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Computed Tomography Dose Check

:

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Foreword

This Standard is intended to be used by medical imaging device manufacturers in the design and manufacture of CT scanner equipment.

This Standard was developed by the CT Group of the X-Ray Imaging Section of the Medical Imaging & Technology Alliance (MITA), a division of NEMA. Inquiries, comments, and proposed or recommended revisions should be submitted to the X-Ray Imaging Section by contacting:

Executive Director
MITA
1300 North 17th Street
Suite 900
Rosslyn, Virginia 22209

Member Company List

At the time of the approval of the Standard, the CT Group was composed of the following members: GE

Healthcare
Hitachi Medical Systems America, Inc.
NeuroLogica, a subsidiary of Samsung Electronics
Neusoft Medical Systems, USA, Inc.
Philips Healthcare
Planmed
Siemens Healthineers
Toshiba America Medical Systems
United Imaging Healthcare
Xoran Technologies, LLC

At the time of the approval of the Standard, the X-Ray Imaging Section was composed of the following members:

Agfa HealthCare
Canon Healthcare Solutions
CurveBeam LLC
EIZO Corporation
EOS imaging
FUJIFILM Medical Systems U.S.A., Inc.
GE Healthcare
Hitachi Healthcare Americas
Hologic Inc.
Konica Minolta Medical Imaging USA, Inc.
Laitek Inc.
Liebel-Flarsheim a wholly owned subsidiary of Guerbet Group
MEDIAN Technologies, Inc.
Medtronic, Inc.
Modus Medical Devices Inc.
NeuroLogica A Subsidiary of Samsung Electronics
Neusoft Medical Systems, USA, Inc.
Philips
Planmed
Samsung Medical Devices
Shimadzu Medical Systems USA
Siemens Healthineers
Swissray International, Inc.
Toshiba America Medical Systems
United Imaging Healthcare
Ziehm Imaging, Inc.

History

This is the second edition of this Standard. Changes from the first edition include:

a. An accommodation is incorporated to the dose alert feature such that the alert triggers only once for procedures deemed interventional by the user or manufacturer.

   1. There are two options for this accommodation: a pre-determined protocol element or protocol element group that is identified for CT guided interventional procedures or a user-activated feature that indicates a CT guided interventional procedure.

   2. While the dose alert only goes off only one time, a passive alert continues.

   3. In interventional mode, the Z position of the highest dose and the associated $CTDI_{vol}$ value is displayed.

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Section 1
Overview

1.1 Scope

This Standard applies to particular dose-related notification and alert messages appearing on the operating consoles of CT scanners.

This Standard is not intended to define all notification, alert, or other messages resident on any CT scanner.

1.2 Rationale

This Standard intends to notify and alert the operating personnel, generally technologists that prepare and set the scan parameters—prior to starting a scan—whether the estimated dose index is above the value defined and set by the operating group, practice, or organization (hereafter referred to as “institution”) to warrant notification to the operator.

In order to accommodate a range of different operational and QA-related features adapted from a variety of technological advances in current and prospective scanner models, dose messages to the operator are not limited to those specified in this Standard.

The IEC 60601-2-44 Ed. 3.1 (*Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*) Standard currently specifies dose notifications and alerts that were included in the first edition of NEMA XR 25. This edition incorporates the portions of IEC 60601-2-44 that contain dose notifications and alert information. However, changes made in this edition of XR 25 are not included in the current IEC 60601-2-44 Ed. 3.1.

1.3 References

1.3.1 Normative References

The following normative documents contain provisions, which through reference in this text, constitute provisions of this Standards publication. By reference herein these publications are adopted, in whole or in part as indicated, in this Standards publication. For updated references, the latest edition of the publication referred to applies (including amendments).

International Electrotechnical Commission
3, rue de Varembé
Case postale 131
CH-1211 Geneva 20
Switzerland

IEC 60601-2-44 Ed. 3.1 *Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography*

International Organization for Standardization (ISO)
1, rue de Varembé
Case postale 56
CH-1211 Geneva 20
Switzerland

ISO 12052 *Health informatics—Digital imaging and communication in medicine (DICOM) including workflow and data management*

1.4 Definitions

Alternate Dose Alert Behavior:
A cessation of active dose alerts after the first alert for CT guided interventional procedures.

> Note: The purpose of alternate dose alert behavior is to avoid situations where a repeated dose alert might interfere with the progress of a CT guided interventional procedure.

CT Guided Interventional Procedure:
Invasive procedure (involving the introduction of a device, such as a needle, into the patient) using computed tomography as the principal means of visual guidance, and intended to effect treatment or diagnosis of the medical condition of the patient.

> Note: In contrast to a radioscopically guided interventional procedure, the extraction of needles is not to be considered essential performance (Reference IEC 60601-2-44).

> Note: A CT guided interventional procedure is based on either:
> a. a dedicated CT interventional protocol element or protocol element group as indicated by the manufacturer, or
> b. a corresponding selection provided by the manufacturer which the operator activates prior to an examination (if configured) or during an examination to indicate an interventional procedure, e.g. a checkbox in the dose alert pop-up window.

Scan or Scanning:
As used in this Standard, scan or scanning denotes the complete process of irradiating a person or an object while collecting x-ray transmission data to produce a tomographic image or to produce a tomographic data set that could be applied for analytical or density-conversion purposes. Data may be collected simultaneously during a single scan for the production of one or more tomographic images or tomographic data sets.

Scanning Parameter:
The individual building block of an acquisition, for example, tube voltage, tube current, rotation time, etc. These are each individual scanning parameters. Multiple scanning parameters are grouped together to form a protocol element.

Passive Onscreen Indication:
A visual, on-console cue, which does not require user interaction, displayed to signify an event(s) has occurred during an examination, e.g., the dose alert threshold has been exceeded while in alternate dose alert behavior mode.

Active Onscreen Indication:
A visual, on-console cue, which requires user interaction, displayed to signify an event(s) has occurred during an examination, e.g., the dose alert.

Protocol Element:
A set consisting of all the scanning parameters necessary to perform a single scan (tube voltage, tube current, rotation time, spatial location, etc.).

> Note: Various CT systems may use terms corresponding to the term “protocol element” that are consistent with the rest of their user interfaces and documentation, e.g., “scan,” “scan group,” “scan series,” etc.

Protocol Element Group:
One or more protocol elements grouped together and executed by the system based on a single press of the Confirm/Go/Load software button on the user interface. The scanning for this group may occur from one or more activations of the “X-ray on” hardware button.

Protocol:
A group of protocol elements predefined for a certain CT examination.

Radioscopy:
Technique for obtaining continuously or periodically a sequence of X-ray patterns and presenting them directly or through a transfer and optional processing simultaneously and continuously as visible images, intended to provide real-time guidance to an ongoing action.

Ready State:
The state of the CT-system, where a single action, e.g., pressing the start button or foot switch, initiates the scan.

Examination:
A protocol or group of protocols used for the entire CT procedure for the current patient.

Notification Value:
A value of $CTDI_{vol,}$ *or* $CTDI_{vol}$ per second (in units of mGy or mGy per second) or of DLP or DLP per second (in units of mGy·cm or mGy·cm per second) that is set by the operating institution to trigger a notification to the operator prior to scanning when exceeded by a corresponding dose index value expected for the selected protocol element.

> Note: A notification value represents a value above which a dose index value would be above the institution's established range for the protocol element.

Alert Value:
A value of $CTDI_{vol}$ or $CTDI_{vol}$ per second (in units of mGy or mGy per second) or of DLP or DLP per second (in units of mGy·cm or mGy·cm per second) that is set by the operating institution to trigger an alert to the operator prior to SCANNING within an ongoing examination if it would be exceeded by an accumulated dose index, on acquisition of the protocol element group.

> Note: An alert value represents a value above which the accumulated dose index value would be well above the institution's established range for the examination that warrants more stringent review and consideration before proceeding.

1.5 Abbreviations

$CTDI_{vol}$: Volume Computed Tomography Dose Index (as defined in IEC 60601-2-44)
DLP: Dose Length Product (as defined in IEC 60601-2-44)

Section 2
Dose Notifications and Dose Alerts

2.1 Dose Notifications

2.1.1 Configuration

Manufacturers shall provide a means for users to enter, save, and modify notification values.

The system shall permit a notification value for each of the protocol elements making up each protocol. The system is not required to support notification values for scan projection radiography.

The system may permit the user to choose not to set notification values for some or all protocol elements in some or all protocols.

2.1.2 Checking Prior to Scanning

The notification value(s) for the current protocol element(s) shall be visible to the operator prior to confirmation of the protocol element group.

When a protocol element group is confirmed or otherwise set to the ready state by the operator, the system shall display a notification (see 2.1.4) on the operator's console if the estimated $CTDI_{vol}$ or *DLP* exceeds the corresponding notification value(s). The notification shall be displayed prior to the start of the scan, and shall never interrupt the scan.

Some protocol elements, such as bolus tracking or interventional, may not have a predefined number of rotations but may have other pre-programmed limits on the number of exposures or exposure time. When estimating the $CTDI_{vol}$ and *DLP* for these types of protocol elements, the estimate shall assume that the scan proceeds to those limits for protocol elements such as bolus tracking; however, for interventional type protocol elements, alternate means may be used such as values in mGy/s. If there are no preprogrammed limits, checking is not required.

The system is not required to display a notification if no corresponding notification values have been set or the dose notification has been disabled.

To exceed a notification value, the system shall require the operator to reconfirm the chosen protocol elements before proceeding to the scan. The system shall permit the operator to enter a diagnostic reason (of up to 64 characters) at the operator's discretion. The system does not have to require the input of such reason(s) in order to proceed.

When a scan is performed that exceeds a notification value, the system shall record the date and time, a unique study identifier, the notification value(s) that were exceeded, and the corresponding dose index value(s) that triggered the notification and any diagnostic reason provided for proceeding after receiving a notification. This record shall be available for site review and audit.

2.1.3 Audit Capability for Protocols and Protocol Elements

The system shall be able to generate a list of all protocols and protocol elements with their corresponding notification values. If the notification value is not set for a particular protocol element, the list will indicate this status. The system shall generate the list on request of the user.

2.1.4 Dose Notification Format

The notification shall include at least three elements: a title, a body, and operator interactions (including a field to enter diagnostic reason(s)).

The title of the notification shall be the text in the following box:

DOSE NOTIFICATION

The body of the notification message shall identify the notification value(s) that would be exceeded, and the corresponding estimated dose index value(s), and may provide additional information for clarity.

The interactions shall allow the operator to:

a. Enter diagnostic reason (optional) then confirm to proceed, or
b. Go back and adjust scanning parameters

2.2 Dose Alerts

2.2.1 Configuration

Manufacturers shall set alert values pre-populated prior to turnover to the customer with a value not to exceed 1 Gy (1000 mGy) for $CTDI_{vol.}$ Manufacturers shall provide a means for users to enter, save and modify alert value(s) in terms of $CTDI_{vol}$, *DLP*, or both.

2.2.2 Checking Prior to Scanning

For each examination, at each position on the z-axis in the DICOM patient coordinate system, the system shall accumulate the $CTDI_{vol}$ values of all executed scans that covered the z-position resulting in the accumulated CTDIvol (z) as the examination proceeds. In addition, the system shall accumulate the DLP values, if configured, of all executed scans as the examination proceeds. The system shall reset the accumulated values to zero when an examination is closed. The system may set the accumulated $CTDI_{vol}$ to zero when the DICOM patient coordinate system shifts, e.g., when the patient changes position on the table. The system is not required to accumulate values for scan projection radiography.

When a protocol element group is confirmed or otherwise set to the ready state by the operator, the system shall display an alert (see 2.2.4) on the operator's console if the accumulated $CTDI_{vol}$ or the accumulated *DLP*, plus the estimated values for the confirmed protocol element group, exceeds the corresponding alert value. The alert shall be displayed prior to the start of the scan, and shall never interrupt the scan.

For CT guided interventional procedures, an option to give the user the ability to limit the dose alert feature to one warning will be provided. The two options for generating this alternative dose alert behavior are:

a. An option will be available to the user to select an interventional protocol element or protocol element group configured to exhibit alternate dose alert behavior. In this case, the dose alert warning will appear only once, the first time the dose alert value will be exceeded at any given position.

b. At the patient examination level, the first dose alert warning box shall have a choice that enables the user to switch to alternative dose alert behavior. When selected, this feature will permit only a single dose alert warning to occur, the first time the dose alert value will be exceeded at any given position, during the examination. After the examination, the dose alert feature will return to normal.

c. For this alternative dose alert behavior, an optional prospective user-activated feature may be provided to allow a user to choose alternate dose alert behavior at the exam-level prior to beginning the examination.

For CT guided interventional procedures where the dose alert value has been exceeded and alternate dose alert behavior has been selected, an on screen indication of the Z position with the highest cumulative dose and the current cumulative $CTDI_{vol}$ shall be made available to the user during the exam. Alternate dose alert behavior shall be configurable by the institution. When alternative dose alert behavior is selected, there shall be a passive on screen indication that the dose alert value is being exceeded.

Note: If more than one Z position corresponds to the highest $CTDI_{vol}$ value, the selection criteria for the appropriate Z position to be displayed shall be described in the accompanying documents.

Some protocol elements, such as bolus tracking, may not have a predefined number of rotations but may have other pre-programmed limits on the number of exposures or exposure time. When estimating the $CTDI_{vol}$ and *DLP* for these types of protocol elements, the estimate shall assume that the scan proceeds to those limits. For interventional type protocol elements, alternate means may be used such as values in mGy/s or alternate dose alert behavior. If there are no preprogrammed limits, checking is not required.

Note: For radioscopy application of CT guided interventional procedures, a preprogrammed time limit is required.

The system is not required to display an alert if a corresponding alert value has not been set or dose alert has been disabled.

To proceed with scanning when an alert value has been exceeded, the system shall require the operator to enter his/her name and reconfirm the chosen protocol elements before proceeding to the scan. The system shall also provide password-protection capability that prevents execution of the scan unless the correct password is entered. The activation of the password-protection capability may be configurable. The system shall permit the operator to enter a diagnostic reason (of up to 64 characters) at the operator's discretion. The system does not have to require the input of such reason(s) in order to proceed.

When a scan is performed that exceeds an alert value, the system shall record the date and time, the operator's name, unique study identifier, the alert value(s) that were exceeded, and the corresponding dose index value(s) that triggered the alert, and any diagnostic reason provided for proceeding after receiving an alert. If alternative dose alert behavior has been active for CT guided interventional procedure, this shall be recorded. This record shall be available for site review and audit.

2.2.3 Checking Prior to Saving Protocols and Audit Capability

When a protocol is saved, the system shall display an alert (see 2.2.4) on the operator's console if the estimated $CTDI_{vol}$ or DLP exceeds the corresponding alert value.

Note: The dose alert may not be displayed for protocols for which it is not possible to predetermine the $CTDI_{vol}$ or DLP (e.g. when patient size dependent Automatic Exposure Control is switched on or fluoroscopic scan modes are included).

The system shall be able to generate a list of alert values. If any alert value has not been set, the list will indicate this status. The system shall generate the list on request of the user.

2.2.4 Dose Alert Format

The alert shall include at least three elements: a title, a body, and operator interactions (including a field to enter diagnostic reason(s)).

The title of the alert shall be the text in the following box:

DOSE ALERT A dose alert value will be exceeded!

The body of the alert message shall identify the alert value(s) that would be exceeded, the corresponding estimated dose value(s), and may provide additional information for clarity.

The interactions shall allow the operator to:

a. Enter diagnostic reason (optional) and enter the user's name and password (if so configured) then confirm to proceed, or

b. Go back and adjust scanning parameters

2.2.5 Pre-population of the Dose Check Alert Value

All CT scanners with Dose Check shall have all Dose Check Alert Values pre- populated by the manufacturer prior to turnover to the customer with a value not to exceed 1 Gy (1000 mGy) for $CTDI_{vol}$.

2.2.6 Instructions to User

Manufacturers shall include in their accompanying documents instructions for set up, user preferences (passwords), and disabling Dose Check features.

ANNEX A
(Informative)

This example does not intend to represent any particular scanner model or brand of equipment and is intended only to assist the reader interpreting the terms used throughout this document.

Consider a typical CT procedure with contrast administration. It typically consists of four parts:

- **Part 1**: Scan projection radiograph, to define the scan location
- **Part 2**: Bolus Locator—axial scan to define slice of patient to track
- **Part 3**: Tracking—Multiple axial scans, monitoring the Bolus Locator slice after contrast has been administered
- **Part 4**: Helical scan—scan of patient, with contrast in the bloodstream

Each of the above parts (1, 2, 3, 4) are separate protocol elements. Protocol elements have their own scan parameters such as kVp, mA, rotation time, etc.

Protocol element group is defined by the Confirm/Go/Load software button:

- **Part 1:** Above is a protocol element group
- **Part 2:** Above is a protocol element group
- **Part 3:** Above together form a protocol element group
- **Part 4:** Above together form a protocol element group

Note: Notification value for Part 1 above is not required by this Standard.

Protocol is associated with a diagnostic task, e.g., tri-phased liver, head with/without contrast. All

four of the protocol elements above together make up a protocol.

Examination is associated with a patient; e.g., trauma examination consisting of head and pelvis protocols. In this example, the protocol also represents the complete examination.

Parts 1 and 2 are each initiated by the technologist, by selecting “Confirm/Go/Load” on the user interface, and then pressing the “X-ray on” button.

Part 3 is initiated by a “Confirm/Go/Load” on the user interface, and then pressing the “X-ray on” button or in conjunction with the Contrast hookup.

Part 4 is automatically initiated (no need for “Confirm/Go/Load”) by the tracking scan, when the contrast is detected in the Bolus Locator slice.

The dose notification values and alert values are checked each time “Confirm/Go/Load” is pressed.

The key issue for comparisons is the combination of selecting “Confirm/Go/Load” on the user interface, and then pressing the “X-ray on” button. In our simple example listed above, Part 2 will be compared to its individual notification value.

Parts 3 and 4 together comprise a single protocol element group. This is because of the automatic transition between parts 3 and 4. Upon pressing “Confirm/Go/Load,” the system will compare the dose index for the Part 3 tracking scans against the corresponding notification value. Additionally, the system will compare the dose index for Part 4, the helical scan, with the corresponding notification value. Finally, the system will compare the accumulated dose index (Part 2 already acquired and estimates for Parts 3 and 4) against the alert value.

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