Urgent Field Safety Notice (FSN)
NephroCam (Gamma Camera)
Risk of patient data mix-up

Language: English / Dansk

2017-12-13

Dear valued customer

The purpose of this letter is to notify users of **NephroCam** systems that under specific conditions there is a risk of patient data mix-up on PACS or workstation.

The purpose of this document is to inform you of an issue which has been brought to our attention, the immediate actions required to mitigate the issue, and the corrective actions which DDD-Diagnostic will take to solve the issue.

This document contains important information regarding the correct use of your equipment. This notice needs to be passed on to everyone who needs to be aware of the issue within your organization and in any other organization to which this issue may apply.

Please keep a copy of this notice together with the Instructions for Use.

Summary

- **Issue**: DDD has identified that the DICOM Study Instance UIDs used by NephroCam systems are not globally unique as required by the DICOM standard. If acquisition data from multiple NephroCam systems is transferred to the same PACS or workstation, this can lead to incorrect storage of acquisition data under another patient's name.

- **Resolution**: DDD will promptly release a software update (version 1.2.2) to ensure that DICOM Study Instance UIDs are globally unique.

- **Precautions**: NephroCam is still considered safe to use as long as patient data is not transferred to PACS or a workstation holding patient data from other NephroCam systems. If data from multiple **NephroCams** has been transferred to the same PACS or workstation, we recommend reviewing of previous patient data to reduce the risk of data mix-up caused by this issue.

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CVR: 11 29 66 45

- **Next Step**: Our DDD service engineer will contact you in the near future to arrange for the software update and closure of the FSCA (Field Service Corrective Action)

Transmission of this Field Safety Notice:

- This notice needs to be passed on to everyone who needs to be aware of the issue concerned within your organization and any other organization to which this issue may apply.
- Please maintain awareness on this notice and the resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

Affected Products: all NephroCam Systems

NephroCam Systems (Model Number: 9KID2275-B02) with the following serial numbers:

13112201, 13112202, 13112203, 14111001, 15061701, 15090701, 15121001, 16062901, 16070401, 16120601, 16122101

Contact Information

If you have any questions regarding this Field Safety Notice, please feel free to contact your Service and Support Manager Albert Radoor or our QA / RA Manager Stephane Labrosse:

Service and Support Manager Albert Rømer Radoor Tel.: +45 2386 7654 Email: support@ddd-diagnostic.dk	**QA / RA Manager** Stephane Labrosse Tel.: +45 6058 8020 Email: sl@ddd-diagnostic.dk

We sincerely apologize for any inconvenience this may cause. Please contact us if you have any questions or concerns.

With kind regards,

Stephane Labrosse

Quality Assurance and Regulatory Affairs Manager

Vigtig sikkerhedsmeddelelse (Field Service Notice)
NephroCam (Gammakamera)
Risiko for sammenblanding af patientdata

Language: English / Dansk

2017-12-13

Til vores kunder

Formålet med dette brev er at informere NephroCam-brugere om, at der under specifikke omstændigheder er risiko for sammenblanding af patientdata på PACS eller arbejdsstation.

Hensigten med dokumentet er at informere om et problem, vi er blevet gjort opmærksom på, de nødvendige handlinger her og nu for at afhjælpe problemet og de korrigerende handlinger, som DDD-Diagnostic vil tage for at løse problemet.

Dette dokument indeholder vigtig information vedrørende korrekt brug af udstyret. Denne meddelelse skal viderebringes til alle, som bør være opmærksomme på problemet i den pågældende organisation og i enhver anden organisation som problemet måtte angå.

Opbevar venligst en kopi af denne meddelelse sammen med brugermanualen.

Resumé

- **Problem**: DDD har fundet, at de DICOM undersøgelsesdata UIDer (Study Instance UIDs), som NephroCam anvender, ikke er fuldstændig unike som DICOM-standarden kræver. Hvis undersøgelsesdata fra flere forskellige NephroCam-systemer overføres til samme PACS eller arbejdsstation, kan dette medføre ukorrekt lagring af undersøgelsesdata under en anden patients navn.

- **Løsning**: DDD frigiver snarest muligt en softwareopdatering (version 1.2.2) for at sikre, at DICOM Study Instance UIDs er fuldstændig unike.

- **Forholdsregler**: Det anses stadig for sikkert at anvende NephroCam, sålænge patientdata ikke overføres til PACS eller en arbejdsstation, der indeholder patientdata fra andre NephroCam-systemer. Hvis data fra flere forskellige NephroCam-systemer er blevet overført til samme PACS eller arbejdsstation, anbefaler vi, at tidligere patientdata gennemgås for at reducere risikoen for sammenblanding af data som følge af dette problem.

- **Næste skridt**: Vores DDD servicetekniker vil kontakte vores kunder i nærmeste fremtid for at aftale tid til at gennemføre softwareopdateringen og afslutte den korrigerende handling (Field Service Corrective Action).

Overbringelse af denne sikkerhedsmeddelelse

- Denne meddelelse skal overbringes til alle, der skal være opmærksomme på det omhandlede problem i organisationen og i enhver anden organisation, som måtte have samme problem.

- Man bør fortsat være opmærksom på indholdet i denne meddelelse samt de affødte handlinger i en passende periode for at sikre den tilsigtede virkning af den korrigerende handling.

Berørte produkter: alle NephroCam-systemer

NephroCam Systems (modelnummer: 9KID2275-B02) med følgende løbenumre:

13112201, 13112202, 13112203, 14111001, 15061701, 15090701, 15121001, 16062901, 16070401, 16120601, 16122101

Kontaktinformation

I tilfælde af spørgsmål til denne sikkerhedsmeddelelse (FSN) kan henvendelse rettes til vores service- og supportleder Albert Radoor eller vores QA/RA-chef Stephane Labrosse:

Service and Support Manager Albert Rømer Radoor Tel.: +45 2386 7654 Email: support@ddd-diagnostic.dk	**QA / RA Manager** Stephane Labrosse Tel.: +45 6058 8020 Email: sl@ddd-diagnostic.dk

Vi beklager meget enhver gene forårsaget af dette problem. Kontakt os venligst i tilfælde af spørgsmål eller betænkeligheder.

Venlig hilsen,

Stephane Labrosse

QA/RA-chef