

# HERCA Report CT Manufacturers Stakeholder Involvement

Nov. 2017

This document was approved by the Board of HERCA on 3 Nov 2017



# Index

Introduction	5
Commitment 1: Characterisation of CT systems standardised benchma 1.1. Background 1.2. Aim 1.3. Concept	6 6
Commitment 2: Implementation of dose reduction measures in CT	
Commitment 3: Dose management and reporting	8
Commitment 4: Provision of specific training curricula	9
HERCA-COCIR annual face to face meetings	11
Position Papers	11
Press releases	11
Conclusions	12
Bibliography	
Annex 1: COCIR CT MANUFACTURER Commitment (13 May 2011)	13
Annex 2: COCIR CT Commitment 1 - Characterization of CT Systems Sta Benchmarking (6 August 2012)	
Annex 3: Reformulation of Commitment 1	33
Annex 4: COCIR CT MANUFACTURER List of Dose Management Feature	es (5 July 2013) 37
Annex 5: COCIR Response CT commitment 4 on Training (5 July 2013)_	47
Annex 6: COCIR CT Manufacturers Reference phantom size FAQ	53



# **HERCA Report**

# CT Manufacturers Stakeholder Involvement

## Introduction

Tremendous developments in CT technology have taken place over the last few years. The growing use of radiation related to this technology is of great benefit to individual patients and to society as a whole. However, it has also led to a large increase in medical radiation exposure, which raises radiation protection concerns.

Concerning medical exposures, it is worth noting that the steady increase in collective effective dose observed during the recent years in developed countries is mainly due to CT scanning and that CT is the most important source of exposures to radiation in most developed countries today. Whole body CT delivers in one single examination the dose to a patient that may exceed the dose limit of 20 mSv per year for occupationally exposed worker. Attention needs to be paid to control exposures delivered by CT since organ doses may reach values beyond 50-100 mGy. The study on European Population Doses From Medical Exposure (DDM2) showed that for the collective effective dose from x-ray procedures, CT yields by far the highest contribution, on average 57,0 % of the dose from all x-ray procedures (range 5,31–83,1 %)<sup>1</sup>. Scientific evidence is sufficient to conclude a statistically significant increase of radiation-induced cancers following medical exposures in this dose range. <sup>2</sup>

HERCA saw the need for actions to be taken against the increasing trend to higher medical exposures of the European population. It was the firm conviction of HERCA that all stakeholders involved in the radiological process should be part of this important initiative to reduce patient dose. In particular, HERCA considered the CT manufacturers to be one of the most important stakeholders in the field of medical radiation protection. For this reason the HERCA working group medical applications created a subgroup "Work Package Stakeholder Involvement of CT Manufacturers".

Initiated by a kick-off meeting organised in Bonn in February 2010, HERCA, through the working group WP CT Manufacturers, started a dialogue with the four main CT manufacturers (GE, Philips, Siemens and Toshiba) and COCIR, which represents the radiological, electromedical and healthcare IT industry in Europe. As an important result of this process, the COCIR CT manufacturers were willing to underline their responsibility on patient dose reduction and provided a voluntary self-commitment by May 13<sup>th</sup> 2011 (annex 1). Hereby, they committed themselves to actions that offer the potential to achieve this goal. The actions included:

- 1. the development and implementation of a standardized benchmarking of CT systems by characterising the dose efficiency related to image quality,
- 2. the implementation of dose reduction measures in CT,
- 3. the implementation of dose management and reporting tools, and
- 4. the provision of specific training curricula.

A further important result of this process was the insight that international cooperation is increasingly important for success, and that this cannot be limited to a European level. To address this issue, HERCA intensified its cooperation with other international regulatory and scientific bodies such as FDA.



# Commitment 1: Characterisation of CT systems standardised benchmarking

The initial formulation of this commitment in 2011 was the following:

#### 1.1. Background

Scan conditions and parameter settings currently used for the specification of image quality and dose differ from vendor to vendor. Therefore, a direct comparison of CT systems can be challenging. Unfortunately, the definition of one single parameter to characterise a CT system is very difficult and may result in a limited and insufficient characterization of system performance. Multiple international expert task groups from the physics community trying to define one single parameter to characterize a CT system have not succeeded so far. Therefore, we believe that the development of a standardized benchmarking will need to be based on several Image Quality and Dose Parameters.

#### 1.2. Aim

CT manufacturers aim to provide transparency and easily understood values that attempt to characterize system performance through standardized test methods and conditions.

#### 1.3. Concept

Dose efficiency requires dose measurement and image quality assessment to be done simultaneously.

In 2012, COCIR provided HERCA with a document describing a method to characterise CT scanners using the Catphan 600 phantom or equivalent model (annex 2). The CT manufacturers then used this method in an attempt to characterise a given CT scanner for each manufacturer. The results of these measurements were provided to HERCA in total confidentiality. Following these measurements COCIR concluded that the definition of one single parameter to characterise a CT system is very difficult and may result in a limited and insufficient characterisation of system performance.

In 2012 HERCA decided to create a Panel of Advisers (PoA) consisting of four experts in CT imaging to advise the WP CT Manufacturers on purely technical and scientific matters. The PoA analysed the data provided by the CT manufacturers. Commitment 1 was discussed in detail with the PoA who made the statement that it is scientifically very difficult to develop a single dose efficiency parameter for CT scanners. For this reason Commitment 1 as initially defined was difficult to fulfil.

In the meantime CT manufacturers' scientists in collaboration with MITA and FDA were pursuing advanced test methods and phantoms to more accurately describe CT system performance for low contrast detectability, these methods would apply not only for filtered back projection but also iterative reconstruction algorithms. The COCIR CT manufacturers were willing to continue to actively participate in the MITA CT Image Quality (IQ) Task Force that was investigating a new test phantom and bench testing methodology for assessing Low Contrast Detectability and the associated dose level. They were also willing to continue to provide feedback and proposed test methods on this work to HERCA as part of this commitment.



In view of these statements the WP CT Manufacturers proposed to reformulate Commitment 1 into a platform of communication between HERCA and COCIR concerning the above-mentioned issues. The proposal was for the PoA to be allowed to actively participate in and be informed of the work carried out by the MITA CT Image Quality Task force. The WP CT Manufacturers requested and received the approval of the BoH to reformulate Commitment 1 into a platform of communication in 2013 (annex 3).

The COCIR CT manufacturers have now, through the coordination of the MITA CT Image Quality (IQ) Task Force designed a reference phantom for objective quantification of head and body Low Contrast Detectability (LCD). This methodology offers the potential to quantitatively assess LCD for clinical protocols in the body and in the head in relation to dose. The FDA presented a model observer program for evaluating task-based image quality, which they developed, and released to the public domain. This promises to provide more uniform claims of Low Contrast detectability and dose reduction claims across all CT manufacturers. The CT-IQ Task Force drafted this assessment method and submitted the outline for consideration and feedback from HERCA. The methods and use of the phantoms were published in September 2017 as a white paper "Computed Tomography Image Quality (CTIQ): Low Contrast Detectability (LCD) Assessment when Using Dose Reduction Technology" https://www.nema.org. The PoA was closely involved in the process and have carried out tests with the head phantom on a number of CT scanners. These tests have shown that it is possible to characterise a CT scanner by using this phantom.

The PoA made the following statement: "The use of task-based observers to quantify lowcontrast detectability as a function of dose reduction provides a practical, repeatable method for measuring performance of both FBP and IR. The phantom designed by MITA, in consultation with the FDA, is an effective tool for conducting observer studies that yields meaningful data when dealing with the classification task of signal detection (signal present/absent in an homogeneous background). It is however limited to this simple task, and does not address objective quantification tasks such as the precision on difference in density measurements and the effect on a structure's size measurements. Nevertheless, when dealing only with the detection task in homogeneous backgrounds, the proposed methodology is adequate for regulatory purposes to verify the low dose claims made by the manufacturers"

The same tests will be carried out with the body phantom.

With the publication of this NEMA paper this commitment is completed.

# **Commitment 2: Implementation of dose reduction measures in CT**

For this commitment CT manufacturers committed to continued innovation in dose reduction and optimised dose management. The aim was to foster the development and propagation of dose reduction measures across CT scanners. This commitment would standardise a process for periodically incorporating appropriate dose reduction capabilities into a standard/list that defines the minimum required on new base CT system configurations available for sale.

The CT manufacturers provided HERCA with a list of available dose reduction features in March 2011 and an updated overview of currently available dose management tools in July 2013 (annex 4) and will continue to do so on a periodic basis.



During the September 2013 MT-30 (IEC maintenance team) meeting, a successor standard to IEC 61223-3-5 and 61223-2-6 (Acceptance and Constancy Testing) incorporating automatic exposure control functional test methodologies and additional image quality metrics, such as noise power spectrum, was discussed. Physicists and manufacturers were to complete additional evaluations and testing to refine the methodologies, finish writing the standard, and demonstrate feasibility.

As part of this ongoing commitment, CT manufacturers have requested IEC SC62B MT-30 consider the following topics for inclusion in upcoming IEC standards applicable to CT equipment:

- Incorporating Size Specific Dose Estimate (SSDE), consistent with the American Association of Physicists in Medicine (AAPM) TG 204 report:

   <u>http://www.aapm.org/pubs/reports/RPT\_204.pdf</u>
   <u>https://www.aapm.org/pubs/reports/RPT\_220.pdf</u>
- Including new image quality and dose metrics based on iterative technology. For example, observer's studies (model or human) as being discussed between CT manufacturers and the US Food and Drug Administration (FDA) in the MITA CT IQ Task Force.
- Harmonizing regional requirements in the revision of the Acceptance (IEC 61223-3-5) and Constancy (IEC 61223-2-6) testing standards for CT scanners to improve global adoption. For example an automatic exposure control (attenuation based mA modulation) functional test method would be useful.
- 4. Consider incorporating NEMA XR 26-2012 (<u>http://www.nema.org</u>): Access Controls for Computed Tomography: Identification, Interlocks, and Logs, into the next edition of IEC 60601-2-44.
- 5. Include an alert when an adult protocol is selected for a paediatric patient. Paediatric alert could be incorporated in the next edition of IEC 60601-2-44.

On Jan 13<sup>th</sup> 2017 Committee Drafts were circulated for both the SSDE and Acceptance and Constancy Testing Standards.

The CT manufacturers will continue to work with Industry Associations (COCIR, MITA) to assess current "state-of-the-art - standard general practice" dose reduction capabilities, and will move to have these capabilities listed in the IEC "Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography" (60601-2-44), making these capabilities part of future CT scanners.

#### For this reason this commitment is ongoing.

## Commitment 3: Dose management and reporting

With this commitment CT manufacturers aimed to support the IHE Radiation Exposure Monitoring (REM) profile and enhance users' dose management and reporting capabilities. This is best accomplished through conformance to accepted communication standards such as DICOM structured reporting (DICOM SR). For CT dose reporting all CT manufacturers display CTDI<sub>vol</sub> and DLP and offer DICOM SR.

For CT dose management two standards have been developed:

1. The NEMA XR 25-2010 Computed Tomography Dose Check standard (<u>http://www.nema.org</u>) provides the ability for institutions to set notification values or DRLs for each protocol and give user feedback when dose is exceeded. This tool is available on all new CT scanners.



2. The NEMA XR 26-2012 Access Controls for Computed Tomography: identification, Interlocks, and Logs standard (<u>http://www.nema.org</u>). This standard relates to who has access/permission to use the system for clinical or other uses. It also allows the capturing of operator and patient information as well as information related to saved changes in protocols. This tool is available on all new CT scanners.

CT manufacturers also contributed to the development of the standard NEMA XR 28-2013 (<u>http://www.nema.org</u>). NEMA XR 28 identifies uniform and standardised manufacturer's information provided to users of a CT scanner. This information includes perfusion scanning, use of Automatic Exposure Control, organisation of dose-related information, and a requirement for listing the reference protocols established on a CT system.

For CT dose reporting AAPM TG204 Report was published in 2011. Following this, AAPM TG220, which includes manufacturers' representatives, worked to resolve outstanding issues from the TG204 report including size estimation technique. The final TG220 report was released in September 2014. This report provides a "robust and scientifically sound metric for automatically estimating patient size in CT that would account for patient attenuation and allow routine determination of SSDE for all patients, with little or no user intervention".

In June 2014 this new working item was submitted by the CT Manufacturers through MITA and accepted by the IEC Technical Committee 62 MT-30 as of February 2015. The IEC 62985 Ed. 1.0 "Methods for calculating Size Specific Dose Estimate (SSDE) on Computed Tomography" is forecasted for publication in August of 2018.

The IEC MT-30 is monitoring progress of scientific endeavours, e.g., AAPM TG246, for progress related to organ dose metrics appropriate for dose reporting.

#### This commitment is completed.

## Commitment 4: Provision of specific training curricula

The aim of this commitment is for manufacturers to ensure the appropriate, safe and effective use of imaging equipment by the clinical user. This includes the provision of specific training curricula on existing and new dose reduction techniques, on how to use these techniques in daily practice, and to enable users to continue to reduce patient dose.

COCIR is involved in EMAN activities and offers its expertise to help develop training curricula. HERCA expressed its great interest in receiving a list of training opportunities for facilities, which are available from manufacturers (on-site, off-site, on-line). COCIR agreed to send HERCA this list. A document "provision of training curricula" was sent to HERCA in 2013 (annex 5).

In order to describe the role of CT manufacturers and other stakeholders in education and training a HERCA Position Paper: "The process of CT dose optimisation through education and training and role of CT Manufacturers" was published in October 2014 (<u>http://www.herca.org</u>). As a next step, CT manufacturers and HERCA acknowledged the need for raising the awareness concerning training and education via the involvement of other stakeholders. The target was a concerted action that would contribute to the adoption of CT dose optimisation and the ALARA principle in daily operational practice.

For this reason, under this commitment, three multi-stakeholder meetings (MSM) were organised one in Paris in 2015 and two in Vienna in 2016 and in 2017. The objective of these meetings was to exchange views with a variety of key stakeholders on issues with regard to the optimised use of CT scanners.#



The stakeholders who participated in these meetings were COCIR supported by the main manufacturers (GE, Philips, Siemens and Toshiba) and the professional organisations: ESR, EANM, ESTRO, EFRS, EFOMP and ISSRT. The international organisations IAEA, WHO, EC and IRPA participated as observers. For the first MSM HERCA sent to the professional organisations the HERCA CT position paper and asked the organisations to respond to the paper during the meeting. The response of the stakeholders was published as an addendum to the position paper in November 2015 (http://www.herca.org).

At the end of the first MSM the stakeholders were asked if they would be willing to propose self-commitments concerning the training and education on CT dose optimisation. Commitments were received from ESR, EANM, EFRS and EFOMP. The commitments proposed by the professional organisations are excellent and the work carried out for these commitments will definitely contribute to the optimised use of CT scanners.

From these multi-stakeholder meetings it became clear that the manufacturer training programs are not always adapted to the needs of the radiographers and the medical physicists. COCIR has accepted to collaborate with EFOMP and EFRS on this issue.

On 3 March 2017 COCIR and EFOMP signed a Memorandum of Understanding focusing on the following elements:

- Foster training of medical physicists on the best use of new equipment and technology in imaging and therapy to reduce radiation exposure of patients and users
- Promote the use and adoption of the best technologies in radiation protection and dose reduction
- Increase awareness of public authorities regarding the aging of the installed base of medical equipment and availability of dose reduction technology
- Develop common understanding of international and European Basic Safety Standards (BSS) requirements referring to medical application
- Mutually promote each other's educational and scientific activities as far as allowed by the societies' rules

The cooperation will concretize in a joint COCIR-EFOMP edition of the EFOMP ESMPE School in January 2018 in Prague and in a joint-session at EFOMP bi-annual congress in August 2018.

The CT manufacturers offer a whole range of training programs for the CT end user and the stakeholders involved are committed to:

- Being made aware of the existence of these tools
- Being trained and educated on the use of these tools
- Making use of these tools in their daily practice
- Working as a team

This commitment is completed.



# HERCA-COCIR annual face to face meetings

For this WP, annual HERCA-COCIR face to face meetings were organised. COCIR provided HERCA with annual reports on actions carried out for the COCIR self-commitments. During these face to face meetings the actions described in the reports were discussed. These meetings also gave the opportunity for HERCA to express its concerns on radiation protection issues concerning CT imaging. The CT Manufacturers would try to propose solutions.

An item that was discussed during the face to face meetings was that some vendors chose to use different  $CTDI_{VOI}$  phantom reference sizes for paediatric techniques. This caused a lot of confusion when carrying out patient dose measurements. As a result a document "COCIR CT Manufacturers'  $CTDI_{VOI}$  Reference Phantom Size FAQ" was provided to HERCA by COCIR in August 2014 (Annex 6). With the release of the IEC 60601-2-44 standard, Edition 3.1, in 2012, the IEC clarified that  $CTDI_{VOI}$  should be displayed for the 32 cm (320 mm)  $CTDI_{VOI}$  phantom for all Body techniques and 16 cm (160 mm)  $CTDI_{VOI}$  phantom for all Head techniques. Another item discussed during these meetings was the proposal by HERCA of the installation of an alert for when the CT user chooses an adult protocol for a paediatric patient. As seen in commitment 2 an alert could be incorporated in the next edition of IEC 60601-2-44.

# **Position Papers**

For this WP a position paper with the title ""The process of CT dose optimisation through education and training and role of CT Manufacturers" was published in October 2014. An Addendum to this HERCA CT Position paper was published in November 2015. This addendum provides the feedback from the stakeholders involved in CT optimisation to the HERCA CT position paper.

## Press releases

Since 2010, the following press releases were published:

- 1. <u>Regulators Work With Medical Industry on Radiation Protection (9.01.2012)</u>
- 2. <u>Medical Applications HERCA approves a HERCA Position Paper on the process</u> of CT dose optimisation through education and training and role of CT <u>Manufacturers (20.11.2014)</u>
- 3. <u>Meeting between European radiation protection authorities and major stakeholders</u> on the optimised use of CT scanners (22.04.2015)
- 4. <u>Medical | Addendum to HERCA position paper on CT dose optimization</u> (05.02.2016)
- 5. <u>Optimised use of CT Scanners: last HERCA Multi-stakeholder meeting</u> (03.04.2017)
- 6. <u>HERCA-COCIR Press release (Nov. 2017)</u>



# Conclusions

The collaboration between HERCA and COCIR has been very beneficial to both parties as a lot of good work has been accomplished in CT dose optimisation, management and reporting as can be seen in this report. The MSMs gave the opportunity to all the stakeholders involved in CT dose optimisation to come together, to exchange views and to commit using CT scanners in the most optimised way possible. The aim of the WP was to reduce patient exposure from CT imaging. With the tools developed through this WP by the CT Manufacturers and with the education and training of the CT end user through the MSMs this has been achieved. This will be of great benefit to the patient which is what HERCA wanted to accomplish.

# Bibliography

- 1. Contract ENER/2010/NUCL/SI2.581237. Study on European Population Doses from Medical Exposure (Dose Datamed 2) DDM2 Project Report on European Population Dose.
- 2. Wall BF, Haylock R, Jansen JTM, Hillier MC, Hart D and Shrimpton PC (2011). Radiation risks from medical x-ray examinations as a function of the age and sex of the patient. Report HPA-CRCE-028 (<u>www.hpa.org.uk</u>)



Annex 1: COCIR CT MANUFACTURER Commitment (13 May 2011)



HERCA Report CT Manufacturers Stakeholder Involvement Nov. 2017 CIK



SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

# CT Manufacturer's Voluntary Commitment Regarding CT Dose

#### To HERCA Working Group "Medical Application"/Sub-Working Group "CT Manufacturers' involvement" Version 2

#### Preamble

This document defines the CT manufacturers' voluntary commitment to HERCA as a result of the meeting held in Bern on 14 June 2010.

The CT manufacturers agree to work under the umbrella of their European Trade Association, COCIR, to ensure a joint approach. The aim of this commitment is to further the initiatives of improving dose reporting, promoting transparency in dose efficacy, continuing reduction of medical exposures, and provision of specific training curricula. The manufacturers agree to complete the voluntary commitments outlined within and provide yearly updates with regard to their status and deliverables. Additionally, if significant delays or advancements in the timelines are expected these are agreed to be communicated in a timely manner.

#### General statement from CT manufacturers

As the developers of sophisticated scanners, CT manufacturers acknowledge their unique role in the process to help optimize patient CT dose in the health care setting: this can be accomplished through 4 major items.

#### Commitment 1: Characterization of CT Systems Standardized Benchmarking

#### Background

Scan conditions and parameter settings currently used for the specification of image quality and dose differ from vendor to vendor. Therefore, a direct comparison of CT systems can be challenging. Unfortunately, the definition of one single parameter to characterize a CT system is very difficult and may result in a limited and insufficient characterization of system performance. Multiple international expert task groups from the physics community trying to define one single parameter to characterize a CT system have not succeeded so far. Therefore, we believe that the development of a standardized benchmarking will need to be based on several Image Quality and Dose Parameters.

#### Aim

CT manufacturers aim to provide transparency and easily understood values that attempt to characterize system performance through standardized test methods and conditions.

#### Concept

Dose efficiency requires dose measurement and image quality assessment to be done simultaneously. Dose and critical image quality parameters will be measured and reported for 4 representative clinical protocols that cover approximately 70% of clinical scans (standard head, high resolution head, standard body, high resolution body). Standardized methods and parameters will be defined with the best overlap between vendors. In the future an analytical expression may allow these dose and image quality parameters to produce a figure of merit for each representative protocol. For transparency purposes, CT manufacturers will make available details on test conditions for dose related claims.

COCIR



SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

#### **Estimated Timelines**

#### Part 1.

Phase 1 (Q1 2011): Provide standardized dose values for different filter settings (per IEC 60601-2-44 Edition 3.0 Standardized base testing). Starting on this date CT manufacturers agree to phase in reporting of these values on new and select CT platforms.
Phase 2 (Q3 2011): Representative image quality and dose measurements at standardized scan conditions (representing four clinical scans) and using standardized measurement techniques. Starting on this date CT manufacturers agree to phase in reporting of these values on new and select CT platforms.

#### Part 2.

• **Goal: Q4 2012** - Following scientific acceptance of an analytical model among CT manufacturers, one figure of merit per clinical task will be constructed to provide CT dose efficiency. At which point the CT manufacturers would transition to including this "figure of merit". The goal outlined in the commitment is for Q4 of 2012, however, if for some reason an analytical model is not available at that time the CT manufacturers will continue to publish the clinically relevant benchmark data defined in phases 1 and 2 and continue to work to drive an agreement on an appropriate analytical model.

#### **Commitment 2: Implementation of dose reduction measures in CT**

#### Background

The CT manufacturers commit to continued innovation in dose reduction and optimized dose management. As manufacturers of CT equipment dose reduction has always been a high priority as can be seen by the long history of dose reduction features developed by the member manufacturers. CT manufacturers commit to a standardized process by which they drive dose reduction features into what can be considered the "state-of-the-art – standard general practice" and thus included in the base configuration for CT scanners.

#### Aim

The aim of this commitment is to foster the development and propagation of dose reduction measures across CT products, with the acknowledgement that certain measures may not be feasible or relevant for implementation on certain product configurations and therefore not appropriate for inclusion in a list of capabilities required on base product configurations. This commitment will standardize a process for periodically incorporating appropriate dose reduction capabilities into a standard/list that defines the minimum required (therefore not available as saleable options) on new base CT system configurations available for sale.

#### Concept

CT manufacturers will identify Safety Measures Against Excessive X-Ray radiation using the IEC process (IEC 60601-2-44). By using this process the periodicity for proposing new dose reduction capabilities will be semi-annual. Based on these proposals, the capabilities will be evaluated for identification in the CT particular standard. Following this identification a timeline is developed to add these as base capabilities on forward production systems. This timeline is then driven and required by harmonized standards. CT manufacturers will additionally evaluate the inclusion of dose reduction capabilities in similarly configured installed base products as part of this process. CT manufacturers commit to providing an updated overview of currently available technologies on a periodic basis.

#### COCIR



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

#### **Estimated timelines**

• **Q4 2010:** CT manufacturers are working through MITA to provide an updated overview of available technologies<sup>1</sup>.

• **Periodic industry assessment:** CT manufacturers will continue to work with Industry Associations (COCIR, MITA) to assess current "state-of-the-art - standard general practice" dose reduction capabilities, and will move to have these capabilities listed in the IEC "Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography" (60601-2-44), making these capabilities part of future base CT product configurations. This assessment will occur semi-annually for input to the IEC committee meetings starting with the Fall of 2011 meeting.

#### **Commitment 3: Dose management and reporting**

#### Background

CT manufacturers continually aim to improve the user interface for dose prescription. CT manufacturers have displayed CTDIvol and DLP on CT scanners which are well defined dose metrics. This provides a way to characterize the output of CT scanners.

#### Aim

CT manufacturers aim to support the IHE REM profile and enhance users dose management and reporting capabilities. This is best accomplished through conformance to accepted communication standards such as DICOM SR as well as the newly developed dose checking standard (XR 25-2010). Effective implementation and responsibility of follow through on this concept lies with the user community and is in the realm of the practice of medicine.

#### Concept

There are 2 ways to do this:

• CT manufacturers have agreed to provide the ability for institutions to set notification values or DRLs for each protocol and give user feed-back when dose index is exceeded. It will be deployed on new releases of CT products and most similarly compatible installed base systems. This complies with the MITA Dose check standard (XR 25-2010).

• CT manufacturers will improve CT Dose reporting by working towards a more patient relevant estimate of dose. We are working with scientific community to define this.

#### Estimated timelines

#### **CT Dose Management**

• Phase 1 (Q3 2010: standard defined, Q2 2011: start of deployment of 1<sup>st</sup> capabilities): Dose Check Feature

Ability for institutions to set dose notification levels and provide feedback to the operator when limits are exceeded as listed in XR 25-2010.

• Phase 2 (Q4 2011 standard to be defined, Q3 2013 start of deployment of  $1^{st}$  capabilities): Security – conceptual

This will provide the ability to control access and audit for setting these dose notification levels and the saving of protocols.

<sup>&</sup>lt;sup>1</sup> List of dose reduction features for CT manufacturers to be released on 4 March 2011.

COCIR CT Manufacturer's Voluntary Commitment Regarding CT Dose Version 2 13 May 2011

## COCIR



SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

#### CT Dose reporting

# • Phase 1 (Q1 2011: start of deployment on newly released CT models): Dose reporting

- Display of CTDIvol and DLP, the most universal and accepted method at this time.

- Delivery of DICOM SR (Structured Reporting) for dose feature, which will enable imaging institutions to start with the implementation of automated exposure dose reporting based on the IHE REM (Radiation Exposure Monitoring) profile which allows third party programs to tabulate dose statistics for a scanner or collection of scanners at a site.

#### • Phase 2 (Q4 2011): Improved patient centric dose indication

- The intent is to have an accepted method such as "patient size adjusted dose" or "organ dose".

- Timelines depend on accepted scientific consensus.

#### • Phase 3 (Q4 2012): Patient Dose estimation

- CT manufacturers will continue to investigate ways to estimate patient dose. Currently, there is no accepted nor easily achievable method to calculate actual medical dose to an individual patient.

– CT manufacturers appreciate HERCA participation in the IEC to develop a standard method.

- Timelines depend on accepted scientific consensus.

#### Commitment 4: Provision of specific training curricula

#### Background

CT manufacturers share with HERCA the concern for keeping the CT user well trained on dose optimization and dose awareness in daily practice. This is of particular importance with the growing number of dose reduction features in CT products.

#### Aim

CT manufacturers' aim is to ensure the appropriate, safe and effective use of imaging equipment by the clinical user. This includes the provision of specific training curricula on existing and new dose reduction techniques, on how to deploy these product features in daily practice, and to enable users to continue to reduce patient dose.

#### Concept

CT manufacturers are committed to make a significant contribution to this aim via:

- 1. The offering of vendor specific equipment training curricula to the CT user, and through user programs that help CT operators optimizing the patient dose settings on their scanners, and the offering of continuing professional education optional training.
- 2. Keeping the vendor's equipment training curricula updated with the recent developments that lead to dose reduction and dose transparency. Examples include new product features about dose reporting via DICOM SR, IHE REM, and the Dose Check feature.
- 3. Being a committed stakeholder, the CT manufacturers will contribute to HERCA related initiatives, such as EMAN, that focus on a cooperative concerted action by all stakeholders for developing a better practice in the management of ionizing radiation dose in CT environments. CT manufacturers welcome invitations to these initiatives.





European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Training and awareness on dose reduction is a broad process that involves more stakeholders to work together on practical approaches that can step up and maintain an active dose reduction policy in daily practice.

Whilst the CT manufacturers accept their responsibility for maintaining the proper competence levels of their trainers, it is the facilities' responsibility, however, to assess and maintain their equipment user's competency and make arrangements with the relevant manufacturers for their training requirements.

#### **Estimated timelines**

• **Q3 2011:** CT manufacturers will inform current situation to HERCA by providing an overview of training categories with real examples.

Currently the manufacturers' process of updating curricula and the creation of new curricula is in sync with the release of a new product model, or a new software version on an existing product model.

In addition we propose a dialogue with HERCA in conjunction with our periodic updates on potential revision of training curricula based on user needs in order to improve effectiveness.

#### Conclusion

As the developers of sophisticated scanners, CT manufacturers acknowledge their unique role in the process of optimizing patient dose in the health care setting. We believe the 4 items above will help in this process.

For a contemporary and unhesitant implementation the COCIR CT manufacturers propose the roadmap and timing as outlined in the voluntary commitment to be completed in the stated phases. COCIR CT manufacturers propose to update HERCA yearly on the progress and challenges associated with the voluntary commitment. Additional updates will be made if there are significant changes or challenges which result in a significant advancement or delay in the road map.

COCIR is representing the following CT manufacturers, which cover the majority of the installed base of CT systems in Europe: General Electric Healthcare, Philips Healthcare, Siemens Healthcare, and Toshiba Medical Systems. These CT manufacturers voluntarily commit to work toward the road map outlined above and ensure timely, effective and consistent implementation of the plan through COCIR's coordination. Therefore, COCIR, as the CT manufacturers' representative, will coordinate and direct these activities appropriately with HERCA in Europe.

Nicole Denjoy COCIR Secretary General



Annex 2: COCIR CT Commitment 1 - Characterization of CT Systems Standardized Benchmarking (6 August 2012)



HERCA Report CT Manufacturers Stakeholder Involvement Nov. 2017

COCIR

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

# **COCIR CT Manufacturer's Voluntary Commitment** Regarding CT Dose<sup>1</sup>

Commitment 1: Characterization of CT Systems Standardized Benchmarking

### 1. Goal

In order to assess the dose efficiency of a scanner, a simple reading of the prescribed dose of a scan is insufficient. Measurements of the image quality (including noise and resolution metrics) are also necessary to characterize the dose efficiency of the scanner. Since the relative importance of different image quality parameters varies across clinical tasks, it is necessary to measure the dose and image quality at individual clinical tasks. For use in standardized benchmarking, this document describes measuring a simplified set of metrics in order to compare image quality and dose performance across scanners, at each of four common clinical tasks (a Low Contrast Detectability (LCD) focused head task, a resolution focused head task, an LCD focused body task, and a resolution focused body task). These tests are designed with the goal of maximizing clinical relevance, accuracy, access, and ease of measurement.

Significant limitations may exist with this methodology and CT manufacturers believe that continued evaluation of the scientific community's progress involving image quality and dose efficiency should be considered.

#### 2. Method Overview

For each clinical task, perform a scan of a phantom using a clinically relevant protocol that meets or exceeds a set of image quality targets and report the dose from that scan as the output. The same scanning parameters will be used to make all measurements, except as noted. All scan and reconstruction parameters must be reported.

#### 3. Phantom

The standard, publically available Catphan 600 or equivalent model, is used as the phantom for this method. To more accurately reflect the challenges of abdomen scanning, the 30 cm Uniformity Body Annulus (CTP 539) is used to increase the attenuation of the phantom for the Body scanning tasks. This is a publically available Catphan attachment. The phantom, its attachments, and the scanning locations for each of the four tasks can be seen in Table 1. An image of the phantom and attachment used can be seen in Figure 1.

06 August 2012

<sup>&</sup>lt;sup>1</sup> http://www.cocir.org/uploads/documents/-59cocir\_ct\_manufacturer\_commitment\_version\_2\_13\_may\_2011.pdf

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking



#### **Table 1.** Phantom, attachments, and scan locations for each task.

Task	Phantom	Attachments	Scan Locations
LCD Head	Catphan 600 (CTP600)	None	All 5 Catphan Modules
Resolution Head	Catphan 600 (CTP600)	None	All 5 Catphan Modules
LCD Body	Catphan 600 (CTP600)		All 5 Catphan Modules
		Body Annulus (CTP539)	
Resolution Body	Catphan 600 (CTP600)		All 5 Catphan Modules
		Body Annulus (CTP539)	



Figure 1. An external view of the Catphan phantom. Source: <u>www.phantomlab.com</u>

#### 4. Method

Each of the four clinical tasks (LCD Head, Resolution Head, LCD Body, and Resolution Body) is measured separately. In each task, the phantom is first placed on the table and centered. For Head tasks, the phantom will rest on the box and hang off of the front of the patient table. For Body tasks, the phantom will be located over the table. In addition, on body tasks, the 30 cm Uniformity Body Annulus (CTP539) is placed on the phantom. Since the Annulus only has a Z length of 5 cm, it will need to be moved over each module of the Catphan when measurements are taken from that module. As all five modules are used, multiple rings will be needed, or five otherwise identical scans need to be taken with the ring over each of the modules. In order to keep the Catphan suspended above the patient table and maintain mechanical stability, a counterweight in the box will be needed or alternatively the phantom with body ring may be place directly on the patient table. In all tasks, care needs to be taken to ensure proper alignment of the phantom, as improper alignment will result in inaccurate measurements. Section "Phantom Position Verification" of the Catphan manual provides guidance on accurately aligning the phantom<sup>2</sup>.

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking 06 August 2012

<sup>&</sup>lt;sup>2</sup> Catphan 500-600 Manual - http://www.phantomlab.com/library/pdf/catphan500-600manual.pdf

# COCIR SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

With the phantom properly aligned, an appropriate factory reference protocol should be chosen. Factory reference protocols are used as they ensure a clinically relevant scanning scenario. In addition, the protocol needs to meet or exceed the image quality targets specified in Table 2. Scan type may be axial or helical, depending on the protocol specification. The results reported shall be based on a scan length of greater than or equal to 160 mm, i.e. enough to cover the Z length of the Catphan. Additionally, the image reconstruction matrix is intended to be 512 by 512 pixels. Scanner and protocol information (including scanner model name, protocol kVp, protocol mA, etc.) shall be reported in sufficient detail to allow recreation of the scan performed. Changes to factory reference protocols should be identified in the scan setup form.

Task	Prescribed Slice Thickness Visual LCD		Resolution
LCD Head	4 to 6 mm	3 mm at 1% contrast	
Resolution Head	0 to 1.25 mm		9 lp/cm at 10% MTF
LCD Body	4 to 6 mm	7 mm at 1% contrast	
Resolution Body	0 to 1.25 mm		8 lp/cm at 10% MTF

**Table 2.** Image quality targets for each task.

Note: if these conditions cannot be met with a factory reference protocol a similar, clinically relevant protocol should be used and its results reported.

To ensure consistent dose and image quality measurements, any automatic exposure control (AEC) shall be turned off. As the AEC otherwise automatically provides control of noise in the image, the mA of the scan may be adjusted in a clinically relevant range to meet the specified targets. The only parameters that should be changed from the factory reference protocol settings are those that are listed in this document as either specifically adjustable or a fixed value.

Then, with these settings, scanning shall be completed and the image quality shall be measured on the resulting central images from each module. Specification of how to perform each of the IQ measurements can be found in the next section. Window width and window level can be selected by the user. All measurements are performed in each of the tasks, except for Visual LCD and Measured Contrast Values in the Resolution focused tasks, as the phantom does not provide large enough contrast to accurately measure LCD in these tasks. In order to reduce the statistical uncertainty in the image measurements, the results of at least five separate scans of each image quality metric shall be performed and averaged to give the final, output result.

At least one full set of vendor reported results shall not use iterative techniques. Additional vendor reported results may be provided which utilize iterative techniques.

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

#### 5. Measurement methods

#### • 10% and 50% Modulation Transfer Function (MTF)

Resolution is objectively measured by reporting the MTF of a very thin wire, which quantifies the attenuation of the scanner per frequency. The frequencies at which the attenuation is equal to 50% and 10% are reported. Higher frequencies show better resolution in the image, allowing for the detection of finer structures.

MTF measurements are taken on the 50  $\mu$ m Tungsten wire in the Bead Geometry Module (CTP591) of the Catphan. This measurement will use the scanner's standard MTF calculation methods. In order to attain greater accuracy in the MTF measurement, a separate reconstruction shall be done with a display field of view (DFOV) of 10 cm and centered on the wire. This additional reconstruction shall only be used for the MTF measurements. In addition, in high noise environments (such as the Resolution Body task), the tester is allowed to average adjacent slices and/or multiple scans to make the MTF measurement. Without this, the MTF may be overly optimistic due to noise.

#### • Visual MTF

Visual MTF is a subjective resolution image quality metric that measures the ability to differentiate narrowly spaced, high contrast bar patterns. It is measured using the High Resolution Module (CTP528) of the Catphan. Higher Visual MTF values are better, as they allow you to see smaller objects. The highest frequency structure that is differentiable is the measured Visual MTF. An image from each protocol should be included in the report. Display window settings may be adjusted to better visualize the bars.

#### • Measured Slice Width

Measured slice width describes the thickness of the output image in the Z direction. Thinner slice thicknesses demonstrate improved Z resolution. To measure the slice width on output images, an image of the CTP401 or CTP404 module is taken. From that image, a plot profile of a 23 degree ramp is taken. The Full Width at Half Max (FWHM) of the plot profile times a scaling factor of  $\tan(23^{\circ})$  –approximately equal to 0.424– represents the measured slice thickness. See the Catphan 500-600 manual, section "Scan Slice Geometry (slice width)", for a detailed explanation of the method. The average of the 4 wires will be the output value.

#### Noise

Noise is objectively measured as the standard deviation of a uniform area in the Image Uniformity Module (CTP486) of the Catphan. The lower the noise, the better the image quality, as higher noises obstruct the visualization of objects. To improve accuracy in the measurement, the standard deviation of 5 regions of interest in each image will be averaged together to get a single slice's noise level. Noise shall be measured in center and peripheral. The center noise will be tested with a Region of interest (ROI) measurement (1 cm radius). Peripheral noise ROI measurements will be at 12, 3, 6, and 9 o'clock positions, centered 4.5 cm from the center of the phantom, each with a radius of 1 cm.

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking 06 August 2012



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

#### Visual LCD

LCD is subjectively measured using a visual evaluation of the CTP515 module. Using the 10 HU (Hounsfield Unit) nominal contrast pins, the smallest detectable size is reported. Visualization of smaller pins demonstrates improved image quality. As this method has large variability between observers, an average of at least 5 different observers shall be the reported value. As the actual 10 HU contrast level may vary between Catphans, a measurement of the actual contrast is required to put the Visual LCD results in context, as described in the "Measured Contrast Values" section. One image from each low contrast protocol shall be included in the report.

#### Measured Contrast Values

As the contrast value of the targets in the CTP515 module may vary from their nominal value, a measurement of the actual contrast is required to put the Visual LCD results in context. A greater 10 HU Measured Contrast results in overly optimistic Visual LCD results. A smaller 10 HU Measured Contrast results in overly pessimistic Visual LCD results. The output contrast is obtained by measuring the difference in average HU value between an ROI placed on the contrast pin and one near it, off of the pin. A full description of the method can be found in section "CTP515 Low Contrast Module with supra-slice and subslice contrast targets" of the Catphan 500-600 manual. Measurements shall be completed for each kV setting used in the test.

#### Dose (CTDIvol) •

CTDIvol is used as the dose metric, as it is standardized between scanners. Values reported shall conform to the IEC edition 3 scheme. In addition, the diameter of the CTDIvol phantom used shall be reported.

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

## **Measurement Output Format**

Forms are provided for reporting the specified measurements.

#### LCD Head Task

	Scan Setup
Scanner Information	
Protocol Information	

			Trial				
Category	Measurement	1	2	3	4	5	Average
	10% MTF (lp/cm)						
MTF	50% MTF (lp/cm)						
Visual MTF	Image Output						
	Twelve o'clock Wire FWHM (mm)						
	Three o'clock Wire FWHM (mm)						
	Six o'clock Wire FWHM (mm)						
	Nine o'clock Wire FWHM (mm)						
Slice Width	Average (mm)						
	Center (HU)						
	Peripheral Twelve o'clock (HU)						
	Peripheral Three o'clock (HU)						
	Peripheral Six o'clock (HU)						
	Peripheral Nine o'clock (HU)						
Noise	Average (HU)						
	Size (mm) of visible pin at 1% contrast (average of 5+ observers)						
Visual LCD	Image Output						
	A: ROI over 1% pin (HU)						
Measured	B: ROI over background (HU)						
Contrast	A-B: Contrast (HU)						
	CTDIvol (mGy)						
Dose	Dose Phantom Diameter (cm)						

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking



### **Resolution Head Task**

Scan Setup	
	Scan Setup

		Trial					
Category	Measurement	1	2	3	4	5	Average
	10% MTF (lp/cm)						
MTF	50% MTF (lp/cm)						
Visual MTF	Image Output						
	Twelve o'clock Wire FWHM (mm)						
	Three o'clock Wire FWHM (mm)						
	Six o'clock Wire FWHM (mm)						
	Nine o'clock Wire FWHM (mm)						
Slice Width	Average (mm)						
	Center (HU)						
	Peripheral Twelve o'clock (HU)						
	Peripheral Three o'clock (HU)						
	Peripheral Six o'clock (HU)						
	Peripheral Nine o'clock (HU)						
Noise	Average (HU)						
	CTDIvol (mGy)						
Dose	Dose Phantom Diameter (cm)						

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking

06 August 2012



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

#### LCD Body Task

	Scan Setup
Scanner Information	
Protocol Information	

				Гria			
Category	Measurement	1	2	3	4	5	Average
	10% MTF (lp/cm)						
MTF	50% MTF (lp/cm)						
Visual MTF	Image Output						
	Twelve o'clock Wire FWHM (mm)						
	Three o'clock Wire FWHM (mm)						
	Six o'clock Wire FWHM (mm)						
	Nine o'clock Wire FWHM (mm)						
Slice Width	Average (mm)						
	Center (HU)						
	Peripheral Twelve o'clock (HU)						
	Peripheral Three o'clock (HU)						
	Peripheral Six o'clock (HU)						
	Peripheral Nine o'clock (HU)						
Noise	Average (HU)						
	Size (mm) of visible pin at 1% contrast (average of 5+ observers)						
Visual LCD	Image Output						
	A: ROI over 1% pin (HU)						
Measured	B: ROI over background (HU)						
Contrast	A-B: Contrast (HU)						
	CTDIvol (mGy)						
Dose	Dose Phantom Diameter (cm)						

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking



#### **Resolution Body Task**

	Scan Setup
Scanner Information	
Protocol Information	

			Trial				
Category	Measurement	1	2	3	4	5	Average
	10% MTF (lp/cm)						
MTF	50% MTF (lp/cm)						
Visual MTF	Image Output						
	Twelve o'clock Wire FWHM (mm)						
	Three o'clock Wire FWHM (mm)						
	Six o'clock Wire FWHM (mm)						
	Nine o'clock Wire FWHM (mm)						
Slice Width	Average (mm)						
	Center (HU)						
	Peripheral Twelve o'clock (HU)						
	Peripheral Three o'clock (HU)						
	Peripheral Six o'clock (HU)						
	Peripheral Nine o'clock (HU)						
Noise	Average (HU)						
	CTDIvol (mGy)						
Dose	Dose Phantom Diameter (cm)						

COCIR CT Commitment 1: Characterization of CT Systems Standardized Benchmarking

06 August 2012



**Annex 3: Reformulation of Commitment 1** 



HERCA Report CT Manufacturers Stakeholder Involvement Nov. 2017



### Proposal for a Reformulation of Commitment 1

#### CT Manufacturer's Voluntary Commitment Regarding CT Dose

#### Commitment 1:

#### Characterization of CT Systems for Standardized Benchmarking

**Background** Scan conditions and parameter settings currently used for the specification of image quality and dose differ from vendor to vendor. Therefore, a direct comparison of CT systems can be challenging. Unfortunately, the definition of one single parameter to characterize performance of a modern CT system with Iterative Reconstruction Methods, is up to date not feasible. COCIR CT manufacturers and HERCA agree that for the current moment no single figure of merit can accurately reflect CT dose efficiency. Scientific groups are currently working on new pathways for characterization of the CT performance.

**Aim** CT manufacturers aim to provide transparency and easily understood values for the end users that attempt to characterize system performance for the clinical tasks through standardized test methods and conditions.

**Concept** The COCIR CT manufacturers are and will continue to actively participate in the MITA CT Image Quality (IQ) Task Force that is investigating a new phantom and bench testing methodology for assessing Low Contrast Detectability (LCD) and the associated dose level. The CT manufacturers are convinced that this methodology offers the potential to quantitatively assess the LCD for clinical protocols in the body and in the head in relation to dose. HERCA through its Panel of Advisers (PoA) in CT technology will be closely involved in this process, be regularly informed about the status of the process and be invited to participate in the analysis of the results. For transparency purposes, CT manufacturers will make available details on test conditions for dose related claims. COCIR and HERCA will install a platform of communication on a yearly bases to address the tasks of clinical detectability and work closely together to improve the understanding of CT dose efficiency.



HERCA Report CT Manufacturers Stakeholder Involvement Nov. 2017



Annex 4: COCIR CT MANUFACTURER List of Dose Management Features (5 July 2013)



HERCA Report CT Manufacturers Stakeholder Involvement Nov. 2017



COCIR

SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

# CT Manufacturer's Voluntary Commitment Regarding CT Dose

## Updated list of dose management features

The CT manufacturers have worked through MITA to provide an updated list of available technologies implemented for dose reduction on CT scanners, in line with Commitment 2 of the CT Manufacturer's Voluntary Commitment Regarding CT Dose.

This following list has been updated and is still based on the MITA list<sup>1</sup>, but contains only the COCIR CT manufacturers: General Electric Healthcare, Philips Healthcare, Siemens Healthcare and Toshiba Medical Systems. This list describes generic categories of features and is not intended to reflect marketing names or be updated to show the evolution of each of these specific features with respect to improvement in performance that all manufacturers continue to develop on an ongoing basis.

### **1. General Electric Healthcare**

- Patient Protocol Selection Guidance
  - Color coded pediatric weight /age-based protocols, pediatric Featherlight (procedure based) protocols, and mA limited pediatric FOV protocols, to minimize technologist errors
  - Preloaded protocols for adults and for pediatric imaging organized by clinical indication to serve as a starting point for optimizing an institution's dose vs. IQ preferences
- <u>Advanced Collimator Design</u>
  - Real time beam tracking during all scanning to minimize beam collimation
  - Dynamic beam size collimation to reduce unused patient exposure at ends of helical scanning
- Automatic Tube Current Modulation (ATCM) and X-ray Initiation
  - Z-axis ATCM that automatically optimize the mA for smaller patient anatomy to achieve the desired image quality
  - X-Y ATCM to optimize the mA to account for changing patient habitus during a scan rotation to achieve the desired image quality
  - ECG initiated cardiac axial scanning to generate x-ray only during the desired heart phase, including irregular heartbeat avoidance. Avoids low pitch helical overlap
  - ECG guided ATCM for cardiac to allow full mA only during the desired heart phase
  - Contrast monitoring to initiate the CT exposure relative to contrast arrival

<sup>&</sup>lt;sup>1</sup> MITA List of dose reduction features for the following CT manufacturers: GE Healthcare, Hitachi Medical Systems, NeuroLogica, Neusoft Medical Systems, Philips Healthcare, Siemens Medical Solutions, Toshiba America Medical Systems, March 2011, released on the 4<sup>th</sup> March 2011.



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

### Precise X-ray Field shaping

COCIR

- Internal tube collimation and stray electron collection devices to reduce off-focal radiation
- Real time active source collimation to reduce unused x-rays
- A variety of beam shaping filters optimally selected based on the patient scan field of view and intended application

#### - Dose Efficient Design

- Helical algorithms that minimize helical overranging
- High resolution detector pitch that maintains high geometric dose efficiency
- High (98%) detector material efficiency
- Low noise data acquisition electronics to preserve patient x-ray measurements under low signal conditions
- Selectable kV imaging at 80, 100, 120 and 140 kV
- Image Reconstruction methods
- Adaptive reconstruction methods and filters to reduce noise and retain image features
- Statistical iterative image reconstruction technique that models system statistics
- Advanced model based iterative reconstruction technique that accurately models both system statistic and optics
- Dose reporting and Awareness
  - Dose display of predicted  $\text{CTDI}_{\text{vol}},$  DLP and associated phantom size prior to and post scan initiation
  - Dose report image containing  $\text{CTDI}_{\text{vol}},$  DLP and associated phantom size that can stay with patient images as a record
  - DICOM CT Dose structured reporting
  - Dose notification and alert features, in conformance with NEMA standard XR-25 (CT Dose Check)
  - HIPAA enabled access controls for system use and protocol management
- Training Opportunities
  - Online TiP TV training sessions
  - GE Healthcare Institute training opportunities
  - Dose symposium offerings
  - On-site applications support
  - Online learning and reference guides
  - Online Center live customer support
  - Applications call center
  - Image Gently training collaboration

#### 2. Philips Healthcare

- Pediatric Protocols
  - A complete group of factory installed age- and weight-based pediatric protocols that provide for appropriately reduced dose and utilize 80 and 100 kVp tube voltages and lower tube-currents
  - Reduced dose for surview, or planning scans, compared to adult settings



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

### Dedicated Infant Imaging Mode

COCIR

- Infant mode activates the infant beam shaping wedge and filter for increased dose efficiency
- Separate infant mode calibrations optimize image quality for newborns and babies
- Dedicated infant phantom utilized for infant calibration and protocol development

#### Advanced Tube and Collimator Design

- Dynamic x-ray beam collimation eliminates unnecessary and unused patient radiation exposure at the beginning and end of a helical scan
- Adaptive collimation to automatically match prospective axial scan length to desired anatomical range
- Tube housing elements to capture stray electrons and reduce off-focal radiation

### - Automatic Tube-Current Modulation during Scanning

- Automatic tube-current selection based on the surview or planning scan patient attenuation
- Z-axis tube-current modulation based on surview patient attenuation
- X-Y, or angular, tube-current modulation within each rotation of a helical scan
- Simultaneous X-Y and Z tube-current modulation based on surview patient attenuation
- Prospective ECG-triggered axial cardiac scans generate radiation only during desired heart phase
- Automatic arrhythmia rejection algorithms that suspend x-ray emission during irregular heartbeats
- ECG-triggered tube-current modulation for helical cardiac imaging modes
- Injector integration to reduce the potential for rescans due to mistimed or suboptimal contrast
- Z-focal-spot deflection to double sampling and prevent helical artifacts without an increase in dose

#### <u>Dose Efficient Detection</u>

- 99% efficient detector material that increases signal and image quality
- Wide detector coverage with high geometric efficiency
- Proprietary 2D antiscatter grids and scatter removal techniques for wider beam collimations increase image quality without a corresponding increase in dose
- Low-noise data acquisition electronics preserve patient x-ray measurements at low-doses
- Multiple beam-shaping wedges and filters to optimize the dose efficiency per protocol
- Multiple flat-field filters to adjust x-ray beam quality (hardness) for a given diagnostic task

#### Optimized Image Reconstruction

- Advanced cone beam reconstruction algorithms
- Iterative reconstruction technique provides dose reduction and maintains or improves image quality
- Dose Display and Recording
  - Predicted dose display of CTDI<sub>vol</sub> and DLP on console prior to acquisition
  - Actual CTDI<sub>vol</sub> and DLP recorded with patient images
  - DICOM dose structured report and IHE REM profile
  - Dose notification and alert features, in conformance with NEMA standard XR-25 (CT Dose Check)



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

- <u>Training Opportunities</u>

COCIR

- Offsite customer application training at three convenient global locations
- On-site customer application training and support
  - On-site pediatric dose course
  - On-site ACR accreditation assistance and dose-management course
  - On-site dose reduction strategies course
- Remote dose management course
- Remote pediatric check-up course
- Brain perfusion course
- NetForum for up-to-date information sharing among customers and Philips
- Philips Online Learning Center
- Image Gently pediatric dose training collaboration
- CustomerCare solutions phone support

#### 3. Siemens Healthcare

#### Predefined Protocols for Adults and Children

- Predefined clinical protocols tailored to various body regions and procedures, which include available dose modulation options
- Dedicated protocols for pediatric patients, utilizing low tube voltage (as low as 70 kV) and mAs-settings. The X-ray exposure is automatically adapted to the child's size, weight, and age, substantially reducing patient dose
- Real-time topogram; manual interruption possible once desired anatomy has been imaged
- Dose Modulation Options
  - Automated real-time tube current adjustment for best diagnostic image quality at lowest possible dose. Tube current is automatically adapted to patient size, to the attenuation of the patient's long axis and to the angular attenuation profile measured online for each single tube rotation
  - Automated tube voltage adjustment, which automatically recommends the optimal tube voltage for each individual patient for each specific exam. Information gathered from the topogram is used to optimize tube voltage and current, so that a userspecified contrast-to-noise ratio is maintained, and thus optimal image quality and lowest dose are achieved
  - Tailored ECG-gated dose modulation for various acquisition types, such as ECGgated cardiac spiral for dose reduction outside the selectable heart phase. Prospective ECG-synchronized cardiac sequence scans allow for maximum dose savings
  - Special scan modes for contrast bolus triggered data acquisition. It enables an optimum spiral scan start after contrast injection based on repetitive low dose monitoring scans



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Modulating the X-ray beam

COCIR

- Specially shaped X-ray exposure filters installed at the tube collimator reduce unnecessary dose at the peripheral FOV. Selection is based on scanned body region and patient size
- Special dynamic tube collimator which prevents pre- and post-spiral overscanning
- Unique X-ray tube utilizes two precisely alternating focal spots. This doubles scan information at each detector without a corresponding increase in dose and eliminates spiral artifacts in the daily clinical routine at any position within the scan field
- Dose Efficient X-ray Detection
  - Ultra fast ceramic detector material with ultra short afterglow, optimized for subsecond and multislice acquisition
  - High efficiency for low exposure requirements to enable best possible image quality with low patient dose
- Optimized Image Reconstruction
  - Spiral reconstruction algorithms that maintain high-quality imaging at any scanning speed
  - Advanced cone beam reconstruction algorithms for elimination of cone beam artifacts
  - Projection data and image based adaptive filtering algorithms to reduce image noise while preserving resolution
  - Advanced iterative reconstruction algorithms improving image quality and allowing for further dose savings
- Dose Information
  - Dose information is displayed on the user interface prior to scanning for the selected scan parameters. Parameter changes are reflected in real-time
  - Dose notification and alert features, in conformance with NEMA standard XR-25 (CT Dose Check)
  - Full dose information of individual scans as well as complete patient exam are automatically stored with the patient's images, both as a DICOM image as well as a DICOM Structured Report. The new DICOM standard, Dose SR, contains comprehensive data for each irradiation event, the accumulated dose and information about the context of the exposure. The data is provided in electronic format that can be sent to any system which receives, stores or processes dose information, such as conventional PACS or workstations
- Educational Opportunities
  - On-Site Clinical Education Support
  - Optimize CARE CT, an innovative consulting service which helps to optimize user's scan protocols and achieve the right dose for routine CT exams
  - Training and Development Centers located in various locations in the United States, Europe and Asia
  - Uptime Applications and Education Phone Support
  - Siemens Remote Assist to help if questions arise
  - Siemens Remote Training to regularly keep customer up-to-date

COCIR

### SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

- Reference Guides as part of the equipment, Workshops and Fellowships
- Siemens Medical Academy web based Educational Material
- Dedicated web site: www. siemens.com/low-dose
- Brochure: "Guide to Low Dose"

COCIR

• Consulting offer Optimize Care CT – a comprehensive dose optimization program also including workflow and general staff education

#### 4. Toshiba Medical Systems

- Default Pediatric Protocol Settings
  - Default age- and weight-based pediatric protocols tailored to pediatric anatomy
  - Automatic activation of pediatric protocol selection based on entered age
  - Variety of kVp options
- <u>Dose Modulation Options</u>
  - 3-dimensional mA modulation is available in the z and xy dimensions, tailoring the dose based on the patient's own size and composition. The user is able to specify a target level of image quality and constrain the minimum and maximum mA used
  - ECG gated to limit exposure during non-desired phases of the heart cycle
  - Prospective ECG gating that shuts X-rays off during non-desired phases of the heart cycle
  - Contrast bolus tracking technology controls start of X-ray exposure based on realtime measured contrast concentration
  - Variable Helical Pitch alters table speed during acquisition to avoid unnecessary low pitches in combination studies

#### Beam Shaping

- Anode grounded tube design and electron collection aperture to minimize off-focal radiation
- Small bowtie filter to shape X-ray beam for pediatric patients
- Dose Reduction wedge to maximally attenuate low energy X-rays

#### <u>Dose Efficient Design</u>

- Highly efficient detector material to maximize signal and low contrast detectability
- Thin septa to reduce scattered radiation while maintaining geometric efficiency
- Efficient acquisition system (including highly shielded electronics and stealth paint on the inside of the gantry) to minimize electronic noise and ensure accurate patient x-ray signal under low dose conditions
- Active Collimation to reduce overranging with helical scans
- Image Reconstruction and Post-processing
  - Projection based adaptive algorithm to reduce noise and streak artifacts in areas with low photon counts
  - Image based adaptive filters to reduce image noise and mottle while preserving resolution and edge information
  - Iterative noise reduction algorithms



COCIR

## SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

- Variety of reconstruction methods to optimize resolution and dose
- Dose reporting
  - Prospective feedback on prescribed dose values for a protocol prior to scanning
  - Detailed dose summary of complete patient exam that is retained with the patient's images
  - Dose notification and alert features, in conformance with NEMA standard XR-25 (CT Dose Check)
  - IHE REM profile DICOM structured report
- Training Opportunities
  - Toshiba Training Academy and Education Center
  - Three phase customer education including 1) didactic and practical training at the Education Center, 2) onsite training, and 3) follow-up onsite training after the customer has some direct experience
  - ToshibaLearningCenter.com provides resources on all courses, physician training, and continuing education courses
  - e-training resources on dose, safety, product info, books and articles
  - On-site applications support as well as InTouch Center phone support

#### Note:

- 1. Not all dose reduction features are available on all products
- 2. Certain features are offered as purchasable options
- 3. Not all dose reduction features can be employed at the same time or for all scan types
- 4. Training and education support processes may differ depending on the region



Annex 5: COCIR Response CT commitment 4 on Training (5 July 2013)



HERCA Report CT Manufacturers Stakeholder Involvement Nov. 2017



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

## CT Manufacturer's Voluntary Commitment Regarding CT Dose COCIR deliverable on Commitment 4 "Provision of specific training curricula"

## **1.** Concept of Commitment 4: Provision of specific training curricula

CT manufacturers are committed to make a significant contribution to ensure the appropriate, safe and effective use of imaging equipment by the clinical user:

- The offering of vendor specific equipment training curricula to the CT user, and through user programs that help CT operators optimizing the patient dose settings on their scanners, and the offering of continuing professional education optional training.
- Keeping the vendor's equipment training curricula updated with the recent developments that lead to dose reduction and dose transparency. Examples include new product features about dose reporting via DICOM SR, IHE REM, and the Dose Check feature.
- Being a committed stakeholder, the CT manufacturers are contributing to HERCA related initiatives, such as EMAN, that focus on a cooperative concerted action by all stakeholders for developing a better practice in the management of ionizing radiation dose in CT environments. CT manufacturers welcome invitations to these initiatives.

Training and awareness on dose reduction is a broad process that involves more stakeholders to work together on practical approaches that can step up and maintain an active dose reduction policy in daily practice. The CT Manufacturers appreciate the contribution from HERCA in raising awareness and promoting dose management in hospital facilities through education and training.

## 2. COCIR CT commitments deliverable

Manufacturers provide training in the use of their equipment. This includes the normal usage of the equipment, and the special features such as setting up protocols and using dose reduction features. Examples include Instructions for Use, both on paper and as on-line help, Computer based training, on-site and off-site training, telephone support, hands-on training, and industry standard educational material.

In addition to manufacturer developed training, professional societies, academic institutions, and healthcare providers share the responsibility to develop and offer educational material on the use of CT imaging in the healthcare setting. This educational material should include the principle of ALARA and how to optimize the dose delivered while still meeting the unique clinical needs of the patient and the institution's accepted practices.

The following examples illustrate the commitment by both the CT Manufacturers' and various stakeholders in promoting dose awareness and the principle of ALARA.

COCIR deliverable on Provision of specific training curricula



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

As a coordinated effort between the Society of Pediatric Radiology, Alliance for Radiation Safety in Pediatric Imaging, and CT Manufacturers, specific and general training for pediatric CT use was developed and made available to users through the Image Gently campaign. These resources are publically available to any user at the following link:

http://www.pedrad.org/associations/5364/ig/index.cfm?page=369

Additionally, the IAEA provides extensive resources on the use of radiation in medicine including CT specific considerations:

https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/1 Radiolo gy/ComputedTomography/index.htm

The COCIR group is also in communication with HERCA and EMAN WG-1 related to the education and training of individuals involved in CT imaging. We appreciate HERCA's initiative to sponsor a multi-stakeholders approach by inviting organizations such as ESR and EFRS.

Lastly, CT Manufacturers are committed to delivering training both on dose awareness and product features related to dose optimization. General dose awareness and optimization training is addressed by various training platforms and modules across the CT Manufacturers and may not be tied directly to product development timelines. However, when new CT systems or features are developed training is made available that describes their operation and the dose impact of operator decisions as applicable. Examples of recent manufacturer specific training items are listed below:

### A. Dose Awareness

**GE Healthcare** – CT Low Dose Webinar Series – Continuing education credit courses available online. Example topics include "CT Radiation Dose – Current Issues and New Techniques", "Fundamentals of CT and Radiation Dose", and "Techniques for Reducing CT Radiation Dose".

**Philips** – Classroom dose and dose modulation training in specific geographies for technicians, doctors and physicists.

**Siemens** – "Easy Guide to Low Dose" and "How to ..." flyers are available to provide detailed information about dose in general, but also to support the user to utilize dose reduction techniques in daily clinical routine.

**Toshiba** – We refer to the document "Ten things you need to know about CT dose" which is available on the following link: http://www.toshiba-medical.eu/en/Our-Product-Range/CT/Dose/

### **B.** System/Feature Specific

**GE Healthcare** – ASiR (Adaptive Statistical Iterative Reconstruction) live training module – Consisting of instruction on applying ASiR during CT scanning and its potential impact on dose.



European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

**Philips** – iDose4 classroom and onsite training including introduction to iterative reconstruction technique and its application in clinical CT.

**Siemens** – Web-based E-training for the most recent software version (*syngo* CT2011A FASTCARE), which includes a specific training for dose reduction feature (e.g. CARE kV and CARE Dose4D).

**Toshiba** – As an integral part of clinical application training onsite, dose reduction tools including AIDR 3D, <sup>SURE</sup>EXPOSURE 3D, etc. are provided.

### C. Training Delivery

**GE Healthcare, Philips, Siemens and Toshiba** – As a part of new system installation typical on-site training would be 1-2 weeks with an Applications Specialist. On-site refreshing training available based on customer needs.

### **D.** Further information

Further information on educational options described, please refer to each company portal:

**GE Healthcare** <u>http://www3.gehealthcare.com/en/Global\_Gateway</u> Select appropriate country / language, then select "Education" and "Computed Tomography".

Toshiba: <u>http://www.toshiba-medical.eu/en/</u>

Philips: <u>http://netforum.healthcare.philips.com</u> and <u>http://www.theonlinelearningcenter.com</u>

**Siemens:** <u>http://healthcare.siemens.com/education/med-imag-therapy</u>

### Conclusion

Manufacturer's training is designed to support customer facilities in an effort to improve operating knowledge and increase the skill level of personnel. These programs consist of a variety of delivery mechanisms that allow hands-on and didactic training to reinforce skills needed to operate equipment. Manufacturer training uses Operator Manuals to demonstrate information on dose optimization tools and dose reduction strategies as well as information on dose related displays, indices, and where dose information is located. Additional delivery mechanisms may include, but are not limited to, onsite training, classroom instruction, remote instructor-led training and observation, online tutorial selfhelp, telephone support, white papers and publications, seminars, peer to peer physician training, and industry association educational material.



Annex 6: COCIR CT Manufacturers Reference phantom size FAQ



HERCA Report CT Manufacturers Stakeholder Involvement Nov. 2017



## **COCIR CT Manufacturers' CTDI**<sub>vol</sub> Reference Phantom Size FAQ

With the release of IEC 60601-2-44, Edition 3.1, in 2012, the IEC clarified that CTDI should be displayed for the 32 cm (320 mm) CTDI phantom for all Body techniques and 16 cm (160 mm) CTDI phantom for all Head techniques. Prior to that, the standard was not as specific, and some vendors chose to use different CTDI phantom reference sizes for pediatric techniques. The exceptions to the 32 cm phantom for all Body techniques are listed below.

### <u>GE</u>

The reference phantom used in CTDI calculations is determined by the SFOV type which determines the bowtie filter selection and the reference phantom used to report the dose delivered. SFOV type is selectable by the user during the exam setup and recorded with the exam data. A table of SFOV types and corresponding reference phantom sizes are located in the Quality Assurance Chapter of the Technical Reference Manual in the Dosimetry Section for each system manufactured after 2006.

The only exception to IEC 60601-2-44 ed.3.1 is that pediatric body scans use the 16cm reference phantom rather than the 32cm. GE Healthcare plans to update these exams to use the 32cm reference phantom for our new product releases starting in 2014.

#### <u>Philips</u>

Philips has always used a 16 cm CTDI phantom for all Head protocols, and 32 cm CTDI phantom for all Body protocols, except for the release of iDose4 in March, 2011, on Ingenuity, Brilliance-64 and iCT. For those three products, the 16 cm CTDI phantom was used to report CTDI for Infant (<18 months old) Body protocols, while 32 cm was used for Child and Adult protocols. When iPatient was released in 2013, Philips changed back to using 32 cm for ALL Body protocols.

#### <u>Siemens</u>

Siemens has always used a 16 cm CTDI phantom for all Head protocols, and 32 cm CTDI phantom for all Body protocols (including child). There are no exceptions to the 32 cm phantom for all Body protocols.

#### <u>Toshiba</u>

Since approximately 2 years all Toshiba CT scanners which comply with IEC 60601-2-44 ed.3.1 display CTDIvol based on 16cm phantom for head protocols and 32cm for body protocols, regardless of age. The exact date of implementation depends on model names per system. The scanners which were shipped before that timing, display CTDIvol based on 16cm phantom for all pediatric protocols, and for adults (>12 years) the scanners display 16cm for head protocols and 32cm for body protocols.