

RightDose Inc. Letter of Compliance XR29

Dept. Radiology
100 Nicolls rd east setauket,
NY 11794.

April 1, 2016

Dear [Recipient],
Hospital
Location
Scanner manufacturer
Model
Serial number
Effective date of Upgrades

In compliance with XR-29 and XR-25 as outlines by MITA/NEMA

RightDose Inc. has manufactured (OEM) the external hardware and software with the oversight by a Licensed and practicing US radiologist. The five basic components of these rules noted above are accordingly in Compliance as they pertain to the following:

1. Automatic Exposure Control (AEC): After evaluation of your CT we have confirmed that this device is capable of performing clinical CT scans using AEC. We have found your device is COMPLIANT with this requirement.
2. Reference Protocols: After evaluation of the internal memory and protocol menu of your CT Console has both pediatric and adult reference protocols. Technologist have specifically been trained to use these protocols. We have found that your device is COMPLIANT with this requirement.

3. DICOM Structured Dose Report: DICOM Radiation DoseStructure Reporting:
Enables recording of post exam dose information in a standardized electronic format. This information can be included in the patient record, promoting the establishment of diagnostic reference levels, as well as facility dose management and quality assurance.

We have found that your device is COMPLIANT with this requirement. Or 4 Below:

4. DICOM SR reports was not available on your CT: Console, However, with the addition of Scannerside Dose Monitoring software a structured report is available which follows ACR guidance on reporting requirements of DIMCOM SR reports. Data in this RDSR is transferable to the Patient's Records. We have found that your device is COMPLIANT with this requirement.
5. Dose Check: Dose Check allows for estimation of radiation dose prior to the scan being performed. In compliance with XR-25 Dose check regulation Dose Notification, and Dose Alerts are available. Dose Check estimates the radiation dose based on 1. Individual patient body habitus and density, 2. CT Scanner specific AEC table estimates 3. Allows for an auditory and visual alert on the scanner console, 4. Causes the CT scanner to pause in the event of a dose alert, and allowing the technologist to change the protocol to decrease radiation dose. After installation of the Dose Check software to your CT Console.

We have found that your device is COMPLIANT with this requirement.

Scannerside Dose Check allows for monitoring/patient reporting and features are present for COMPLIANCE with XR-29 and XR-25.

RightDose Inc supplemental information:

RightDose Inc. XR29 U/L number for the equipment mentioned in this Compliance letter is _____.

RightDose Inc XR29 Hardware and software are all external to the OEM Scanner/firmware and are therefore FDA exempt at the time of this Compliance Letter.

RightDose Inc. is a manufacturer of XR29 components only. RightDose Inc. does not sell directly to any end user and therefore cannot guarantee medical reimbursements or the like. RightDose Inc. limits its liability as a manufacturer to repair or replacement of its product in a timely manner based on management's sole discretion.

Sapheneia Inc purchases the manufactured XR29 product exclusively from RightDose Inc. Sapheneia/Scannerside is the national reseller of the XR29 product for the US market. Sapheneia/Scannerside provide all after sales service support in the USA.

Sapheneia/Scannerside, from time to time will engage in sub distributor/service organizations.

Sapheneia/Scannerside recognize there are many variables that are involved in medical reimbursements beyond the control of Sapheneia/Scannerside, Therefore there is no guarantee or implied acceptance of liability with regard to medical reimbursements as the National or sub distributors of RightDose XR29 upgrades. Sapheneia/Scannerside provide for a limited 2 year parts and operational service warranty. This is a pass through warranty from RightDose Inc. This warranty is specific to the location and equipment mentioned in this Letter of Compliance only. Relocating equipment to other scanners, Change of physical locations, termination of VPN connections or tampering with the XR29 hardware or software without prior consent of the national distributor is an immediate violation of the warranty.

You are now XR25 and XR29 Compliant as defined by MITA/NEMA

Warm regards, RightDose Inc.