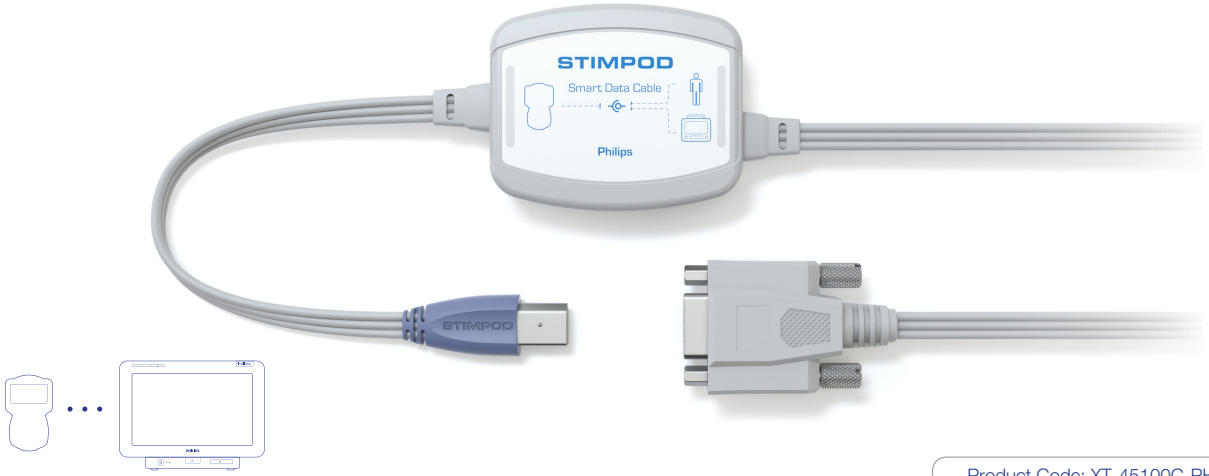
STIMPOD NMS 450X

Instructions for Use:
Smart Data Cable Philips

X-AVANT TECHNOLOGY



Connect a STIMPOD NMS450X to a Philips IntelliVue Patient Monitor

Product Code: XT-45100C-PHI	
CE 1639	XM400-21SA04-01


STIMPOD
NMS 450X
Simple. Economical. Complete.

Contents:

1. Introduction 1
2. Instructions for Use 1
2.1. Connection & Interface Protocol Configuration 1
    2.1.1 Philips IntelliBridge Interfacing Components 2
    2.1.2 Xavant Smart Data Interfacing Components 3
    2.1.3 Setup & Configuration Instructions 4
2.2 Compatibility 5
    2.2.1 Philips Compatibility Requirements 5
    2.2.2 Xavant Compatibility Requirements 7
2.3 List of Labels 8
2.4 Data Mapping 9
    2.4.1 Common Data Parameters 9
    2.4.2 TOF Mode 10
    2.4.3 DB Mode 12
    2.4.4 PTC Mode 14
    2.4.5 Alerts 16
2.5 Regulatory 17
    2.5.1 Regulatory Symbols 18
    2.5.2 Regulatory Detail 19

List of Figures:

Figure 1: Connecting the Stimpod NMS 450X to a Philips Patient Monitor with an Intellibridge Interface 1
Figure 2: Philips IntelliBridge Interfacing Components 2
Figure 3: Xavant Smart Data Interfacing Components 3
Figure 4: TOF Stimulation Sequence 11
Figure 5: TOF Data Mapping 13
Figure 6: DB Stimulation Sequence 13
Figure 7: DB Data Mapping 14
Figure 8: PTC Stimulation Sequence 15
Figure 9: PTC Data Mapping 16

List of Tables:

Table 1: Required Philips IntelliBridge Interfacing Components 2
Table 2: Required Xavant Component Parts 4
Table 3: Compatibility Requirements for Connection to Philips IntelliVue Patient Monitor 6
Table 4: Compatibility Requirements for Direct Connection to Philips IntelliBridge System/PIC iX 7
Table 5: Xavant Compatibility Requirements 8
Table 6: List of Data Fields Sent to the Philips Patient Monitor 9
Table 7: Mapping: NMS 450X Warning Messages to Alerts Displayed on the Patient Monitor 17
Table 8: Mapping: Smart Data Cable Warning Messages to Alerts Displayed on the Patient Monitor 18

STIMPOD NMS 450X | Smart Data Cable Philips

1. Introduction

This document provides detailed instructions on how to connect the STIMPOD NMS450X of Xavant Technology to a Philips Patient Monitor with an IntelliBridge open interface.

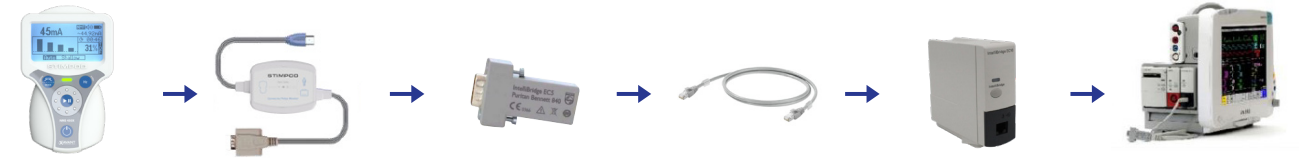
The document, furthermore, provides a detailed description of the NMT data and alarms that are available for display and storage on the monitor once connected.

2. Instructions for Use

2.1 Connection and Interface Protocol Configuration

Several component parts are required to successfully connect the STIMPOD NMS450X to a Philips Patient Monitor with an IntelliBridge interface, as illustrated in the schematic representation of Figure 1 below:

Figure 1: Connecting the Stimpod NMS 450X to a Philips Patient Monitor with an Intellibridge Interface



Xavant
STIMPOD NMS 450X

Xavant
Smart Data Cable Philips

Philips EC5
RS232 Cable Adaptor

Philips
Connection Cable

Philips EC10
Device Interfacing Module

Philips
IntelliVue Patient Monitor

2.1.1 Philips IntelliBridge Interfacing Components

The Philips IntelliBridge interface consists of two component parts (1) an EC10 device interfacing module that is plugged into the patient monitor itself, and (2) an EC5 cable adaptor that allows for an RS232 or ethernet connection to a patient care device such as the STIMPOD NMS450X.

Within the context of Figure 1 and Figure 2, the following IntelliBridge interfacing components shall be required in order to connect the STIMPOD NMS450X to a compatible Philips Patient Monitor:

Figure 2: Philips IntelliBridge Interfacing Components

Table 1: Required Philips IntelliBridge Interfacing Components

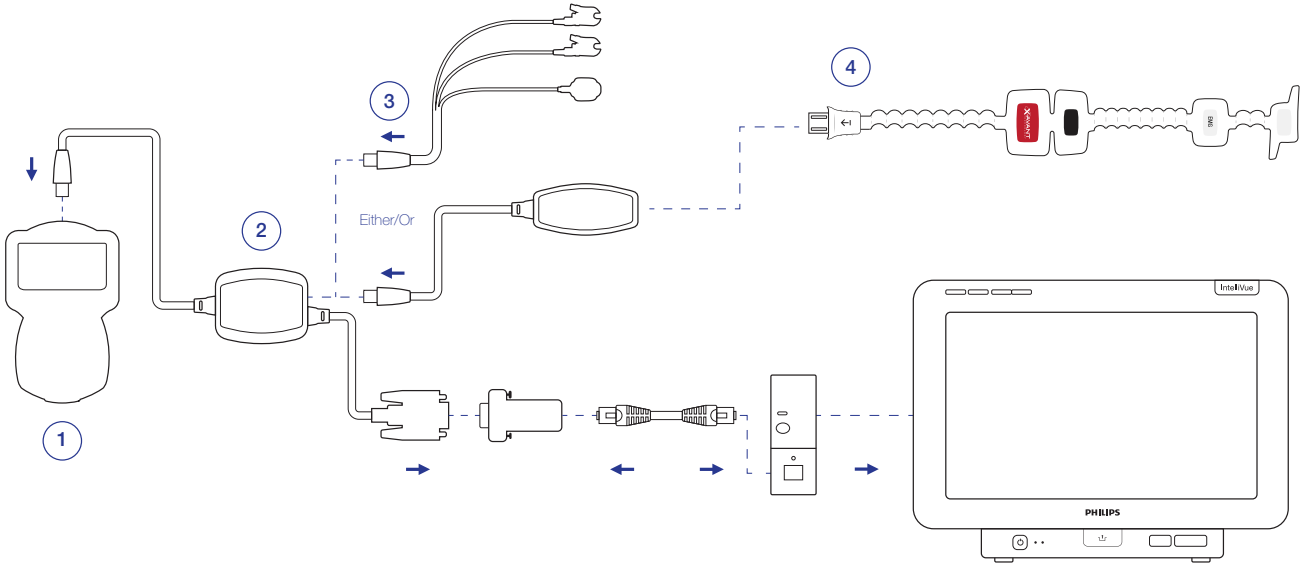
Data Cable Part Numbers			
Name	**Part No**	**Option #**	**Connector**
IntelliBridge EC10	865115	101	Open interface driver
IntelliBridge EC5	865114	101	DB9 Male

2.1.2 Xavant Smart Data Interfacing Components

The STIMPOD NMS450X is a self-powered handheld device that makes provision for a single firewire port for connectivity to an NMT Monitoring Cable. Under standard operating conditions and in the absence of a patient monitor, the NMT Monitoring Cable is ordinarily inserted directly into the firewire connector.

In order to connect the STIMPOD NMS450X to a Philips Patient Monitor with an IntelliBridge Open Interface, however, the Xavant manufactured Smart Data Cable Philips must be used as illustrated in Figure 3:

Figure 3: Xavant Smart Data Interfacing Components



Within the context of Figure 1 and Figure 3, the following component parts from Xavant shall be required in order to connect the STIMPOD NMS450X to a compatible Philips Patient Monitor:

Table 2: Required Xavant Component Parts

No.	Item Description	Product Code
1	STIMPOD NMS450X - Peripheral Nerve Stimulator	XT-45000
2	Smart Data Cable Philips IntelliBridge with RS232 Interface	XT-45100C-PHI
3	NMT Monitoring Cable: AMG (1.8m, 3.5m) NMT Monitoring Cable: EMG (1.8m, 3.5m)	XT-45025, XT-45025A XT-45003, XT-45003A
4	EMG Electrode Large	XT-45009L

2.1.3 Setup & Configuration Instructions

With all devices switched off, follow the steps below to connect the STIMPOD NMS450X to the Philips patient monitor:

1. Insert the male firewire connector of the Smart Data Cable Phiips into the firewire socket of the STIMPOD NMS450X.

2. Insert the male firewire connector of the NMT Monitoring Cable into firewire socket of the Smart Data Cable Philips.

3. Plug the DB9 female connector of the Smart Data Cable Philips into the DB9 male connector of the EC5 RS232 cable adaptor of the Philips Patient Monitor.

4. Connect the RJ45 ethernet plug of the EC5 RS232 cable adaptor into the RJ45 socket of the EC10 interfacing module of the Philips Patient Monitor.

5. On Power up, the Philips Patient Monitor shall initiate a communications session that the Smart Data Cable Philips shall respond to – this occurs by default, and no additional settings are required for the STIMPOD NMS450X to start sharing data with the Patient Monitor.

2.2 Compatibility

2.2.1 Philips Compatibility Requirements

The compatibility requirements for the Philips manufactured devices necessary for successful integration with the STIMPOD NMS450X, is presented in Table 3 and Table 4 below:

Table 3: Compatibility Requirements for Connection to Philips IntelliVue Patient Monitor

Philips Product	Interfacing Hardware Required	Other Requirements
Patient Monitor	IntelliVue MP50 to MP90 or IntelliVue MX400 to MX850	S/W Version H.15 or Higher or All S/W Versions
IntelliBridge Interface	IntelliBridge EC10 Module PN 865115 opt A01,101 or EC10 Integral I/F Board (MX400-MX550 opt J32 only)	Open Interface Driver Version A.6 or Higher
IntelliBridge EC5 ID Module	PN 865114 opt 101	
Connection Cables	PN 865114 opt L01 Connection Cable 1.5m PN 865114 opt L01 Connection Cable 3.0m PN 865114 opt L01 Connection Cable 10m or PN 865114 opt L00 Client Supplied Cable	LAN CAT5 or Better, Max 10m Length

Table 4: Compatibility Requirements for Direct Connection to Philips IntelliBridge System /PIC iX

Philips Product	Interfacing Hardware Required	Other Requirements
Patient Information Center	Philips PIIC iX with opt DEV, or Philips PIC iX with opt DEV	S/W Version B.0, or S/W Revision C.0 or Higher
IntelliBridge Interface	IntelliBridge EC40 Hub PN 865056 opt H04, or IntelliBridge EC80 Hub PN 865056 opt H08	Open Interface Driver Version A.6 or Higher
IntelliBridge EC5 ID Module	PN 865114 opt 101	
Connection Cables	PN 865114 opt L01 Connection Cable 1.5m, PN 865114 opt L01 Connection Cable 3.0m, PN 865114 opt L01 Connection Cable 10m, or PN 865114 opt L00 Client Supplied Cable	LAN CAT5 or Better, Max 10m Length

2.2.2 Xavant Compatibility Requirements

The compatibility requirements for the Xavant devices necessary for successful integration with a Philips patient monitor via an IntelliBridge Open Interface, is presented in Table 5 below:

Table 5: Xavant Compatibility Requirements

Xavant Product	Interfacing Hardware Required	Other Requirements
Stimpod NMS450X	Smart Data Cable Philips	NMS450x Software Version: v10.x or greater.
Smart Data Cable Philips	DB9 Female RS232 Data Connector	Smart Data Cable Software Version: v3.x or higher

The STIMPOD NMS450X must be running embedded software version 10.x or greater for successful integration with a Philips patient monitor over an Intellibridge Open Interface.

To find the software version of a STIMPOD NMS 450X device, turn it off and then on again. The software version will be displayed momentarily on the LCD screen just below and to the right of the Xavant logo.

For more information on the STIMPOD NMS450X please refer to the Instructions for Use (IFU) – Xavant Document Reference [XT-45006-EN] which can be downloaded from the following url:

www.xavant.com/docs

2.3 List Of Labels

The list of data parameters sent by a STIMPOD NMS450X when it is successfully integrated with a Philips Patient Monitor over an IntelliBridge Interface, is provided in Table 6 below:

Table 6: List of Data Fields Sent to the Philips Patient Monitor

Parameter Label	Description	MDIL Text ID	MDC Code	Default	Range	Unit
TOFrat	Ratio of the 4th pulse to the 1st pulse.	0002-f897	151780	Yes	0-999	%
TOFcnt	Number of TOF pulses which caused a detectable twitch.	0002-f8ab	194731	Yes	0-4	Unitless
PTC	Number of post tetanic pulses which caused a detectable muscle twitch.	0002-f88b	194699	No	0-20	Unitless
DBS	Response value of a double burst sequence.	Custom 1	-	No	0-999	Unitless
TOF1	1st TOF pulse response value	0002-f8a7	194727	No	0-500	Unitless
TOF2	2nd TOF pulse response value	0002-f8a8	194728	No	0-500	Unitless
TOF3	3rd TOF pulse response value	0002-f8a9	194729	No	0-500	Unitless
TOF4	4th TOF pulse response value	0002-f8aa	194730	No	0-500	Unitless
Set mA	Current to deliver to the patient.	Custom 1	-	No	0-80	mA
Act mA	Measured current delivered to the patient.	Custom 1	-	No	0.0-99.9	mA
sMode	Current NMT mode of the Stimpod	Setting	67303669	No	-	-

Note 1: Parameters labels marked as “Custom” cannot be trended on Philips IntelliVue monitors and have no steady code assignment in the Philips PIC iX HL7 data output, instead they are embedded as “text” within the HL7 data stream output from Philips PIC iX.
These labels cannot be used in a pre-configured IntelliVue monitor-screen layout and are not displayed on Philips PIC iX patient sectors.

2.4 Data Mapping

The STIMPOD NMS450X is specifically used for quantitative NMT monitoring for patients where the administration of a Muscle Relaxant is deemed a requirement.

The STIMPOD NMS450X consequently provides support for the generation and monitoring of the following industry standard NMT stimulation sequences amongst others:

- Train Of Four (TOF)
- Double Burst (DB)
- Post Tetanic Count (PTC)

Within the context of this document, the patient's reaction in response to each of the above listed stimulation sequences is measured on a real time basis by the sensor attached to the NMT Monitoring cable, and the results are passed on to the Smart Data Cable Philips for transmission to the Philips Patient Monitor via the IntelliBridge Interface.

The NMT Monitoring cable may make use of either an AMG or an EMG sensor, but the magnitude of the measured results shall be handled in the same way.

This section describes how the data that is broadcast by the Stimpod NMS 450X is mapped to parameters supported on the Philips Patient Monitor.

2.4.1 Common Data Parameters

The following data parameters shall be presented to the patient monitor for all supported NMT stimulation sequences:

- The STIMPOD NMS450X allows the user to select a specific stimulation sequence type from a list. The selected stimulation sequence type is presented to the patient monitor as the Stimulation Mode and is displayed on the monitor under the label.

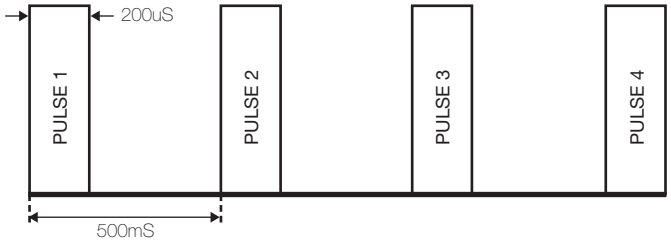
- The STIMPOD NMS450X allows the user to set the magnitude of the stimulation current of any stimulation sequence in increments of 5 mA, ranging from 0 mA to a maximum value of 80 mA. The stimulation current setting is presented to the patient monitor as the Set Current and is displayed on the monitor under the Set mA label.

- The STIMPOD NMS450X measures the actual current delivered to a patient during a stimulation sequence and is presented to the patient

2.4.2 TOF Mode

The STIMPOD NMS450X shall generate the TOF stimulation sequences illustrated in Figure 4 below, when used in the TOF and AUTO Stimulation Modes:

Figure 4: TOF Stimulation Sequence



The STIMPOD NMS450X uses the measured response data from each TOF stimulation sequence to determine the extent of muscle paralysis in a patient due to the presence of a Muscle Relaxant in their system – this is achieved as follows:

- If the magnitude of the sensor readings for all four stimulation pulses in a TOF sequence is larger than zero, then the ratio of the magnitude for the fourth reading relative to that of the first reading is calculated as the resultant outcome and presented to the patient monitor as the TOF Ratio.

  In the absence of a Muscle Relaxant the magnitude of the sensor readings will all be comparable to each other and the TOF Ratio will assume a value of 100% or above. As the Muscle Relaxant starts to take effect, the magnitude of the fourth reading will progressively fade over time and the TOF Ratio will drop accordingly.

  The TOF Ratio will be displayed under the TOFrat label on the patient monitor and the total number of non-zero readings (in this case 4) will be presented to the patient monitor as the TOF Count. The TOF Count will be displayed on the monitor under the TOFcnt label.

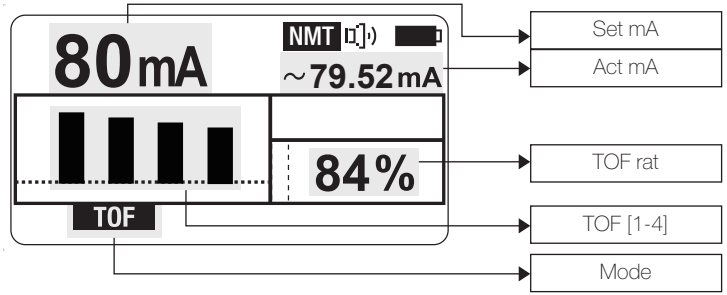
- As the effect of the Muscle Relaxant becomes more pronounced over time, the magnitude of the fourth sensor reading will eventually fade away completely leaving only three readings, the third reading will then eventually fade away completely leaving only two, and so on until there are none.

  The TOF Ratio (in this case 0%) will be displayed under the TOFrat label on the patient monitor, and the TOF Count (in this case 3, 2, 1 or 0) will be displayed under the TOFcnt label.

Aside from the common data parameters (Stimulation Mode, Set Current and Actual Current), the magnitude of the measured response data for each stimulation pulse in a TOF stimulation sequence shall also be presented to the patient monitor and displayed under the TOF1, TOF2, TOF3 and TOF4 labels for the first, second, third and fourth readings respectively.

The data mapping relating TOF parameters displayed on the STIMPOD NMS450X to data labels displayed on the patient monitor, is illustrated in Figure 5 below.

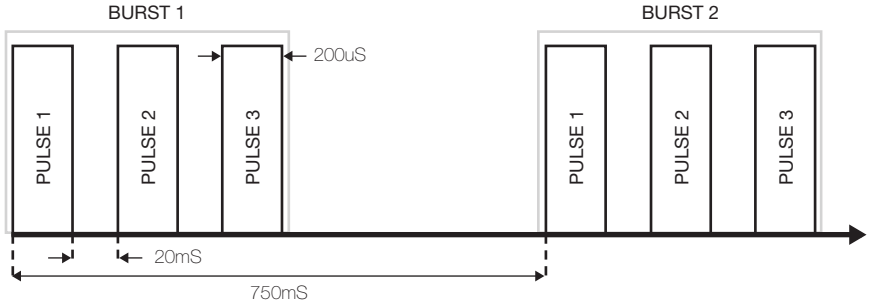
Figure 5: TOF Data Mapping



2.4.3 DB Mode

The STIMPOD NMS450X shall generate the DB stimulation sequences illustrated in Figure 6 below, when used in the DB Stimulation Mode:

Figure 6: DB Stimulation Sequence



The STIMPOD NMS450X uses the measured response data from each DB stimulation sequence to determine the presence of residual Muscle Relaxant in their system.

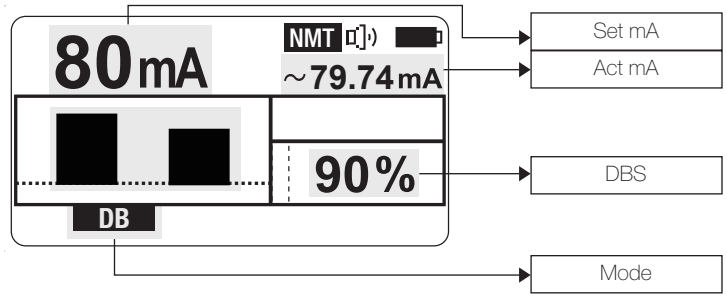
If the magnitude of the sensor readings for the two stimulation bursts in a DB sequence is larger than zero, then the ratio of the magnitude for the second reading relative to the first reading is calculated as the resultant outcome and presented to the patient monitor as the DB Ratio.

In the absence of a Muscle Relaxant the magnitude of the sensor readings will all be comparable to each other and the DB Ratio will assume a value of 100% or above. As the Muscle Relaxant starts to take effect, the magnitude of the second reading will progressively fade over time and the DB Ratio will drop accordingly.

Aside from the common data parameters (Stimulation Mode, Set Current and Actual Current), the DB Ratio will be displayed under the DBS label on the patient monitor.

The data mapping relating DB parameters displayed on the STIMPOD NMS450X to data labels displayed on the patient monitor, is illutrated in Figure 7 below:

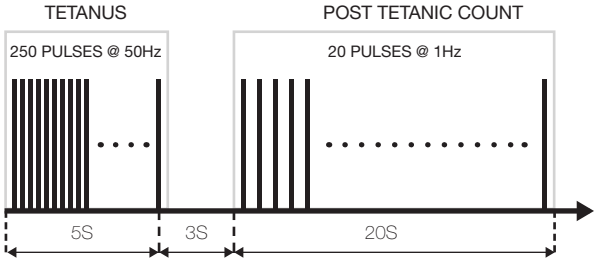
Figure 7: DB Data Mapping



2.4.4 PTC Mode

The STIMPOD NMS450X shall generate the PTC stimulation sequences illustrated in Figure 8 below, when used in the PTC and AUTO Stimulation Modes:

Figure 8: PTC Stimulation Sequence



The STIMPOD NMS450X uses the measured response data from each PTC stimulation sequence to determine when a patient enters, resides in or exits a deep or profound blocking state where muscle paralysis is at its most extreme due to the presence of a muscle relaxant – this is achieved as follows:

- If the magnitude of the sensor readings for any of the 20 Post Tetanic stimulation pulses in a PTC sequence is larger than zero, then the number of non-zero readings is calculated as the resultant outcome and presented to the patient monitor as the PTC Count.

  The PTC Count will be displayed under the PTC label on the monitor.

- A patient is considered to be in a deep blocking state when a TOF Ratio of 0% and a TOF Count of 0 is consistently obtained in response to a TOF stimulation sequence, but a PTC Count of at least 1 is obtained in response to a PTC stimulation sequence.

The PTC Count (1 - 20 in this case) will be displayed under the PTC label on the patient monitor.

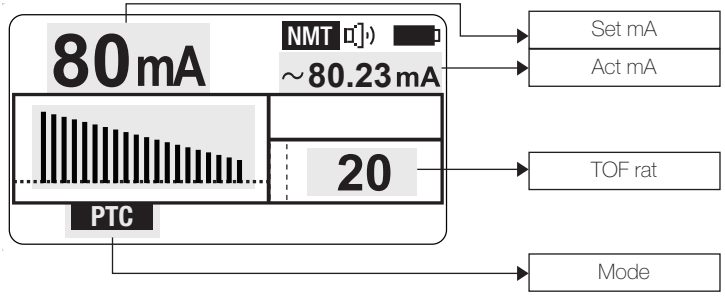
- A patient is considered to be in a profound blocking state when a TOF Ratio of 0% and a TOF Count of 0 is consistently obtained in response to a TOF stimulation sequence, and a PTC Count 0 is obtained in response to a PTC stimulation sequence.

  A PTC Count (0 in this case) will be displayed under the PTC label on the patient monitor.

The common data parameters (Stimulation Mode, Set Current and Actual Current) will also be displayed in conjunction with the PTC Count on the patient monitor.

The data mapping relating PTC parameters displayed on the Stimpod NMS 450X to data labels displayed on the patient monitor, is illustrated in Figure 9 below:

Figure 9: PTC Data Mapping



2.4.5 Alerts

Some of the warning messages that are raised by STIMPOD NMS450X are mapped to alerts on the Philips Patient Monitor as per the list given in Table 7 below.

A description for each Alert is given in the table column entitled “Alert Description”, and the corresponding text that will be displayed on the patient monitor for each Alert is found in the table column entitled “Alert Display Text”.

Table 7: Mapping: Stimpod NMS 450X Warning Messages to Alerts Displayed on the Patient Monitor

Alert	Alert Description	Alert Display Text	Impact
Open Circuit	NMT Monitoring Cable probes are in an open circuit configuration.	NMT Open Circuit	Not available
Battery Low	The STIMPOD NMS450X batteries are almost depleted.	NMT Batt. Low	Valid
Exceedance warning	The measured current differs more than 10% from the set current.	NMT mA Exceedance	Questionable

The Smart Data Cable Philips is responsible for managing the reliable exchange of data between the STIMPOD NMS450X and the Philips Patient Monitor in accordance with the Philips IntelliBridge Open Interface Protocol.

The Smart Data Cable Philips raises an error when it ascertains that a message from the STIMPOD NMS450X was corrupted or not received – the corresponding error message is also mapped to an alert on the patient monitor.

Table 8: Mapping: Smart Data Cable Warning Messages to Alerts Displayed on the Patient Monitor

Alert	Alert Description	Alert Display Text	Impact
Communication error*	A message from the STIMPOD NMS450X got lost during transmission.	NMT Comms Error	Questionable

2.5.1 Regulatory Symbols

Consult Instructions for Use

CE Mark and Notified Body Identification Number

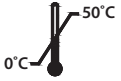
Separate collection for electrical and electronic equipment (Applicable to EU community only)

Manufacturer

Authorized representative in the European Community

Type BF Applied Part

Non-sterile



Temperature limit

Caution

Humidity limitation

2.5.2 Regulatory Detail

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XAVANT TECHNOLOGY

STIMPOD NMS 450X

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