

PHILIPS HEALTHCARE

Trainee Name:	
Trainee Signature:	
Date:	

Course Title	Local Course Code	Revision
PCCI Service Installation Reporting Process	5104-0271	E

By submitting this form, I agree that I have completed the required training for this course and understand the material and the impact on my job responsibility.

Signed by 3rd Party Contractor Training Representative:

_____ Date: _____

This form is to be kept as a formal training record by the 3rd Party Contractor Agency

PHILIPS PHNA

Document Number: 5104-0271 E
Title: PCMS Service Installation Reporting Process
Effective Date: See PDM

Approvals:	Title	Name	Date
Process Owner:	Project Manager 5	Wallace Ervin	See PDM
Designated User(s):	Director, Regulatory Affairs	Althea Lawrence	See PDM
	Director, Business Operations	Robert Seifert	See PDM
	Director, PCMS Project Management	Craig Beason	See PDM

Note: The Process Owner and Designated User names are here for reference only and may not be current. See PDM for the current Process Owner and Designated User names.

This document and the information contained in it is proprietary and confidential information of Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips"). Use, duplication, modification, and disclosure of it by unauthorized persons is strictly prohibited and subject to the restrictions, if applicable, set forth in a confidentiality agreement with Philips.

Rev	Major / Minor	Description
E	Major	Added Canada to scope. Section 3.2 MDIR requirements; acceptance criteria as it differentiated between the US and Canada.
A – D	Major	See PDM History

1.0 PURPOSE AND SCOPE

1.1 Purpose This process describes the methods used by Philips authorized Installers (either Philips Field Personnel or authorized 3rd party Subcontractors) to complete the Performance Assurance Tests via the Performance Assurance (PA) Tool and create the data required to document proper installation, as required by the government Regulatory Agencies (FDA or Health Canada).

1.2 Scope In Scope: This process applies to installations in the United States and Canada of PCMS products that require installation, as defined by the Business Innovation Unit (factory). The installations are completed according to the installation instructions provided by the Business Innovation Unit available in the published service manuals. This process describes actions taken by the Installer to compile, record and submit the data that will become the Installation Report (IR). The Installation Report is comprised of the PA test results and the Installation Service Work Order.

Out of Scope: This process does not address revenue recognition or the management of Test and Inspection (T&I) matrices and does not apply to the following product lines:

OBTV except Fetal Monitors, DECG, ECS except where it is a networked solution.

2.0 EXPLANATION OF KEY TERMS

BIU	Business Innovation Unit (factory)
CFC	Customer Fulfillment Center, a centralized order desk (formerly the Business Center)
DECG	Diagnostic Electrocardiography
DEFOA	Defect on Arrival – Defective equipment/or missing in shipment
ECS	Emergency Care Solutions
Installer	Any individual, whether a Philips employee or an authorized 3 rd party Subcontractor who performs the actual installation of the Philips equipment.
IR	<p>Installation Report as described in this document meets government Regulatory Agencies (FDA / Health Canada) and PNA requirements for documentation of proper installation. The IR confirms that the equipment has been installed and is performing in accordance with the performance specifications for the equipment.</p> <p>In One Mobile, the IR data is generated from both the PA tool application and the PA- related Service Order.</p>
MDIR	<p>Medical Device Installation Record: This is the revenue recognition document that must be Used to obtain customer acceptance of the installation, when appropriate.</p> <p>For determination and application of the MDIR, consult with the Dir., NCC or PCMS Sector Controller.</p>

NCC	National Competency Center
OBTV	OB TraceVue
ONE MOBILE	Work Order Management: ONE MOBILE is a tool that chronicles work activity types and times.
OMS	Order Management Specialist
PA	Performance Assurance: The PA tool is independent of the ONE MOBILE application. The PA tool contains the device - specific automated test and inspection requirements as defined by the Business. The PA module also interfaces with our deployed test equipment and accepts the test results from a variety of testing devices (e.g. Fluke 620, volt meters, etc.), where applicable.
PHNA	Philips Healthcare North America
Planner	Dispatcher of the installation Service Work Order from Alpharetta back office support.
PM	Project Manager - The Philips employee responsible for an installation. The Project Manager oversees all installation activities, whether they are performed by Philips employees or 3 rd party Subcontractors. The Project Manager could be an Installation Team Leader, a Project Manager, a Project Consultant, a Field Service Engineer, Technical Support Engineer, Technical Consultant or Network Engineer, etc. Hereinto referred to as the Project Manager or PM.
QSP	Qualified Service Provider: This could be a Philips employee or an authorized 3 rd party Subcontractor.
Regulatory Agencies	US Food and Drug Administration or Health Canada
SAP	System Applications and Products an Enterprise Resource Planning (ERP) software used by Philips
SWO	Service Work Order. An SAP generated electronic document that records time and activities.
T & I	Test and Inspection, or test and inspection data. The Businesses define and manage the installation T& I requirements for each medical device and transfer them to the PA tool via template format.
VAS	Value Added Services

3.0 INSTALLATION REPORTING PROCESS

3.1 Security

When using OneMobile on a laptop, the user must have the computer configured to 'time-out' after a 15-minute period of inactivity. Users must not share user names and/or passwords in order to prevent falsification of records.

3.2 MDIR Requirements

If the order has a Net Value of \$250K USD or greater in the United States, both customer signature and Philips representative signature is required. In Canada both customer and Philips representative are required to sign the MDIR where the value exceeds 250K CDN. An exception exists for Canada: if there is a delayed acceptance clause in the order, the customer signs the MDIR regardless of value. Delayed acceptance is unique to Canada.

- All Lease and Government orders require a customer / Philips signed MDIR.
- Delinked Orders: (Not applicable to Lease / Government orders)
 - Defined as: Single customer P.O. broken into multiple sales orders.
 - Any customer P.O. broken into multiple sales orders will be automatically linked by the Customer Fulfillment Center (CFC) for coordinated revenue recognition. To unlink a sales order, a request must be made to CFC Invoicing and Finance for review and approval, to ensure there are no inter-dependencies between sales orders and to ensure the customer intentions are being fulfilled as ascribed by the order.
 - **Approved 'unlinked' orders will require the Philips Installation Field Service Engineer or Philips Project Manager to sign the MDIR form, when the Sales Order value is under \$250K USD. *The customer signature is no longer required on the MDIR for delinked orders when the combined value of all orders on the MDIR is under \$250K USD.***
- Notification of closure of any order, with or without a MDIR, must be sent via email to the OMS by the Philips FSE or Philips PM indicating installation is complete.
 - **Prior to closure of any order, a full and successful completion of the BIU T&I and CAV (for telemetry systems) must occur.**
- The closure notification and customer's signed MDIR must be submitted to the OMS via attachments in an email, sent to na_invoicing_team@philips.com
- Any questions regarding the requirement for a MDIR should be directed to the OMS.

- Problem resolution regarding MDIRs should be directed to the Director of PCMS Project Management, and/or Sector Controller.

3.3 Installation Process Responsibility

The Sr. Managers, Installation Operations (US) from Commercial Operations and Region Service Managers from Customer Services (US and Canada) do not typically participate directly in installations, however, they are responsible for ensuring that all required installation activities and processes are executed in their assigned territories. The PHNA PCMS Commercial Operations Project Management team and the PCMS Customer Services Organization are responsible for the implementation business, associated processes, and to ensure the organization is adhering to the process.

The PM works directly with the Region Service managers to identify the number and timing of installation resources required, and to identify for every project a lead installation FSE who is responsible to ensure completion of the test and inspection (which is comprised of the PA test results).

Prior to closing an installation SWO, the lead installation FSE confirms that all required installation related activities, including test and inspection, have been completely executed and documented in the PA tool and OneMobile. The lead install FSE will email the project manager and order management specialist the day of installation completion. This Installation Reporting process requires that the data comprising the IR be submitted to SAP within 5 business days of Actual Install Complete Plan date.

If an installation SWO is assigned and the employee does not participate in the installation, the employee needs to add external comments in OneMobile “I did not participate in the installation.”

3.4 Installation Report Contents

The Installation Report [IR] provides the record of proper installation. Any Installer who installs Philips Medical Equipment that requires installation must complete all the data requirements for an IR. The Business Innovation Unit determines which products require installation and associated Test and Inspection protocols.

The IR contains, at a minimum:

- Sales Order number [Only one Sales Order per Service Order]
- Where installation was completed [customer name and address]
- The name of the Philips Project Manager responsible for the installation
- Who performed the installation [name(s), Organization [if using only external installation resource(s)]]
- What was installed, including system/device numbers and product numbers with corresponding serial numbers
- Date the installation was completed

- PA – to record test and inspection results for the product / system for the specific sales order installed. The PA results must conform to the specifications specified by the business unit.

3.5 Installation Report Record Creation

The data elements that comprise the Installation Report are captured by the Installer in the PA tool, then synchronized/stored in SAP attached to the service work order. The Installation Report record will be pulled from SAP.

To create the Installation Report, the Installer must ensure that:

- The inventory is scanned or downloaded into the PA tool and delta report verification is completed
- Serial numbers are verified against the inventory.
- Test and inspections are completed, passed, and recorded in the PA tool (see sections 3.7 and 3.8 for exceptions).
- PA will have been completed during the process of the installation, and will be done no later than five days post Actual Install Complete date.

Once the IR information is completed and synched with SAP it becomes a record and cannot be changed. Any needed changes or additions to IR data must be accomplished by opening a new service order operation. The Installer must:

- open a new service order operation associated with the sales order number being installed,
- add or update the necessary information in the PA module,
- synchronize with SAP

3.6 If the Installer (3rd party resource) performs the test and inspection and Does NOT Have Access to the PA tool:

Flagging of the SWO with the activity code “PA by other FSE”, and use of the External Comments field in OneMobile by the PM to reflect who actually completed the T&I. The information needed is:

- Test and Inspection Work Done By (WDB)
- Name and 3rd Party Company or Philips employee Name
- Date the tests were performed. For example: [WDB: John Doe, ACME Installers, 1/13/2008].
- OMS will create the attestation template and forward to the PM.
- PM will forward to the assigned third party resource for completion.
- Third party resource will complete the test and inspection and sends signed completed 3P Installation Certification Form to the PM.
- PM verifies attestation template for signature and date of completion.
- PM sends completed, signed shipment list template with closure notification to the OMS.
- OMS sends closure notification with signed shipment list template to the business center for storage in Filenet.

3.7 If No Service Order Is Found In ONE MOBILE

If no Service Order is preloaded, then the Philips Project Manager must request the Planner to create an Installation Service Order. Once created, the Installer will scan the inventory into the PA tool and complete the PA template.

3.8 If Installable Equipment Was Never To Be Installed by Philips

If the Sales Order was defined as “customer installable” or “no installation required” an installation SWO will NOT have been created and the customer assumes all responsibility to ensure the device is operating according to specifications.

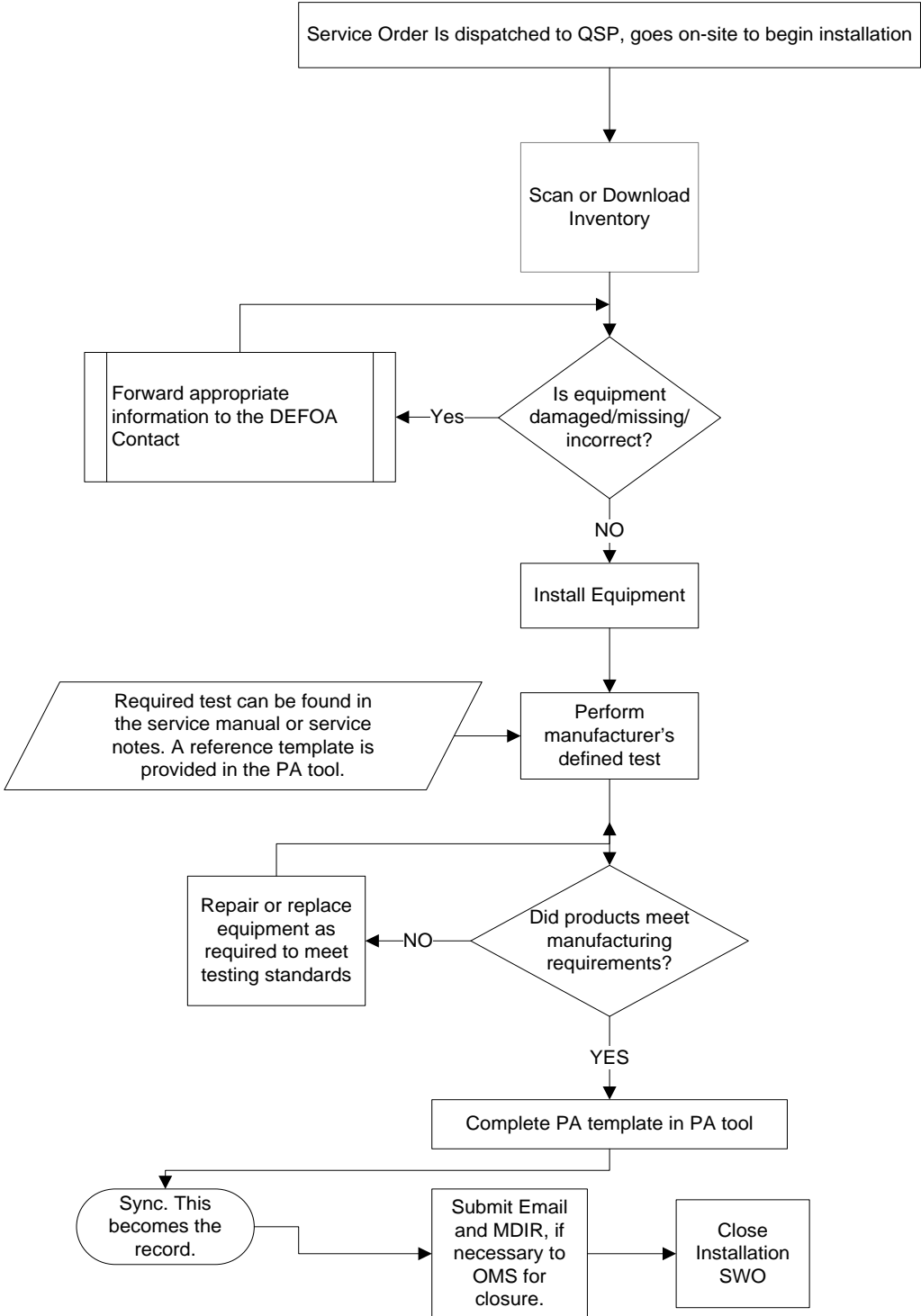
3.9 If Equipment Was To Be Installed by Philips But Something Has Changed

If the Sales Order was scheduled as a Philips planned installation and the customer releases Philips from the installation responsibility, the PM must ensure that the following actions occur, regardless of who was to perform the installation (Philips employee or 3rd party Subcontractor):

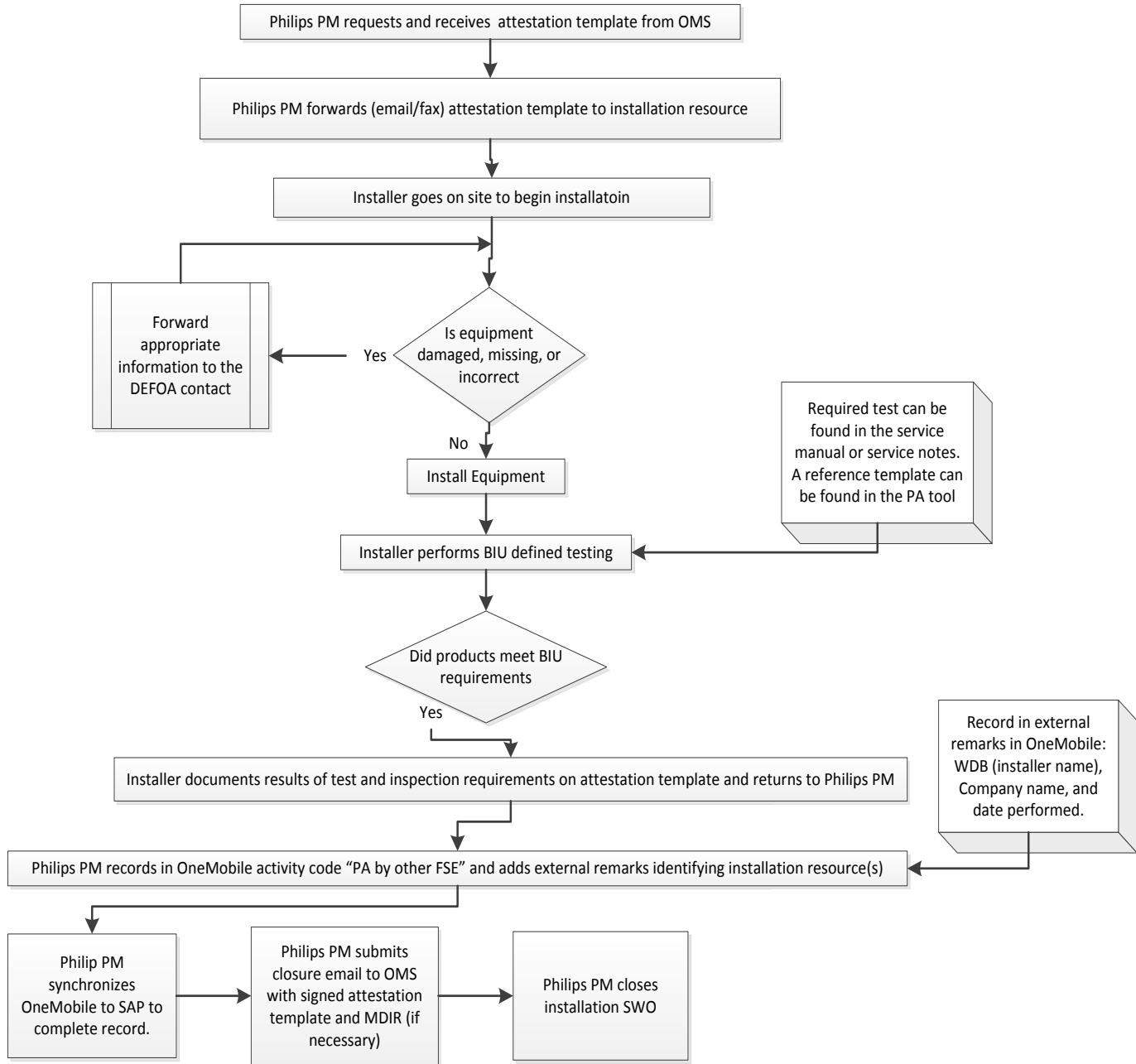
- Open the appropriate installation SWO.
- In the ONE MOBILE, choose “Executed by customer” in the “None PA Reason” field.
- Refer to Section 3.2 MDIR Requirements for completion of the MDIR.
- All MDIR forms must be submitted by either the PM or Installer to the OMS (Order Management Specialist) for review and triggering order closure with comments in the email indicating the installation is complete. The MDIR is submitted by the OMS to the Business Center Invoicing Team and vaulted by the Business Center.
- Complete SWO and synchronize with SAP.

3.10 Installation Process Overview

The following flowcharts provide an overview of the standard installation process, of which capturing the Installation Report data is a part.



Scenario 2 | Installer has neither OneMobile nor access to the Philips intranet



4.0 METRICS

This Installation Reporting process requires that the data comprising the IR be submitted to SAP within 5 business days of Actual Install Complete Plan date.

To monitor compliance with this requirement, a monthly report will be extracted from SAP and distributed to Installation Management. The ONE MOBILE / PA IR compliance report will contain:

ITEM	DESCRIPTION
SON	Sales Order Number
Region Work Center	Will allow linkage between the installation and the responsible Sr. Manager Installation Operations in the US or Region Service Manager in Canada
PA module date	Confirms that T&I was completed.
PA SWO closure date	The date the IR was closed in ONE MOBILE.
PA SWO SAP synch date	The date the IR information was submitted to SAP. This date ends the "5 business day" clock.

*****END OF DOCUMENT*****