AGFA *Agfa*

H e a l t h C a r e

Global Services

DX-D 100 Type 5410   SB No. 104

DX-D 100 Wireless Type 5411   SB No. 120

Document ID 62351194

Mandatory Service Bulletin

Mandatory check of activities triggered by previous MSBs

Task

Timing		Category			Subject
⦿	**Immediately. Completion anticipated by date 31.12.2018**	⦿	**Mandatory for all affected sites**	☑	**Problem Record: CAPA0000352**
				☑	**Problem affects serial number(s) / batch(es) / customer(s) listed below.**

Risk

Activity is only a check on the medical devices placed on the market (specific serial number range= list). There is no intention to provide a resolution to reduce a risk to patients and therefore this Mandatory Service Bulletin is seen as a non-reportable correction. The MSB is our vehicle in this activity to demonstrate an adequate effectiveness check on the listed medical devices and the planned instructions/training for our Field Service Engineers/Dealers.

Task Tracking

After completion of your task the following entry in your Service Report is required:	**62351194**	*

* Insert the document number into the field "Comment" (SMS form).

Task Code where the time and materials have to be expensed to:	**SMS: MIW** (Modification in Warranty) **CRM: 5QB5U** (HQ Instructed Modification) **ASSM:5QB5U** (HQ Instructed Modification)

Purpose of this document:

This document contains the required information to check the rollout of the previous Mandatory Service Bulletins (MSBs) for DX-D 100 / DX-D 100 Wireless.

Affected serial number(s) / batch(es) / customer(s): For details refer to the attached Excel sheet.

DX-D 100-100WL - SB104-120 - MANDA

List of contents

1   Introduction/purpose

By performing the steps listed in this MSB, the rollout of the previous MSBs for DX-D 100 / DX-D 100 Wireless are checked.

With this MSB also a new "MSB documentation concept" is introduced:

- A separately available video clip illustrates the mandatory actions.
- The service engineer documents the specific steps by taking a picture with the mobile phone or a digital camera.
- The service engineer fills in a feedback form and returns this to Headquarters by clicking a button in the feedback form.

1.1   Overview of steps

The following components which can have an impact on the driving behavior of the DX-D 100 / DX-D 100 Wireless must be checked.

#	Topic	Activity
1	Evidence that a specific system/serial number is checked.	Photo of type label has to be taken where serial number is clearly visible.
2	DMC hardware revision must be "H" and DMC firmware V11R3b5 or higher.	Effectiveness check, picture of revision and firmware version
3	DMC isolation kit (plastic spacers + screws) must be mounted.	Effectiveness check, picture of plastic spacers and screws
4	Capacitor C16 of DMC board must be coated.	Effectiveness check, picture of coating
5	Chain tension of both drive chains must be checked.	Effectiveness check, two pictures of force shown on dynamometer
6	Cleanliness inside the unit must be checked.	Effectiveness check, picture of clean unit
7	Resistive arrestor of must be mounted and must touch the ground.	Effectiveness check, picture of arrestor
8	Softconsole version 5.5 or higher must be installed.	Effectiveness check, picture where Softconsole version can be easily checked

For detailed instruction, refer to section 3 Instructions.

2   Prerequisites

The following hardware and software is required for these sites only, where the mandatory actions of previous DX-D 100 / DX-D 100 Wireless MSBs have not been performed yet.

SOFTWARE:

In case firmware **below** V11R3b**5** is present on an installed DMC board revision "H":

- Download the DMC firmware V11R3b5 (mandatory) or V11R3b7* from the Agfa HealthCare Library:
  Direct Radiography > DX-D 100 > DX-D 100 Generic

Observe that a DMC Programming cable is required for firmware upgrade.
It has to be ordered if not present, see Spare Parts below.

* NOTE:

DMC firmware V11R3b7 improves the DX-D 100 driving behavior. The installation of version V11R3b7 is not mandatory but recommended in case of issues.
Refer to DX-D 100 - SB076 - Introduction of DMC firmware version 11R3b7, Document ID 52181220.

SPARE PARTS:

- Resistive arrestor kit   SC+A9365-01
- DMC Isolation Kit   SC+A521093-01
- DMC board:

  For DX-D 100 / 100 Wireless units with installed DMC board with **a revision lower than "H"**, order the following kit:
  - Digital Motion Control V11R3b5   SC+A521079-03
    consisting of
    - DMC board rev H with firmware V11R3b5 already loaded
    - buzzer
    - instructions
    - tie wraps

- Cable to upgrade firmware on DMC board:
  Only in case the programming cable is not present, order the following kit:
  - Upgrade dig. mot. control V11R3b5   SC+A521065-05
    consisting of
    - Windows Serial Downloader Program on CD ROM
    - DMC firmware V11R3b5
    - DMC Programming cable

TOOLS:

- Service PC with serial port or USB to serial port (RS 232) converter, the following installed:
    - o HyperTerminal software
    - o Adobe Acrobat Reader
    - o E-mail software/client

- Digital camera / camera in mobile phone
  (Recommended: Use low camera resolution to reduce file size.)
- DMC programming cable
  (part of SC+A521065-02 UPGRADE DIGITAL MOTION CONTROL).
- Loctite 7400 for coating
- Dynamometer (spring scale, mechanical or electronic), to measure force in the range of 25 N to 35 N (2.5 to 3.5 kg)

Figure 1

REFERENCED DOCUMENTS:

- DX-D 100 / DX-D 100 Wireless - Mobile X-Ray Unit - Service Manual, Document ID 41600560.
- DX-D 100 - SB049 - MANDATORY - Mandatory upgrade to DMC board Rev. H with firmware V11R3b4, Document ID 45415049.
- DX-D 100 - SB059 - USA ONLY - MANDATORY - update to SoftConsole 5.5 and attachment of Agfa Subpart J label, Document ID 48274721.
- DX-D 100 - SB062 - USA ONLY - MANDATORY - DMC firmware V11R3b5 and resistive arrestor strap, Document ID 49682716.
- DX-D 100 - SB064 - WORLDWIDE except USA - MANDATORY - SoftConsole 5.5_DMC firmware V11R3b5_resistive arrestor strap, Document ID 47178120.
- DX-D 100 - SB076 - Introduction of DMC firmware version 11R3b7, Document ID 52181220.

3   Instructions

REQUIRED TIME:

Approximately 2 hours, if all actions of previous MSBs have been performed already

- 5 minutes: Watching the instruction video
- 5 minutes: Evidence that a specific system/serial number is checked
- 10 minutes: Checking DMC hardware and firmware revision
  (includes cover removing)
- 5 minutes: Checking DMC isolation kit
- 5 minutes: Checking coating on capacitor of DMC board
- 60 minutes: Checking chain tension
- 5 minutes: Checking cleanliness
- 5 minutes: Checking arrestor
- 5 minutes: Checking Softconsole version
- 10 minutes: Assembling system
- 5 minutes: Verification

Watching the instruction video

(1)   Download the instruction video clip from Agfa Healthcare Library, Document ID 63072301.

It shows the mandatory tasks, which are described in sections 3.1 to 3.8.

Figure 2

In case you are using "Agfa HE Offline Sync", the video clip is located on your Service PC in the following directories:

- **My Documents\Agfa HE Library Offline\Direct Radiography\DX-D 100\DX-D 100 Generic** AND
- **My Documents\Agfa HE Library Offline\Direct Radiography\DX-D 100 Wireless\DX-D 100 Wireless Generic**

(2)   Watch this video as preparation or in case you need additional support for the descriptions.

Performing the mandatory tasks and completing the feedback form

A feedback form is part of this document. This form has functionalities that require the Adobe Acrobat Reader. It is mandatory to create your electronic signature.

The enclosed guideline describes how to create the electronic signature in Acrobat Reader and how to use the feedback form.

Guideline_How_to_use_Feedback Form.
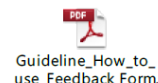
! IMPORTANT:

It is mandatory to use Adobe Reader:

1. Fill in the feedback form* completely,
2. validate the data,
3. sign it electronically, save and send it.

Do NOT sign the document on paper or send it as a scanned document !

* Only check the "Done" checkboxes if the task has been finished successfully and, where requested, add a picture as proof.

✓ NOTE:

The feedback form will be stored/sent together with the complete Mandatory Service Bulletin.
To keep file size of the completed feedback form small, only add photos with maximum 1 MB file size.

3.1   Checking System/serial number

(1)   Verify that your system is affected by checking the system/serial number.

For the position of the type label refer to Figure 3.

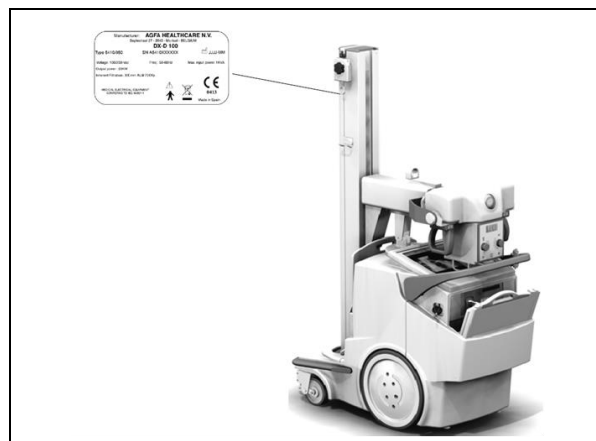The type label can be positioned on the left or right hand side of the column.

Figure 3

! IMPORTANT:

(2)   Take a photo of the affected site type label with the serial number clearly visible.

(3)   Fill in the feedback form Agfa Serial Number and upload the photo: Mandatory action # 1

3.2 Checking DMC hardware and firmware version

Preparation: Removing power input for the NX PC:

(1)   Shut down the system.

(2)   Open the front cover.

(3)   Disconnect power input of the NX PC.

For systems with DX-D 40 / DX-D 45: The SCU power supply needs to be removed to get access to the power input connector.
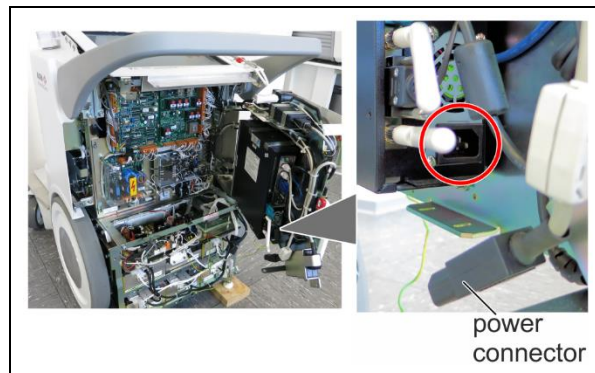

power connector

Figure 4

NOTE:

The system needs to be powered on and off a few times.
With NX PC disconnected, the system can be powered off via emergency switch. This saves about 5 minutes per power on/off activity.

Hardware and Firmware check:

(4)   Connect the **J8** connector of the DMC Programming Cable (A7130--xx) to J8 of the Digital Motion Control Board.

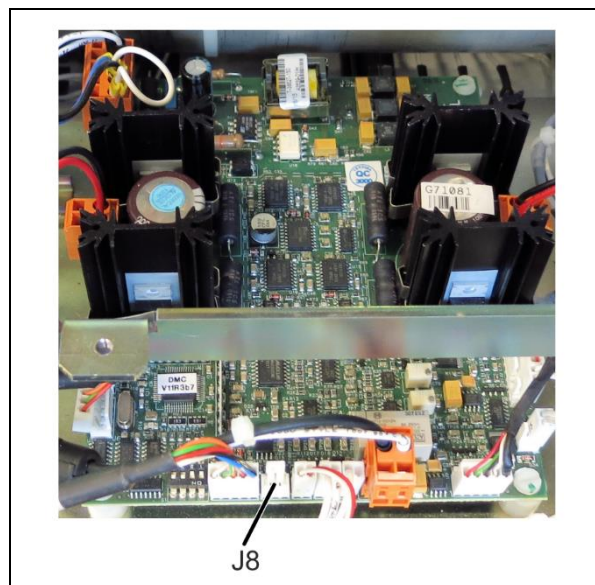(5)   Connect the other end (SubD9--PC) of the cable to the available COM Port of the service PC.

J8

Figure 5

(6) Start **HyperTerminal** on the Service PC with default settings.

(7) Switch on the DX-D 100 / DX-D 100 Wireless.

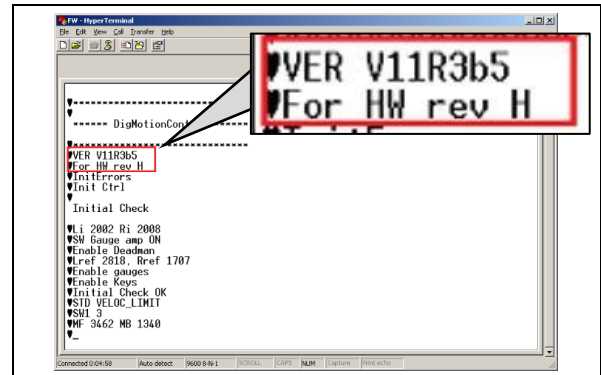(8) Check DMC software version and DMC hardware revision shown in the HyperTerminal.

Figure 6: DMC boot log

There are the following upgrade scenarios:

(9) When DMC firmware (on a board revision H) is **below** V11R3b**5**, an upgrade to V11R3b**5** (mandatory) or higher (V11R3b7*) is required.

  o In case the cable to load firmware on the board is present:
    - Download firmware from the Agfa HealthCare Library.
    - Upgrade firmware to V11R3b5 or higher.

  o In case the cable to load firmware on the board is NOT present:
    - Order the cable, which is part of "Upgrade dig. mot. control V11R3b5".
    - If required, download firmware from the Agfa HealthCare Library.
    - Upgrade firmware to V11R3b5 or higher.

The firmware upgrade is described in DX-D 100 - X-Ray Mobile - Troubleshooting - Chapter 6.8.6 Updating the Microcontroller, Document ID 41600560.

(10) When DMC hardware is NOT revision H, new DMC board revision H has to be ordered and replaced.

The replacement of the DMC board to rev H is described in the attached Service Information Note SIN 13-08-13 Replacement of the DMC board to rev H.

02_Service
Information Note SIN

IMPORTANT:

(11) Take a photo or screenshot of HyperTerminal where hardware and firmware are shown clearly (example see Figure 6).

(12) Fill in the feedback form and upload the picture: Mandatory action # 2

* NOTE:

DMC firmware V11R3b7 improves the DX-D 100 driving behavior. The installation of version V11R3b7 is not mandatory but recommended in case of issues.
Refer to DX-D 100 - SB076 - Introduction of DMC firmware version 11R3b7, Document ID 52181220.

3.3   Checking DMC Isolation Kit

(1)   Check that DMC board is fixed
      with 4 plastic screws.

(2)   Check that the board is isolated from
      the metallic mounting plate by 4 plastic
      spacers.
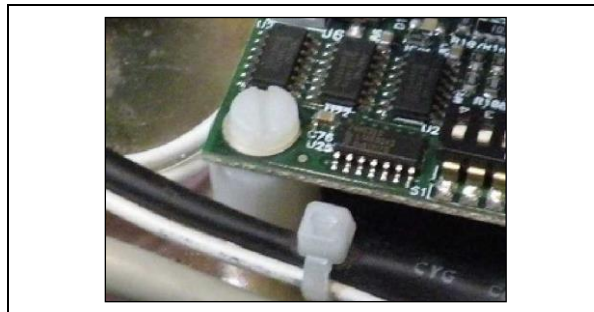
Figure 7: plastic screw and plastic spacer

(3)   When plastic screws and spacers are NOT present, the DMC isolation kit has to be
      ordered and mounted.

!   **IMPORTANT:**

(4)   Take a photo of the installed DMC
      isolation kit. At least three plastic
      screws and plastic spacers should be
      visible – see red circles in Figure 8.

(5)   Fill in the feedback form and upload
      the photo: Mandatory action # 3
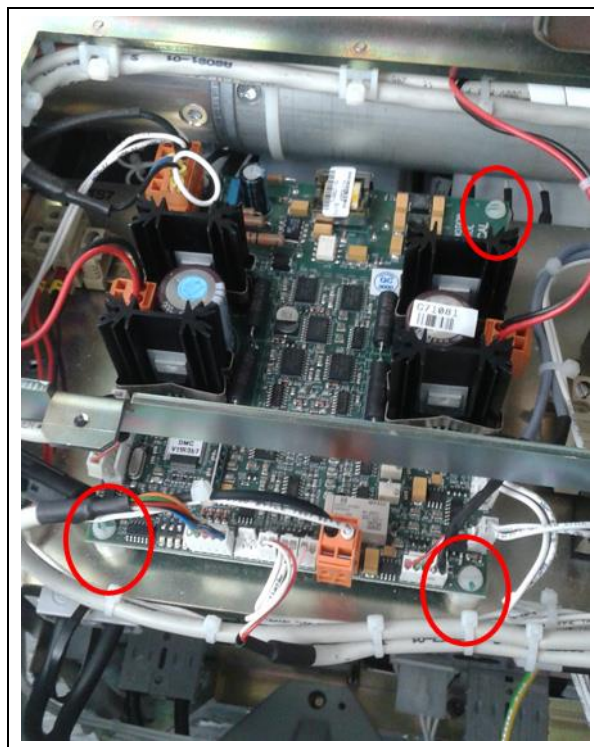
Figure 8: Example photo

3.4 Checking coating on capacitor C16 of DMC board

(1) Check that the DMC board is protected against possible damages during measurements.
This requires a coating protection over the C16 capacitor.

(2) Make sure that the coating is undamaged and does not cover the TP8.

(3) Use Loctite 7400 for coating (recommended).
In case Loctite 7400 is not available, use a piece of electrical tape over the C16 capacitor.

Figure 9:

!

IMPORTANT:

(4) Take a photo of the coating on the capacitor (image area as shown in Figure 10).

(5) Fill in the feedback form and upload the photo: Mandatory action # 4

Figure 10: Example photo

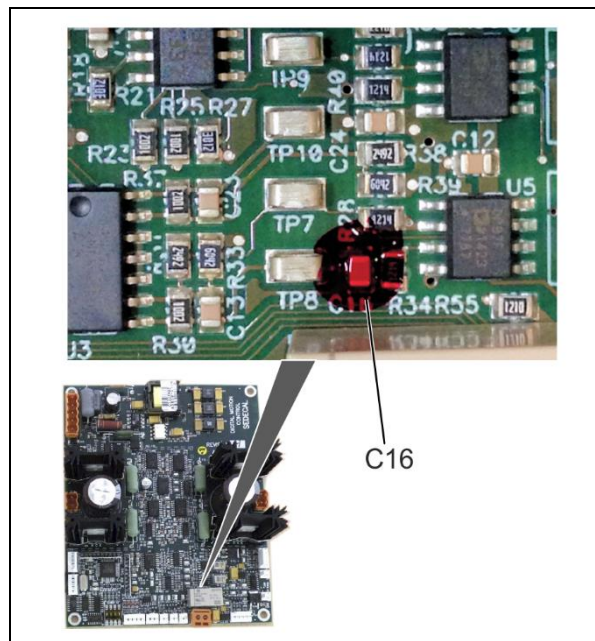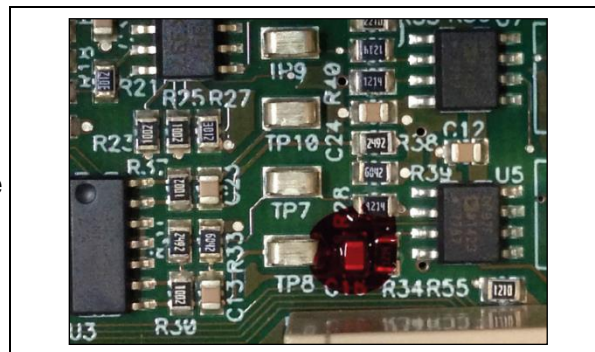### 3.5   Checking the tension of the drive chain

(1)   Check the chain tension at **both drive chains** as described in the
        attached Service Information Note
        SIN 14-01-03, Adjustment chain in mobile.
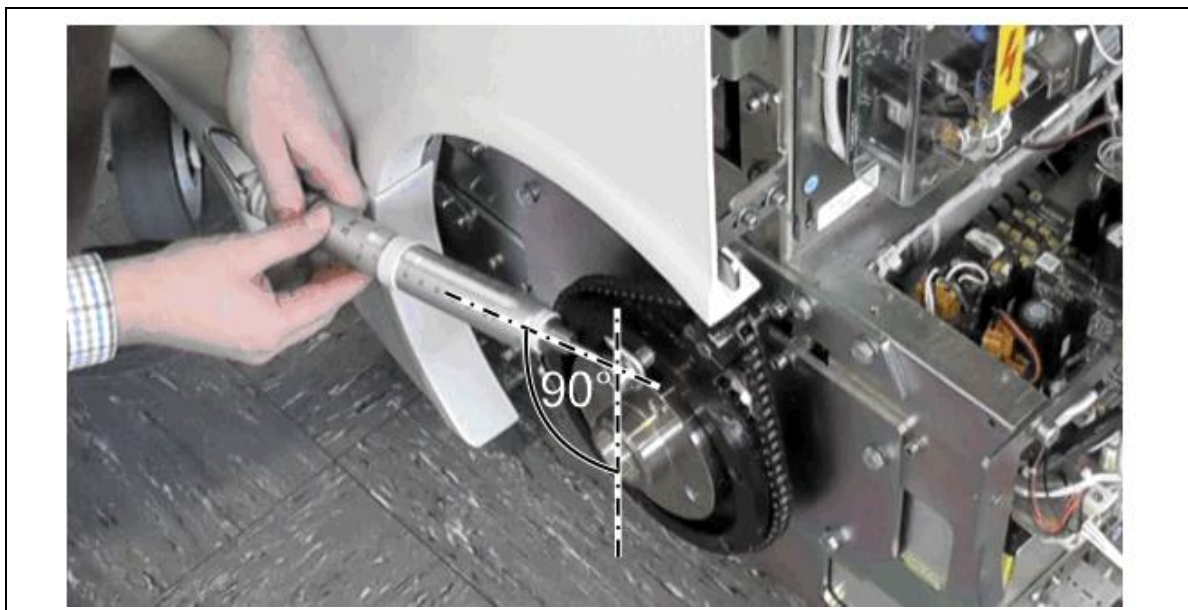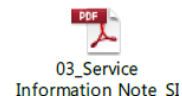
Figure 11: measuring the force with a spring scale

(2)   The force displayed on the
        dynamometer / spring scale, when the
        pulley start rotating, must be between
        25 N and 35 N (approx. 2.5 - 3.5 kg).

Figure 12: Example photo

IMPORTANT:

(3)   Take a photo of the **left** dynamometer / spring scale showing the measured value.
        In the background the respective **left** drive should be visible (image area as shown in
        Figure 12).

(4)   Take a photo of the **right** dynamometer / spring scale showing the measured value.
        In the background the respective **right** drive should be visible (image area as shown
        in Figure 12).

(5)   Fill in the feedback form and upload both photos: Mandatory action # 5

3.6 Checking the cleanliness inside the unit

(1)   With front cover open, check the cleanliness inside the unit.
       Also take into account the dirt that was present at the drive chains at tension measurement.

(2)   In case the unit is NOT clean, perform an "internal cleaning" as described in the DX-D 100 / DX-D 100 Wireless - Mobile X-Ray Unit - Service Manual, section "Periodic maintenance procedures", Document ID 41600560.

Figure 13: Example photo

!   **IMPORTANT:**
(3)   Take a photo that shows the clean unit inside (image area as shown in Figure 13).
(4)   Fill in the feedback form and upload the photo: Mandatory action # 6

3.7   Checking arrestor

(1)   Visually check that the correct arrestor (see Figure 14) with protection plate is installed.

(2)   Check that the ball is touching the ground.

Figure 14: Arrestor

(3)   When the correct arrestor is NOT present, the Resistive arrestor kit has to be ordered and mounted.

! **IMPORTANT:**

(4)   Take a photo of the arrestor (image area as shown in Figure 14).

(5)   Fill in the feedback form and upload the photo: Mandatory action # 7

3.8 Checking SoftConsole version

(1)   Go to **Start > All Programs > NX > Service > About NX.**

(2)   In the "About XRDI" box which opens, check the Sedecal Soft Console version.
It must be minimum version 5.5.

(3)   If NOT, install SoftConsole 5.5 or higher.
Status 02-2018: Latest SoftConsole version is 5.7, which is compatible with NX 20.00 only.
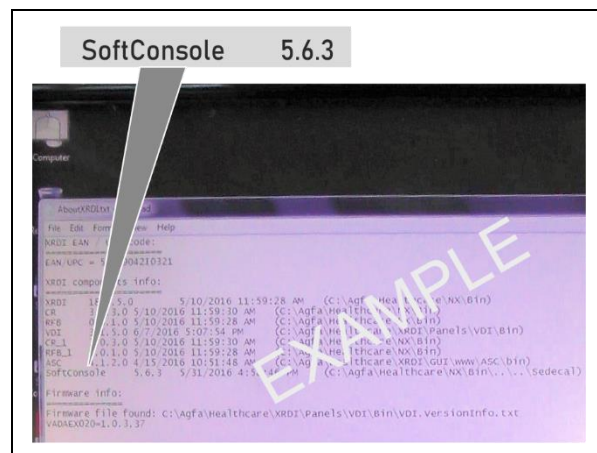
Figure 15: Example where the SoftcCnsole version is displayed on the monitor

⚠ **IMPORTANT:**

(4)   Take a photo or screenshot of displayed SoftConsole version. The version must be clearly visible.

(5)   Fill in the feedback form and upload the picture: Mandatory action # 8

4   Verification

Drive and stop the unit a few times. The unit must start driving and stop as expected.

5   Keywords

Improvements, driving behavior

6   Version history

Version	Change	Date
1.0	Initial version	02-2018

7   Mandatory Service Bulletin - Feedback Form

This document is part of: DX-D 100 - MSB 104   Document ID: 62351194
                                 DX-D 100 Wireless - MSB 120
                                 Version 1.0

Customer Data

Name of the Hospital *	
City *	
Country *	
Customer/Operator Name *	

Field Service Engineer Data

FSE Name *	
FSE Phone Number *	
FSE Email Address *	

System Data

Agfa Serial Number * *Type the Serial Number shown on the type label:*	SN	

For the position of the type label refer to Figure 3.
For details refer to section 3.1.

AGFA HEALTHCARE N.V.
Septestraat 27 - 2640 - Mortsel – BELGIUM
DX-D 100
Type 5411/050   SN A5411XXXXXX   JJJJ-MM
Voltage: 100/110/120/127/220/230/240 V~   Freq.:50/60Hz   Max.Input power: 1.5kVA
Output power: 32kW
Inherent Filtration: XX mm Al@75kVp
Mass : 580 kg
MEDICAL ELECTRICAL EQUIPMENT
CONFORMS TO AAMI ES60601-1
CERTIFIED TO CAN CSA 22.2
no.60601-1-08
CE
0413
Made in Spain

* Mandatory Field

7.1   Mandatory tasks to be finished

1   **Make sure that a specific system/serial number is checked.**
For details refer to section 3.1.
Confirm with Done checkbox and upload a photo (1 MB max.). *   * Done*

Comments / issues:

2   **DMC hardware revision must be "H" and DMC firmware V11R3b5 or higher.**
For details refer to section 3.2.
Confirm with Done checkbox and upload a picture (1 MB max.). *   * Done*

Comments / issues:

* Mandatory Field

3   **Check that DMC isolation kit (4 plastic spacers + 4 screws) are mounted.**
For details refer to section 3.3.

*Confirm with Done checkbox and upload a photo with at least 3 plastic screws and spacers visible (1 MB max.). ***   ** Done*

Comments / issues:

4   **Check that a coating protection over the C16 capacitor is applied.**
For details refer to section 3.4.

*Confirm with Done checkbox and upload a photo (1 MB max.). ***   ** Done*

Comments / issues:

* Mandatory Field

5   **Check the chain tension <u>on both chain drives</u>. The force displayed on the dynamometer, when the pulley start rotating, must be between 25 N and 35 N (approx. 2.5 - 3.5 kg).**

     For details refer to <u>section 3.5</u>.

     Confirm with Done checkbox and upload one photo that shows tension at left drive* and one photo that shows tension at right drive* (e*ach photo 1 MB max.).*

☐
* Done

Comments / issues:

6   **Check cleanliness inside them unit. In case the unit is NOT clean, perform an "internal cleaning".**

     For details refer to <u>section 3.6</u>.

     Confirm with Done checkbox and upload a photo (1 MB max.). *

☐
* Done

Comments / issues:

* Mandatory Field

7   **Check that the resistive arrestor is mounted and touches the ground.**
For details refer to section 3.7.
Confirm with Done checkbox and upload a photo (1 MB max.). *

                                                                                                          * *Done*

Comments / issues:

8   **Check that SoftConsole version 5.5 or higher is installed.**
For details refer to section 3.8.
Confirm with Done checkbox and upload a picture (1 MB max.). *

                                                                                                          * *Done*

Comments / issues:

* Mandatory Field

7.2   Validating the data

Validate that all mandatory data fields are filled in:
Only after successful validation the signature field will be available.

7.3   Signing and sending the form

Sign the form with your *electronic signature*:
A description how to create the electronic signature is attached in section 3.

After signing, you are asked to save the pdf file.
Use a new filename.
Note that this signed pdf file cannot be changed anymore.

Date and Signature

! **IMPORTANT:**
After having signed and saved the pdf file, a new e-mail message with pre-defined address and signed MSB form attached, will be opened in your e-mail client.
Send this e-mail to the pre-defined address.

If, for any reason, it should not open automatically, proceed as follows:

(1)   Open an empty e-mail message in your e-mail client.
(2)   Attach the file you have just signed to the e-mail.
(3)   Fill in the subject field:
       <name of device> - <MSB No.> - <Serial number of device>
       e.g. DX-D 100 - MSB 76 – A123456
(4)   Send this e-mail to: BD_Imaging.Vigilance_Managers@agfa.com