



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.



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.



Estimated timelines

- **Q4 2010:** CT manufacturers are working through MITA to provide an updated overview of available technologies¹.
- **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 1st 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 1st capabilities): Security – conceptual**

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

¹ List of dose reduction features for CT manufacturers to be released on 4 March 2011.



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.



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.

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