

The corrective action described in this document shall be carried out in order to mitigate an issue that may exist on the equipment specified in the scope. The corrective action is mandatory and shall be executed.

Unity MR Software 5.7.1 to 5.8.1 Upgrade

Product: Unity

Date: 11/04/2025

Reference number (Field Change Order, FCO): 200-06-801-032

Field Corrective Action (FCA) number, if applicable: N/A

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Relates to:	E070211 Release Notes for Unity MR 5.8.1 in CLM (and translated versions)
Scope:	NRT software version 2.1.1.0.
Description:	Upgrade of the Philips MR system in Unity from 5.7.1 to 5.8.1. Upgrade of Elekta NRT system from 2.1.1.0 to 2.1.1.1.
Technical Reference:	Elekta FCO 200-06-801-032 Philips commercial order NMRZ134 is the R5.8.1 software upgrade for Marlin and this can only be ordered in combination with Philips Upgrade BASIC UPGRADE for MRL, NMRF361.
Manpower:	20 hours split between Philips and Elekta SMEs
Tools & Test equipment:	None
Parts Required:	5.8.1 Upgrade provided by Philips 2.1.1.1 NRT Patch Kit P/No: 1570735 IFU Kit – Please refer to section 3.6 instructions for use (IFU) kits to order
Installed By:	Elekta FSE Philips FSE

1 Details

The R5.8.1 software release introduces new protocols and new software to Unity. It includes new Compressed SENSE acquisition for faster acquisition in additional anatomical areas, consensus-based protocols for Head-and-Neck (H&N) and Pelvis, and new cine protocols to support Comprehensive Motion Management (CMM), including T2 cine protocols for better visualization of pelvic targets.

In addition, some of the changes in R5.8.1 will support the introduction of the new Philips scan control computer. Refer to the product release notes E070211.

The upgrade requires co-ordination between resources in Elekta Key market (Local FSE and MOSAIQ upgrade engineer), Philips Key Market (Local service) and the customer. See section 3 for more detail.

Elekta will need to purchase the upgrade from Philips but Elekta will not be charging the customer to upgrade at site.

This upgrade is targeted for release in April 2025.

2 Safety reference

Please refer to E070211 Release Notes for Unity MR 5.8.1 in CLM (and translated versions) and the Unity Instructions for Use. See sections 3.1 and 3.2 for details.

3 Procedure

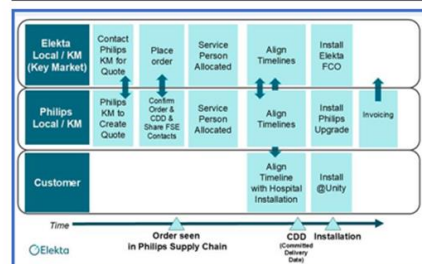
1. As a prerequisite the delivery device is required to have Comprehensive Motion Management (CMM) hardware and NRT version 2.1.1.0 before starting this upgrade.
2. For a system which has been shipped with 5.8.1 and having had the CMM upgrade to version 2.1.1.0 completed, it will be necessary to only order and install the Tacq patch (part number 1570735).
3. For a system that has been shipped with NRT version 2.1.2.0, it is not required to order and install the Tacq patch or any Instructions for Use (IFUs).
4. It is recommended that contact is established with the local Philips entity as a first step prior to raising a Purchase Order (PO) or booking a date for an upgrade to take place with a customer. In order to raise the PO assistance from local Commercial Team/Admin will be required.
5. Please ask your local Philips contact to raise a quote for the items required as follows:
 - NMRZ134. This is the R5.8.1 software upgrade for Marlin.
 - NMRF361, BASIC UPGRADE for MRL.
6. As part of the upgrade, Philips needs to provide a 5.8.1 specific label (identified by Philips code 989603083921 UPG L + SW 782126 Upg Marlin to R5.8 MD). Please be aware that this item has a 14 days lead time from the moment the PO is placed and therefore must be taken into consideration when planning the upgrade dates with Philips and the Customer.
7. The TAcq patch modification kit should be installed on NRT version 2.1.1.0 systems only, using the 1570969 Unity Control System 2.1.1.1 TAcq Patch Upgrade Manual.
8. Deviations from the released Service manuals (STW, DAT and CM) are detailed in 1571512 Addendum to Elekta Unity Setting to Work and Device Acceptance Tests for Philips Marlin R5.8.1.
9. Use the drawing(s) supplied and/or the installation instructions, follow the step-by-step instructions and implement the modification.
10. If applicable, place the modification instructions and FCO in the service documentation for a reference.
11. Make sure that all paperwork is completed in full and sent to the local Elekta Office and/or its representative, to add to the Configuration Database. In the cases where there has been a change to the configuration (e.g., a serialized part has been replaced or software version upgraded, etc.), the Elekta office must ensure that these changes are recorded in the relevant configuration database (CLM or other, as applicable).

3.1 Upgrade Activities RACI

Sequential Order	Task Duration (hrs)	Upgrade Activities	Elekta Service	Elekta Key Market	Elekta BL	MSQ Support	Clinical Training	Philips Service	Philips Key Market	Philips BL	Customer Clinical	Customer ICT Support
1	1	Release FCO Product Modification (Mandatory FCO)	I	I	R					A	I	
2	1	Order NRT SW Patch 2.1.1.1 NRT Patch > WO > DO > P/No 1570735	R	A	I							
3	1	Order IFU Kits WO > DO > P/No XXXXXXX	R	A	I							
4	0.5	Commercial Transactions - Contact Philips Key Market / Request Quote	R	C	A				C	I		
5	0.5	Commercial Transactions - Raise Philips Quote	C	C	I				R	A		
6	1	Commercial Transactions - Create / Submit PO (Follow Procurement Instructions)	R	C	A				C	I		
7	1	Schedule / Secure MOSAIQ resources	R	A	I	C						
8	2	Committed Delivery Date (CDD) by Philips Supply chain	C	C	I			C	A	R		
9	2	Align on upgrade timelines based on CDD	R	A		C		C	I		C	I
10	0.5	Install NRT Patch P/No 1570734 and update tracked IP in CLM	R	A	I						I	
11	2	Philips SW - System Backup > Config Backup > Install SW > Install SP & SecFix > Import Config	C					R		A	I	I
12	2	Philips SW - Install License File > Install ECDB > Network Config (manually Time Synchronization)	C			C		R		A	I	I
13	0.5	Customer to perform END TO END workflow (connectivity test with Philips console)	R			C		C			A	I
14	1	Philips SW - complete service work order issued for the task / install new label required as part of upgrade (physical kit needed alongside a new license file)	C			C		R		A	I	I
15	1	Philips SW - Export configuration > System Full Backup (task completion leadtime could vary from site to site)	A			C		R		A	I	I
16	1	Customer Training (e-Learning)	I	C	I		R				A	
17	1	Complete MR Upgrade paperwork (Philips / Prontoforms)	C	I	I			R	I	A	I	
18	1	Update CLM (WO details / IP Config)	R	A	I							

5.8.1 SP2 Rollout RACI

R - Responsible The group who take action to get the task done. They are responsible for the work or making the decision. To make the decision-making process effective, only one person responsible for a single task.	A - Accountable The group who owns the task or deliverable. They might not get the work done themselves, but they are responsible for making sure it is finalized. To avoid confusion and the diffusion of responsibility, only one accountable group per project task.
C - Consulted The group who will help complete the task. They will have two-way communication with the other responsible group for the task by providing input and feedback over the task completion.	I - Informed The group that need to be up to date on the task's progress. They will not have two-way communication, but it's essential to keep them informed since they will be affected by the final outcome of the task/project.



Preparation for Upgrade (hours)	10
On-site Upgrade Activity (hours)	8
Post Upgrade Activity (hours)	2

3.2 Supported Upgrade Configurations

Installed Base Baseline / IP		Post FCO 5.8.1 sp2 Upgrade	
CMM sites		CMM sites	
NRT	2.1.1.0	NRT	2.1.1.1
MOSAIQ	3.2.1.1 or 3.2.1.3 or 3.2.2	MOSAIQ	3.2.1 or 3.2.2
MONACO	6.2.1 or 6.2.2	MONACO	6.2.1 or 6.2.2
MR	5.7.1	MR	5.8.1



3.3 Requesting OIS support

This upgrade will require support from oncology information system (OIS). The method of contacting OIS support is region dependent.

1. For Regions REU and RTIMEA only, use the existing booking system to schedule OIS software specialist assistance for the DPPC and ECDB Upgrades. The URL is <https://ecscsequencerswaps.as.me/>. This is also available as a designated Teams channel to handle requests for Sequencer swaps and Unity Assistance in REU and RTIMEA:



< SELECT APPOINTMENT
Date & Time

APPOINTMENT



Unity Upgrade OIS Assistance with Unity Upgrades
4 hours

×

TIME ZONE: LONDON (GMT)

IN 8 WEEKS Monday Apr 7	IN 8 WEEKS Tuesday Apr 8	IN 8 WEEKS Wednesday Apr 9	IN 8 WEEKS Thursday Apr 10	IN 8 WEEKS Friday Apr 11
09:00	09:00	09:00	09:00	09:00
13:00	13:00	13:00	13:00	13:00

2. For all other regions, raise a case with the local ECSC resources in accordance with the local process.

3.4 Purchasing

Refer to document **E075509 5.8.1 Upgrade Purchase Order – Instruction for Creating a Coupa PO** for information on how to purchase the 5.8.1 upgrade from Philips.

3.5 Release Notes

The following translated release notes are available in CLM:

Files (20)

For more search options, go to Files.

Actions	Name	Owner	Last Modified
	E070211_02 Release Notes for Unity MR R5.8.1	Shibu John	21/01/2025
	E070211_Release Notes for Unity MRI R5.8.1	Shibu John	15/02/2024
	E070211-02-PL_01 Release Notes - Polish	Neil Henderson	10/01/2025
	E070211-02-ES_01 Release Notes - Spanish	Neil Henderson	10/01/2025
	E070211-02-DA_01 Release Notes - Danish	Neil Henderson	10/01/2025
	E070211-02-CS_01 Release Notes - Czech	Neil Henderson	10/01/2025
	E070211-02-SR_01 Release Notes - Serbian	Neil Henderson	10/01/2025
	E070211-02-FR_01 Release Notes - French	Neil Henderson	10/01/2025
	E070211-02-PT_01 Release Notes - Portuguese	Neil Henderson	10/01/2025
	E070211-02-KO_01 Release Notes - Korean	Neil Henderson	10/01/2025
	E070211-02-KK_01 Release Notes - Kazakh	Neil Henderson	10/01/2025
	E070211-02-ZH_01 Release Notes - Chinese (Simplified)	Neil Henderson	10/01/2025
	E070211-02-IT_01 Release Notes - Italian	Neil Henderson	10/01/2025
	E070211-02-TR_01 Release Notes - Turkish	Neil Henderson	10/01/2025
	E070211-02-RU_01 Release Notes - Russian	Neil Henderson	10/01/2025
	E070211-02-JA_01 Release Notes - Japanese	Neil Henderson	10/01/2025
	E070211-02-SV_01 Release Notes - Swedish	Neil Henderson	10/01/2025
	E070211-02-DE_01 Release Notes - German	Neil Henderson	10/01/2025
	E070211-02-LT_01 Release Notes - Lithuanian	Neil Henderson	10/01/2025

3.6 Instructions for use (IFU) kits to order

For sites that are clinical with CMM/2.1.1.

IFU Kit	Part Number
MRT 44310, UNITY 2.1.1 CIFU (CMM) ENGLISH	1574952
MRT 45040, UNITY,R2.1,ESAB,FRENCH, LOC KIT	1574255
MRT 45050, UNITY,R2.1,ESAB,GERMAN, LOC KIT	1574256
MRT 45060, UNITY,R2.1,ESAB,ITALIAN, LOC KIT	1574257
MRT 45110,UNITY,R2.1,ESAB,SPANISH, LOC KIT	1574262
MRT 45120, UNITY,R2.1,ESAB,SWEDISH, LOC KIT	1574263
MRT 45030, UNITY,R2.1,ESAB,DANISH, LOC KIT	1574254
MRT 45070, UNITY,R2.1,ESAB,JAPANESE, LOC KIT	1574258
MRT 45080, UNITY,R2.1,ESAB,KOREAN, LOC KIT	1574259
MRT 45090 ,UNITY,R2.1,ESAB,LITHUANIAN, LOC KIT	1574260
MRT 45100, UNITY,R2.1,ESAB,POLISH, LOC KIT	1574261
MRT 45130, UNITY,R2.1,ESAB,TURKISH, LOC KIT	1574264

For sites that are upgraded to 2.1.1 but not clinical with it yet (pending MSQ/Monaco upgrades) but will use the machine with 5.8.1 installed.

IFU Kit	Part Number
MRT44320,UNITY 2.0.3 CIFU (Non CMM) ENGLISH	1574953
MRT 44560, UNITY IFU R2.0.3, FRENCH	1574357
MRT 44570, UNITY IFU R2.0.3, GERMAN	1574358
MRT 44580, UNITY IFU R2.0.3, ITALIAN	1574359
MRT 44630,UNITY IFU R2.0.3, SPANISH	1574364
MRT 44640, UNITY IFU R2.0.3, SWEDISH	1574365
MRT 44550, UNITY IFU R2.0.3, DANISH	1574356
MRT 44590, UNITY IFU R2.0.3, JAPANESE	1574360
MRT 44600, UNITY IFU R2.0.3, KOREAN	1574361
MRT 44610,UNITY IFU R2.0.3, LITHUANIAN	1574362
MRT 44620, UNITY IFU R2.0.3, POLISH	1574363
MRT 44650, UNITY IFU R2.0.3, TURKISH	1574366

3.7 UDI Labes

New UDI labels are not required for this release.

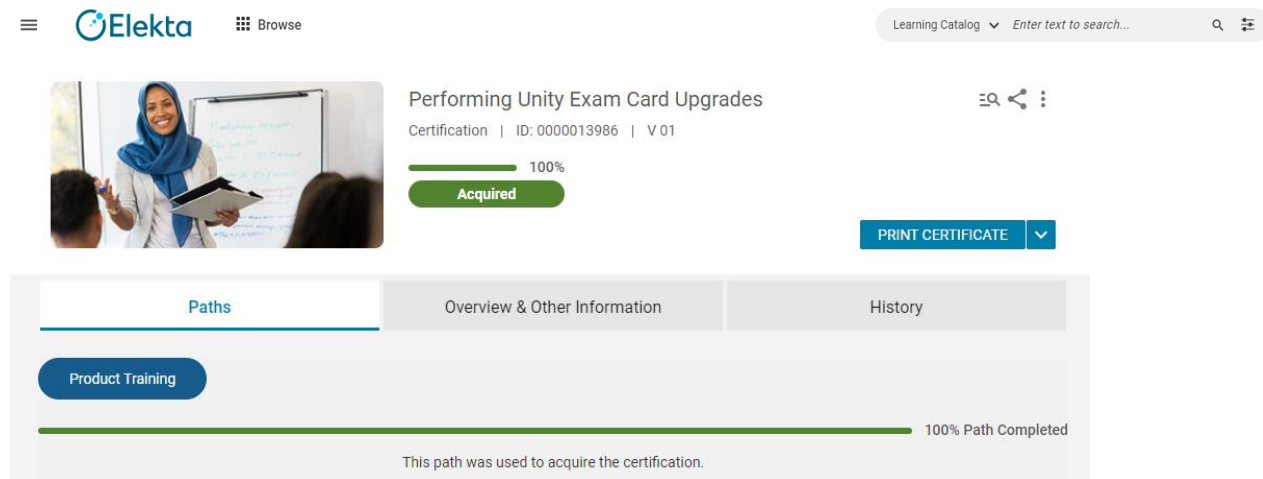
3.8 Training

3.8.1 Elekta Engineers Training

Learning for linking the MOSAIQ ECDB (Exam Card Database) with the Philips ECDB and generation of the two report files is available in the Elekta LMS (Learning Management System).

The module is **30 minutes** in duration and applicable to all compatible versions of MOSAIQ.

Search for **Performing Unity Exam Card Upgrades** under keywords in the Learning Catalog search.



The learning module contents are:

- Introduction: What are we doing and why?
- Performing the ECDB Update: Process
- Performing the ECDB Update: Recording
- Next Steps
- Assessment

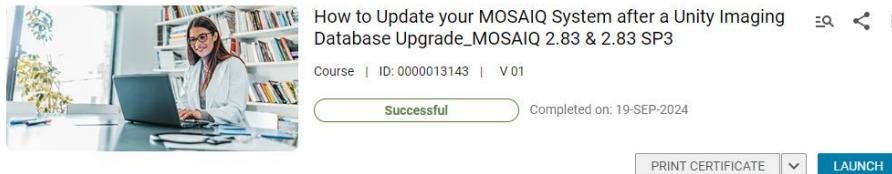
3.8.2 Customer Training

Training from Elekta

After the new 5.8.1 exam cards have been installed, the service engineer will hand the customer two report files. The clinical user (Customer) will have to make the necessary changes in the MOSAIQ system. There is a learning module that explains the process.

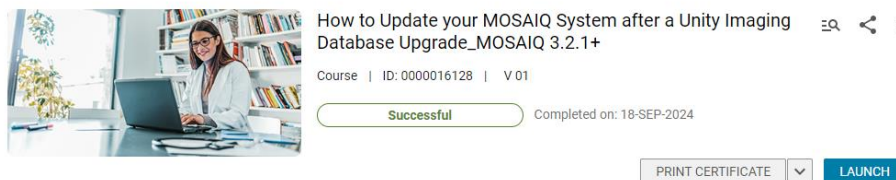
There is a different learning module for each release of MOSAIQ:

- **How to Update your MOSAIQ System after a Unity Imaging Database Upgrade_MOSAIQ 2.83 & 2.83 SP3**



- This is a short **5-minute** video to show the customer how to update the system.

- **How to Update your MOSAIQ System after a Unity Imaging Database Upgrade_MOSAIQ 3.2.1+**



- This is a **16-page** document to show the customer how to update the system.

Training from Philips

The product training modules are:

- **What's new in Release 5.8.1**
 - Overview of new features in Release 5.8.1
 - Fat suppression for Unity
 - Using 3D geometric correction for 2D scans
- **Introduction of Release 5.8.1**
 - Quality Assurance procedures for the Unity MR system
 - MR imaging with Unity MR system

They are in the Philips learning center.

<https://www.philips.com/learn>

The enrolment keys to access the modules are in a PDF document contained in this Elekta learning module:

Accessing Philips Self Directed Learning Modules

[Back](#)



Philips for Unity

Course | ID: 0000013966 | V 01

Successful
Completed on: 11-SEP-2024

PRINT CERTIFICATE

▼

LAUNCH

Progress and Activities

Overview & Other Information

History

English | Self-Training Paper | Class ID: 0000003499

0 ECL

Total duration: 00:10 Hrs

Activities



Accessing Philips Self Directed Learning Modules

Completed on: 11-SEP-2024




Completed

VIEW RESULTS ▼

Course name	Enrolment key
MRT What's New in Marlin 1.5T, Release 5.8.1	6548cc6bf1ccd
MRT Introduction to the Marlin 1.5T, Release 5.8.1	654b4625b6c24

Welcome, Asif

Add Enrollment Keys

Search enrolled learning

Click the **Add Enrolment Keys** button or scroll to the bottom of the page.

Add enrollment keys

Insert the enrollment key to add a course to your list

Submit

Add the applicable enrolment keys to access the online learning modules.

Further learning modules are available in the Philips learning system.

3.9 CLM updates to system configuration

Upon completion of Upgrade, the following Item parts are to be created or Updated in CLM for the given customer & system configuration:

To track the 5.8.1 sp2 MR Module SW upgrade in CLM, please update the FCO line Work order with either of the installed parts applicable, depending on your system's region (IB Global or IB region China).					
	Item Parts to TRACK in CLM (Upgrade to SW 5.8.1)	Part Description	previously Existing Part number	Create Dummy IP	Replace 'Dummy IP' or 'existing IP' with this 'new IP'
1	With 5.7.1 as a pre-requisite part should exist in most sites across the installed base	MRT 44000 UNITY MR IMAGING SW VER 5.8.1	1556057	Not required	1573102 Update the sub-versions field
Or					
2	With 6.1.571 as a pre-requisite this part should exist in Region China installed sites	MRT 44010 UNITY MR IMAGING SW VER 6.1.581	1567593	Not required	1573103 Update the sub-versions field
To track the NRT SW 2.1.1.1 upgrade in CLM > order P/No 1570735 via DO > update IP in WO > Close WO					
	Item Parts to TRACK in CLM (NRT Patch Upgrade)	Part Description	previously Existing Part number	Create Dummy IP	Replace 'Dummy IP' or 'existing IP' with this 'new IP'
3	With CMM Rollout this part should exist in most sites	UNITY NRT SOFTWARE Version 2.1.1.1	1568942	Not required	1570735 Update the sub-versions field

Product Modification Acknowledgment

The installing engineer is required to complete the details in the boxes below and sign the document to confirm completion or obtain the customer's signature in the refusal section, in the event the corrective action is refused. Please return this report to the local Elekta Office or its Representative.

Classification:	Product Modification	FCO Ref:	200-06-801-032
Description:	Upgrade of Philips MR system from 5.7.1 to 5.8.1 Upgrade of NRT from 2.1.1.0 to 2.1.1.1		
Scope:	Unity NRT Software Version 2.1.1.0		
Hospital:			
Device Serial No(s): (e.g. linac, if applicable)		Location or Site No.:	
Action on this unit/device was (<i>select one</i>): ☐ Completed as per instructions on (date: day/month/year): ☐ Not completed, because (<i>give reason</i>): ☐ Not completed, because the unit/device is in storage (<i>if applicable</i>): ☐ Refused by customer, because (<i>give reason</i>):		Note: If you use a work order in the CLM configuration database, you do not have to complete this section. The work order will be used to add the information to the system.	
Modification not Completed / Refused by customer because: This section is to be completed by the customer. Reason: Name: _____ Title: _____ Signature: _____ Date: _____			
Acknowledgement by installing engineer: This section is to be signed by the installing Elekta representative or a hospital employee. Name: _____ Title: _____ Signature: _____ Date: _____			