User Manual PSM Connectivity box

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Revision	Date	Description of Change
01	2023-06-29	Creation of document
02		Updated section 5 to describe the values actually presented on the IntelliVue monitor and the handling of an invalid signal. Added the INOP indications "BAD SIGNAL" and "BLUETOOTH DISCONN.", under which the Pain, AUC and NBV numerics are displayed as -?- instead of a numeric value. Corrected the statement that BS is presented as a numeric value (it is presented as a wave) and that no waves are connected to the labels. Added warnings on the interpretation of -?- and of the

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		pain wave during an INOP, and a troubleshooting subsection for INOP messages. Repaired the cross-reference at the end of section 4.2, added a reference from the set-up error condition in section 4.2 to section 4.5, and enabled numbering of the level-3 subsections.

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PSM Connectivity box

User Manual

VERSION 1

ENGLISH

PSM Connectivity box

REF 6015

Connectivity box for connecting MedStorm's PainSensor to Philips Intellivue monitors

Read all instructions, warnings and precautions prior to use.

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1. Introduction

This user manual covers the operation of PSM connectivity box REF 6015 for connecting MedStorm's PainSensor to Philips Intellivue monitors.

The purpose of the PSM connectivity box is to receive data from the PainSensor and forward it to medical monitors. The data is transferred from the PainSensor to the PSM connectivity box using Bluetooth Low Energy, BLE. No data is stored in the PSM connectivity box.

2. Warnings and precautions

- *The PSM Connectivity Box shall not be placed in the patient zone, meaning it should be placed minimum 1,5 m from the patient.*
- *For any issues related to the external products / monitors used with the PainSensor that are not delivered by MedStorm Innovation AS, contact the manufacturer for that respective product.*
- *Modification of the PSM Connectivity Box is not permitted.*
- When the signal from the PainSensor is not valid, the Pain, AUC and NBV numerics are displayed as -?- on the IntelliVue monitor together with an INOP message. A value of -?- means that no valid measurement is available. It must not be interpreted as an absence of pain. See section 5.2.
- During a BAD SIGNAL condition the pain wave continues to be drawn from the unvalidated signal. The wave shall not be used for patient assessment while an INOP message is displayed.

3. System overview

The connectivity box with the power supply is delivered by MedStorm Innovation (it is not battery operated).

The PSM connectivity box has one micro-usb port, one RS232 port, one button and one LED. The functionality of the Button and the LED is described in the table below.

Button press	Action/State	LED

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N/A	When the connectivity box is connected to the monitor and ready to be connected to a **new** sensor	Steady green (ready to use with a new sensor)
Short press	Connect sensor to patient monitor	Blue (while connecting)
N/A	Ongoing connection	Cyan (successfully connected)
Long press	Reset – remove connection to the sensor. Then a new PainSensor can be connected.	Changing back to steady green when reset is successful.
N/A	Sensor disconnected, searching for remembered sensor (the last one that was connected)	White
N/A	Communication error with the monitor	Purple

4. Operating instructions

4.1 Installation and setup

For Connecting to Philips Monitors, you will need:

- Philips IntelliVue Monitor
- IntelliBridge EC5, part nbr 865114 #104 (9 pin DSUB female connector)
- IntelliBridge EC10, part nbr 865115 #A01, 101
- Ethernet cable (part of Philips 865114 #L0x)
- PainSensor REF1002 from MedStorm Innovation AS

Table 1 lists the monitors compatible with the PSM connectivity box.

Table 1: Compatibility list of monitors that can be used with the PSM connectivity box

The communication to IntelliVue monitor is compatible with the following Philips IntelliVue Patient Monitoring Systems through the Philips IntelliBridge EC10 Interface module and/or the Philips EC40/EC80 hub as validated by Med-Storm:
IntelliVue MP40/50/60/70/80/90 Software Revision H.15 or higher (with EC10)
IntelliVue MX400/450/500/550 all Software revisions (with EC10)
IntelliVue MX600/700/800, Software Revision H.15 or higher (with EC10)
IntelliBridge System A.0 or higher (with EC40/80)
Philips IntelliVue Infomation Center PIIC iX B.0 or higher (with EC40/80)

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Patient Information Center PIC iX C.02 or higher (with EC40/80)

4.2 Setting up the Philips monitor

Figure 1 shows how to Philips monitor is connected to the PSM Connectivity Box:

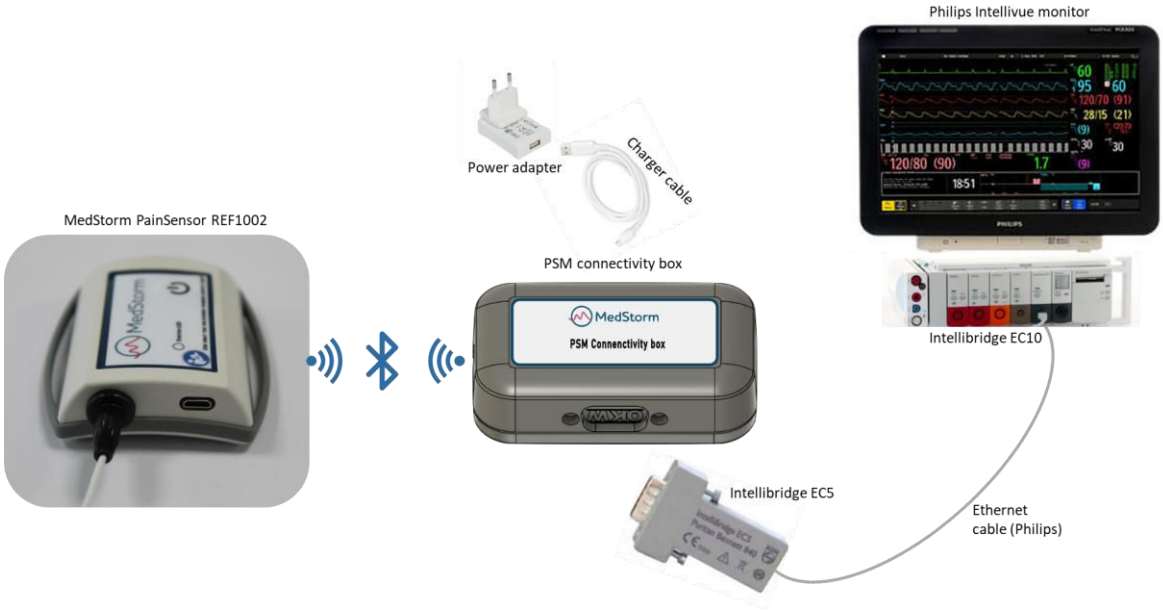

Figure 1: Philips monitor connected to the PSM Connectivity Box

Follow these steps to connect the PSM Connectivity Box to the Intellivue monitor:

1. Connect to a Philips Intellivue monitor
    - Ensure the Philips monitor is switched on. Connect the PSM connectivity box through the RS232 connector to the EC5. The other end of EC5 shall be interfaced with the IntelliVue Monitor via an external/inbuilt EC10 module via Ethernet cable.
2. Power the connectivity box
    - Connect the Charger cable to the Power adapter (only use products delivered by MedStorm). Plug the Power adapter to wall/main electricity. Power the connectivity box by inserting the cable with micro USB in the micro USB port. When the connectivity box is powered and in search mode, a green light is shown on the LED.
    - On the EC10, a green light will start blinking ending with a constant green light, indicating that the Philips monitor has verified the PSM Connectivity Box and they are communicating.
    - The set up with EC5, EC10 and Philips patient monitor is valid if the light under the Ethernet cable is changing from a blinking green to a constant green color. If a blue

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color shows up, the system has an error – see section 4.5 Error conditions / troubleshooting.

After connecting the PSM connectivity box to the Philips monitor, the PainSensor can be connected as described in section 4.3.

4.3 Connecting a PainSensor to the Connectivity box

1. Ensure that the Connectivity box is connected to the monitor and ready to connect to a sensor (steady green light)
2. Press the button on the connectivity box and on the PainSensor to establish connection. The Bluetooth LED will first be blue for a few seconds, before switching to a steady cyan light when connection is successful.
    - Once a PainSensor is connected to a connectivity box, this connection is remembered until reset. How to reset the connectivity is described in the next section
3. When connection is successful, data will be displayed on the monitor. Note that data will only be visible when electrodes are attached to the sensor and to the patient.
4. The connectivity box can be connected during the whole time the patient monitor is connected. If it is necessary to switch off the connectivity box, this can be done by unplugging the power cable, and the LEDs will switch off.

Note: Compared to the PainSensor Application on a tablet, it is expected a delay of approximately 5 seconds before the values from the PainSensor are displayed on the patient monitor.

4.4 Removing a connection to a device / switch to a different PainSensor

The connection between a PainSensor and a connectivity box is remembered after the first pairing which occurred during the first connection. If the connectivity box is not switched off in between, and you want to use a different PainSensor, hold the button for approximately 3 seconds to reset the connectivity. Once this is successful, the light will switch back to a steady green light, indicating that the device is ready to connect to a new PainSensor.

4.5 Error conditions / troubleshooting

4.5.1 PainSensor does not connect to the PSM connectivity box

If you experience that PainSensor does not connect to the PSM connectivity box, do the following steps:.

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1. Ensure that the PSM connection box has not been disconnected from power.
2. Check if the Bluetooth LED is flashing.
3. If the Bluetooth LED does not flash, press the pairing button and verify that the Bluetooth LED starts flashing. Then turn on the PainSensor for connection.
4. If the Bluetooth LED flashes and you cannot connect to PainSensor. Hold down the pairing button on the connectivity box for about 10 seconds or until the Bluetooth LED stops flashing. Then, start the pairing process again by turning on the PainSensor and pressing the pairing button on the connectivity box.

4.5.2 An INOP message is shown and the numerics display -?-

The numerics are replaced by -?- whenever the connectivity box cannot provide a valid measurement. The INOP message on the monitor identifies the cause. This is normal behaviour and not a fault of the connectivity box.

- BAD SIGNAL – the PainSensor reports that the measured signal is not valid, for example because the electrodes have loosened, have dried out, are badly positioned, or because the patient is moving. Check that the electrodes are correctly attached to the patient and to the sensor and that they are within their expiry date, and replace them if necessary.
- BLUETOOTH DISCONN. – the Bluetooth connection between the PainSensor and the connectivity box has been lost, or the PainSensor has been switched off. Check that the PainSensor is switched on and within range, and follow the steps above if the connection is not re-established automatically.

Note: while an INOP message is active, the monitor suppresses other alarms and INOP messages from the connectivity box.

4.5.3 Setting up Philips IntelliVue Monitor

If display of pain value does not automatically start, you may have to carry out the following steps:

a) On the IntelliVue monitor's screen, select **'Main Setup'**.
b) Select **'Equipment'** from the menu that shows up.
c) Click on the **'Measure. Select.'** button from the bottom panel.
d) Select the EC10 module to which the Monitor is interfaced from the pop-up window.
e) Select **'Activate'** to enable the selected EC10 to communicate with the PC.
f) Refer to Philips IntelliVue Instructions for Use for further detail. Contact your local Philips customer support in case you cannot make the connection work.

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5. Indices and values shown on the Philips monitor

The connectivity box presents the PainSensor data on the IntelliVue monitor as three numeric values and two waves.

5.1 Numeric values and waves

The Pain, AUC and NBV values are presented as numerics. The label text for the pain index is "Pain" and the value is shown in the range 0-10. For the awakening index the label text is "AUC" and the value is shown in the range 0-100. For the nerve block value the label text is "NBV" and the value is shown in the range 0-10.

The pain index is in addition presented as a cyan wave in the range 0-11, and the Bad Signal information is presented as a magenta wave with the values 0 (signal valid) and 1 (signal not valid). The Bad Signal information is presented as a wave only; it is not presented as a separate numeric value.

No patient alarms are connected to these labels. The connectivity box provides INOP indications only, as described in the next section.

5.2 Handling of an invalid signal (INOP indications)

Reason for this behaviour

The PainSensor can only calculate the Pain, AUC and NBV indices from a valid skin conductance signal. If the signal is not valid, no meaningful index exists. Presenting the value 0 in that situation would be misleading, because 0 on the monitor means "no pain detected" and not "no measurement available". To prevent this, the connectivity box marks the numerics as invalid instead of presenting a number.

How it works

The PainSensor transmits a Bad Signal (BS) flag together with every measurement. For every data telegram sent to the monitor, the connectivity box evaluates the following:

- if the Bluetooth connection to the PainSensor is not established, the INOP indication "BLUETOOTH DISCONN." is set;
- otherwise, if the PainSensor reports BS = 1, the INOP indication "BAD SIGNAL" is set;
- otherwise no INOP indication is set, and the measured values are transmitted normally.

The INOP indication is applied both as a general INOP in the status telegram and individually in each of the Pain, AUC and NBV numeric telegrams. Both INOP conditions are declared in the device driver as hard INOPs of the type "invalid / useless". This instructs the IntelliVue

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monitor to disregard the transmitted number and to display its invalid-value indication, -?-, in place of the digits.

What is shown on the monitor

Table 2: Presentation of the numerics for each signal condition

Condition	INOP message on the monitor	Pain / AUC / NBV numerics
PainSensor connected and signal valid (BS = 0)	None	Measured value is displayed
PainSensor connected, signal not valid (BS = 1)	BAD SIGNAL	-?-
Bluetooth connection to the PainSensor lost	BLUETOOTH DISCONN.	-?-

The numerics return to their measured values automatically, without any user action, as soon as the signal is valid again and the connection is re-established.

Limitations

- The waves are not affected by the INOP indication. During a BAD SIGNAL condition the pain wave continues to be drawn from the unvalidated signal, and the BS wave rises to 1. The pain wave shall not be used for patient assessment while an INOP message is displayed.
- A value of -?- indicates that no valid measurement is available. It shall never be interpreted as an absence of pain.
- The delay of approximately 5 seconds described in section 4.3 applies also to the appearance and the clearing of the INOP indications.

5.3 Customization of the view of indices on the Philips monitor

If you do not wish to see all the indices from the PainSensor on the Philips monitor, it is possible to remove some of them by following these steps:

1. Press the trend graph for either «Pain / Pain» or «BS».
2. Press «Fan» or “Ventilator”.
3. Press «Device Driver».
4. You can only remove the numeric numbers and not the graphs, select «Setup Numerics».
5. Select the value you do not have and press «delete».

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6. Care and maintenance

The Connectivity box can be cleaned by using a cloth/paper humidified with water or disinfectant but should never be dropped in liquid. When the connectivity box is not in use, remove the power and store it in the original box.

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