Mandatory Service Bulletin

This document is valid for USA only!

Mandatory update to Sedecal SoftConsole 5.5 and attachment of Agfa Subpart J label at DX-D 100 / DX-D 100 wireless

Task

Timing	Category	Subject	
⊙ **Immediately. Completion anticipated by date 30.06.2015**	⊙ **Mandatory for all affected sites**	☑	**Problem record (ASSM): PR1406020002, PR1501070006**
		☑	**Problem affects serial number(s) / batch(es) listed below.**

Risk

Risk description PR1406020002 (SoftConsole 5.5):
The probability of potential harm is set to the level "Negligible" available in our risk management procedure.

Risk description PR1501070006 (Subpart J Label):
This is a regulatory and administrative issue. No harm possible to user or patient. No HHE needed. The same product is being distributed to other countries. The missing label has no impact on safety and efficacy.

Task Tracking

After completion of your task the following entry in your Service Report is required:	**DD+DIS189.14E** *
* Insert the document number into the field "Comment" (SMS form).	

Purpose of this document:

- This document contains all necessary information about the mandatory installation of SoftConsole 5.5. and the attachment of the Agfa Subpart J label.

- It is not necessary to reinstall SoftConsole 5.5 if the update was already performed before.

Affected serial number(s) / batch:
Refer to list of serial numbers attached to this document. 📎

This Mandatory Service Bulletin has been issued as part of the Global Corrections and Removals Procedure. It is connected to a product recall. Check with your local QA/RA and HE Sales/Marketing teams to make sure that your service activities are coordinated with their associated responsibilities.

List of contents

1   Mandatory Update to SoftConsole 5.5

1.1   Introduction (PR1406020002)

Symptom   Value for KV, mA and ms scrolls to its maximum.
In this case the kV goes up to 150 kV and mAs goes up to 320 mAs, which is the highest value for this setup. The exposure was taken with this high values and patient was overexposed.

Risk   By providing resolution/correction the residual risk has been reduced to the lowest possible level meaning "Broadly acceptable region"

Cause   When some liquid (like a drop of water) contacts the touch screen, the device interprets that as a click. If this drop touches the arrows for value modification of the softconsole it raises the values to its maximum.

Background info: There must be a drop to cause this. Wet hands (with water or disinfection fluid) do not cause this.

Solution   (1)   Install SoftConsole 5.5.

✓ **NOTE:**

This issue is solved with Sedecal SoftConsole 5.5 by adding the following feature:
Holding the up or down button will make just a single step up or down of the value.
To change the values several steps a separate click for each step is necessary.

SoftConsole 5.5 is only compatible with XRDI 15.1 or higher.

1.2   Prerequisites

SOFTWARE:

Download the "X-Ray Generator - Software - Sedecal SoftConsole 5.5 " software from the Agfa HealthCare Library:
Direct Radiography > DX-D Components > Generator

TOOLS:

Portable storage medium (checked to be virus-free, e.g. USB Flash Drive).

REFERENCED DOCUMENTS:

- DX-D 100 Service Bulletin No. 57 / DX-D 100 Wireless Service Bulletin No. 51, document ID 46759296 (📄 Agfa Intranet / 📄 Agfa Portal via Internet).
- DX-D 100 Service Bulletin No. 63 / DX-D 100 Wireless Service Bulletin No. 57, document ID 48118871 (📄 Agfa Intranet / 📄 Agfa Portal via Internet).

1.3   Instructions / Verification

REQUIRED TIME:

30 minutes for installation and configuration of Sedecal SoftConsole 5.5.

(1)   To install the SoftConsole 5.5 follow the installation and verification instructions in the DX-D 100 Service Bulletin No. 57 / DX-D 100 Wireless Service Bulletin No. 51, document ID 46759296 (📄 Agfa Intranet / 📄 Agfa Portal via Internet).

NOTE:

It is not necessary to install SoftConsole again if the update to version 5.5 was already performed before.

SoftConsole 5.5 is only compatible with XRDI 15.1 or higher. The update is supported from the following previous versions:

- SC 2.0 and SC 2.0 SU1
- SC 4.0
- SC 5.0, SC 5.0 SU1, SC 5.1, SC 5.2., SC 5.2, SC 5.2 SU1, SC 5.3, SC 5.4

2   Attachment of Subpart J Label

2.1   Introduction (PR1501070006)

There are several DX-D 100 / DX-D 100 wireless systems installed in the field where the Subpart J label is missing and the CD/DVD with the manuals are not available.

The label must be attached afterwards and also the manuals must be handed over.

2.2   Prerequisites

SPARE PARTS:

A package which includes the following parts:

- Subpart J label
- CD/DVD

This package will be made available by Cassandra Watts (Cassandra Watts/AXARZ/AGFA).

TOOLS:

- Digital Camera or cell phone with camera

2.3   Instructions / Verification

REQUIRED TIME:
5 minutes

(1)   A package with the subpart J label and the DVD will be distributed by Cassandra Watts (Cassandra Watts/AXARZ/AGFA). She will coordinate the delivery to the respective field service engineers.

(2)   Choose the appropriate subpart J label according to the important note below.

Check the production date on the serial label. The Date JJJJ-MM on the serial label must be equal with the date MMMMM-YYYY on the subpart J label.
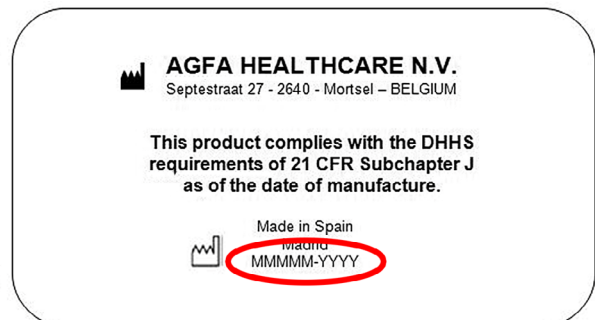

Figure 1 – Type label   Figure 2 – Subpart J label

(3)   Attach the label next to the type label. See figure below for the position of the type label.

✓ **NOTE:**

The Subpart J label must be attached directly next to the type label and nowhere else. The type label is located at the left top side of the vertical column.
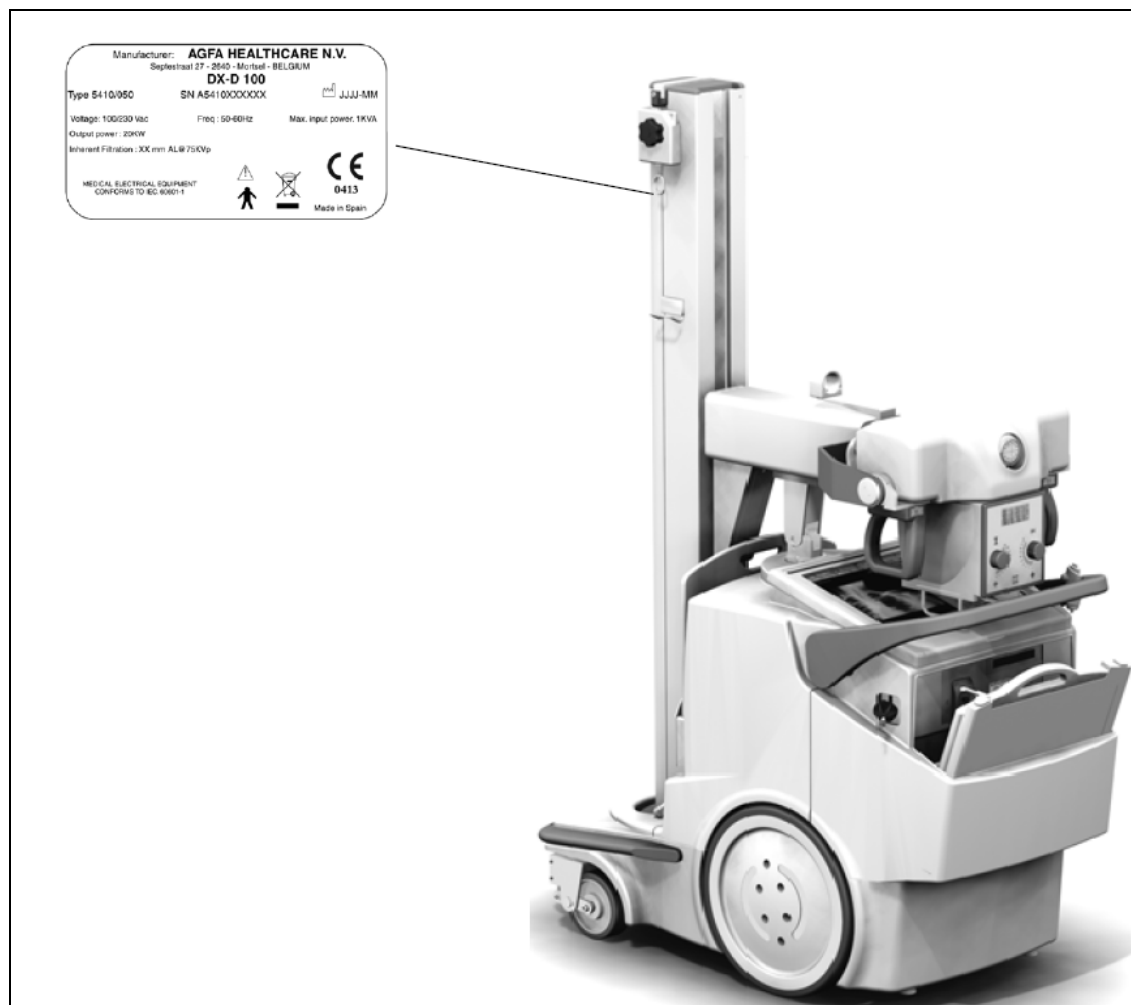

Figure 3

(4)   Hand over the DVD with the manuals to the customer.

(5)   Use a digital camera or cell phone to take one picture with both labels (type label and Subpart J label) as a proof of completion.

(6)   Send the picture to Cassandra Watts (AXARZ/AGFA) for repository reasons.

3   Keywords

Label, Subpart

4   Version history

Version	Change	Date
1.0	Initial Version	02-2015