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September 28, 2011

**Notice of RECALL - URGENT**

TO: International Distributors of CooperSurgical's Norland Illuminatus DXA Software with the DICOM Option (Part Number 434A133) version 4.2.0 through 4.3.1.

RE: VIGILANCE in the usage of this DICOM software

Dear Valued Norland Customer:

It has come to CooperSurgical's attention that the DICOM Software referenced above which is installed on the XR-600, XR-800, XR-46 and EXCELL DXA Bone Densitometers, one of which our records indicate has been shipped to your facility, could lead to improper patient information getting into a previous patient's record.

Problem/Situation

A patient's demographic information can be entered into the Norland Illuminatus DXA software with the DICOM option enabled, either manually or automatically, utilizing a DICOM Modality Worklist Server. If a combination of the automated and manual methods are used, the possibility exists for the manually added patient's report to be attached to the previous patient.

When can this problem occur?

If you query the DICOM worklist and save at least one patient from the worklist, but then decide to manually enter a new patient — for example if the patient was not scheduled on the worklist server — then the problem may occur.

1. If you always manually enter patient information, and never utilize a worklist, **this problem will not occur.**
2. If you always save patient information from a worklist, and never manually enter a new patient, **this problem will not occur.**


We will send you a new revision of Illuminatus software once available.

Distributors shall provide a copy of this recall letter to all customers who have purchased the DICOM option for the Norland Illuminatus Software Ver. 4.2.0 through 4.3.1. Additionally, distributors will be provided with the authorized instruction form titled "Process to Manually Add Patients to the Norland Illuminatus DXA Software Versions 4.3.1 or lower when DICOM Worklist is not available" [FRM-201 Rev. A] to allow use of the current software until the new revision of software is released.

If you have any concerns about your existing database of patients, please contact our Norland Technical Support team at (203) 601-5200 Extension 9888 or 9889 to discuss this matter. Our team of experts will walk you through your next steps with this software.

CooperSurgical deeply regrets the inconvenience that this problem has caused and is working diligently to provide you with a new revision as soon as possible.

Sincerely,

  
Vice President, Regulatory and Business Assurance