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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.

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.

A Quality Assurance (QA) procedure protocol was formed comprising a generic part about the implementation of a QA programme in CBCT, followed by a specific part on the SEDENTEXCT tools (the phantom and the software) used for running the respective tests described in the QA protocol.

The results lead to the conclusion that SEDENTEXCT has met the WP3 objective, to develop a phantom, software and a QA procedure protocol for CBCT QA analysis that will be used to inform the writing of the Guidelines (WP1).

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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 programme, including a tool/tools for quality assurance 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

1.3 Anticipated impact of the work

This section describes the impact of the work in this Work Package as anticipated at the start of the project.

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 the QA protocol frequently, and using the phantom and the software ensures 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.

Stakeholder(s)	Impact
Radiologists Dentists	follow QA protocol, use phantom + software to test CBCT equipment efficacy
Medical physicists	advanced imaging performance tests
Research community	studies on imaging characteristics
CBCT unit manufacturers	testing prototypes units and new equipment

1.4 Current state of the art

Due to the increasing use of Cone Beam CT (CBCT) in dental practice and the large number of devices on the market, there is a need for a quantified and objective analysis of the technical image quality and radiation dose to enable an optimal use for this imaging modality (Horner *et al.* 2009, Loubele *et al.* 2008). Three different aspects have to be considered in the optimization of an X-ray imaging modality: quantifying the radiation dose and risk for patients, assessment of technical image

quality and assessment of diagnostic image quality. By means of an appropriate test object, the first and second aspect can be studied in one investigation process. Ideally, the development of test objects goes along with the formation of Quality Assurance (QA) protocols. During these activities, the diagnostic image quality must always be considered, implying that dose measurements are to be reported in terms of diagnostic needs, and technical image quality assessments need to be evaluated for their diagnostic relevance. This is particularly the case for dental imaging, as it involves a large variety of diagnostic indications requiring different imaging approaches (Scarfe *et al.* 2002).

There is a lack of standardized tools for image quality analysis for dental CBCT. To develop such a tool, all available knowledge regarding image quality assessment on other 3D or pseudo-3D imaging modalities (spiral CT, tomosynthesis, kV-CBCT used in radiotherapy, *etc.*) (Du *et al.* 2007, Daly *et al.* 2006, McCann *et al.* 2004, Suess *et al.* 1999) needs to be combined with the existing knowledge of CBCT and previous studies on CBCT image quality. Even though a large number of CBCT image quality studies have been published over the last few years, most have focused on the diagnostic image quality. However, a number of studies have already assessed technical image quality for one or more CBCT devices, using an existing commercial Quality Control (QC) phantom (Jaffray *et al.* 2000, Marguet *et al.* 2009), a phantom provided by a CBCT manufacturer (Loubele *et al.* 2008, Watanabe *et al.* 2010), a water phantom (Jaffray *et al.* 2000, Vassileva *et al.* 2010), a customized test object (Bryant *et al.* 2008, Lascalea *et al.* 2004, Katsumata *et al.* 2009, Lagravère *et al.* 2008) or clinical data (Loubele *et al.* 2006, Naitoh *et al.* 2009). Although these studies have provided useful insights regarding certain image quality aspects, they also show the need for a standardized QC phantom which is suited for use on all CBCT devices, and which provides results that are relevant to dental imaging and that can be compared between systems. Commercial QC phantoms have been described for conventional CT, but these are not applicable for dental CBCT due to the difference in performance for certain image quality aspects. CT phantoms use soft tissue-equivalent materials for gray value analysis, which are not relevant for dental CBCT (McCann *et al.* 2004, Suess *et al.* 1999). Furthermore, dental imaging requires a high spatial resolution and a limitation of metal artifacts, both of which are not assessed by conventional CT phantoms.

A CBCT system uses a cone- or similarly shaped X-ray beam that rotates around an object and acquires two-dimensional projections, reconstructed into a three-dimensional volume (Scarfe *et al.* 2008). There is a variety of CBCT devices available with large differences for a number of imaging parameters: peak voltage, amount of filtration, quantity of X-rays (mAs), pulsed versus continuous exposure, beam geometry, number of projections, detector type, field of view (FOV) size, reconstruction algorithm, reconstructed voxel size, pre- and post-processing of raw and reconstructed data, *etc.* Designing a QC phantom requires a cross-section of all available CBCT devices, identifying common properties. These properties, most of which are intertwined, are (ordered from general to specific): (1) CBCT images show very poor soft tissue differentiation, as they are meant for the visualization of hard tissues (bone, teeth) and air (sinus and air cavities); (2) spatial resolution is high (voxel sizes are generally below 0.4 mm) and nominally identical in all planes (isotropic); (3) most devices expose at a kVp below 100, and a low mAs; (4) there is a relatively large degree of scattered radiation resulting in image noise and

nonuniformity; (5) voxel values are not standardized and cannot directly be used as quantitative CT numbers for use in bone mineral density (BMD) evaluation; (6) high density tissues and metal objects result in metal artifacts due to scatter, beam hardening and photon starvation. All of these considerations affect the design of a QC phantom. Another limitation is the minimum FOV size of all currently available CBCT devices; the phantom must be suitable for all CBCTs, including those with a FOV of a few cubic centimeters.

The objective of the current study is to develop a quality control phantom which is suited for dental CBCT imaging, can be used on any CBCT device and allows for the measurement of parameters which are relevant to dental imaging requirements. As an initial evaluation of the phantom, it was scanned using a variety of CBCT devices to evaluate the reproducibility and applicability of the evaluated parameters and to investigate CBCT imaging performance.

1.5 Deliverable D3.4

Deliverable D3.4 is the final deliverable of SEDENTEXCT Work Package 3. The objects of deliverable D3.4 are:

- To summarise earlier work
- To describe new work in this Work Package in the last period. The purpose of this work is to form a QA protocol for periodic QA tests in daily clinical practice and determine its implementation on CBCT units
- To describe the possible impact of work in this Work Package
- To outline dissemination plans and possible future work

2. Earlier Work in WP3

2.1 Deliverable 3.1

The purposes of Deliverable 3.1 were:

- to provide a 1st prototype phantom together with inserts for the testing of the imaging performance characteristics
- to provide results on the suitability of the phantom and the inserts for their intended purpose
- to reveal the required changes and improvements to the design of the 1st prototype
- to test a preliminary version of the software tools that help in the interpretation of the results and the evaluation of the image quality

The evaluating procedures carried on the first prototype phantom and the results obtained by the first version of the software tools (D3.1) lead to important conclusions regarding required improvements of the design of the prototype phantom and inserts at the next phase (2nd prototype).

2.2 Deliverable 3.2

The purposes of Deliverable 3.2 were:

- to provide a 2nd prototype phantom together with inserts for the testing of the imaging performance characteristics
- to provide results on the suitability of the phantom and the inserts for their intended purpose
- to reveal the required changes and improvements to the design of the prototype for the development of the final phantom
- to test the 2nd beta version of the software that help in the interpretation of the results and the evaluation of the image quality, using a beta test evaluation form.

The design changes that were implemented into the 2nd prototype are found appropriate for both the phantom body and the inserts for the different image quality tests. A final round of small design changes that will further improve the suitability of the phantom for QC testing are recorded and will be implemented into the final version of the phantom.

The beta testing of the software revealed that the following should be implemented in the final version:

- Compatibility with DICOM data from all available CBCTs
- Optimisation of viewing (MPR scrolling, window/level adjustment)
- Optimisation of insert selection (Manual insert selection tool, 3D selection)
- Insert analysis (implementation of all image analysis parameters)
- Automatic report creation

2.3 Deliverable 3.3

The purposes of Deliverable 3.3 were:

- 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:
 - the software is able to open datasets from all available CBCT devices;
 - the software allows for the measurement of all image quality parameters that are relevant for quality control;
 - there is a sufficient agreement between repeated measurements (by different observers or by the same observer).

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.

3. Work in the Final Period: Methodology

Sections 3, 4 and 5 of this deliverable report the work in WP3 in the last period. The purpose of this work is to form a QA protocol for periodic QA tests in daily clinical practice and determine its implementation on CBCT units.

As reported in earlier deliverables, the tools (phantom and software) were developed in three rounds during the project and tested by NKUA and KUL resulting in the construction of the final QA phantom and the accompanying software for semi-automatic image evaluation of the phantom images. 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. Validation of the associated software by five consortium partners was successful and a clear scanning procedure protocol for all measurements was established as part of D3.3.

The methodology used in the previous deliverable (D3.3) for the evaluation procedure carried out on the definitive phantom with the use of the validated software formed the basis for the writing of the QA Procedure (QA Protocol) as part of the final deliverable (D3.4).

4. Work in the Final Period: Results

A Quality Assurance (QA) procedure protocol comprises two parts. The first is a generic part about the implementation of a QA programme in CBCT (Appendix I) that was formed based on previous knowledge on QA programmes with special consideration of the particularities of the CBCT technology. The generic part is followed by a specific part on how to use the SEDENTEXCT tools (the phantom and the software) for running the respective image quality tests (Appendix II).

4.1 Generic QA protocol

The Quality Control Programme in general lays out the necessary testing to ensure that all parameters during the examination procedure are in accordance with the standard operating protocol, thus resulting in images with diagnostic value, without exposing the patient to unnecessary risk.

The programme of equipment tests for dental cone beam CT considers the following aspects:

- Performance of the X-ray tube and generator
- Patient dose
- Quantitative assessment of image quality
- Display screen performance

This protocol outlines those physical tests and measurements that are considered to be part of a standard quality control programme for a dental CBCT unit. It does not cover quality assurance of the clinical image.

A range of tests are appropriate for dental CBCT looking at different aspects of the equipment and image display. Some of the tests are straightforward and can be readily performed by the clinical staff using the CBCT equipment. Other tests are more complex and the input of a medical physicist is required. Therefore, the expertise required for each test is indicated in the protocol.

Routine quality control tests primarily involve comparison of results with those determined during commissioning. Significant variation, as indicated by pre-determined action levels, should be investigated, either with the help of a medical physics expert (MPE) or the equipment service engineer.

Not all possible methods of assessment are considered essential. It is important to perform enough tests to confirm that the equipment is operating as intended. More complex tests do add extra information that is helpful in the optimisation process and they are detailed here for completeness. However, whether the more detailed tests are undertaken will depend on the availability of expert support and the necessary resources.

The tests described in the generic part are summarised in the table at the end of the Appendix I.

4.2 User manual for using the SEDENTEXCT phantom and software

The user manual describing how to use the SEDENTEXCT tools (the phantom and the software) for running the respective image quality tests is provided in Appendix II. There are detailed instructions on the phantom handling and positioning, test inserts selection, inserts placing in the phantom and using the software for specific image quality tests, based on the knowledge acquired from the past deliverable D3.3. This is supplemented by the Leeds Test Objects specification sheet for the phantom (Appendix III).

5. Work in the Final Period: Conclusions

5.1 Conclusions

In conclusion, the SEDENTEXCT project has met the WP3 objective, to develop a phantom, associated software and a QA procedure protocol for CBCT QA analysis that will be used to inform the writing of the Guidelines (WP1).

5.2 Implications for future work

The recommendations of priority, level of expertise, frequency and action levels are based on published guidance and the experience of the SEDENTEXCT team in validating the use of the SEDENTEXCT QC test phantom. This represents an initial assessment of what is sensible and achievable but, as experience of testing these units is obtained over a period of years, these recommendations should be critically reviewed as new evidence becomes available.

Apart from the obvious future use of the QA protocol and QC phantom (i.e. to be used in a long-term assessment of CBCT performance), the QC phantom can also be used as a tool for CBCT optimisation. The phantom is applicable on all CBCT devices that are currently on the market. Furthermore, it can be applied to any new or upgraded devices that will be released in the coming years, providing an initial assessment of imaging performance. By using the QC phantom and evaluating technical image quality parameters in relation with radiation dose, it can be ensured that new and upgraded CBCT devices are optimized for dental imaging.

The QC phantom can also be used as a research tool for various applications. Algorithmic improvement of CBCT image quality can be investigated using raw data of the phantom. Improvements of image reconstruction in terms of noise, spatial and contrast resolution, and metal artefacts can be evaluated this way.

Furthermore, it can be used as a validation tool for a Monte Carlo simulation framework, to verify if the imaging chain is modelled appropriately. Subsequently, a voxel model of the phantom can be used to optimise CBCT imaging through simulation.

6. Overall Work Package Conclusions

This section considers both the earlier work and the work in the final period, to draw conclusions regarding the SEDENTEXCT Guidelines and the overall impact of the work, and to summarise the implications for further work.

6.1 SEDENTEXCT Guidelines

A Quality Control Programme lays out the necessary testing to ensure that all parameters during the examination procedure are in accordance with the standard operating protocol, thus resulting in images with diagnostic value, without exposing the patient to unnecessary risk. The resulting QA procedure protocol of this deliverable (D3.4) will feed into the Guidelines as an essential chapter regarding safety and efficacy of CBCT in daily practice.

6.2 Impact

The outcome of 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 the QA protocol frequently and using the phantom and the software to ensure 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.

6.3 Roadmap

Less than a decade has passed since CBCT has been widely accepted in dental practice. Therefore, there is no information available on image quality issues for CBCT devices that have been in commission for several years. X-ray tube or detector degradation can lead to a progressive deterioration of image quality. This topic can be addressed using the QC phantom and QA protocol, as it allows for a long-term assessment of image quality and can help to define clear and evidence-based action levels for different image quality parameters.

The QC phantom can serve an additional purpose as a research tool for optimisation, enabling the accurate evaluation of the variability in image quality for different exposure settings and reconstruction algorithms.

6.4 Future dissemination

WP task	Topic	(Provisional) Title	Main responsible	journals/conferences targeted
WP3.1	Phantom evaluation prototype 1	Development and applicability of a quality control phantom for Cone Beam CT	KUL / NKUA	Journal of Applied Clinical Medical Physics
WP3.2	Artefact analysis	Evaluation of metal artefacts on Cone Beam CT	KUL / NKUA	Clinical Oral Implants Research
WP3.2	Image analysis	Image quality evaluation of Cone Beam CT part 1: contrast resolution, noise and uniformity	KUL / NKUA	Dentomaxillofacial Radiology (or alternative)
WP3.1	Phantom evaluation prototype 2 Image analysis	Stability and reproducibility of image quality parameters measured on a quality control phantom for Cone Beam CT	KUL / NKUA	Unknown (not yet decided)
WP3.2	Image analysis	Image quality evaluation of Cone Beam CT part 2: spatial resolution, MTF and geometric accuracy	KUL / NKUA	Dentomaxillofacial Radiology (or alternative)
WP3.2	Image analysis	Accuracy and stability of density measurement with Cone Beam Computed Tomography	KUL / NKUA	Dentomaxillofacial Radiology (or alternative)
WP3.3	Quality assurance	Development of a quality assurance protocol for dental Cone Beam CT	UNIMAN / NKUA / KUL	Unknown (not yet decided)

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Appendix I: Generic QA Protocol: Quality Control for Dental Cone Beam Computed Tomography (CBCT) Systems

Quality Control for Dental Cone Beam Computed Tomography (CBCT) Systems

1 Introduction

A Quality Control Programme lays out the necessary testing to ensure that all parameters during the examination procedure are in accordance with the standard operating protocol, thus resulting in images with diagnostic value, without exposing the patient to unnecessary risk.

A programme of equipment tests for dental cone beam CT should consider the following aspects:

- Performance of the X-ray tube and generator
- Patient dose
- Quantitative assessment of image quality
- Display screen performance

Such a programme is a requirement of the European Union Medical Exposures Directiveⁱ as part of the optimisation process to ensure patient dose is as low as reasonably practicable whilst achieving clinically adequate image quality. Any practice undertaking medical exposure should have access to the advice of a medical physics expert on such matters. The Medical Exposures Directive is currently under revisionⁱⁱ and the role of the Medical Physics Expert is given higher prominence in the most recent draft.

Testing and patient dose assessment is carried out when the equipment is first installed as part of the commissioning process and then throughout the life of the equipmentⁱⁱⁱ. This protocol outlines those physical tests and measurements that are considered to be part of a standard quality control programme for a dental CBCT unit. It does not cover quality assurance of the clinical image.

A range of tests are appropriate for dental CBCT looking at different aspects of the equipment and image display. National guidance exists in some EU countries^{iv} and the SEDENTEXCT project^v has developed phantoms to facilitate carrying out a wide range of measurements. Some of the tests are straightforward and can be readily performed by the clinical staff using the CBCT equipment. Other tests are more complex and the input of a medical physicist is required.

Routine quality control tests primarily involve comparison of results with those determined during commissioning. Significant variation, as indicated by pre-determined action levels, should be investigated, either with the help of a medical physics expert (MPE) or the equipment service engineer.

Not all possible methods of assessment are considered essential. It is important to perform enough tests to confirm that the equipment is operating as intended. More complex tests do add extra information that is helpful in the optimisation process and they are detailed here for completeness. However, whether the more detailed tests

are undertaken will depend on the availability of expert support and the necessary resources.

The tests are summarised in the table at the end of the manual. The recommendations of priority, level of expertise, frequency and action levels are based on published guidance^v and the experience of the SEDENTEXCT team in validating the use of the SEDENTEXCT QC test phantom. This represents an initial assessment of what is sensible and achievable but it must be borne in mind that, as experience of testing these units is obtained over a period of years, these recommendations should be critically reviewed as new evidence becomes available.

Some manufacturers of dental CBCT systems provide a quality assurance phantom with their system, which should come with recommendations on the tests that should be performed, the best way to perform them, how often they should be performed and how the results should be interpreted. Some of these quality assurance phantoms are also provided with software that automatically performs analysis of the acquired image.

Where a phantom has been supplied, the manufacturer's recommendations are likely to be broadly similar to those contained within this manual. Where there are some tests that are included in the manufacturer's recommendations but not in this manual, they should be performed as there may be a specific reason for its inclusion. Where a test is included in this manual but not in the manufacturer's recommendations, consideration should be given to performing the test. Consult a medical physicist if necessary.

2 X-ray tube and generator

The correct and reliable performance of the X-ray tube and generator is crucial to the production of consistent images. Both radiation output and tube kilovoltage should be regularly monitored whilst tube filtration and leakage should be performed as part of the equipment commissioning and should be repeated if major repair work is carried out on the tube head.

2.1 Radiation output

This is assessed by measuring the absorbed dose in air at a fixed point in the X-ray beam, e.g. by using a small thimble ionisation chamber placed at the isocentre. It should be noted that the ionisation chamber should have isotropic sensitivity.

2.1.1 Radiation Output Repeatability

This test monitors the consistency of the radiation output for a series of radiation exposures using constant exposure parameters.

Example: Repeat five measurements using constant exposure parameters at a typical clinical setting.

2.1.2 Radiation Output Reproducibility

This test monitors the effect of the exposure parameters (tube voltage and mAs) on the radiation output. Comparison should be made with the baseline values established at commissioning.

Example: Measure at a range of tube voltages e.g. 70, 80, 90kV_p at a range of typical clinical mAs settings.

Note: Many CBCT units do not allow a manual selection of tube voltages and mAs. For these units, the above exposures should be made at the automatically selected exposure settings.

2.2 Tube potential

The voltage applied to the X-ray tube determines the energy of the X-ray photons and is a major factor in determining the contrast in the image.

Assessment of the tube potential ensures that the delivered kV_p is close to that set on the unit by the operator. Poor agreement between the two would affect clinical image quality, equipment radiation output and patient dose.

2.2.1 kV accuracy

The kV_p should be measured directly using a kV divider device at intervals of 10kV_p across the full range the unit is capable of producing.

2.2.2 kV repeatability

The consistency of the tube potential should be monitored by repeating five measurements at at least two clinically relevant kV_p values, where possible.

2.2.3 kV reproducibility

The reproducibility of the tube potential over time should be monitored by comparing the measured results for kV_ps at intervals of 10kV across the full range the unit can produce with those established as baseline values at commissioning.

2.3 Filtration

The filtration of an X-ray tube absorbs the low energy photons that do not contribute to the image formation but do contribute to patient skin dose. Having adequate filtration is essential to ensure that patient dose is controlled. The total filtration should be marked on the X-ray tube housing.

Total filtration can be estimated by measuring the Half-Value Layer (HVL). The HVL is the thickness of the absorber required to reduce the intensity of the incident X-ray beam by half. The HVL is an estimate of the penetrating power of the X-ray beam which means that the higher the HVL the more penetrating the X-ray beam is.

2.3.1 How to measure HVL

A dosimeter such as a thimble ionisation chamber should be positioned at the isocentre of the X-ray beam or at the surface of the detector. If possible, the scanner should be set to operate in 'service mode' so that the X-ray tube is stationary. If this is not possible, then alternatives should be considered, such as the possible use of the 'scout' mode. Alternatively the scanner can be operated under normal conditions with care taken in setting up the dosimeter and the filters. A typical protocol for measuring HVL should be followed^{vi}, in which the transmission through known thicknesses of high purity aluminium is assessed. Using this HVL measurement and knowledge of the X-ray tube design, the total filtration can be estimated from look-up tables^{vii}.

2.4 Radiation Field of View

The field of view (FOV) of a dental CBCT scanner is usually defined at the isocentre. The scanner should be set to operate in 'service mode' and a film or a CR cassette can be placed at the isocentre and exposed to different field sizes. The size of the film or the CR cassette should be chosen so as to extend over the nominal dimensions of the FOV. The dimensions of the imaged field can be measured and compared to the nominal FOV, as quoted by the manufacturers, and the dimensions of the FOV measured at baseline. If the manufacturers state that it is necessary to irradiate beyond the nominal FOV for the purposes of image reconstruction this should be taken into account.

If the scanner cannot be operated at the 'service mode', then the film or the CR cassette could be placed on the detector and exposed to the maximum and different FOVs. If the distance of the focal spot to the detector is known, then the dimensions of the nominal FOV on the detector can be calculated and compared to the imaged FOV. Alternatively, two sets of thermoluminescent dosimeters (TLDs) could be placed using holders at the isocentre with the first set placed vertical and the second set placed parallel to the z-axis and exposed to one FOV at a time. The number of TLDs should be chosen so as to extend over the nominal dimensions of the FOV. The TLDs are read out and the dimensions of the irradiated FOV are compared with the dimensions of the nominal FOV.

In addition, it should be confirmed that the X-ray beam is contained within the detector. A film or a CR cassette should be placed on the surface of the detector and the edges of the active area of the detector should be marked on the film or CR cassette and then exposed to radiation. The radiation field should not extend beyond the marked edges on the film or the CR cassette.

2.5 X-ray beam alignment

This test is to assess the coincidence of the centre of the radiation and imaged FOV with the isocentre as defined by the alignment lasers or the scout view.

Any radiopaque object positioned at the isocentre allows for a measurement of the distance between the imaged object and the centre of the imaged FOV using the measuring tool of the scanner's software. Note that the accuracy of this measurement is reliant on the correct calibration of the measurement software (see section xxx) and the voxel size of the reconstructed image.

2.6 Leakage

Radiation is emitted from all directions from the focal spot, not just in the direction of the primary X-ray beam. The tube housing is designed to attenuate the radiation outside the main beam so that patient and staff are not significantly exposed. This source of secondary radiation is known as leakage.

On standard X-ray equipment, leakage is measured during commissioning, usually by a medical physics expert, to confirm that the tube head design and construction is adequate. It should also be measured if physical damage to the tube head has occurred or the tube head has been dismantled during repair.

The measurement of leakage on a dental CBCT is problematic and can only reliably be achieved if the movement of the tube head can be stopped (likely to be available in 'service mode' only) and the primary beam can be blocked either by the use of collimators or a lead block at least 1mm thick placed as close to the tube window as possible. If this can be achieved, standard methods for leakage measurement can be applied^{viii}, involving the identification of areas of leakage and the measurement of dose rate at these areas. When interpreting the results, due regard should be made to the effectiveness of the attenuation applied at the tube window.

If the movement of the tube head cannot be stopped, securely fixing a lead block as close to the tube window as possible should still allow meaningful measurements of secondary radiation to be made at accessible points adjacent to the unit. These results will give an indication of whether the leakage from part of the tube housing is higher than expected. The use of film or computed radiography plates around the tube housing can also be useful in detecting small areas in which there is less shielding, or where the shielding is absent altogether. If detected, measurements of secondary radiation can be focussed in these areas.

3 Patient dose

Knowledge of patient dose is essential for clinicians who are making the decision regarding the justification of the exposure. It is also important to ensure that doses are optimised and in line with any national and international guidelines. The dose quantity 'effective dose' gives an indication of radiation risk and can be compared to doses from other radiation sources. However, effective dose cannot readily be measured and must be inferred from more easily measureable dose quantities.

3.1 Dose measurement

A variety of dose indices are used to characterise patient dose.

3.1.1 CTDI

For CT scanners the CT dose index (CTDI) is usually used. This is a measurement of the dose integrated across the dose profile along the patient's length. It is measured using a pencil detector either in air or in a perspex phantom^{ix}. Such a dose index has drawbacks for use in dental CBCT units due to the greater beam size and asymmetry of the dose distribution. However, if a CTDI is quoted by the manufacturers, it is suggested that this be measured by the medical physics expert at commissioning for comparison with the specification.

3.1.2 CBCT dose index

The SEDENTEXCT project has investigated the use of a dose index obtained from measurements using a small volume dosimeter in a Perspex phantom. This is measured at points across the X-Y plane in the centre of the Z axis.

Measurements can be performed using an ion chamber or TLDs, within a suitable PMMA phantom (diameter 16cm is recommended). Two CBCT dose indices are currently proposed. Index 1 requires measurements along a diameter of the phantom (Figure 1) and is calculated as the mean of the readings. Index 2 involves measurements at the centre of the phantom and at points around the periphery. Index 1 allows the measurement of an index for on-axis and off-axis exposures, and full and partial dose distributions simply by rotating the phantom in such a way that the isocentre of the x-ray beam lies on the measuring diameter as shown in Figure 1. Index 2 is only suitable for symmetrical dose distributions.

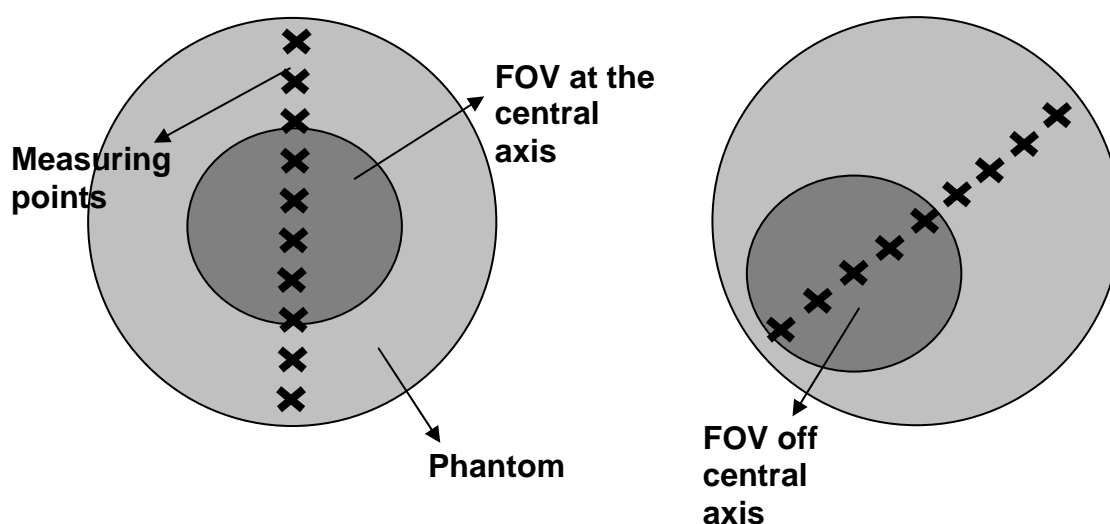


Figure 1 Measurement points for Index 1

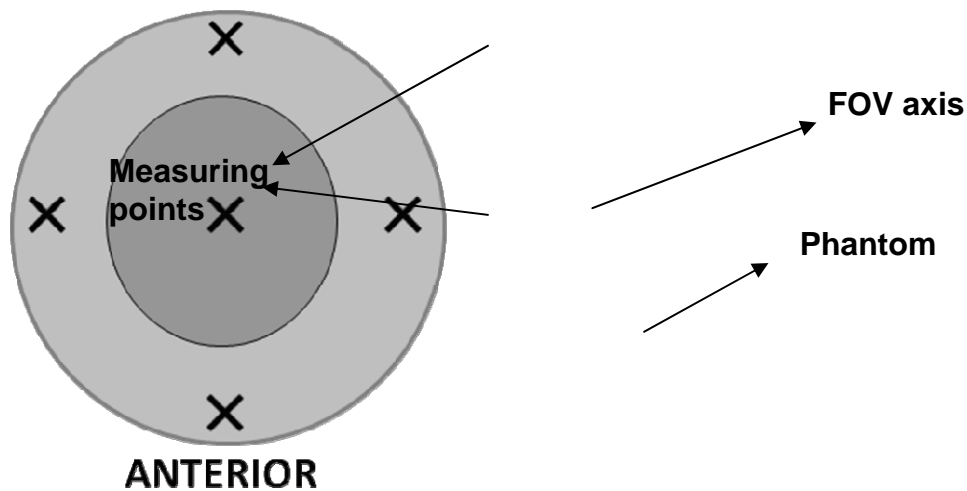


Figure 2 Measurement points for Index 2

Such indices can be used to monitor the reproducibility of the dose distribution over time, to relate to manufacturer's specification and national or international diagnostic reference levels if set using a dose index.

3.1.3 Dose area product (DAP)

The product of the dose in the beam multiplied by the area of the beam at that point is known as the dose area product (DAP) and is a dose index routinely used in general radiography and fluoroscopy.

DAP can readily be measured by the medical physics expert using either a calibrated ionisation chamber that integrates the dose across the primary beam (DAP meter) or by measuring dose and beam size at a fixed point. Care should be taken on units where the beam size changes during the scan and a suitable DAP meter must be used for these units.

If a DAP reading is provided on the equipment readout, the medical physics expert should confirm the accuracy of such a readout. The readout may then be used by the dentist to audit and monitor dose and compare to any national or international audit levels (see diagnostic reference levels).

If no DAP reading is provided, the medical physics expert should provide the DAP readings for all standard settings of the equipment so the dentist can compare the levels to any national or international audit levels (see diagnostic reference levels).

3.2 Diagnostic reference levels

The European Medical Exposures Directive requires that diagnostic reference levels are set and used as part of the optimisation process. Exactly how this requirement is applied varies from country to country depending on how it has been implemented into national legislation. However, the overall aim is that patient dose is audited and the dose for a typical patient is compared to past levels and any national and international levels. This will give the dentist

confidence that doses in their practice are not unnecessarily drifting upwards and that they are in line with accepted levels.

Diagnostic reference levels may be set using a variety of dose indices. The UK Health Protection Agency has recommended the use of dose area product (DAP) and has proposed setting reference levels for the UK for both adult and child procedures. The adult level is for the clinical protocol for the placement of an upper first molar implant in a standard male patient and the child level is for the clinical protocol used to image a single impacted maxillary canine of a 12 year old male. Based on current national audit data an initial achievable level of 250 mGy cm² is proposed and further data is requested so that national reference levels for both adult and child can be set.

It is recommended that clinical dose levels are determined in a practice (by measurement of standard protocols or by patient dose audit if dose index readouts are provided by the equipment) and compared to past results and any national and international levels when set. Dose levels higher than these standards merit investigation as this would suggest that dose is not optimised.

4 Quantitative image quality performance

A range of image quality indicators can be measured using phantoms designed for such measurements. A variety of different phantoms are available.

Phantoms, such as the Catphan, designed for use on CT scanners can be used for dental CBCT units but are difficult to position and tend to use soft tissue-equivalent materials for the more accurate evaluation of grey scale accuracy.

Dental imaging has a few specific requirements (e.g. hard tissue visualisation and sub-millimetre spatial resolution) which are not assessed by phantoms not specifically designed for the purpose. Some manufacturers provide phantoms with their scanners and the SEDENTEXCT project has designed a phantom specifically with dental CBCT units in mind.

In addition, software tools are required to analyse the images of the phantom. These may be available as part of the image viewing software or may be separately provided with the phantom. The SEDENTEXCT phantom is provided with standard software for image analysis.

Acquisition of such a phantom and software tools is essential if the image quality measurements are to be performed. MPEs should normally have access to such phantoms and software and will be able to carry out these measurements.

Note that whilst most systems exhibit a linear relationship between image pixel value and object density within a single scan, the use of histogram shifting by some units means that this is not always the case from scan to scan. Care should be taken when comparing uncorrected data across scans or from unit to unit.

4.1 Image density values

A clinically useful image relies on the system's ability to distinguish between and clearly display the different materials in an image. The accuracy with which a system can continue to do this over time can be determined quantitatively.

4.1.1 Setting a baseline

- Acquire an image of the image density value section of the phantom. This should be an area in which there are many different materials clearly distinguished from one another
- Draw a region of interest in each of the different materials and record the mean pixel value and standard deviation in each

4.1.2 Routine measurements

- In future visits, expose the same test object using the same protocol, draw a region of interest in each of the different materials and record the mean pixel value and standard deviation in each
- Compare the mean pixel value for each material with that measured on the first visit

4.2 Contrast detail assessment

Assessing a system's ability to display details of known varying contrast can give important information as to the deterioration of image quality over time. A phantom containing objects with a range of different sizes and/or contrasts is required.

4.2.1 Setting a baseline

- Acquire an image of the contrast detail section of the phantom. This should be an area in which there are various details of the same material that vary in diameter and depth, or various details of different materials
- The simplest check of contrast detail is counting the number of details that can be clearly resolved on a reporting monitor
 - It may be useful to derive a single value for contrast detail assessment, for example the threshold detection index, the image quality factor or the contrast to noise ratio^{xii}. Action levels will depend on the test object and scoring methodology used
 - Some phantoms may provide software that calculates contrast detail values after analysing images. In these cases, follow the instructions that come with the phantom

4.2.2 Routine measurements

- Acquire an image of the contrast detail section of the same phantom using the same exposure protocol as at baseline
- Count the number of details on the image using the same monitor as at baseline where possible
 - If a threshold detection index, image quality factor or contrast to noise ratio is being used, compare with the baseline results
 - If automated scoring with phantom software is being used, results should be compared with baselines

Scoring test objects by eye is very subjective. It should be ensured that where there are different personnel scoring the details, they use a similar methodology.

4.3 Uniformity and artefacts

It is important that the entire detector is capable of producing a useful image, and so it must be ensured that there are no significant areas of damage or problems with detector calibration that could lead to artefacts in acquired images. Similarly it must be confirmed that damaged or dead pixels are appropriately corrected for in the final image.

4.3.1 Where a QC phantom is available:

- Acquire an image of the uniformity section of the phantom. This should be a large homogeneous area so that it can be assured that any deviations on the image are the result of the imaging system and not the phantom itself
- A visual check of the uniformity of the image will reveal any significant uniformity problems
- Where quantitative tools are available, draw a region of interest in the centre of the test object and then four evenly spaced regions around the periphery and measure the mean pixel value in each. Assess the image uniformity using the results

4.3.2 Where no QC phantom is available:

- Acquire an image with nothing in the beam. Be aware that this could give odd images on some scanners if the reconstruction relies on a head or equivalent phantom being present. In these cases consider the use of a scout view
- A visual check of the uniformity of the image will reveal any significant uniformity problems. In this case, some windowing of the image may be necessary to better assess uniformity
- Where quantitative tools are available, draw a region of interest in the centre of the test object and then four evenly spaced regions around the periphery and measure the mean pixel value in each. Assess the image uniformity using the results

4.4 Noise

There are many processes that could affect the quality of a clinical image, including tube output, detector efficiency and image processing. A quantitative assessment of the noise in an image can identify any deterioration in image quality with time and help determine the cause of the deterioration.

4.4.1 Setting a baseline

- Acquire an image of the uniformity section of the phantom. This should be a large homogeneous area so that it can be assured that any deviations on the image are the result of the imaging system and not the phantom itself
- Draw a region of interest in the centre of the test object, with diameter no greater than one fifth the diameter of the test object. Record the standard deviation

- Repeat for five consecutive axial slices and calculate the average standard deviation.

4.4.2 Routine measurements

- Acquire an image of the uniformity section of the same phantom using the same protocol as at baseline
- Draw a region of interest in the centre of the test object, as close in size and position to that at baseline as possible, and record the average standard deviation across five consecutive axial slices

Further analysis:

Consideration should be given to the calculation of a signal to noise ratio in addition to the noise measurements described above. The information provided by signal to noise ratios can be useful in investigating potential problems with the system where they are suggested by noise measurements alone.

4.5 Spatial Resolution

Spatial resolution is a measure of the ability of the system to detect small high contrast detail.

4.5.1 Limiting resolution

This test measures the smallest high contrast detail that can be detected, usually by using a phantom in which small lines get closer and closer together.

Method

Place a suitable object made of a high contrast material on the detector and expose at clinically relevant exposure factors. Magnify the reconstructed image of the test object and optimise the window level. Score the number of resolvable groups of lines and convert to the corresponding resolution. Be sure to use the same exposure factors as at baseline year on year.

4.5.2 Modulation Transfer Function (MTF)

Measurement of the limiting resolution will assess the system's ability to transfer the high frequencies (finest details) but it does not provide any indication on how other frequencies are transferred. This can be assessed by measuring the modulation transfer function (MTF) of the system. The MTF can be calculated by measuring the Point Spread Function (PSF) or the Edge Spread Function (ESF).

The PSF can be measured directly by imaging a high contrast wire. The wire is embedded in a suitable medium and placed perpendicular to the scan plane. The PSF is obtained by plotting the pixel values across the image cross-section of the image of the wire. Resolution can be measured directly from the PSF by measuring the full width at half maximum (FWHM).

The ESF is measured by imaging an edge of a block of material embedded in a suitable material with the face of the block perpendicular to the scanned plane.

The ESF is obtained by plotting the pixel values across the image. Differentiating the ESF will give the Line Spread Function (LSF). The LSF can be used to assess the spatial resolution of the system similar to the PSF.

The MTF can be calculated as the modulus of the Fourier transform of the PSF or the LSF. The values quoted are the frequencies at which the modulation falls to 50% or 10% of its initial value.

A more detailed description of the MTF method is given in the IPEM Report 32, Part VII.^x

4.6 Geometric Accuracy

Where it may be clinically useful to perform measurements of distance or angle on an image, it must be ensured that measurements made on a system accurately reflect true distances and angles. A phantom is required that contains an area with objects at known distances and angles from one another.

- Acquire an image of the geometric accuracy section of the phantom.
- Where quantitative test tools are available, measure distances and angles across a variety of the objects within the phantom
- Compare the measured values with known distances and angles. A more detailed analysis can be performed by calculating the aspect ratio and pixel pitch if required.
- Ensure the aspect ratio is correct by calculating measured x / measured y for distances of the same intended length. The ratio should be 1 ± 0.04
- Ensure the pixel pitch is as stated by the manufacturer by calculating measured distance (mm) / number of pixels covering the measured distance. Measure the pixel pitch for various distances in the x and y axes

5 Display equipment

Regardless of the quality of the x-ray equipment with which an image is acquired, a clinical image can only be digitally displayed as well as the monitor on which it is viewed is capable of. It is essential therefore to ensure that any monitor that is used to report on clinical images is well set up and subject to regular QC.

The QC programme outlined in the report of the AAPM task group 18^{xi}, or equivalent, is an appropriate methodology for MPE tests. Regular in-house checking of the display monitors should also be performed, as follows:

5.1 General condition

- A suitable test pattern, such as an AAPM TG18 or SMPTE image, should be installed on the computer and viewed on the monitor, which should be clean
- It should be ensured that all distinct greyscale levels on the test pattern can be individually resolved. The small black and white squares within the larger black and white squares should also be clearly resolved
- Where two monitors are used for reporting, it should be ensured that the perceived contrast of each of the distinct greyscale levels is consistent between the two

5.2 Monitor resolution

- It should be ensured that all of the bars on each of the resolution patterns on the AAPM TG18 or SMPTE test image can be clearly resolved

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Summary

	Test	Priority	Level of expertise*	Suggested frequency	Action levels**
X-ray tube and generator	Output repeatability	Essential	MPE	12 monthly	Mean $\pm 10\%$
	Output reproducibility	Essential	MPE	12 monthly	Baseline $\pm 10\%$
	Filtration	Essential	MPE	When new, if output changes or tube head dismantled	< 2.5mm aluminium (of which 1.5mm should be permanent)
	Tube potential	Essential	MPE	12 monthly	> $\pm 5\%$ of intended kV
	Field size and alignment	Essential	MPE	12 monthly	>10% expected field size
	Leakage	Essential	MPE	When new and if damage suspected	> 1000 μ Gy hr-1 at maximum tube rating.
Quantitative image Quality	Image density values	Recommended	In house/MPE	Monthly	>10% from baseline
	Uniformity and artifacts	Essential	In house	Monthly	Visible artefacts on the image or $\geq \pm 10\%$ of the mean
	Noise	Recommended	In house/MPE	12 monthly	> $\pm 10\%$ from baseline
	Limiting resolution	Essential	In house/MPE	12 monthly	> $\pm 20\%$ from baseline
	Contrast detail	Recommended	In house/MPE	12 monthly	Dependent on method used.
	Geometrical accuracy	Essential	In house/MPE	12 monthly	within $\pm 2\text{mm}$ and $\pm 2^\circ$
Display specific	General condition	Essential	In house	Monthly	Failure to resolve different contrasts in test pattern/ not consistent between monitors
	Monitor resolution	Recommended	In house	Monthly	Not consistent with baseline image
Patient dose	Patient dose index	Recommended	MPE	12 monthly	Outside $\pm 15\%$ of manufacturer's specification
	Patient dose audit	Essential	In house/MPE	At least 3 yearly	> national or international reference level

Notes

* **Level of expertise:** MPE indicates that this test would normally require the input of a medical physics expert with sophisticated test equipment whereas in house indicates that the tests can normally be performed by clinic staff using standard phantoms

** **Action level:** Results outside these levels should be investigated and action taken. The advice of a medical physics expert or service engineer may be required

N.B. This table represents initial guidance based on current experience of dental CBCT units. It should be kept under critical review as experience is gained in testing such units.

Appendix II: SEDENTEXCT User Manual - Image Quality Scanning Protocol

SEDEXCT Image Quality Scanning Protocol

This protocol provides specific instruction for performing CBCT scans of the SEDENTEXCT image quality phantom. It is important to place some of the inserts in a specific way, to avoid interference between inserts. Furthermore, the phantom should be scanned using an accurate and reproducible positioning, as deviations in positioning may lead to variable results for a few image quality parameters.

Placement of inserts

As seen in Figure A1, the phantom has six rows for insert placement, numbered 1 (bottom) to 6 (top).



Figure A1. Six phantom rows for insert placement.

There are seven columns (one central, six peripheral) named A to G (Figure A2).



Figure A2. Columns for insert placement.

The distribution of the inserts over the different rows is determined in a more or less strict way, with limited user freedom. There are a few other restrictions regarding the choice of columns.

Row 1

Place 'Artefacts Titanium' inserts inside a column that enables the rods to be placed along the radius of the phantom (*i.e.* perpendicular to the edge). Place second 'Artefacts Titanium' insert at a position which enables the rods to be placed (approximately) parallel to the edge of the phantom. The two artefact inserts cannot be adjacent; they should be separated by 2 peripheral columns. Fill up other (central and peripheral) columns using PMMA inserts.

Row 2

Fill up all columns using PMMA inserts. This row is used to separate the artifact inserts from all other inserts, avoiding interference.

Row 3

Place the five 'Contrast Resolution' inserts at peripheral positions. The placement of these inserts is not crucial, as long as the central hole is not used. Place the 'Pixel Intensity Value' insert in the remaining peripheral hole. Use a PMMA insert for central hole.

Row 4

Distribute 4 remaining inserts (LSF – PSF – Spatial Z – Spatial XY) along peripheral holes. Fill up remaining holes using PMMA inserts.

Rows 5&6

Fill up all columns using PMMA inserts.

Scanning protocol

Phantom and FOV positioning

The positioning of the phantom should be done with a tripod or stable platform, ensuring that the phantom is level. Having the phantom level is one of the key factors for accurate software measurements.

The positioning of the FOV depends on the size of the FOV. When considering the number of columns obtained in once scan, there are different possibilities:

- Large FOV (15cm diameter or larger): scan all columns in one scan by placing phantom centrally in the FOV. If there is considerable image quality loss at the border of the FOV (streaks / darkening) affecting the peripheral inserts, the FOV should be considered as 'Medium' (see below).
- Medium FOV (8-14cm diameter): scan 2 or 3 columns per scan, depending on the actual size of the FOV and the image quality near the border of the FOV. If scanning 2 columns, place the centre of the FOV (isocentre) in the mid-point between the two columns. If scanning 3 columns, place the isocentre between the middle of the peripheral columns and the central column (so you will actually be scanning 4 columns).
- Small FOV (up to 6cm diameter): scan 1 column per scan.

When considering the number of rows included in one scan, the height of FOV should be considered as well as image quality loss, artifacts and FOV narrowing near the upper and lower edge of the FOV. Use the minimum amount of scans without hampering image quality.

For the PMMA portion and geometric pattern (at the border between the PMMA portion and the insert portion), it is important not to position the FOV too low if using a tripod or other high-density phantom support to avoid artifacts. If possible, place the phantom on rigid object of medium density (another phantom if available, papers, books, etc.) and not directly on a metal platform. For medium and small FOVs, scan the peripheral PMMA portion of the phantom as well as the central portion. For large FOVs, position the FOV centrally to scan the entire PMMA portion in one scan.

Exporting data

Export (only) axial slices using the thinnest slice thickness and smallest slice interval. Check the folder after exporting for any non-DICOM files (e.g. DICOMDIR) and delete them, as they will hamper the import of the dataset into the SEDENTEXCT software (see below).

Software protocol final phantom

Setting up the software

No installation is required, just download the file “SedentexCT.zip” and unzip into a chosen folder. To run the program, run the executable file “Sedentex.exe”.

NOTE: The program must be placed within folders (folders and subfolders) which have no space in their names. For example: Path:

“C:\My Folder\My Program\SedentexCT”

is incorrect because there are spaces between words in two folder names: “My Folder” and “My Program”. A few examples of a correct path:

“C:\MyFolder\MyProgram\SedentexCTsoftware”

“C:\SedentexCTsoftware”

“C:\CBCT\QC\SedentexCTsoftware”

Stack of images (datasets)

Similar to the software, datasets used in the software must be placed within folders which have no space in their names.

For example: Path: “C:\My Folder\DeviceName” is incorrect. The most convenient place for the datasets would be in a subfolder of the SedentexCT software. You can create a first subfolder called ‘datasets’ in the main folder of the software (e.g. “C:\SedentexCTsoftware\datasets”) and create further subfolders showing the type of device, the name of the imaging protocol (FOV / resolution / mA / ...), the date of exposure, etc, for example:

“C:\SedentexCTsoftware\datasets\Scanora\60x60_HR_8mA\2010_11_14”

Make sure there are no spaces in any of the folder names.

Also, the stack of images must be placed on a writeable medium (hard drive) with at least 1 GB of free space. Opening the images from CDs/DVDs is not possible as the program will not be able to convert the images.

To load a stack of images click on: “File” and then on “Open set of images”. In the pop-up window, browse to the folder containing the dataset, click on any file within this folder and click on the “Open” button to start the loading process. This process is divided into 7 steps (Figure A3). It is possible to cancel the loading process during these steps (except for Step 2 – Converting files).

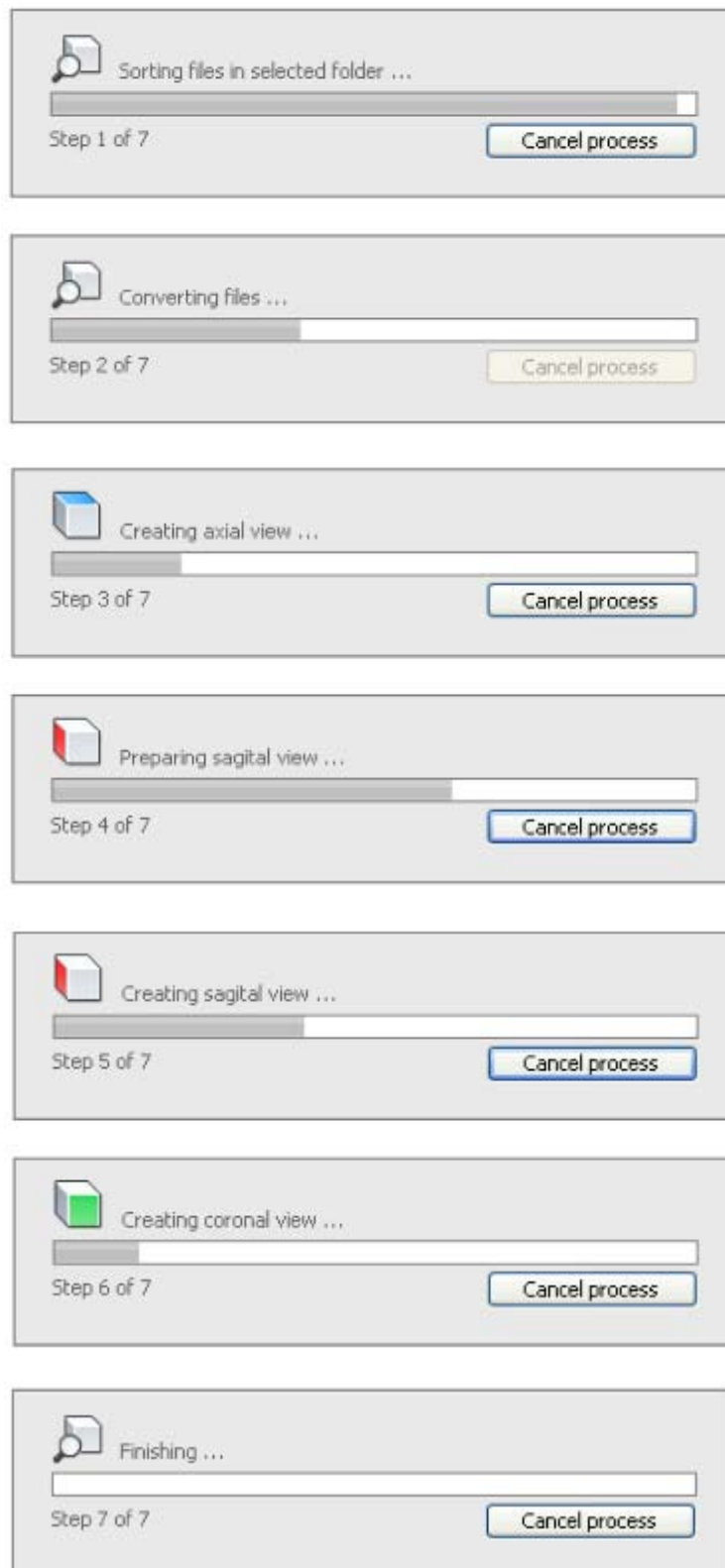


Figure A3. Seven consecutive steps in the dataset loading process.

Main control elements of the program

On the left side, there are three preview panels showing a slice of each of the three views (axial, coronal, sagittal). It is possible to change the view (in main window) by clicking on them or on the bookmarks which are placed on the top right side of program window.

On the “preview panels”, there are also scroll bars to enable scrolling through the slices in all three directions.

Inserts menu manager

To open the inserts menu manager click on: “Options” and then on “Insert menu manager”. It is possible to add, change and remove inserts (name and measurement file). The software provided to the user will have implemented all required measurements; normally, the user does not have to add or change anything to this manager.

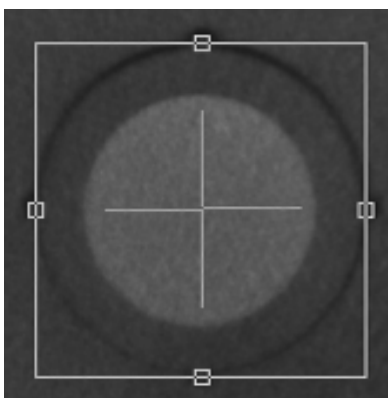
Insert measurements

Software measurements

Contrast-to-noise ratio

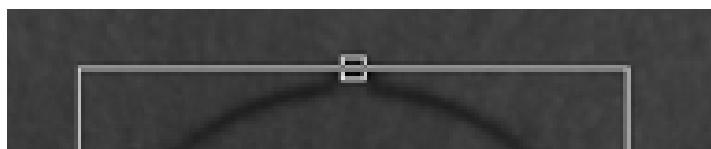
Use the dataset containing the ‘pixel intensity value’ insert. Scroll through the axial slices using the slider underneath the top window of the three small windows at the left. Scroll until you have a clear view of the ‘pixel intensity value’ insert.

Click and drag the left mouse button to create a selection window. After releasing the left mouse button, you can still change the position of each border by selecting the small squares in the middle of the borders and dragging them:

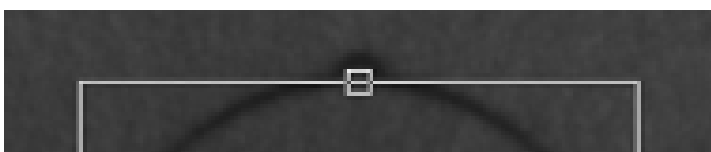


Align the border of the selection with the border of the insert. Do not align them with the small wedges you see at the top, bottom, left and right. Align them as if the insert would be a perfect circle:

NO:

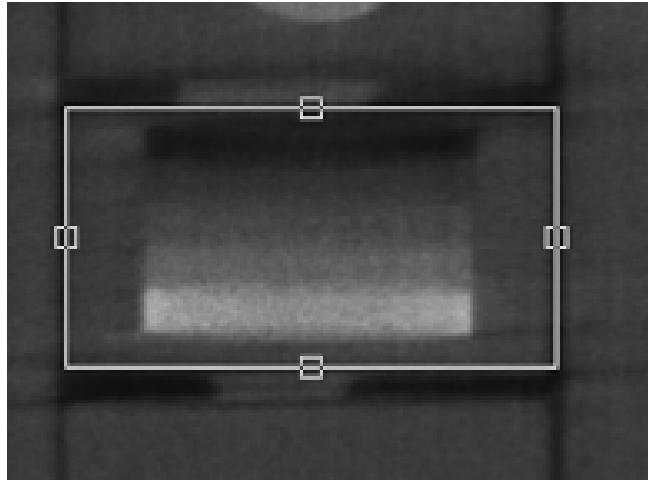


YES:



The most crucial borders are the top and left border. The size of the selected region is not important, as long as those two borders are aligned with the insert border.

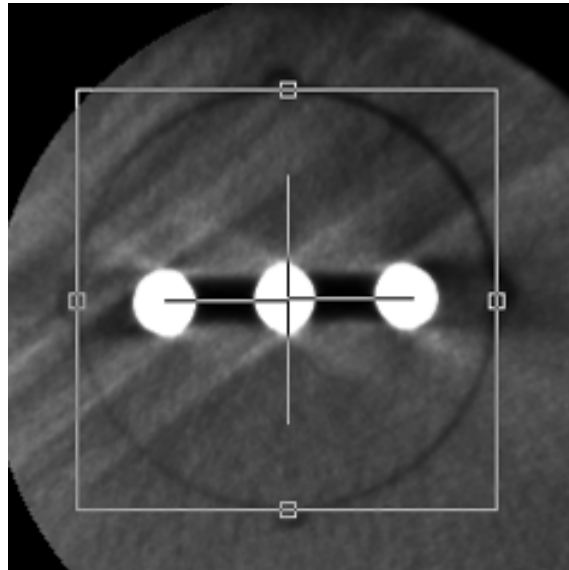
Once the borders have been set in the axial view, switch to either the coronal or sagittal view by clicking in the middle or bottom (small) window on the left side of the screen. Scroll through the slices until you are at the position of the insert (around slice nr. 180 in the coronal view and nr. 270 in the sagittal view). Adjust the top border with the top of the insert. The lower border is not important.



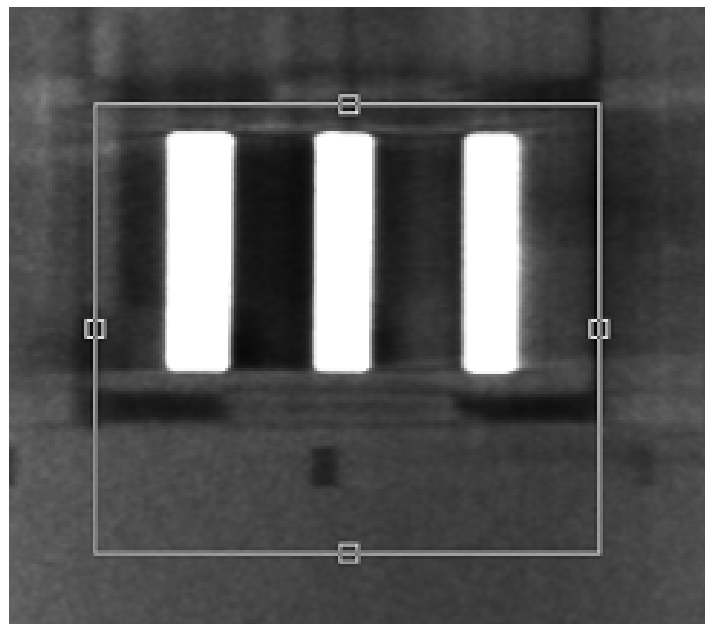
Select 'CNR' from the insert list from the bottom and press 'Evaluate'. After some processing time, the results will appear in a pop-up screen. Copy the CNR values into the QC form (see below).

Metal artefacts

In a dataset containing the 'metal artefacts' inserts, in the axial view, scroll to the insert and position the selection box using the same criteria as for the CNR insert (again, the top and left borders are the ones that should be accurate):



Switch to the coronal or sagittal view and align the top border of the selection with the top of the insert. The lower border is not important, as demonstrated:

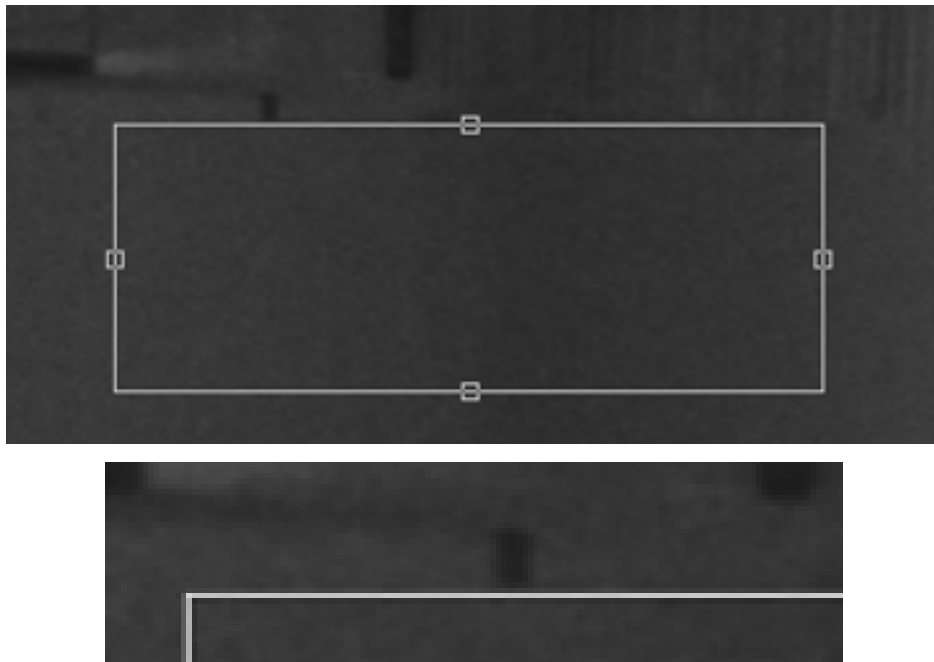


Select 'Artefacts' from the insert list and press Evaluate. Copy the value from the pop-up window into the form.

PMMA (noise & uniformity)

In the dataset containing the PMMA portion of the phantom, in the axial view, scroll to the homogeneous PMMA section. For large FOV devices, place the selection box by putting all four corners of the box on the edge of the phantom. For medium and small FOV devices, make the box as large as possible without going outside the phantom. Also be sure to avoid artifact regions at the border of the FOV, as they will hamper the analysis.

Next, switch to the coronal or sagittal view. Align the top border of the selection with the top border of the PMMA section, so at the bottom border of the geometric pattern (the small holes).



Select 'PMMA' from the insert list and press Evaluate. Copy the 'NOISE' and 'UNI' values into the form.

Visual analyses

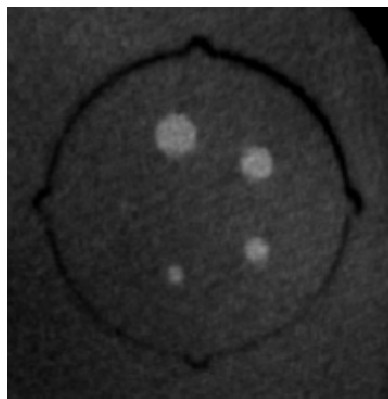
For all visual analyses, the first choice should be to perform them using the workstation and software provided by the manufacturer of the CBCT device. Visual

assessments can be affected by the screen, room conditions and software function, so ideally this should be performed in clinical conditions. If it is not possible to perform this analysis on the manufacturer's workstation, the SEDENTEXCT software can be used, providing that optimal viewing conditions are ensured.

All analyses require an optimal setting of the grey levels displayed, by adapting the so-called 'window' (number of grey values displayed) and 'level' (grey value of the center of the window). Any software use for image viewing should have a window/level (or brightness/contrast) tool.

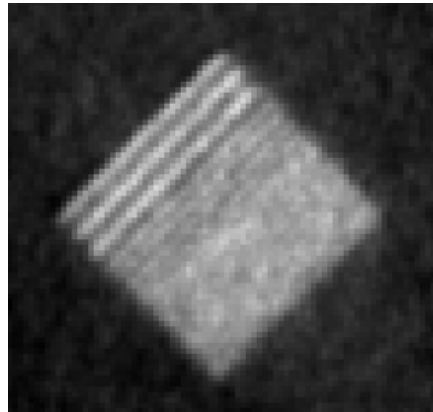
Contrast resolution analysis

Five inserts are used for this analysis, each containing five rods of a certain material in PMMA surrounding. Open a dataset containing the contrast resolution insert(s) and adjust the level and window for optimal viewing of the rods. Then, count the number of distinguishable rods for each insert and fill in the number of visible rods in the form below. Do not count these rods using 1 axial slice, but scroll through the slices; this can help to determine whether or not the smallest rods are visible. Repeat for all five inserts.



Spatial resolution analysis

There are two inserts for spatial resolution, containing the same pattern but in a perpendicular (X-Y and Z) orientation. Open the dataset contain the spatial resolution insert(s). For this insert, the window and level need to be adjusted for optimal contrast between the different lines in the pattern. Also, it is needed to zoom into the insert (using the zoom tool of the software) to make sure you can accurately count the number of lines.



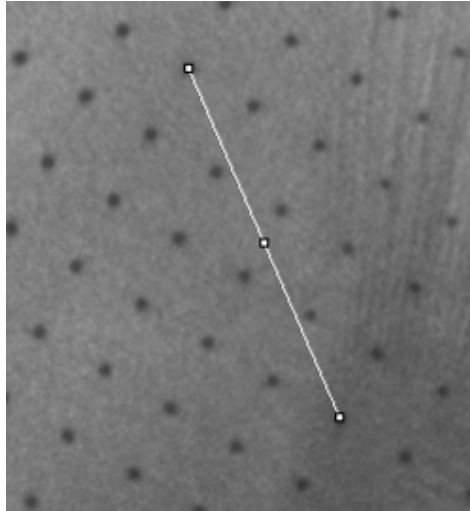
Count the number of white lines that can be distinguished from the next. NOTE: a line can only be counted if the separation with the previous line, but also with the next line can be identified.

Fill in the number of counted lines for the X-Y and Z insert into the QC form. This concludes the spatial resolution analysis.

Geometric accuracy (linear measurements)

As this analysis requires some degree of visual interaction to enable accurate measurements, the software and workstation provided by the manufacturer should preferably be used. If this is not possible, the SEDENTEXCT software package can be used.

Adjust the window and level to enable optimal viewing of the hole pattern between the PMMA portion and the insert portion of the phantom. Measure the length between the centre of two (randomly chosen) holes.



Calculate the deviation by subtracting the measured length with the actual length (in the example above, the actual length was 50mm). For holes that are in-line, the distance is 10 mm per hole. For other measurements, use the Pythagorean Theorem to calculate the distance between the holes.

Perform at least 3 measurements using different angles and combinations of holes. Calculate the average deviation and enter it into the form. Do not enter the measurement itself, the value entered in the form should be the difference between the measurements and the real distance.

This concludes the geometric accuracy measurement.

SEDEXCT phantom QC form

QC information	
User	
Date & hour	
QC measurements	
Geometric accuracy	Average deviation: ... mm
Contrast resolution	Air: ... rods visible Aluminium: ... rods visible Delrin: ... rods visible LDPE: ... rods visible PTFE: ... rods visible
Contrast-to-noise ratio (CNR)	Air: ... Aluminium: ... Delrin: ... LDPE: ... PTFE: ...
Noise & uniformity	Noise: ... Uniformity: ...
Artefacts	...
Spatial resolution	X-Y: ... lines visible Z: ... lines visible

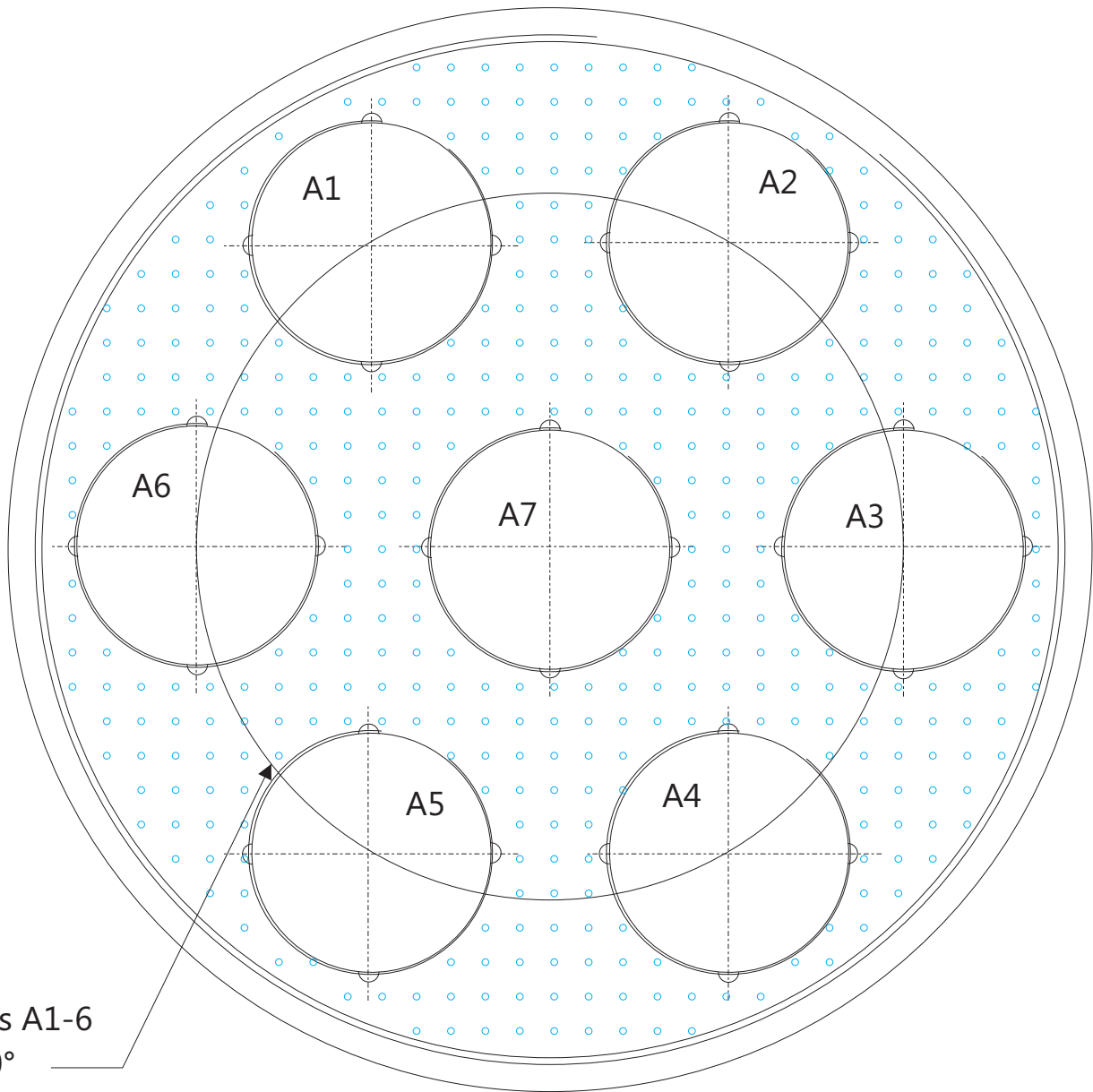
Appendix III: SEDENTEXCT Quality Control Phantom Specification Sheet



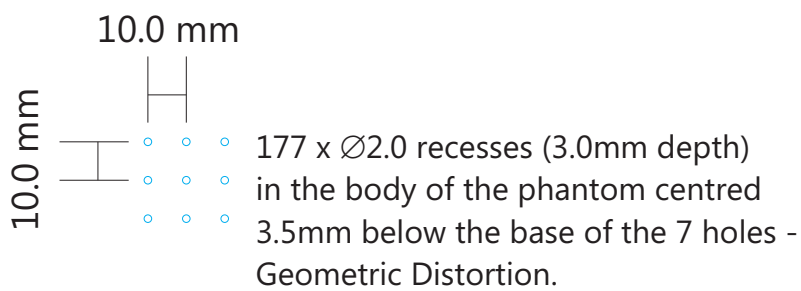
user manual

Draft Summary

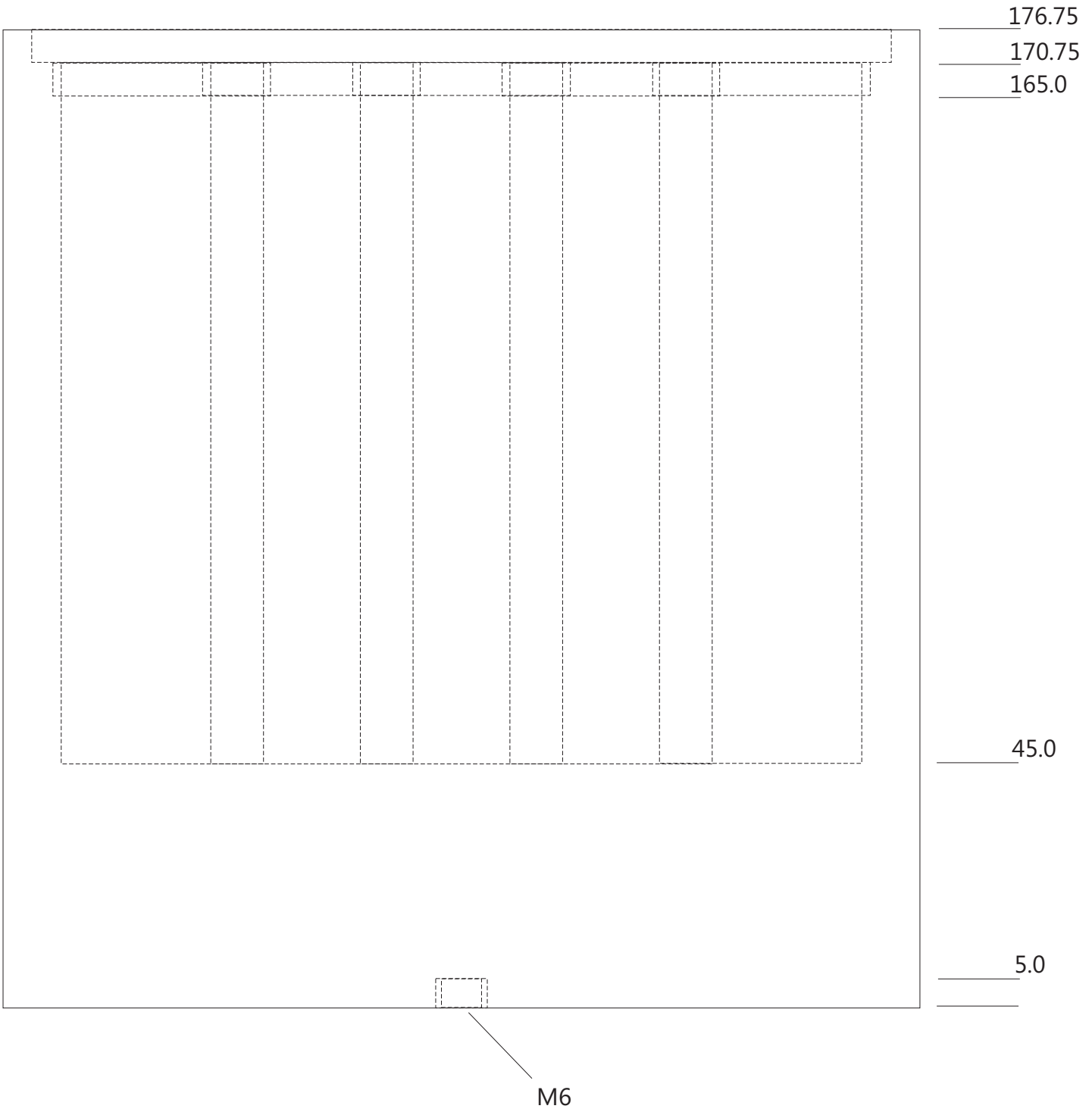
Medical Imaging Phantoms



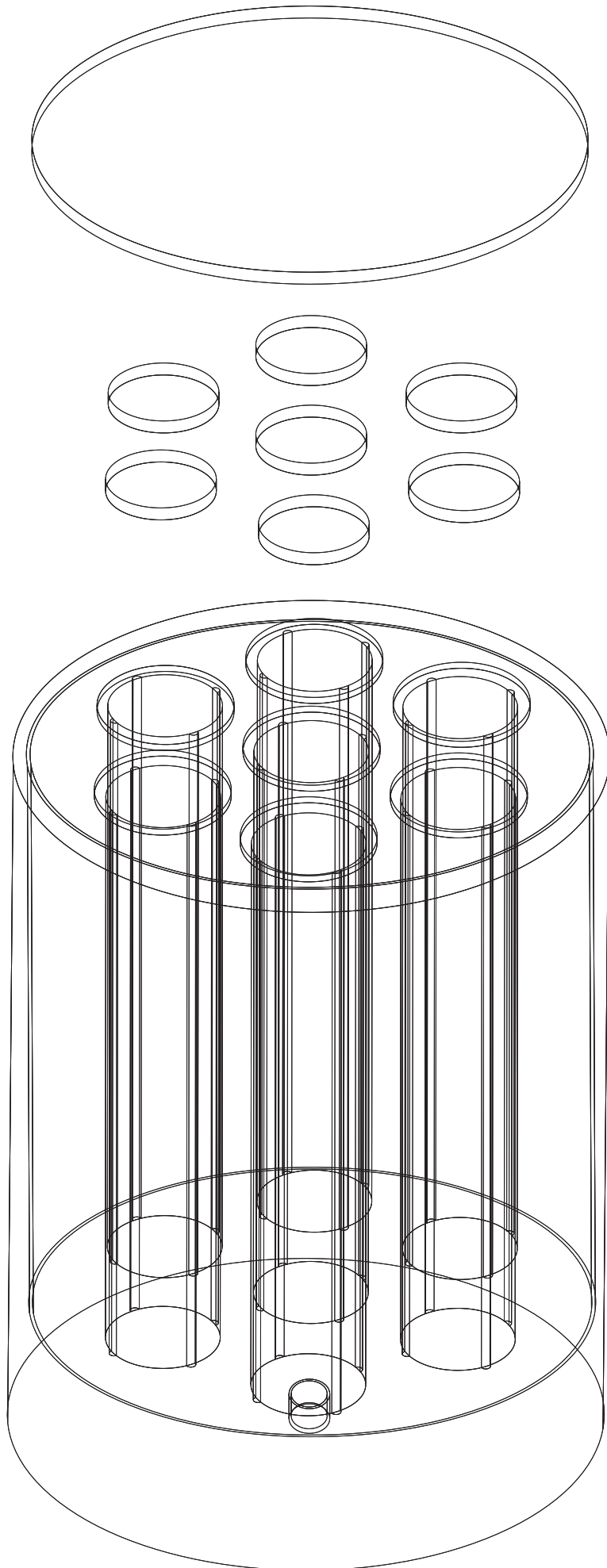
Holes A1-6
at 60°
intervals on
circle Ø 104.8mm



PHANTOM HOUSING (PMMA)



Housing
(1 per set)

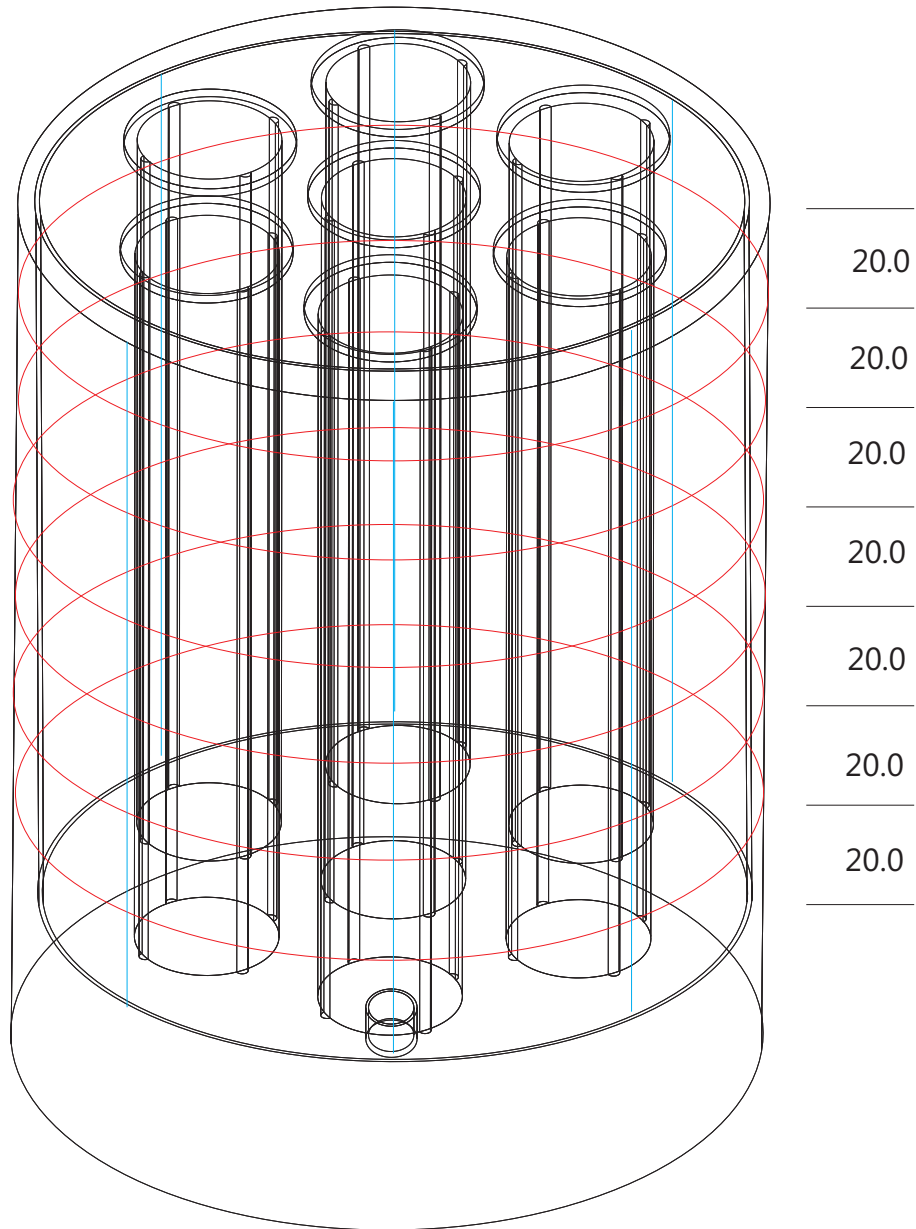


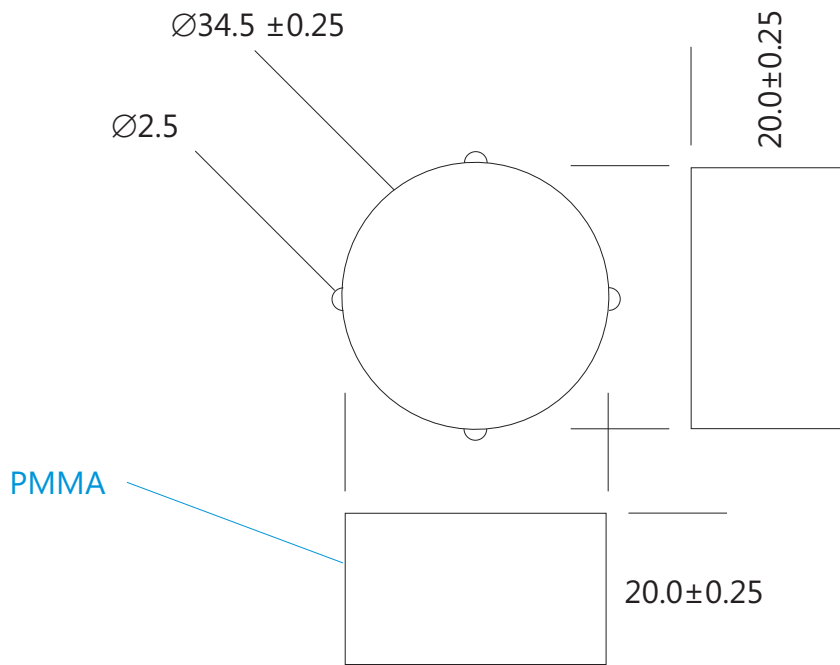
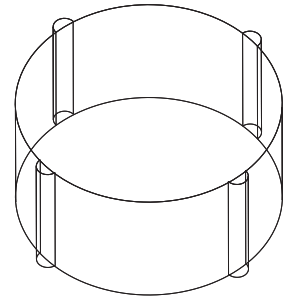
HORIZONTAL ENGRAVED LINE

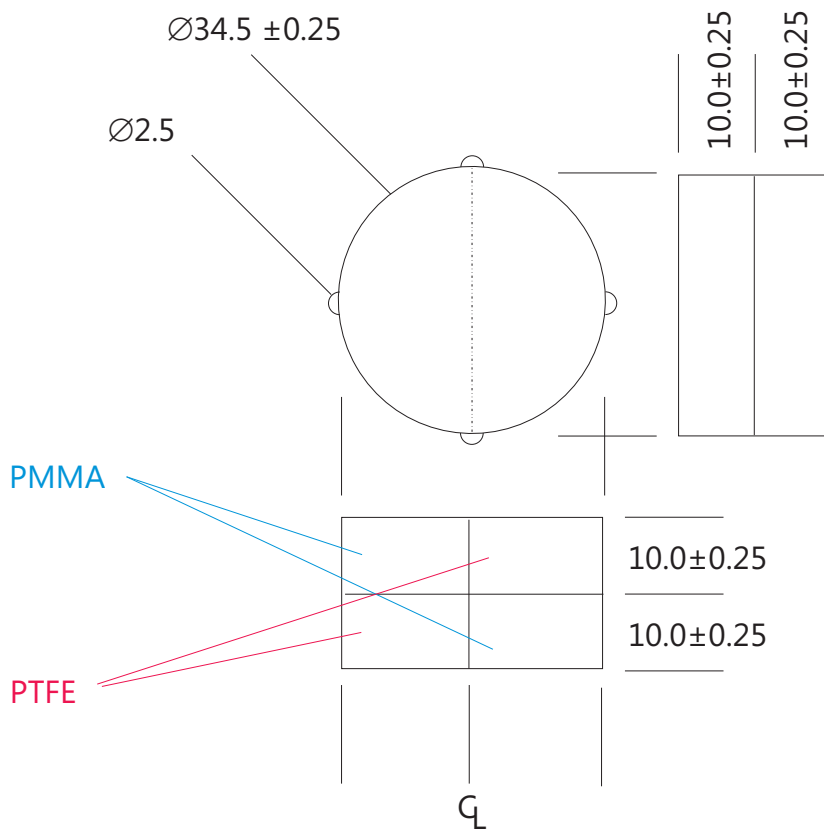
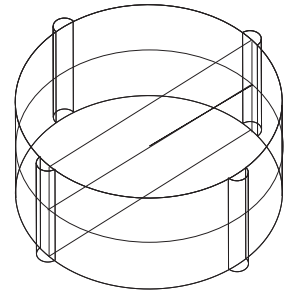
(6 lines, labelling 6 x 20.0mm intervals through 140.0mm depth of holes)

VERTICAL ENGRAVED LINE

(Centred on each of 6 peripheral holes)

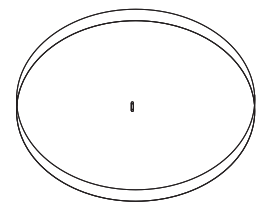
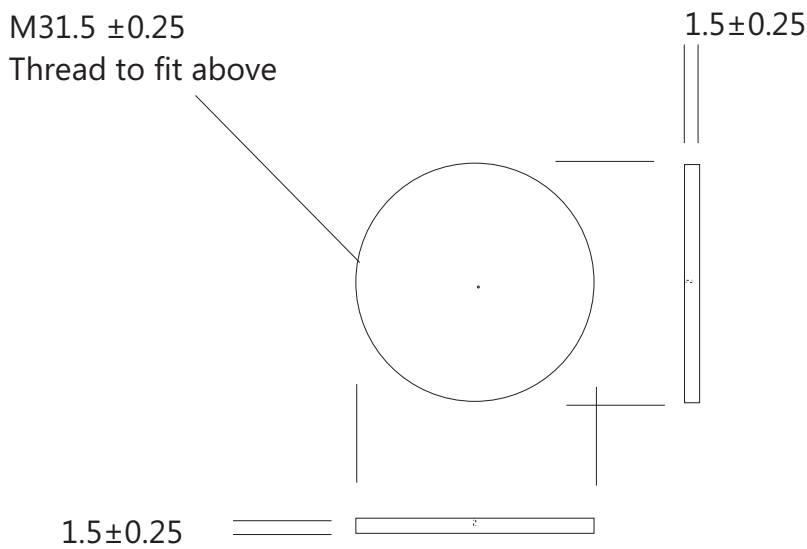
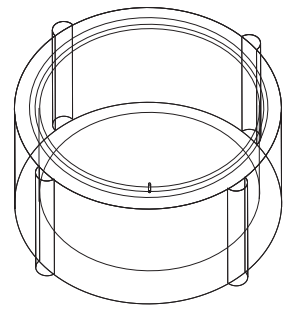
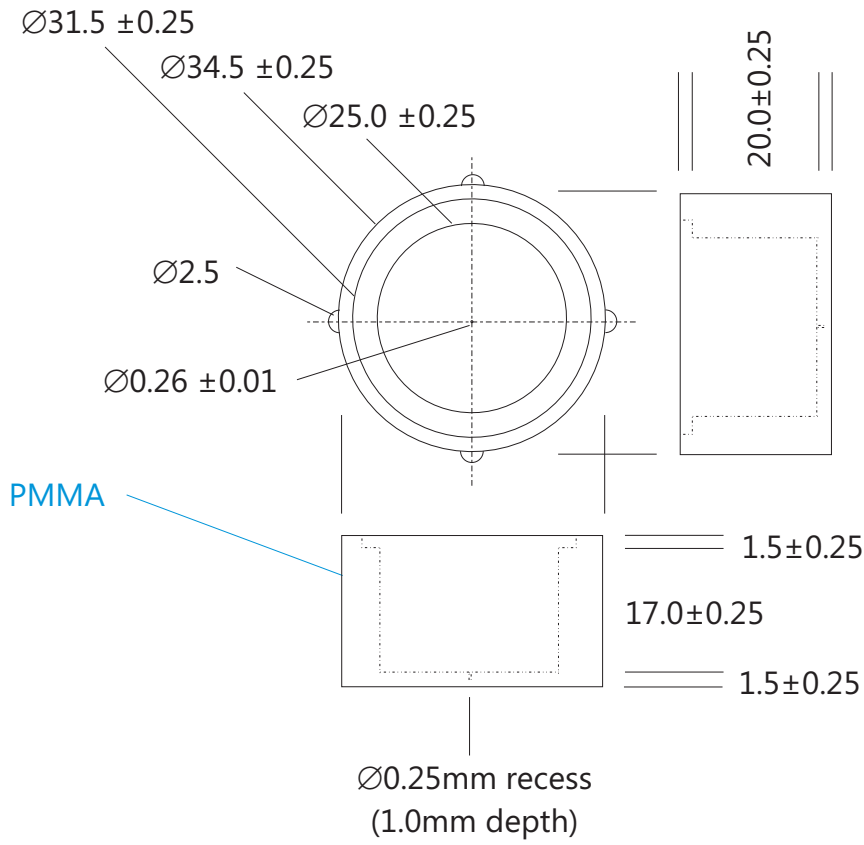






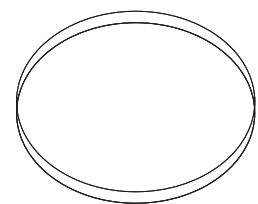
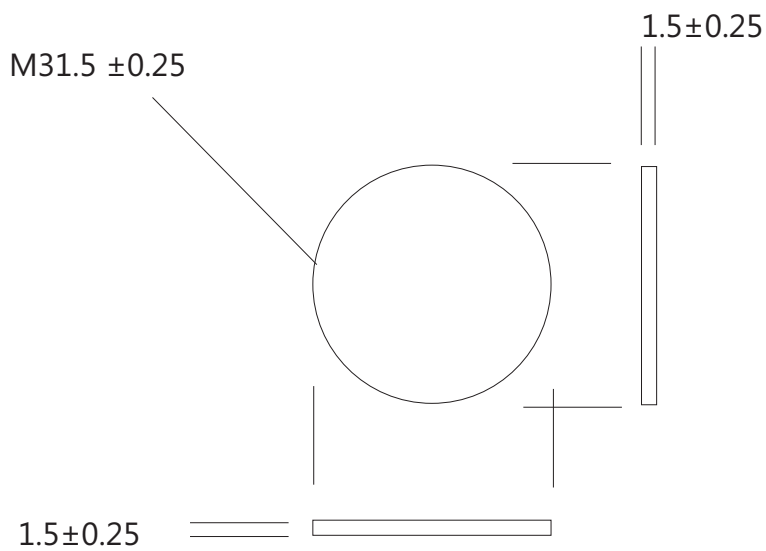
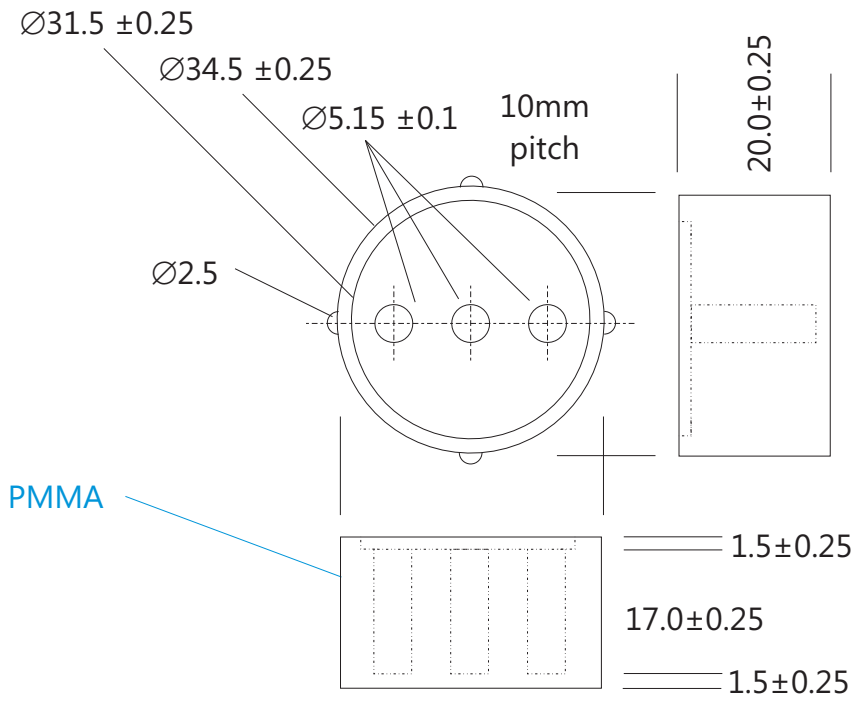
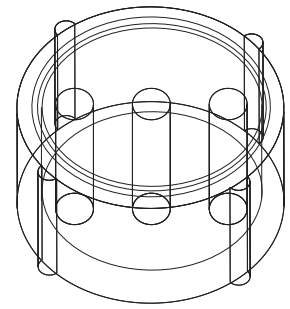
PSF INSERT (1 PER SET)

0.25mm diameter Stainless Steel Wire



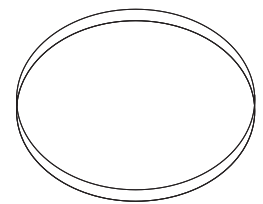
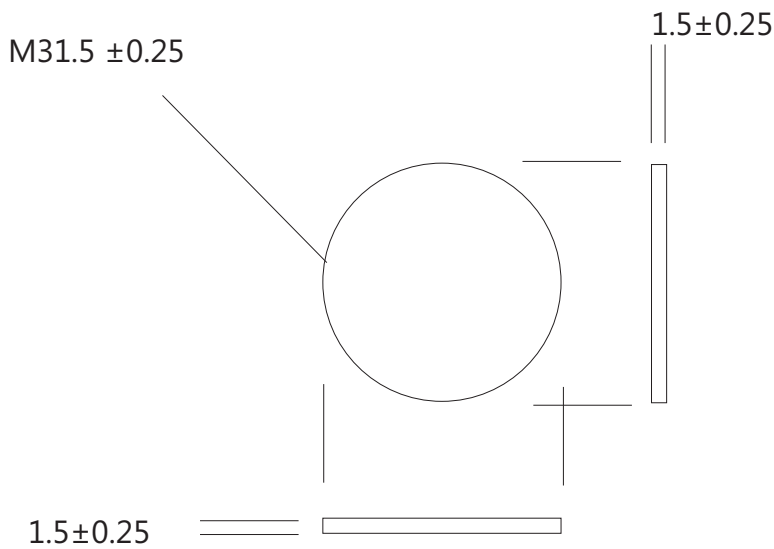
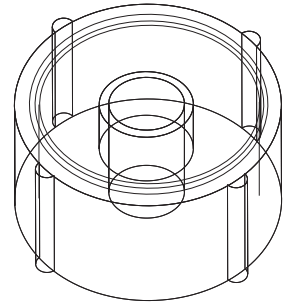
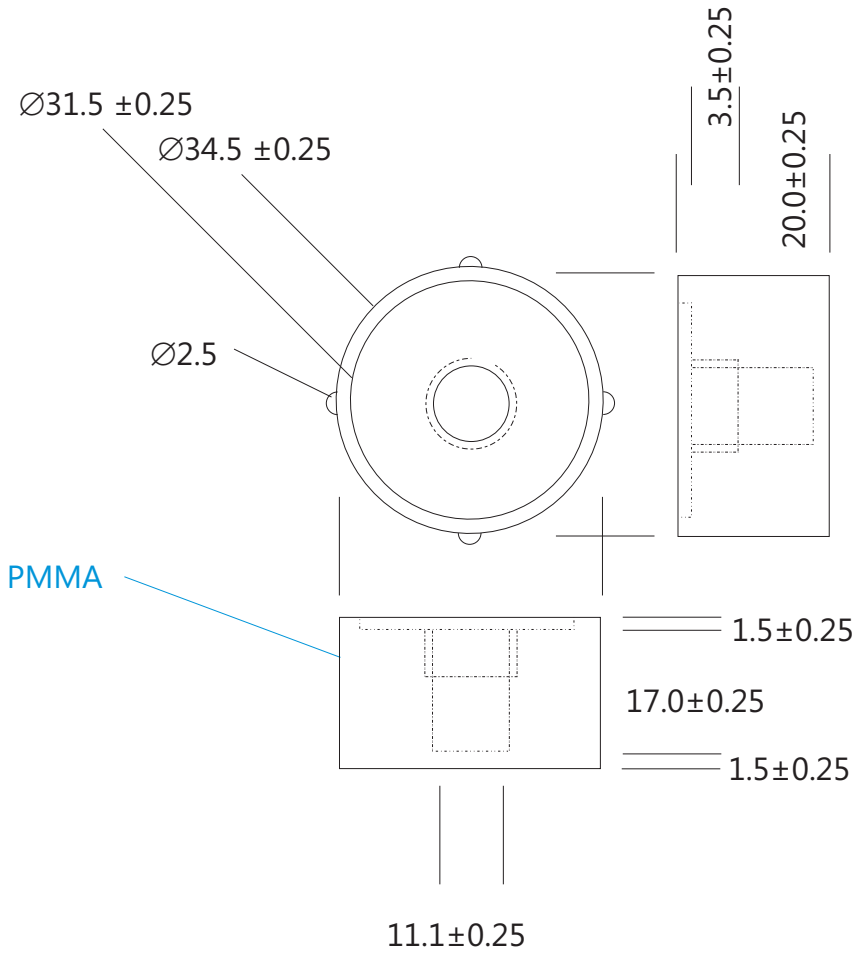
ARTEFACT (BEAM HARDENING) INSERT

2 per set
Titanium inserts

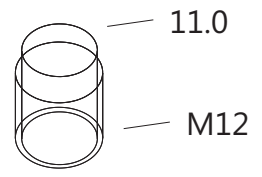
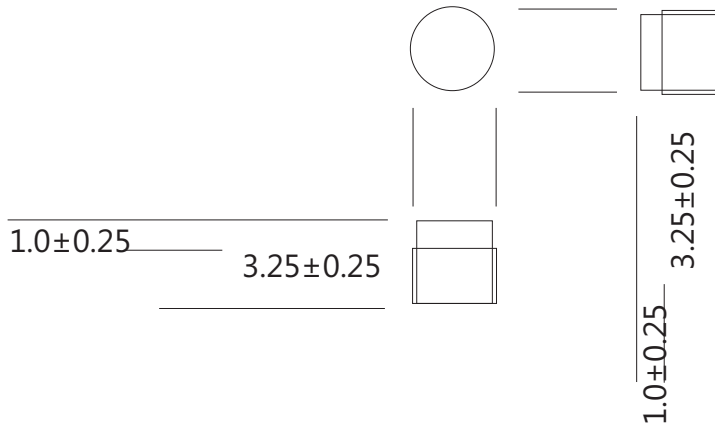


SPATIAL RESOLUTION Z (1 PER SET)

- 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



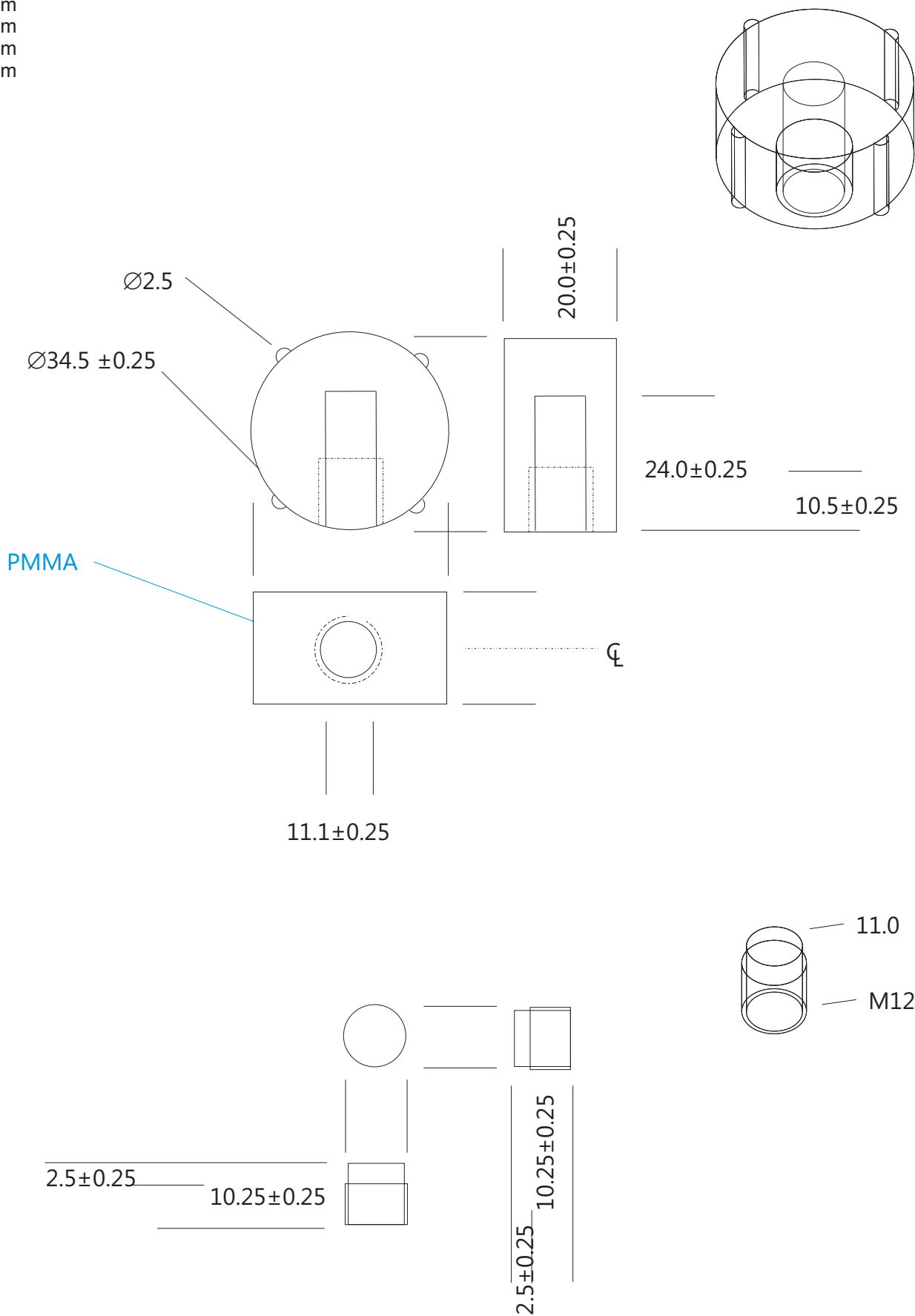
Continued...



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

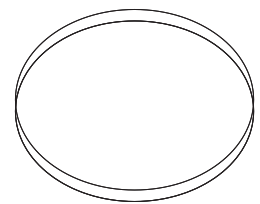
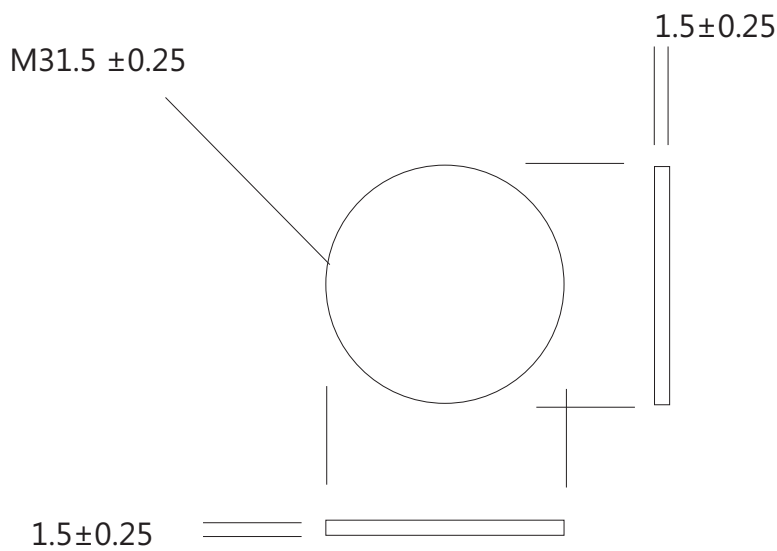
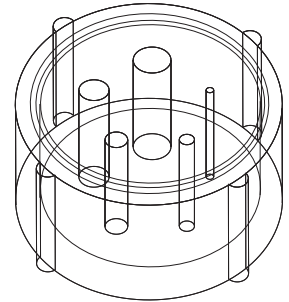
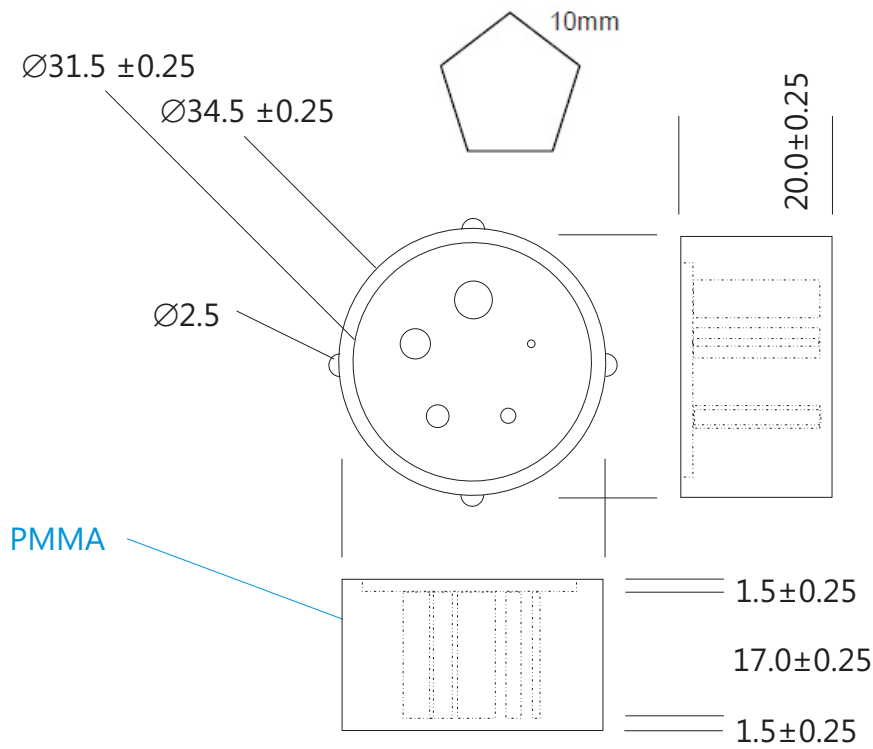
4.0±0.1mm

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

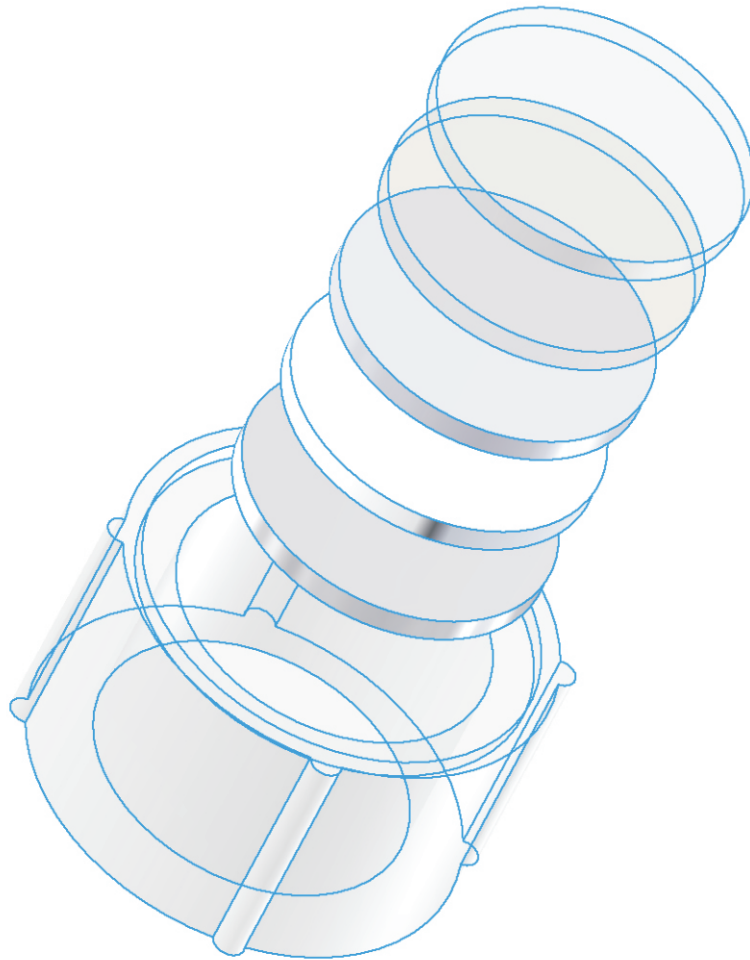
PTFE 2.16 g/cc

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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