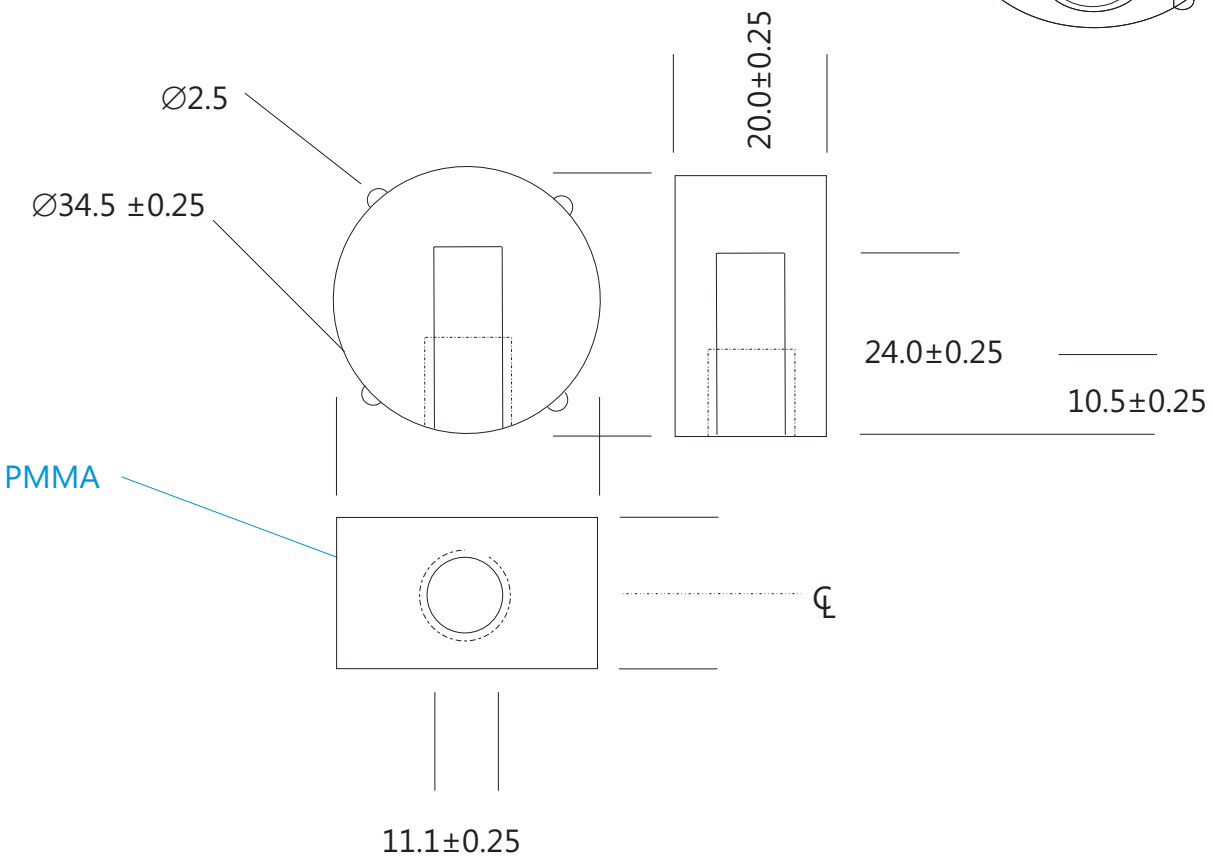


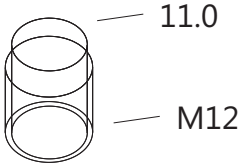
SPATIAL RESOLUTION INSERT XY

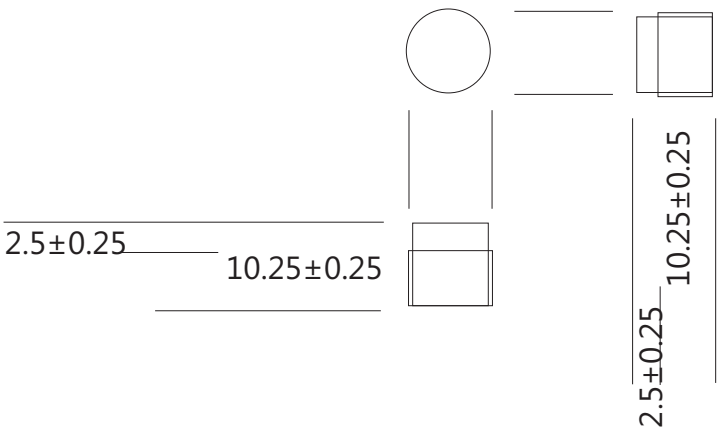
1 x XY per set

1.0 LP/mm
1.7 LP/mm
2.0 LP/mm
2.5 LP/mm
2.8 LP/mm
4.0 LP/mm
5.0 LP/mm







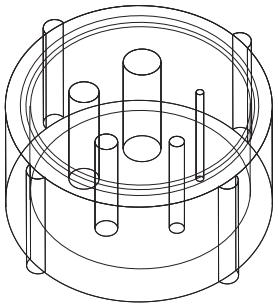


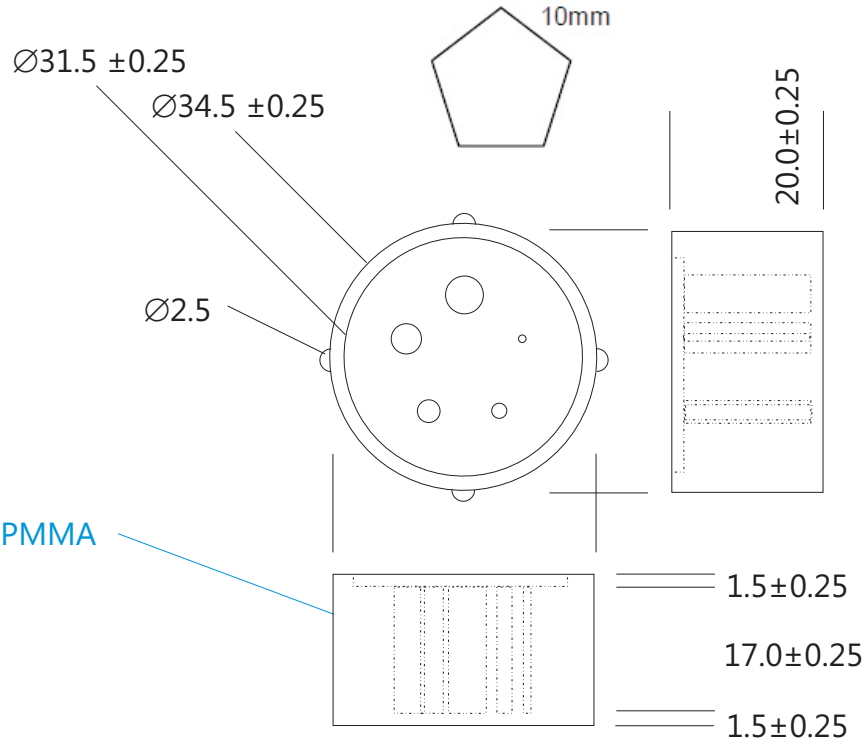
CONTRAST RESOLUTION INSERT (5 PER SET)

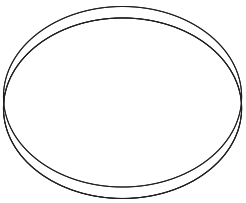
Aluminium 2.70 g/cc
PTFE 2.16 g/cc
Delrin 1.42 g/cc
LDPE 0.92 g/cc
Air
Water (PMMA - use blank insert)

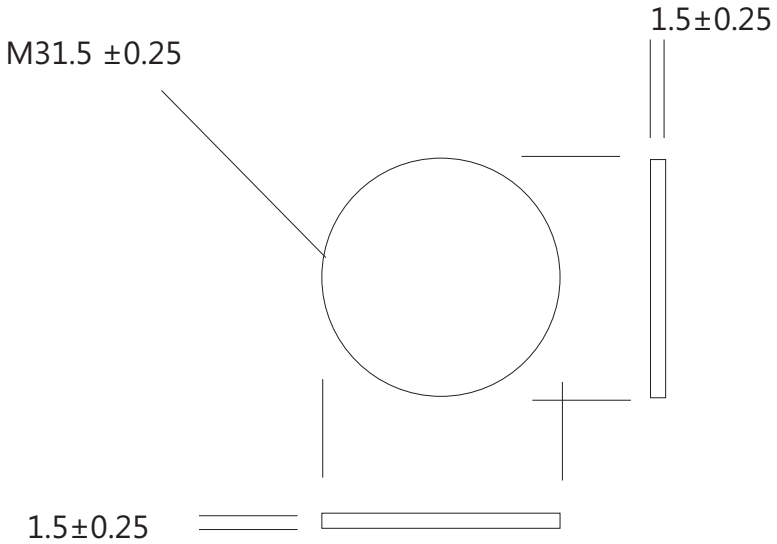
5 x holes:

5.0±0.1mm
4.0±0.1mm
3.0±0.1mm
2.0±0.1mm
1.0±0.1mm
each centred on a corner of a pentagon with 10mm sides, centred in the cylinder



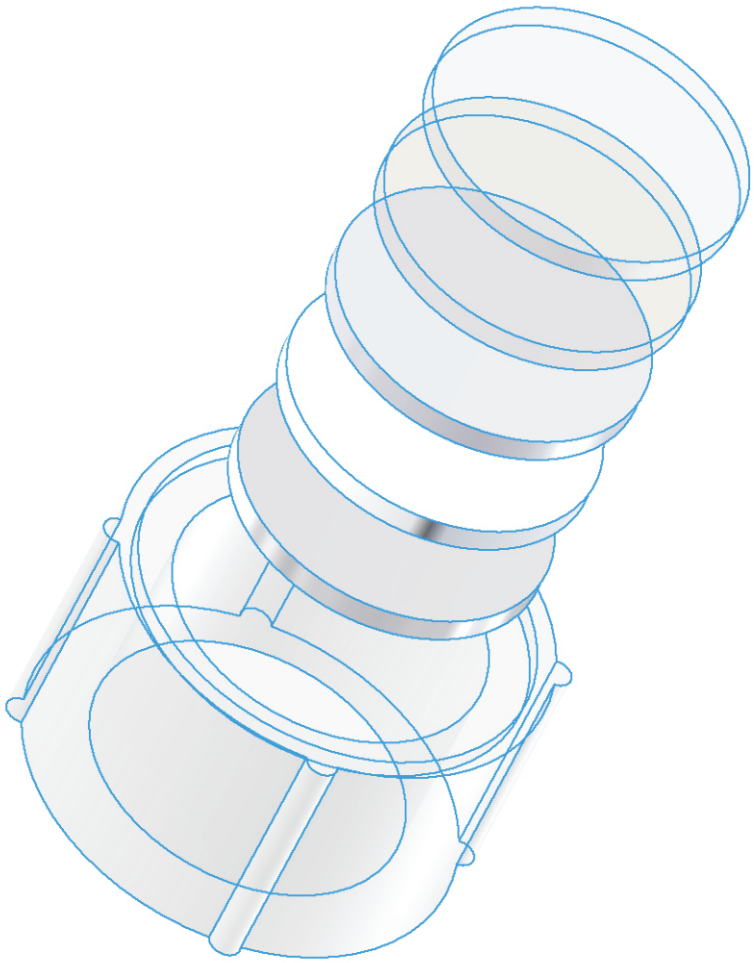






PIXEL INTENSITY INSERT (1 PER SET)

Aluminium 2.70 g/cc
PTFE 2.16 g/cc
Delrin 1.42 g/cc
LDPE 0.92 g/cc
Air
Water (PMMA)



Each disc is 3.3mm thick, from aluminium at the base up to air at the top

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