



IMPORTANT FIELD SAFETY MODIFICATION



PRODUCT: 3DLINE DMLC

Date: 07-2013

FCO Ref: 200 02 602 032

Device identification of the DMLC IV and DMLC V systems on an Elekta digital linear accelerator with bar codes and a bar code scanner

Relates to: Important Field Safety Notice 200 01 602 031

Scope: All 3DLINE DMLC systems on an Elekta Digital Linear Accelerator

Description: Device identification of the DMLC IV and DMLC V systems on an Elekta Digital Linear Accelerator with bar codes and a bar code scanner.

Technical reference: DMLCLIN-JD EOS 110045

Manpower: One person for 3 hours

Tools & test equipment: Standard tool kit for Elekta engineers

Parts required: Upgrade kit MRT 19791, which contains:

- Bar code scanner hardware kit
- Bar code label sheets
- CD with the COPY 1026634 MCS S/W Rev 2.5.4

Note: This FCO does not apply to Agility. DMLC IV and DMLC V systems are not compatible with Agility.

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1. Details

This Important Field Safety Modification (IFSM) gives you the instructions to:

- Add a bar code scanner to your system.
- Add bar code identification to the related devices.
- Upgrade to the DMLC control software.
- Update the Clinical User Manual to include the associated clinical workflow changes.

Used with the prerequisite upgrades for ERGO++™/ Monaco® and MOSAIQ®, the treatment system gives dedicated device identification in the DICOM format and in the MOSAIQ® characterization file for the device. This makes sure that the correct device is installed and the device identification is related to an interlock in the treatment system.

IMPORTANT:

It is possible that more than one host machine is configured to use the DMLC system. This can be identified - if there are four mounting holes on the face of the integrated radiation head.

Examine all digital linear accelerators at the site for these signs.

If more than one host machine is configured, Important Field Safety Notice 200 01 602 031 will apply and also one of the two:

- The IFSN 200 01 602 031 must be signed for this new machine, or
- Upgrades must be applied for the new machine to be in compliance with this IFSM (200 02 602 032).

1.1. Prerequisites

The digital accelerator must be configured with these products at the defined version level of software:

- MOSAIQ® R2.4.1 minimum.
- Monaco® 3.3 or ERGO++™ R1.7.7 (or later).
- Desktop Pro™ R7.01 SP2 or Integrity™ R1.1.
- The DMLC system workstation must be the HP6600 or Z210.

This FCO cannot be applied to other configurations.

IMPORTANT: If the configuration is not in compliance with the prerequisites, it is necessary to install or upgrade the products before this FCO installation is done.

Elekta recommends that you refer to PMI B437 on the Elekta Marketing web page: Supporting Upgrade Information for Stereotactic Circular Collimators, DMLC MKIV & MKV Device Identification FCO.

1.2. Preparation

Before you start the modification, you must find out the information identified in this section.

The information that follows is necessary for the MOSAIQ® characterization file. OIS Support updates the characterization information by remote connection.

For each type of Dynamic Multileaf Collimator (3 mm, 5 mm or 7 mm), supply the field size used when the dosimetry data was collected.

DMLC system type (mm)	Dosimetry Field Size	
	IEC 1217 Scaling - Field size X (mm)	IEC 1217 Scaling - Field size Y (mm)

Before you set a date to install this FCO upgrade kit, you must schedule a date and time for the OIS Support (MOSAIQ®) and supply the above information about the field sizes.

Speak to OIS Support through your local free telephone number or use the applicable e-mail address:

- For Region North America: support@impac.com
- For Region Europe and AFLAME: Europe.Support@impac.com
- For Region APAC: For Australia and New Zealand: ANZ-software@elekta.com

If it is necessary to schedule upgrades for the prerequisite configurations, put this quantity of time in the plan:

- Approximately ten weeks for a hardware upgrade to MOSAIQ® or ERGO++™, and
- Approximately six weeks for a software upgrade.

To schedule these upgrades, speak to OIS Support through your local free telephone number or use the applicable e-mail address:

- support-europe@elekta.com

When it is necessary, always refer to the latest Instructions for Use (IFU) manual. Make sure that you have a copy of the IFU before you start the upgrade.

A hospital physicist must log on to MOSAIQ® to give approval of the characterization changes to MOSAIQ® after the upgrade and before the treatment of patients.



Before you do the upgrade, contact your local business unit to get a copy of Work Instruction MCS254BR_HPZ10+xw6600-ELD11+31 for the installation of the MCS 2.5.4 patch release.

IMPORTANT:

To support bar codes, it is necessary to schedule the upgrade of the new DMLC control software (MCS) and ERGO++™ / Monaco® together. MCS rejects treatment plans sent from ERGO++™ 1.7.7 / Monaco® 3.3 until it is upgraded.

The Standard Therapy program cannot be used after the MCS upgrade.

The recommended upgrade sequence is:

1. Upgrade to MOSAIQ® 2.4.1.
2. Schedule the MCS and ERGO++™ 1.7.7 and/or Monaco® 3.3 upgrades together.
3. Dosimetry data collection to define MOSAIQ® characterization field size settings for the DMLC system.
4. Install the FCO hardware and test it (this uses most of the upgrade time).
5. The help desk configures MOSAIQ® by remote connection.

The hardware upgrade does not have an effect on the performance of the system until the MOSAIQ® characterization is updated. The hospital physicist and the local service engineer can schedule the characterization of MOSAIQ® with remote support at a later date.

IMPORTANT:

The characterization of MOSAIQ® and a full system integration check are necessary to complete the FCO, and are mandatory before the equipment can be used for clinical treatments.

Notes:

Before you do the installation, you must buy an extension cable locally. The extension cable connects to one of the two IEC 60320 C13 sockets at the top of the reeling post, or the RIC with an IEC 60320 C14 plug. This extension cable then connects to the applicable adapter on the PSU.

As an alternative, you can use an applicable mains power supply socket in the digital accelerator equipment room to connect to the adapter on the PSU. The mains power supply socket must have a switch. Elekta supplies seven Friwo GPP Primary Inlet adapters. The transformers and the adapters are in one packaging box. Select the correct adapter for your location:

- USA/Japan Friwo number 1827422
- Korea Friwo number 1835619
- Argentina Friwo number 1831610
- India Friwo number 1831323
- China Friwo number 1835620
- Brazil Friwo number 1835621
- UK Friwo number 1827420.

Install the cables to minimize the trip hazard. You must show the users the cables and tell them about the trip hazard from trailing cables. If none of these power sources are available, see section 1.3.6 for an alternative where you use a split power cable. Elekta supplies the split power cable in the packaging.

Make sure that you download all the necessary drivers for section 1.3.7.1. Install them on the MOSAIQ® computer before you connect the bar code scanner. Do the procedure in section 1.3.7 and connect the bar code scanner directly to the MOSAIQ® computer before you install the USB extender. This charges the battery in the bar code scanner while you do the other tasks.

1.3. Instructions

Only do this procedure if you are an Elekta engineer who is fully trained on the DMLC system And Elekta digital linear accelerators.

1.3.1. Attaching the warning label on the DMLC

1. Select the Dynamic Multileaf Collimator
2. Make sure that the DMLC surface where you attach the bar code label is clean.
3. Select the correct bar code label from the supplied bar code label sheet (part number 1500927). It must be the same as the correct type of DMLC.
4. Attach the label in the correct position (see Figure 1).

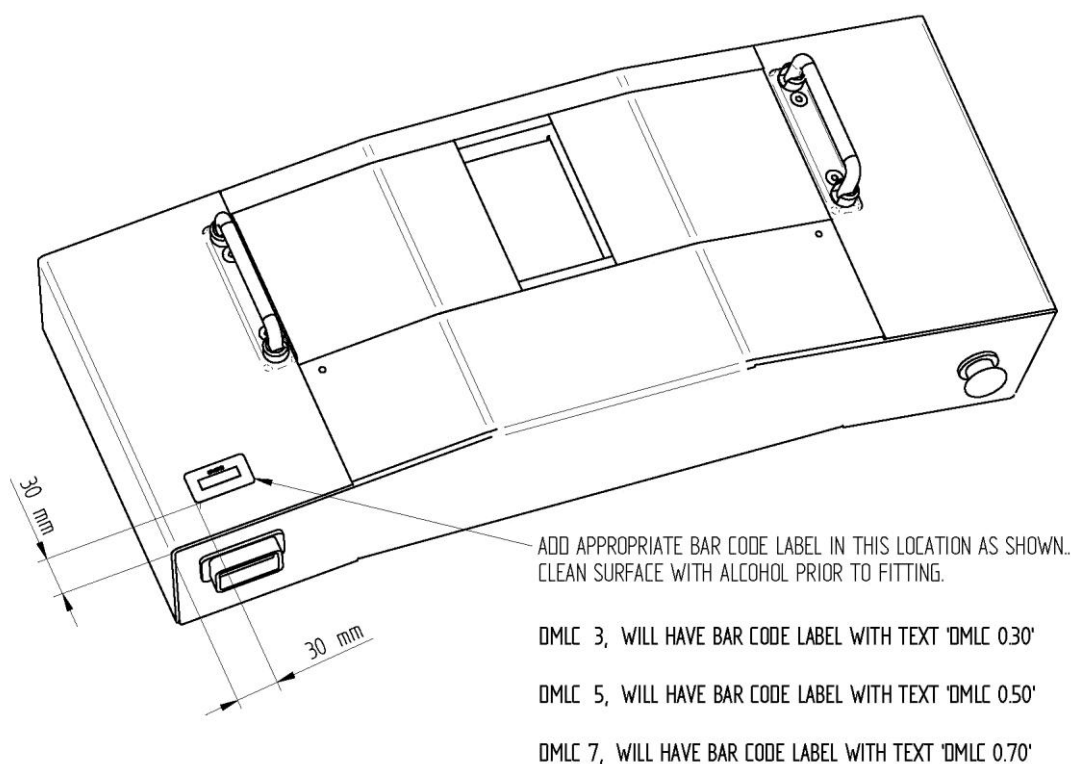


Figure 1: Label position

1.3.2. Installing the MCS 2.5.4 patch release

Refer to the procedure in the Work Instruction for the MCS 2.5.4 patch release.

IMPORTANT:

To support bar codes, it is necessary to schedule the upgrade of the new DMLC control software (MCS) and ERGO++™ / Monaco® together. MCS rejects plans sent from ERGO++™ 1.7.7 / Monaco® 3.3 until it is upgraded.

1.3.3. System overview

See Figure 2 for a technical description of the system.

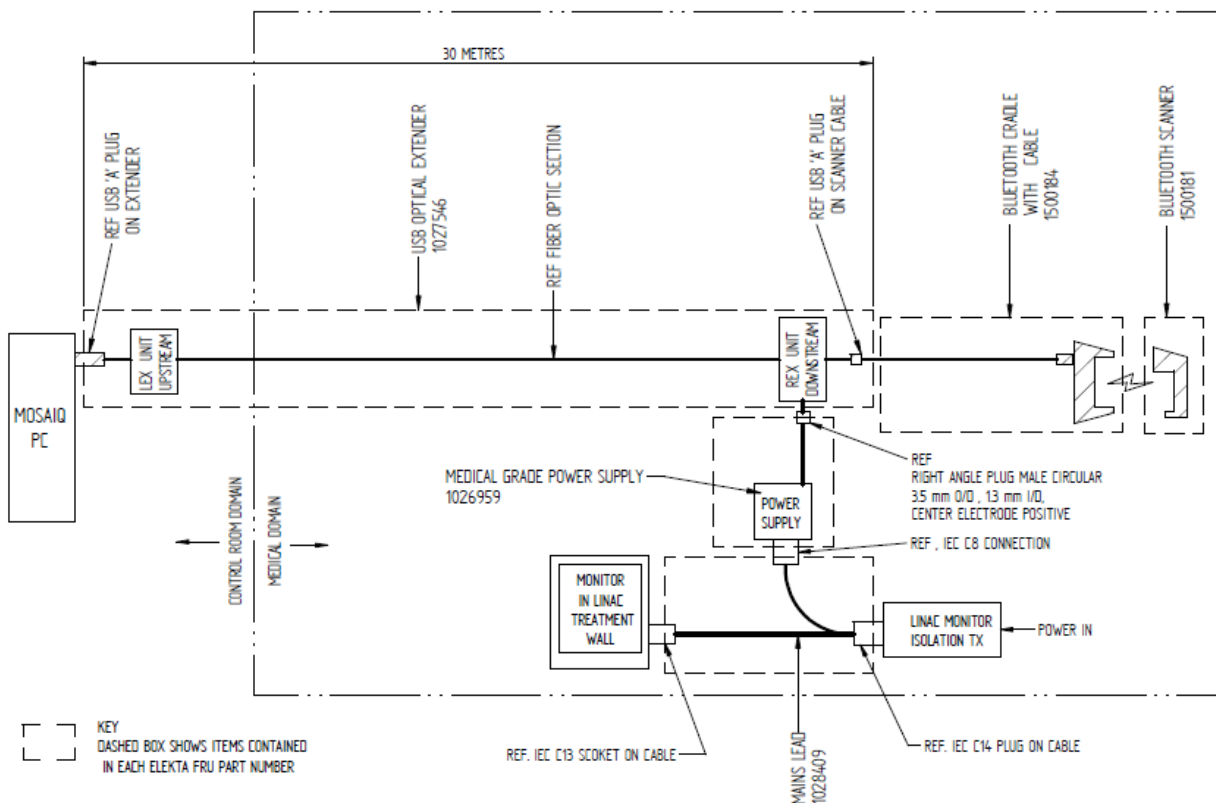


Figure 2: System overview

1.3.4. Installing the optical cable for the bar code scanner

If a bar code scanner is installed, ignore the instructions about the scanner installation which follow and go to section 1.3.7.

1. Attach the male USB connector of the fiber-optic cable (1027546) to the MOSAIQ® computer.
2. Make a sleeve around the female connector of the fiber-optic cable with plastic packaging, or equivalent, and tape to prevent damage to the fiber-optic cable. The fiber-optic cable is easily damaged.
3. You can use a pen to make a loop to attach a draw-string to the end of the fiber-optic cable (see Figure).



Figure 3: Loop and sleeve on the female connector

4. Attach the draw-string to the sleeve and tape it to the primary part of the cable. This prevents pressure on the connection between the interface box and the fiber-optic cable (see Figure).



Figure 4: Draw-string through the loop at the end of the fiber-optic cable

5. Carefully pull the fiber-optic cable through from the control room to the treatment room.

6. Run the cable to behind the digital accelerator (or to a suitable table in the treatment room). If you run the cable to a table, there must be a monitor with an IEC power cable on the table to connect the power supply to the bar code scanner.

1.3.5. Installing the bar code scanner on the digital accelerator fascia, right side (recommended option)

To change the cradle to hold the bar code scanner in a vertical position:

1. Use a cross-head screwdriver to turn the Wall Mount Conversion Dial to the correct position to hold the bar code scanner in a vertical position (on a wall). The front latches move out to engage the bottom of the scanner handle.
2. Use a cross-head screwdriver to remove the screws on the rear of the cradle (see Figure 5), and follow the steps in Figure 5 to install the wall cup.

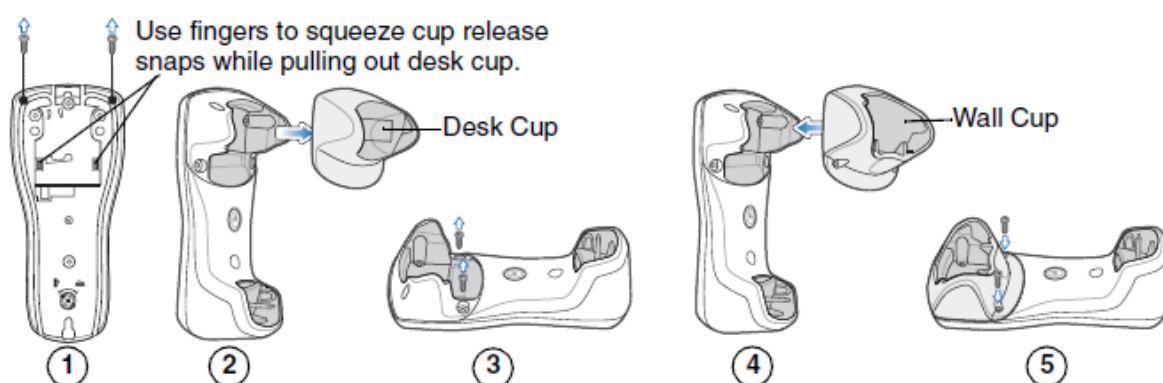


Figure 5: Change to a vertical cradle

3. Attach the interface and power cables to the applicable ports. Use force to push them in.
4. Press the cables into the cable grooves.
5. Install the cradle to the cradle bracket (part number 1500125).

1.3.6. Installing the cradle bracket to the fascia

The cable routing in the figures in this section is not representative of a device from the manufacturing process. The treatment room monitor (TRM) must be removed before you install the cradle bracket.

1. Hold the TRM and remove the bolts (see Figure 3). Be careful with the cables.

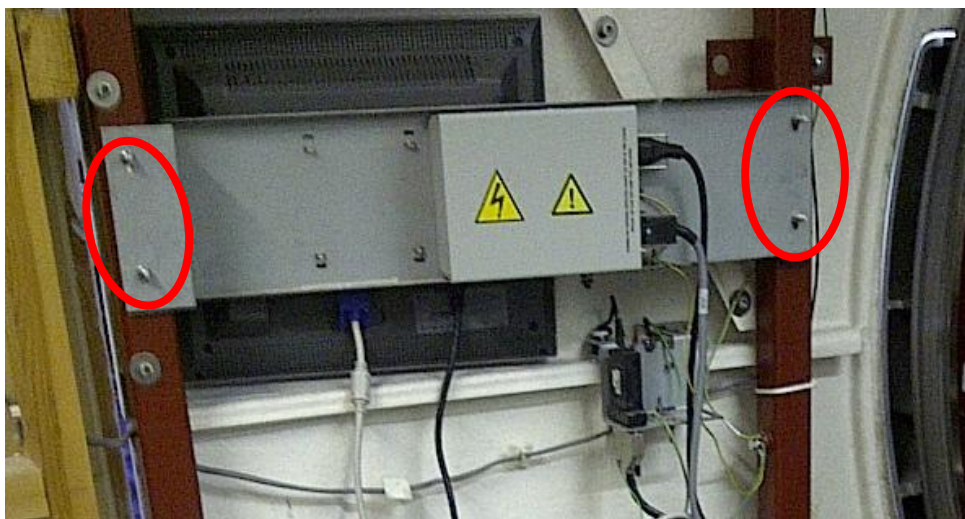


Figure 3: Bolts for the treatment room monitor

2. Remove the TRM.
3. Remove the second set of 4 bolts (see Figure 7).

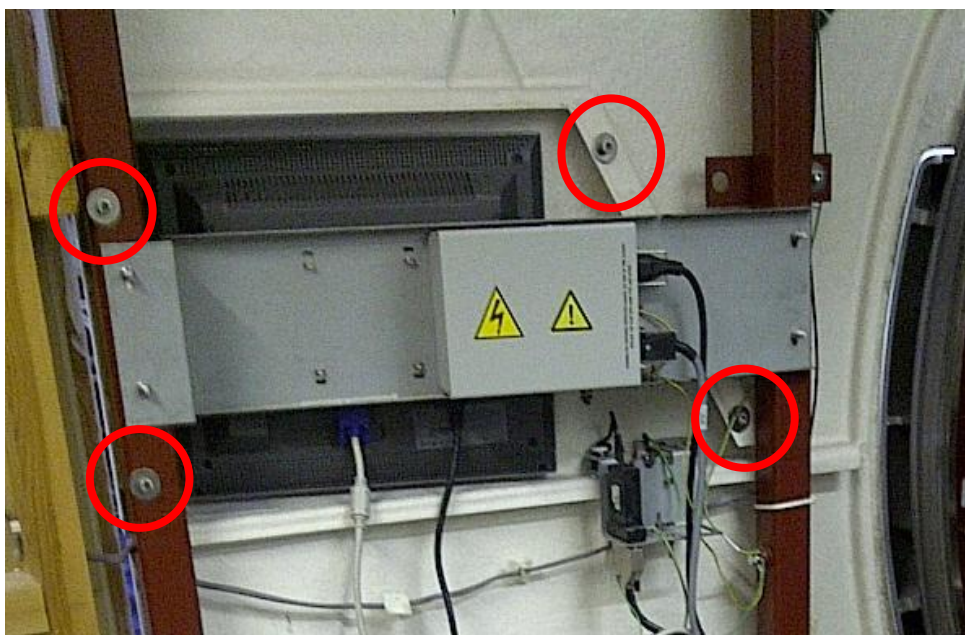


Figure 7: Second set of bolts

4. Lift the fascia panel.
5. Put the cradle bracket on the lower fascia panel (see Figure 8).

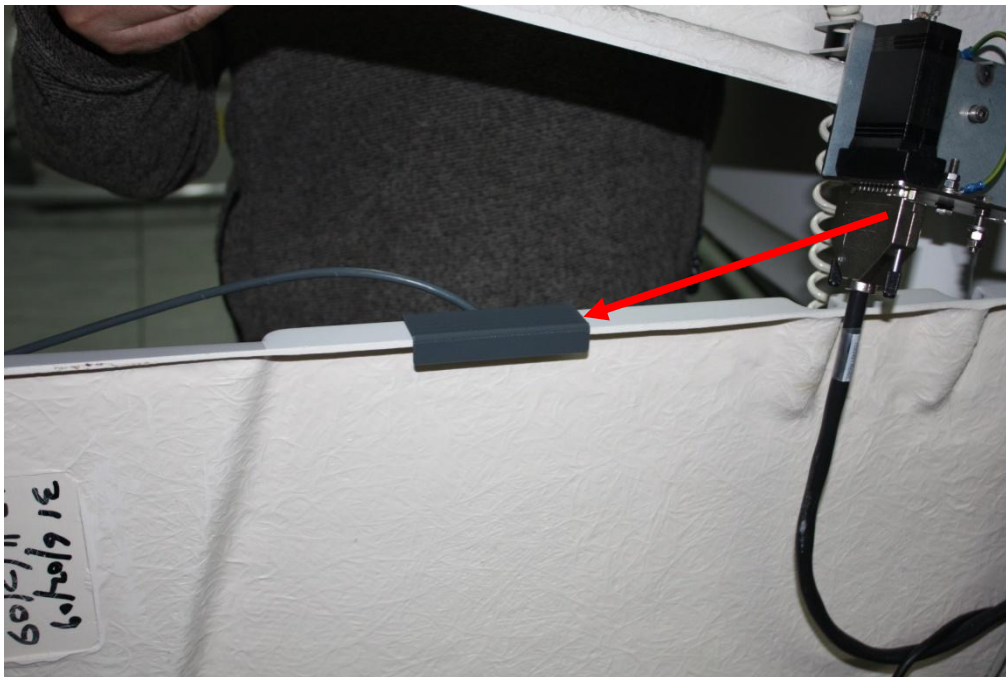


Figure 8: Cradle bracket on lower fascia panel



Figure 9: Cradle for the bar code scanner attached to the cradle bracket

6. Route the cable for the handheld controller again from the left hole in the bracket (viewed from the back) to the right hole.
7. Route the USB cable for the bar code scanner through the hole nearest the bar code scanner (see Figure 4 and Figure 5).

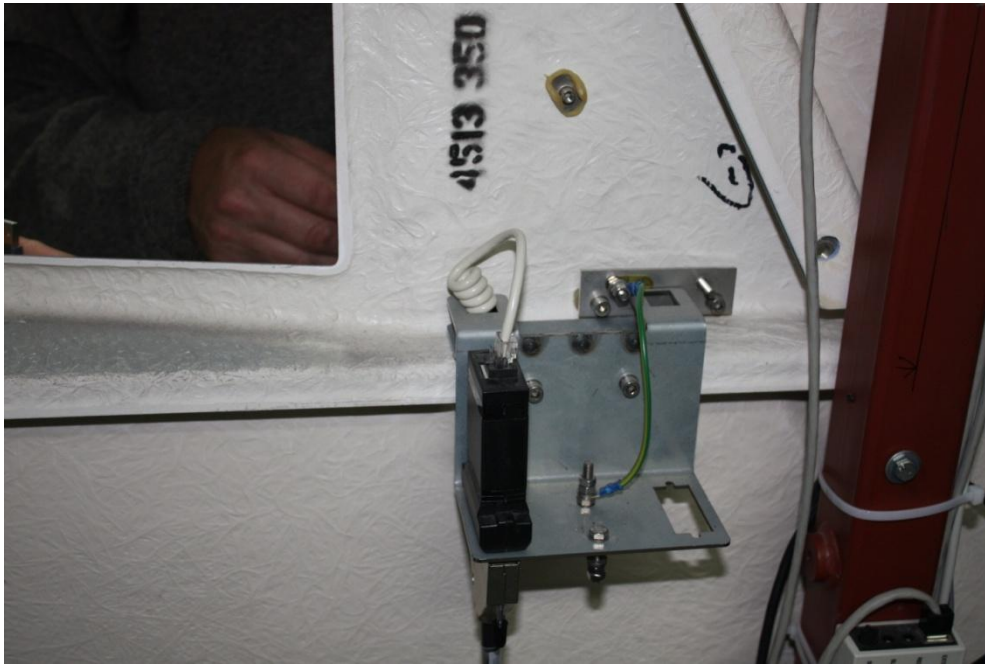


Figure 4: Route the USB cable

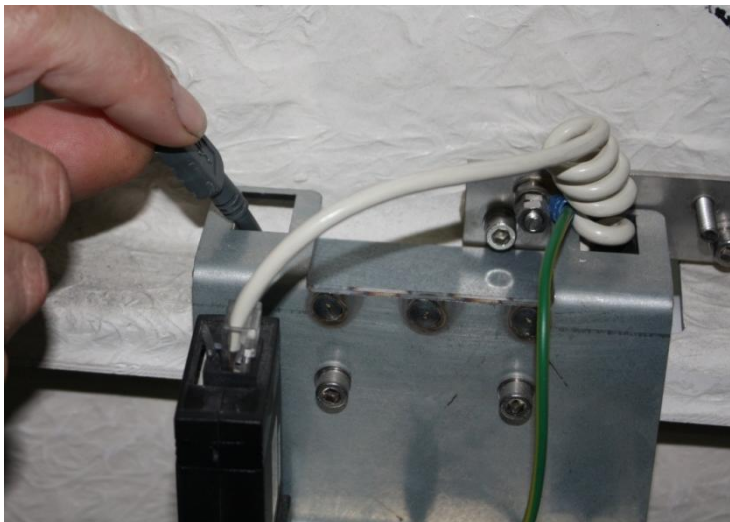


Figure 5: Cable in right bracket hole

8. Install the panel again.
9. Install the bolts and TRM again.
10. Connect the external PSU (1026959) to the small box on the female end of the fiber-optic cable extender.
11. Connect the split power cable (1028409, part of the upgrade kit) to the mains power supply for the TRM (see Figure 6).

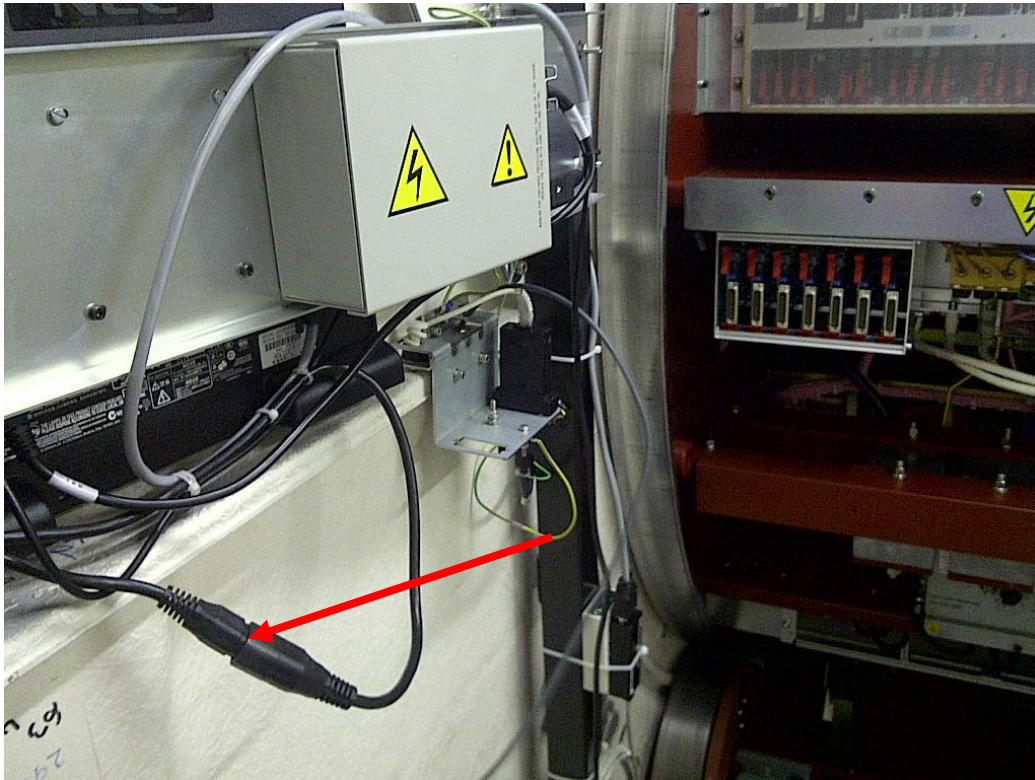


Figure 6: Split power cable

12. Connect one of the female connectors of the split power cable to the TRM (see Figure 7).
13. Connect the other female connector of the split power cable to the PSU for the fiber-optic cable.

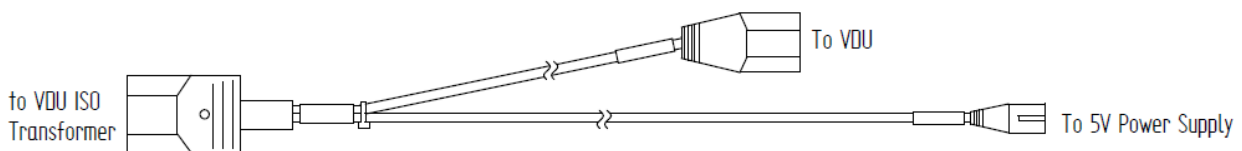


Figure 7: Split power cable diagram

14. After you pulled the fiber-optic cable through the cable ducts, put the end behind the fascia near the selected TRM. Install it to the frame with cable ties (see Figure 8). Be careful not to attach the cable tie too tightly.

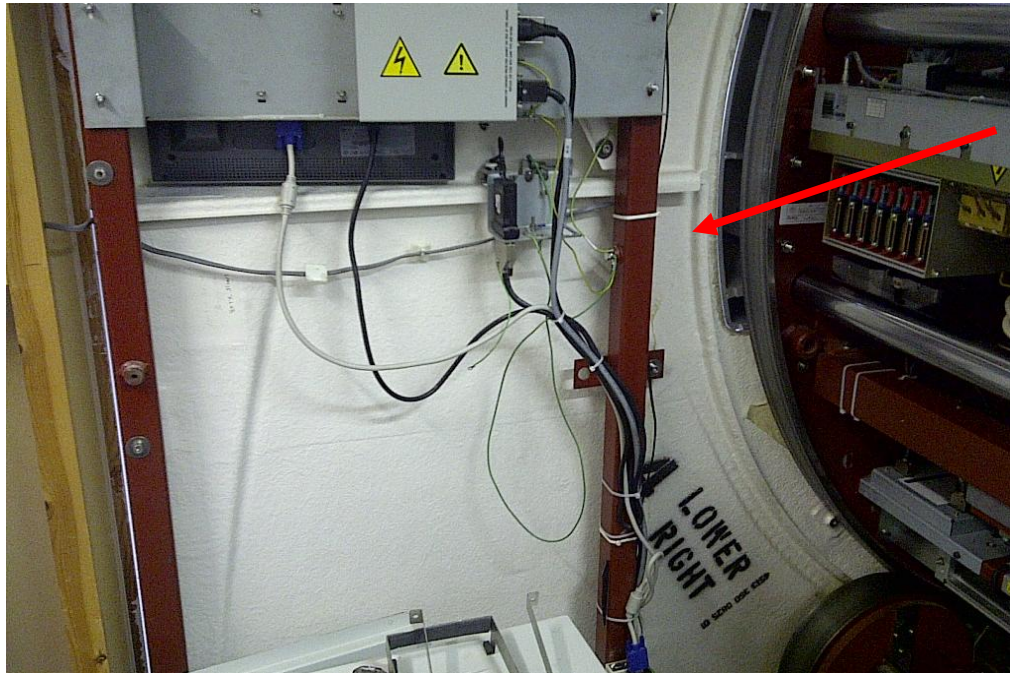


Figure 8: Cable tie to frame

15. Use cable ties to attach the power supply cable to the extension cable (see Figure 9).



Figure 9: Cable tie for the power cable

1.3.7. Configuring the bar code scanner with MOSAIQ®

1.3.7.1. Installing the drivers for the bar code scanner on the MOSAIQ® computer

Do not connect the bar code scanner and cradle (1024731) to the MOSAIQ® /extension terminal USB port until the drivers are correctly installed.

1. Make sure that the **usbser.sys** file is in **c:\Windows\System32\drivers**. If it is not, search for this file in drive C and copy it to **c:\Windows\System32\drivers**. The **usbser.sys** file can be found as follows:
 - For Windows 7 (x86 32bit):
C:\Windows\System32\DriverStore\FileRepository\mdmcpq.inf_x86_neutral_XXXXXXXXXX (archive file)
 - For Windows 7 (x64 64bit):
C:\Windows\System32\DriverStore\FileRepository\mdmcpq.inf_amd64_neutral_XXXXXXXXXX (archive file)
2. Make a new folder on the desktop for downloaded scanner drivers.
3. Save a copy of **usbcdd.inf** to the new folder. You can find this file at:
<ftp://ftp2.impac.com/eng/install/barcoding/usbcdd.inf>, or
<https://docs.symbol.com/downloads/usbcdd.inf>
4. Save a copy of **usbcddcrw.inf** to the new folder. You can find this file at:
<ftp://ftp2.impac.com/eng/install/barcoding/usbcddcrw.inf>, or
<https://docs.symbol.com/downloads/usbcddcrw.inf>
5. Connect the bar code scanner to the MOSAIQ® computer.

Note: When the battery is fully discharged, it can be 30 minutes before you can use the bar code scanner.

1.3.7.2. Configuring the bar code scanner

Configure the bar code scanner as a serial device:

1. When the bar code scanner is sufficiently charged, press ENT on the bar code scanner.
2. Do a scan of the Set Factory Defaults code from the bar code scanner manual (see Figure 10 for an example. If you do not have the documentation, go to <http://support.symbol.com> and search for the MT2070/MT2090 User Guide.)



Set Factory Defaults

Figure 10: Set Factory Defaults bar code example

3. Do a scan of the PAIR code in the cradle to make sure that the bar code scanner is paired with the cradle. It is possible that this step is not necessary for bar code scanners that are connected directly to the USB cable.
4. On the scanner, press **Close** to get back to the Home screen.
5. Use the 4-way navigation key to select **6 – Config** then press **ENT**.
6. Use the 4-way navigation key to select **5 – Configure USB** then press **ENT**.
7. Use the 4-way navigation key to select **Retail CDC (STB2078 Only) – Config** then press **ENT**.
8. Select **Close**.
9. Select **0 – Up** then **ENT**.
10. Select **1 – Scan Item** then **ENT**. The operating system shows a **new hardware was found** message.

11. If the system shows a dialog box to update the driver, select to update the drivers manually.
12. If the system does not show a dialog box to update the driver, do these steps:

Note: The steps that follow apply to Windows® 7. For Windows® XP, the steps are almost equivalent. For more information about the Windows® XP installation, go to <https://docs.symbol.com/ReleaseNotes/USBCDCINF%20Release%20Notes.pdf> (and <http://www.microchip.com/forums/m488342-print.aspx>)

- a. Open the Windows® Device Manager.
- b. In the **Other devices** folder, right-click **Symbol Bar Code Scanner**, and then select **Update Driver Software** (see Figure 11).

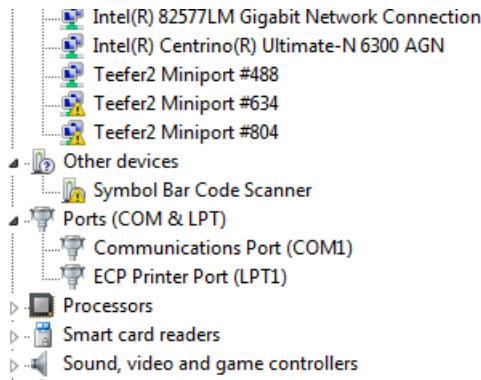


Figure 11: Symbol Bar Code Scanner in Other devices

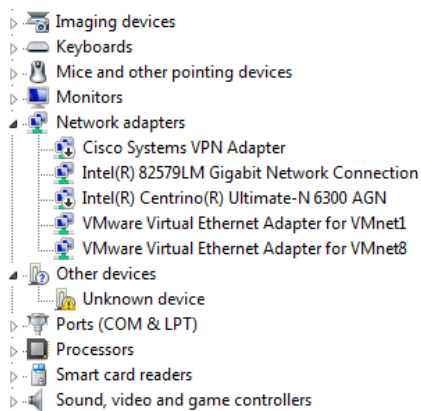


Figure 18: Unknown device in Other devices

- c. If **Unknown device** appears in **Other devices** (see Figure 18), right-click **Unknown device**, and then select **Update Driver**.

The **Update Driver Software** dialog box appears (see Figure 12).

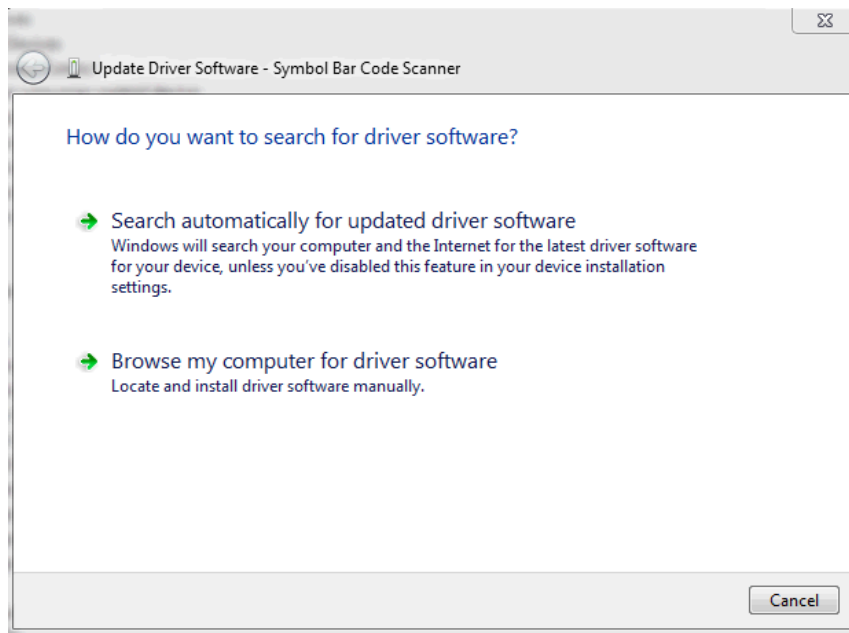


Figure 12: Searching for driver software

- d. Click **Browse my computer for driver software**.
- e. In the dialog box that appears, click **Let me pick from a list of device drivers on my computer** (see Figure 13).

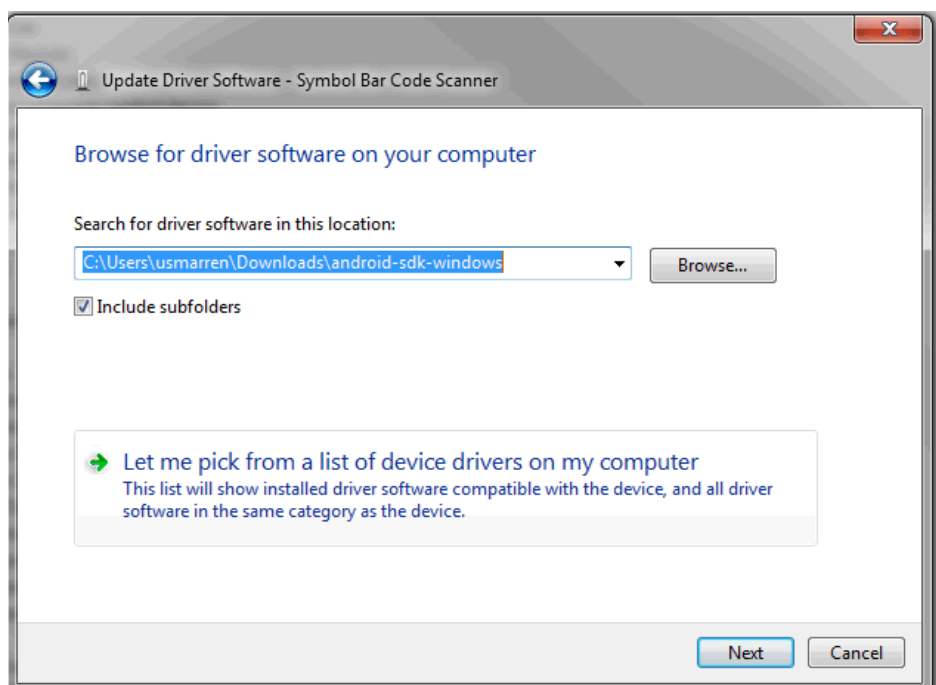


Figure 13: Browse for driver software on your computer

- f. In the **Common hardware types** list, select **Ports (COM & LPT)** (see Figure 14).

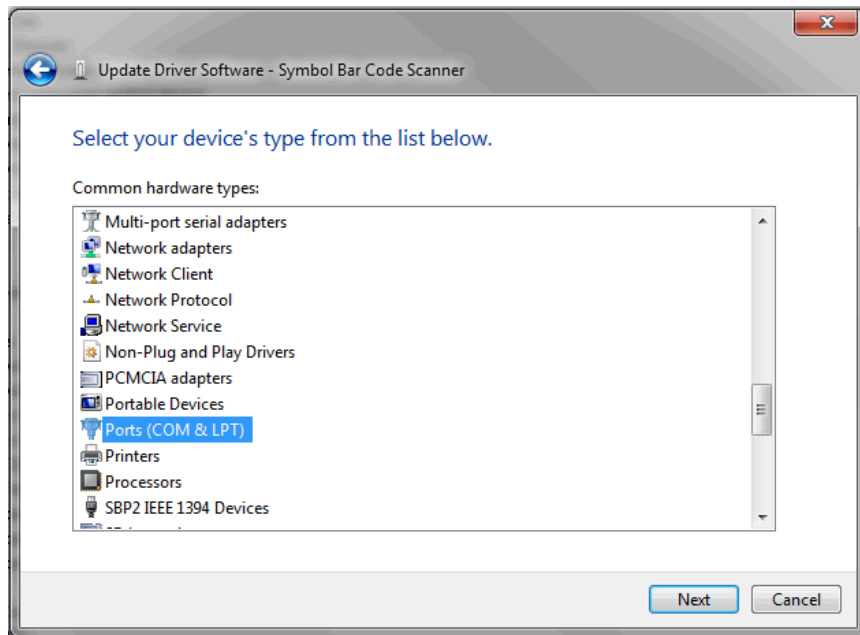


Figure 14: Select Ports (COM & LPT)

- g. Click **Next**.
- h. In the dialog box that appears, click **Have Disk** (see Figure 15).

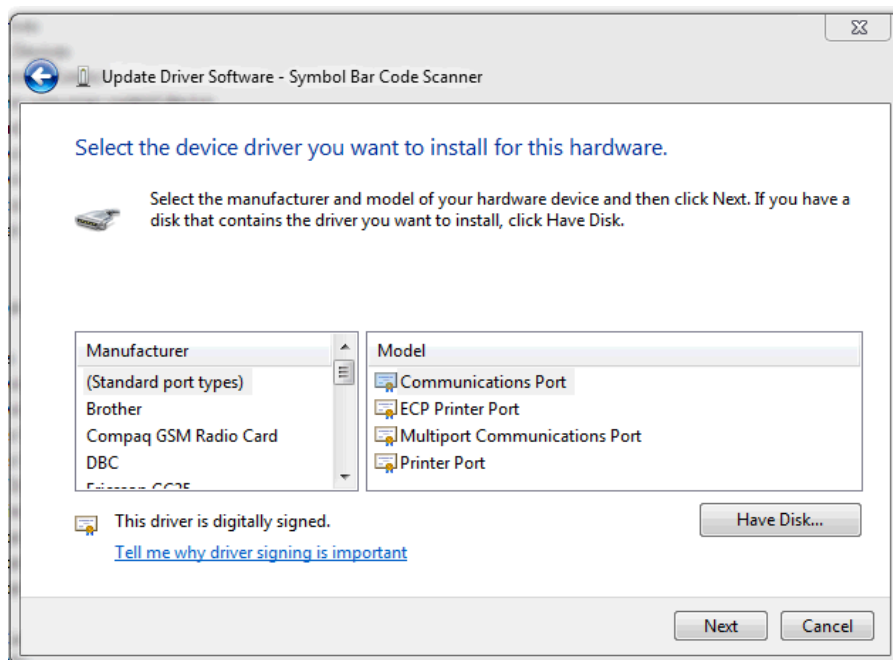


Figure 15: Device driver selection

- i. Browse to the folder that has the **usbcdc.inf** and **usbcdcrw.inf** files that you saved earlier.
- j. Select the file.

- k. Click **OK**.

A dialog box appears with the hardware device (see Figure 16).

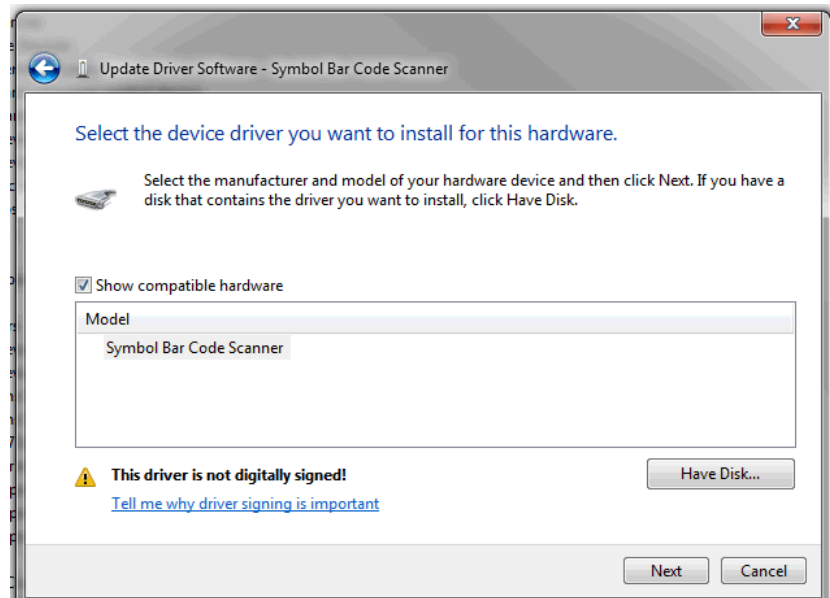


Figure 16: Driver selection

- l. Click **Next**.

- m. If a Windows® security warning appears about the publisher of the driver, ignore the warning and continue to install the driver.

A driver successfully installed message is displayed. The **Symbol Bar Code Scanner** item is displayed in **Ports (COM & LPT)** in the **Device Manager**. The COM port used is also displayed (see Figure 17, in the example, it was assigned as **COM6**).

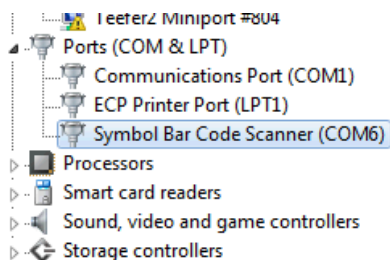


Figure 17: COM port assignment

- n. To select a COM port, right-click the **Symbol Bar Code Scanner**, and then click **Properties**. The **Properties** dialog box appears.
- o. Click the **Port Settings** tab.

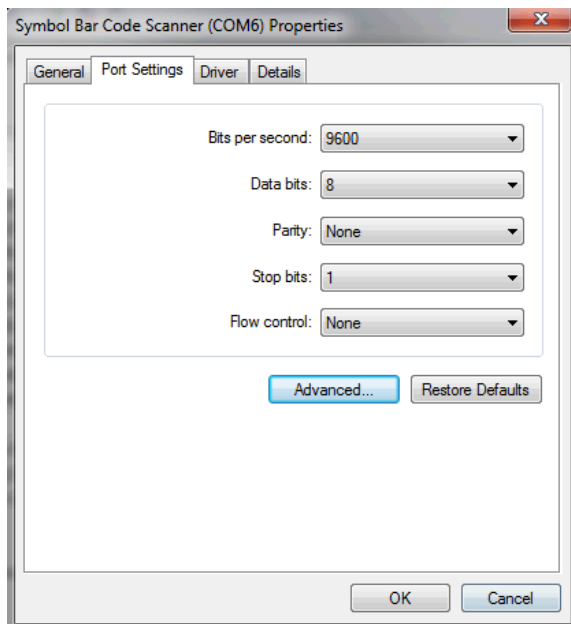


Figure 185: Properties dialog box

- p. Click **Advanced** (see Figure 18).
The **Advanced Settings for COM<x>** dialog box appears (see Figure 19).

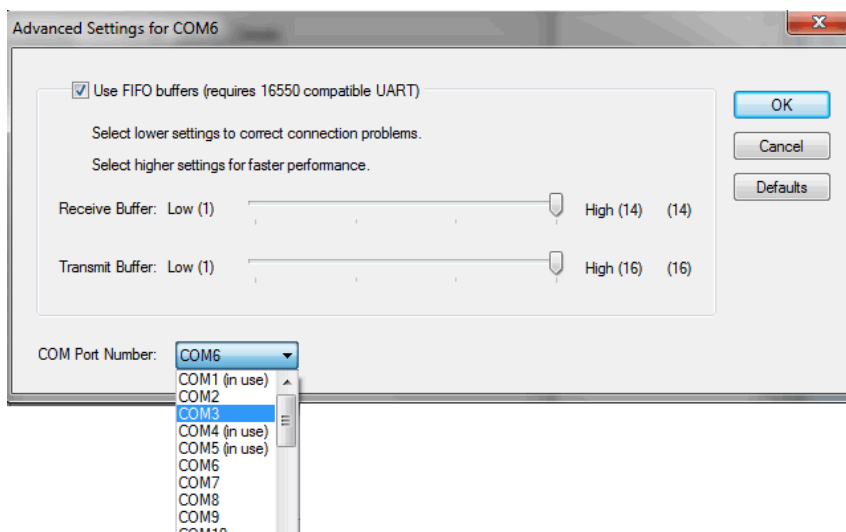


Figure 19: COM port selection

- q. Select the necessary COM port for the bar code scanner. In this example, COM3 is selected (MOSAIQ® accepts COM1 through to COM4).
The **Symbol Bar Code Scanner** is then assigned to the selected COM port (see Figure 20).

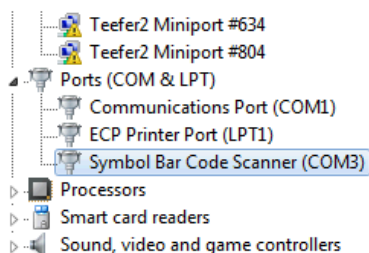


Figure 20: Selected COM port for the bar code scanner

1.3.8. Configuring MOSAIQ®

After the bar code scanner is configured, set up MOSAIQ® (versions 2.41.01 F1+ and 2.50.01 I5+ only) to communicate with the bar code scanner through the serial port:

1. Start MOSAIQ®.
2. On the menu bar, click **File > System Utilities > Barcode Configuration** (see Figure 21).

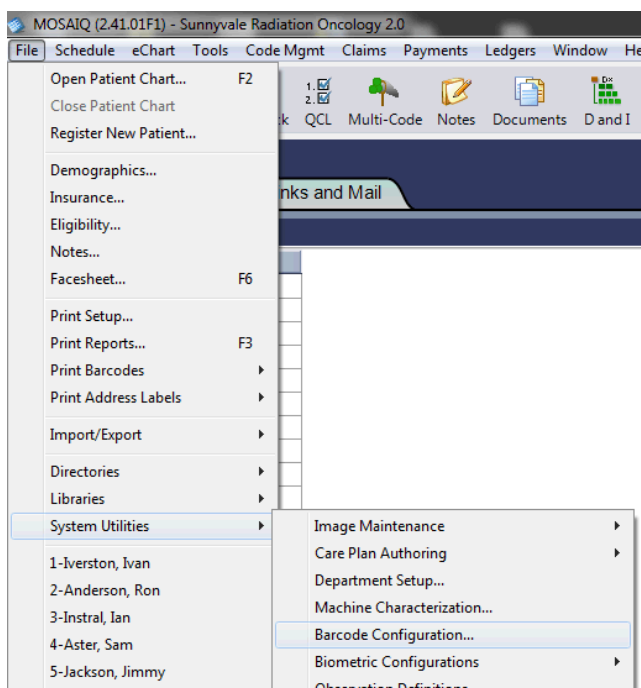
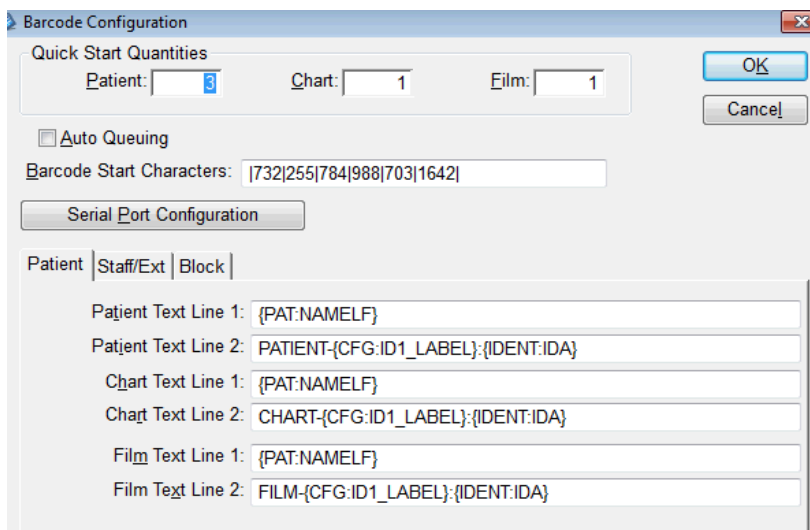


Figure 21: MOSAIQ® Barcode Configuration

The **Barcode Configuration** dialog box appears (see Figure 22).



Barcode Configuration

Quick Start Quantities
 Patient: Chart: Film:

☐ Auto Queuing

Barcode Start Characters:

Patient | Staff/Ext | Block |

Patient Text Line 1:

Patient Text Line 2:

Chart Text Line 1:

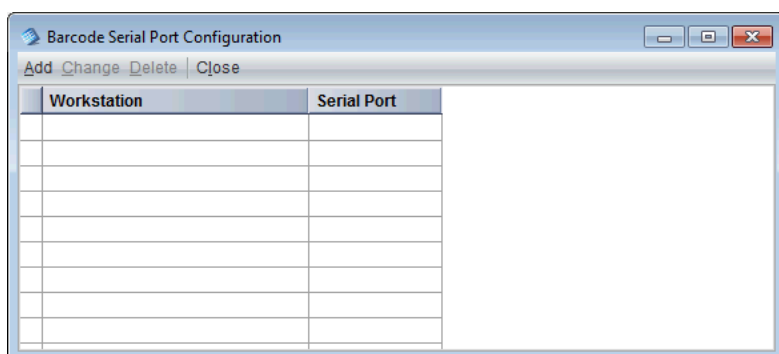
Chart Text Line 2:

Film Text Line 1:

Film Text Line 2:

Figure 22: Serial port configuration

- Click **Serial Port Configuration**.
 The **Barcode Serial Port Configuration** dialog box appears (see Figure 23).

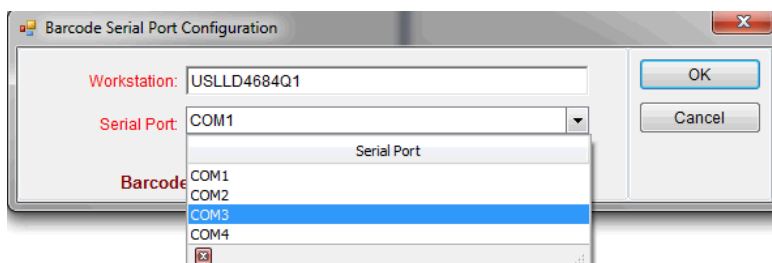


Barcode Serial Port Configuration

Workstation	Serial Port

Figure 23: Barcode Serial Port Configuration dialog box

- On the menu bar, click **Add**.
 The **Barcode Serial Port Configuration** dialog box appears (see Figure 24).



Barcode Serial Port Configuration

Workstation:

Serial Port:

Barcode:

Serial Port

- COM1
- COM2
- COM3
- COM4

Figure 24: Serial port selection in MOSAIQ®

- In the **Workstation** box, type the workstation name (the workstation IP address can also be used).
- Select the COM port to use.

7. Click **OK**.
8. The system updates the MOSAIQ® configuration (see Figure 25).

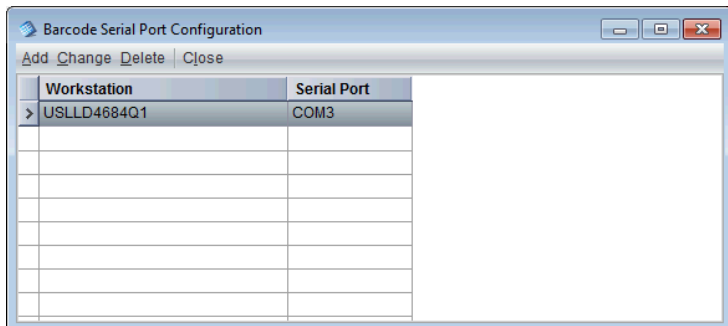


Figure 25: Updated configuration

The bar code scanner is prepared for operation.

9. If it is necessary, close the **Barcode Serial Port Configuration** and **Barcode Configuration** dialog boxes.

1.3.9. Setting the bar code scanner to the correct mode

After the bar code scanner is configured in MOSAIQ®, it must be set to the correct mode:

1. Do scans of the three bar codes in Figure 26 in this sequence:
 - a) SCAN OPTIONS
 - b) DATA SUFFIX
 - c) ENTER.

Note: These three bar codes are in the documentation for the bar code scanner that is supplied in the upgrade kit. If you do not have the documentation, go to <http://support.symbol.com> and search for the MT2070/MT2090 User Guide.

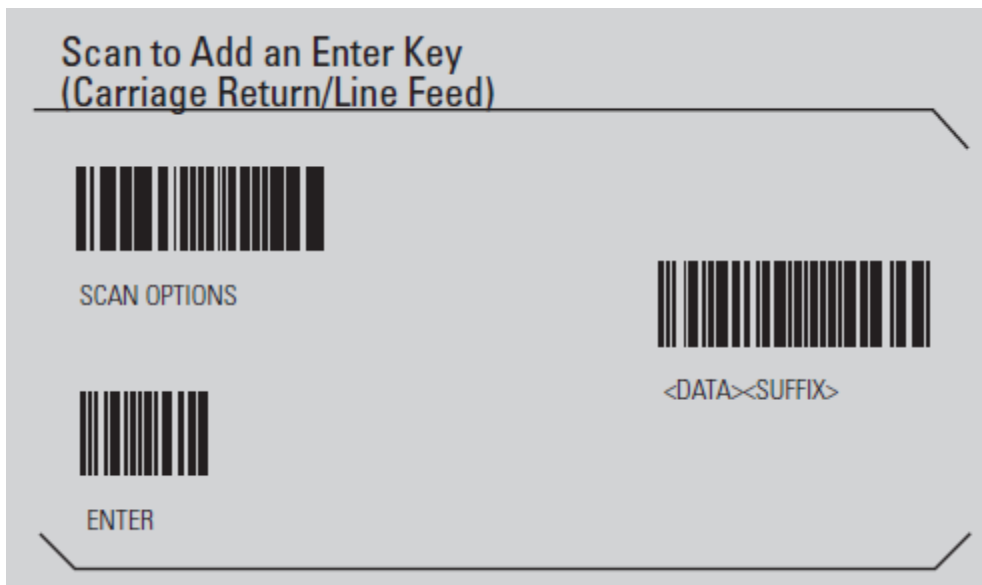


Figure 26: Configuration of the bar code scanner mode

2. Load a patient.

3. Make sure that the prescription cannot be delivered.
4. Do a scan of the bar code on the DMLC system.
5. Make sure that the prescription can be delivered. Do troubleshooting and do the applicable procedures again if this is not a successful test.

1.3.10. Restarting the bar code scanner if it discharges completely

The bar code scanner must be charged for a minimum of 30 minutes before you can use it.

If there is an error when the bar code is transmitted to the host, it can be necessary to do a 'warm reboot'. To do a warm reboot:

1. Hold button **2** on the bar code scanner and then at the same time press the scanner trigger for 5 seconds.
The bar code scanner restarts.

Note: If you hold button **2** and the trigger for 10 seconds, the bar code scanner fully resets. The bar code scanner configuration is erased and you have to do the procedure to configure it again.

2. When it is fully prepared, do a check that the bar code scanner operates correctly.

There are no more steps to this upgrade.

Procedure:

- 1 Read the instructions in the upgrade kit before you start the change. Make sure that all the parts on the dispatch list are delivered.
- 2 Use the drawing(s) supplied and/or the installation instructions and follow the step by step instructions to do the modification.
- 3 When the modification is complete, update the modification record label on the applicable assembly with the ECO number in the Technical Reference Number if applicable.
- 4 If applicable, put the modification instructions and the FCO in the service documentation.
- 5 If it is necessary by local procedures, make sure that all documentation is completed fully and sent to the local Elekta Office and/or representative to add to the Configuration Database.
- 6 Make sure that parts sent back to Elekta Limited are in the correct packaging and sent immediately with a **Returns Authorization (RA)** number. You can get a RA number from the Elekta spare parts department.

IMPORTANT

- 7 Make sure that the section of this FCO for the new clinical workflow instructions is removed and put in the Important Notice section of the Clinical User Manual.
- 8 On the FCO Action Notification Report, ensure you record the following information:
 - Host Machine make and Model
 - Host Machine Control System Type and Software Revision
 - Treatment Planning System Type and Software Revision
 - OIS System Type and Software Revision.

NOTE: Parts that are in contact with body fluids (for example, top of treatment table) or are a radiation hazard must have a signed **Declaration of Contamination Status** included with the part **BEFORE** it is sent back to Elekta.

IMPORTANT
Remove this section and add it to the
Important Notice section of the Clinical User Manual

Date: 07-2013

FCO Ref: 200 02 602 032

Changes to your system to improve the safe operation of DMLC IV and DMLC V systems

It is possible for errors to occur in the clinical workflow for the operation of 3DLINE DMLC systems.

This upgrade kit, when used in conjunction with the pre-requisite changes for TPS and OIS will help to prevent these possible errors:

ID	Function	Possible Error
1	The TPS automatically transfers the DMLC identifier to the R&V system and the R&V system automatically loads the DMLC identifier.	This prevents: <ul style="list-style-type: none"> No DMLC system installation at the necessary time.
2	Each DMLC is identified by a unique bar code.	This prevents: <ul style="list-style-type: none"> No DMLC system installation at the necessary time. A diaphragm size incorrectly set in the TPS.
3	If a DMLC is indicated for use for a treatment, the correct bar code scan data must be available before treatment is permitted by the system.	This prevents: <ul style="list-style-type: none"> No DMLC system installation at the necessary time.
4	MOSAIQ® does a check that the prescribed diaphragm settings are the same as for the DMLC, and prevents treatment delivery if it is not correct.	This prevents: <ul style="list-style-type: none"> A diaphragm size incorrectly set in the TPS.
5	The diaphragm settings for the DMLC cannot be changed in MOSAIQ®.	This prevents: <ul style="list-style-type: none"> A diaphragm size incorrectly set in the TPS.
6	Standard Therapy must be blocked by DMLC MCS.	This prevents: <ul style="list-style-type: none"> A diaphragm incorrectly set in Standard Therapy
7	The system must prevent treatment delivery if the DMLC cannot find the EPID file.	This prevents: <ul style="list-style-type: none"> A diaphragm incorrectly set in Standard Therapy Different patients and/or beams selected in MOSAIQ® and MCS.

DMLC system workflow changes with the bar code scanner in operation

The DICOM data that is exported from the treatment planning system to MOSAIQ® includes an accessory code for the DMLC system. After you import the code, the field size of the digital accelerator diaphragms is fixed for the applicable DMLC system size, and you cannot change this value. This prevents irradiation of a field size that is larger than the maximum field size of the DMLC system. Before treatment, you must do a scan of the correct bar code on the applicable DMLC system to clear the accessory inhibit.

In the updated system, it is not possible to deliver treatments to patients in Standard Therapy mode. All treatments must be completed with the R&V system.

New Clinical Workflow

This is the new clinical workflow:

1. Complete the plan in ERGO++™ with the applicable size of DMLC system, in compliance with the usual hospital protocol.

2. Export the plan to MOSAIQ®.

This automatically adds the accessory code to the applicator/wedge field (in the treatment definition window) of the treatment field and sets the field size to the correct field size for the DMLC.

3. Prepare the plan in MOSAIQ® in compliance with the usual hospital protocols.

4. Load the patient and field in MOSAIQ® for treatment.

5. Set up the patient on the treatment table in compliance with the usual hospital protocols.

WARNING



Do not do a scan of the bar code until after you attach the dynamic multileaf collimator. If you ignore this warning, you can cause clinical mistreatment.

6. With the bar code scanner, do a scan of the bar code on the DMLC system.

This step clears the inhibit in MOSAIQ® when the bar code which was read and the prescribed accessory code agree.

7. Deliver the treatment to the patient in compliance with the usual hospital protocols.

The DMLC system size used is recorded in the treatment record in MOSAIQ® as an accessory in the applicator/wedge field.

Follow the necessary procedures of the manufacturer of the bar code scanner supplied with the upgrade kit.

Pacemakers

The Motorola bar code scanner can have an effect on pacemakers because of electronic interference. Refer to the documentation from the manufacturer of the bar code scanner for more information.

If a person has a pacemaker, make sure that:

1. You follow the necessary procedures of the pacemaker manufacturer.
2. You keep a minimum distance of 15 cm between the bar code scanner and the pacemaker to prevent electronic interference between the devices. This is recommended by the pacemaker manufacturers.

Restarting the bar code scanner after the digital accelerator is switched off

If the power supply to the bar code scanner is from the digital accelerator, when the digital accelerator is switched off the bar code scanner discharges. This is because it is energized from the treatment room monitor that is switched off.

When the digital accelerator is switched on, it is possible that the bar code scanner is fully discharged. It must be charged for a minimum of 30 minutes before you can use it.

When you switch on the digital accelerator, make sure that the bar code scanner clears the bar code inhibit. If it does not, you must do a 'warm restart' of the bar code scanner. This prevents an error that can occur when the bar code is transmitted to the host.

To do a warm restart:

1. Hold the button identified by **2** on the bar code scanner and then at the same time press the scanner trigger for 5 seconds.
The bar code scanner restarts.

*Note: If you hold the **2** button and the scanner trigger for 10 seconds, the bar code scanner will fully reset. The bar code scanner configuration is erased and you have to do the procedure to configure it again.*

2. When it is fully prepared, do a check that the bar code scanner operates correctly.

Configuring the bar code scanner after the bar code scanner is fully reset

This procedure is only necessary if there are no configuration settings for the bar code scanner.

1. Do a scan of the Set Factory Defaults code from the bar code scanner manual (see Figure 1 for an example).

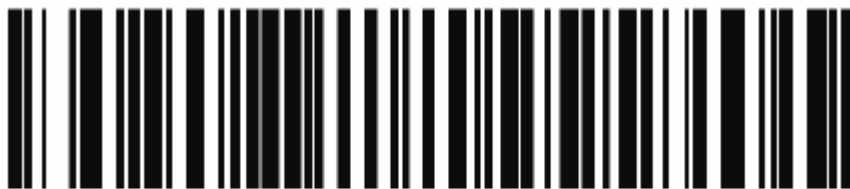


Set Factory Defaults

Figure 1: Set Factory Defaults bar code example

2. Do a scan of the PAIR code in the cradle to make sure the bar code scanner is paired with the cradle. It is possible that this step is not necessary for bar code scanners that are connected directly to the cradle by the USB cable.

3. Do a scan of the CDC COM Port Emulation code (see Figure 2 for an example).



CDC COM Port Emulation

Figure 2: CDC COM Port Emulation code example

4. Do scans of the three bar codes in Figure 3 in this sequence:
 - a) SCAN OPTIONS
 - b) <DATA><SUFFIX>
 - c) ENTER.

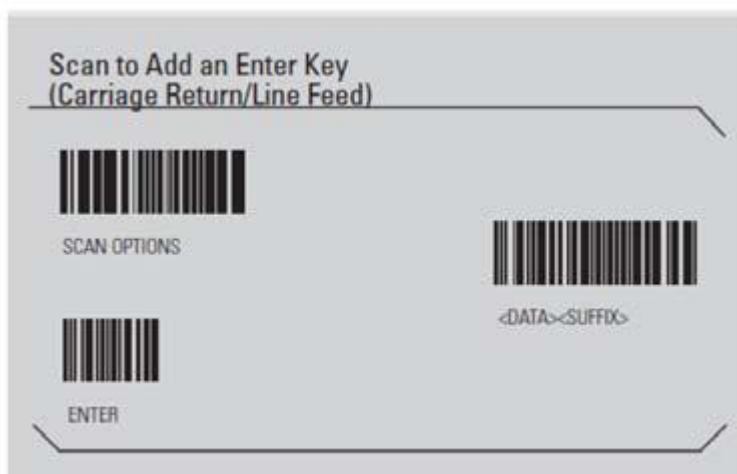


Figure 3: Configuration of the bar code scanner mode

5. Load a patient.
6. Make sure that the prescription cannot be delivered.
7. Do a scan of the bar code on the dynamic multileaf collimator.
8. Make sure that the prescription can be delivered. Do troubleshooting and do the applicable procedures again if this is not a successful test.

Safety reference:

The following warnings and cautions are associated with this notice:

1. Do not do a scan of the bar code until after you attach the dynamic multileaf collimator. If you ignore this warning, you can cause clinical mistreatment.

Procedure:

- 1 Read the instructions in the modification kit (ModKit) before you start to implement the change. Make sure that all the parts on the dispatch list are delivered.
- 2 Use the drawing(s) supplied and/or the installation instructions, and follow the step by step instructions and implement the modification.
- 3 When the modification is complete update the modification record label on the applicable assembly with the ECO number in the Technical Reference Number, if applicable.
- 4 If applicable, put the modification instructions and the FCO in the service documentation for reference.
- 5 If required by local procedures, make sure that all paperwork is completed in full and sent to the local Elekta Office and/or representative, to add to the Configuration Database.
- 6 Make sure that any parts to be returned to Elekta Limited are packaged correctly, and dispatched without delay using a **Returns Authorization (RA)** number. An RA number is supplied by the Spares Department on request.

NOTE: Parts that have come into contact with body fluids (for example, top of treatment table) or constitute a radiation hazard must have a signed **Declaration of Contamination Status** included with the part **BEFORE** it is returned.

FCO ACTION NOTIFICATION REPORT

<Give this Notice to the customer, and then complete and return this report to your local Elekta Office or Representative for the Configuration Database.>

Classification: Important Field Safety Modification	FCO Ref: 200 02 602 032
FCO description: Device identification of the DMLC IV and DMLC V systems on an Elekta Digital Linear Accelerator with a bar code and a bar code scanner	
Scope: All 3DLINe DMLC systems on an Elekta digital linear accelerator	

Hospital:	
Device Serial No: (eg linac - if applicable)	Location or Site No:

<p>Action on this unit/device was: (select one)</p> <p><input type="checkbox"/> Completed as per instructions on: <date day/month/year></p> <p><input type="checkbox"/> Not completed because: (give reasons)</p> <p><input type="checkbox"/> Not completed because the unit/device is in storage (if applicable).</p> <p><input type="checkbox"/> Refused by customer because: (give reasons)</p>	<p>Note: If you use a work-order in the CLM configuration database, then you do not have to complete this section. The work-order will be used to add the information to the system.</p>
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<p>Acknowledgement / Acceptance / Refusal by customer: This notification to be signed by the customer.</p> <p>The REASON and PURPOSE of this modification has been explained.</p> <p>Name: _____ Title: _____</p> <p>Signature: _____ Date: _____</p>	
<p>Acknowledgement by installing engineer: This section is signed by the Elekta representative, for example, Installation Engineer, Service Engineer, Distributor, or who installed the modification kit, for example, a hospital representative or system operator.</p> <p>Name: _____ Title: _____</p> <p>Signature: _____ Date: _____</p>	