USER MANUAL

External Input Module NUMI2A-HE

ascom

DISCLAIMER

Ascom (Sweden) AB has taken due care in preparing this document including research, development and testing to ascertain the effectiveness of any programmes and data on electronic media which accompany this document. Ascom (Sweden) AB makes no guarantees as to the contents of this document and specifically disclaims any implied guarantees pertaining to fitness for any particular purpose. Ascom (Sweden) AB further reserves the right to make changes to the specifications of the programme and contents of this document without obligation to notify any person or organization of such changes.

TRADEMARKS

teleCARE is a registered trademark of Ascom (Sweden) AB in certain jurisdictions. Microsoft® is a registered trademark of Microsoft Corporation. Adobe® and Acrobat® are registered trademarks of Adobe Systems Incorporated.

CH REP Ascom (Solution) AG, Gewerbepark Hintermättlistrasse, 5506 MÄGENWIL, Switzerland

CE
2460

ADDRESS

Ascom (Sweden) AB
Grimbodalen 2
SE-417 49 Göteborg
Sweden
Phone: +46 31 55 93 00
Fax: +46 31 55 20 31
www.ascom.com/ws

Contents

1 Intended Purpose

Intended Purpose for NUMI2A-HE

The External Input Module (item number NUMI2A-HE) is, in combination with the Medical Device Cable (NUMDC-H), specific Room Controller (NIRC4) software, and corridor lights (NICL4) software, intended to interface with primary medical devices equipped with dry contact relay closure circuits in order to provide automated, reliable, near real-time visual indication of alarm conditions to corridor lamps in the telecare IP nurse call system (class IIb).

The External Input Module does not replace or alter the behavior of the primary medical devices. When used for indication of alarm conditions, the External Input Module does not modify, change or add information to the alarm condition.

The External Input Module incorporates both hardware and software and is intended to be installed in close proximity of a patient, while the Room Controller software is intended to be installed on specified hardware modules located outside the patient area. The External Input Module is not intended to be used for diagnostic purposes or to come in physical contact with patients.

The External Input Module is intended for use by professional clinical personnel and relies on proper use, installation and operation of the communication infrastructure at the healthcare facility.

2 Symbols

CE mark: Indicates the conformity of the device with the provisions of REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, to enable it to move freely within the Community and to be put into service in accordance with its intended purpose.

Caution: Use extreme caution and follow instructions carefully.

Waste Electrical and Electronic Equipment Directive (WEEE Directive)

Medical Device Cable - Test button.

Medical Device Cable - Disconnect button.

Medical Device Cable - Priority select slider, for example:
1: High priority
2: Medium priority
3: Low priority

3 Caution and Notes

WARNING: This product can expose you to chemicals including Antimony trioxide, which is known to the State of California to cause cancer, and Di-isodecyl Phthalate (DIDP), which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

WARNING: The Product must only be used by trained professional clinical personnel qualified to understand its use. The Product cannot be used without having a proper training, performed and authorized by Ascom/Partners staff.

4 MDR Compliance

The devices included in the solution are identified by the following Unique Device Identifiers:

Device	UDI-DI (Unique Device Identification - device identifier)
NUMI2A-HE	17350088671037
NUMDC-H	17350088670764
SW000884 (for NIRC4)	17350088670757
SW000860 (for NICL4)	17350088670962

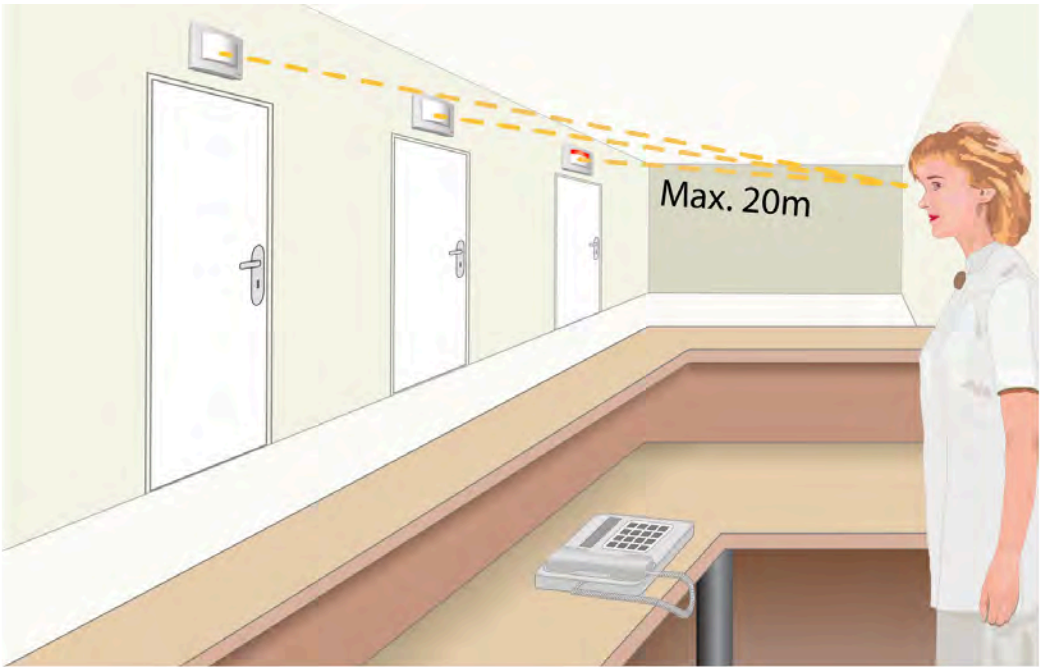
4.1 MDR Class IIb compliance

The NUMI2A-HE is an MDR Class IIb compliant device in combination with the Medical Device Cable (NUMDC-H) connected to a room bus of the room controller NIRC4 using an RJ45 cable. A corridor lamp (room controller NIRC4 or corridor lamp NICL4) is mandatory for reliable alarm indications from medical devices to a location outside the patient room. The corridor lamp must have a visibility of at least 20 meters and must be directly visible from the nurse station staffed at all times. The corridor lamp must use colors according to EN60601-1-8 (red, yellow, cyan or yellow).

IMPORTANT: *It is mandatory to use the corridor lamp (NICL4 or NIRC4 lamp) at the entrance of locations (rooms) where NUMI2A-HE modules are used as the primary source for alarm signalling.*

IMPORTANT: *The corridor lamp must have a visibility of at least 20m and must be visible from the nurse station staffed at all times.*

Figure 1. Corridor lamp visibility



The Response times of the system are shown in the table below.

Table 1 Response timing

Event	Response time
Any alarm signalling from NUMI2A-HE to corridor lamp	< 1s
Peripheral lost signalling of NUMI2A-HE to corridor lamp	< 1s
Reboot of Room Controller (NIRC4) and restoring of signalling on corridor lamp	< 180s

During a room controller reboot only a dedicated room controller that is setup as a supervisor will detect within 30 seconds that a room controller is lost and starts flashing the yellow lamp. When the room controller reboot sequence has finished and the connection has been restored, the supervisor will stop flashing.

		Supervisor Flashing Pattern
Reboot	No signalling for up to 30s	

During the reboot sequence no medical alarms will be visible on the corridor or room controller lamp. If a medical alarm was already active during a reboot, or a new medical alarm is generated, the medical alarm will (re)appear on the corridor or room controller lamp immediately after the connection has been restored. See 12.5 Supervision, page 26 for detailed information on how to proceed when the supervisor continues to flash for more than 90 seconds.

4.2 Vigilance and Reporting Incidents

End users, or resellers / distributors must inform Ascom in writing, within five (5) business days from knowledge of an event, of all incidents relating to the Products. A complaint in this instance may be an oral or written statement or insinuation that the Product fails to meet requirements with respect to identity, quality, durability, reliability, safety, effectiveness, or performance of a device.

Any serious incident, that is any incident that directly or indirectly led, might have led or might lead to the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat, that has occurred in relation to the Product should be reported to the manufacturer, via email to vigilance@ascom.com, and the competent authority of the Member State in which the user and/or patient is established.

For any serious incident, or if there is a perceived Product malfunction that could contribute to death or injury, or if a customer expresses concern about patient safety, then end users or resellers / distributors will notify Ascom as soon as possible using best efforts to provide such notice orally (Ascom Technical Assistance Center) within twenty-four (24) hours of gaining knowledge, or from the receipt of such complaint, or becoming aware of such Product issue. Oral notification shall be followed with written (email) confirmation within 24 hours to vigilance@ascom.com.

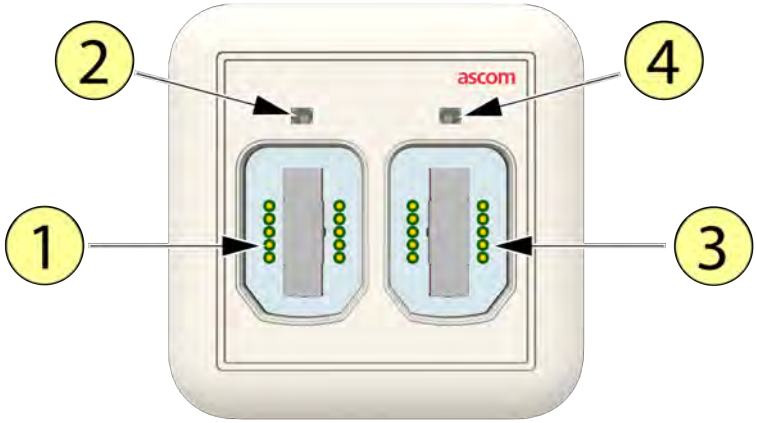
End users or resellers / distributors will provide sufficient information to allow Ascom to fulfil its regulatory reporting obligations for incidents and events that must be reported and registered according to national regulations within the Territory. If an event is considered to be an incident which must be reported to National Competent Authorities, then Ascom shall prepare and submit a report.

If any regulatory body or competent authority provides written notice to an end user, or reseller / distributor with respect to inquiries about, or investigations of any Product, or to conduct an inspection or audit of

facilities used for the storage of Products, or request any information related to the any Product, then end user, or reseller / distributor shall promptly notify Ascom.

5 External Input Module (NUMI2A-HE) Components

5.1 NUMI2A-HE Module

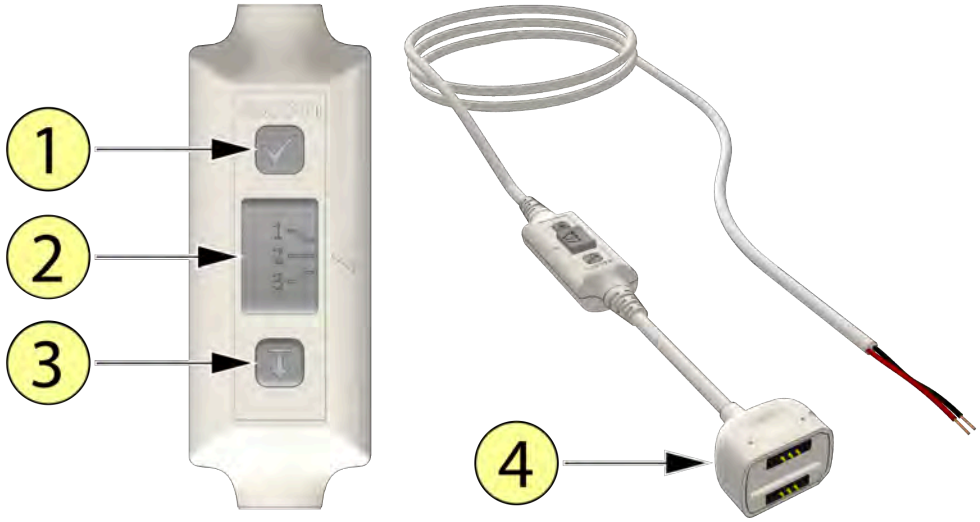


1. SafeConnect socket 1
2. SafeConnect socket 1 - Status LED
3. SafeConnect socket 2
4. SafeConnect socket 2 - Status LED

5.2 Class IIb labels

NUMI2A-HE

5.3 Medical Device Cable NUMDC-H



1. Test button.
2. Priority select slider.
   Example of the priority order used in this document:
   1: High priority.
   2: Medium priority.
   3: Low priority.
3. Disconnect button.
4. Ascom SafeConnect Plug.

IMPORTANT: *In order to fulfill the requirements of EN 60601-1-8, the use of the Ascom Medical Device Cable (NUMDC-H), including an End-of-Line (EOL) resistor across the alarm contacts of the medical device to monitor the continuity of the electrical connection to the NUMI2A-HE module, installed by an Ascom representative, is mandatory when connecting primary medical devices to the NUMI2A-HE.*

5.4 Modifications

Any modification to the NUMI2A-HE module or the NUMDC-H Medical Device Cable is strictly prohibited.

5.5 Calibration

Neither the Module NUMI2A-HE, nor the Medical Device Cable NUMDC-H need any calibration.

5.6 Disposal

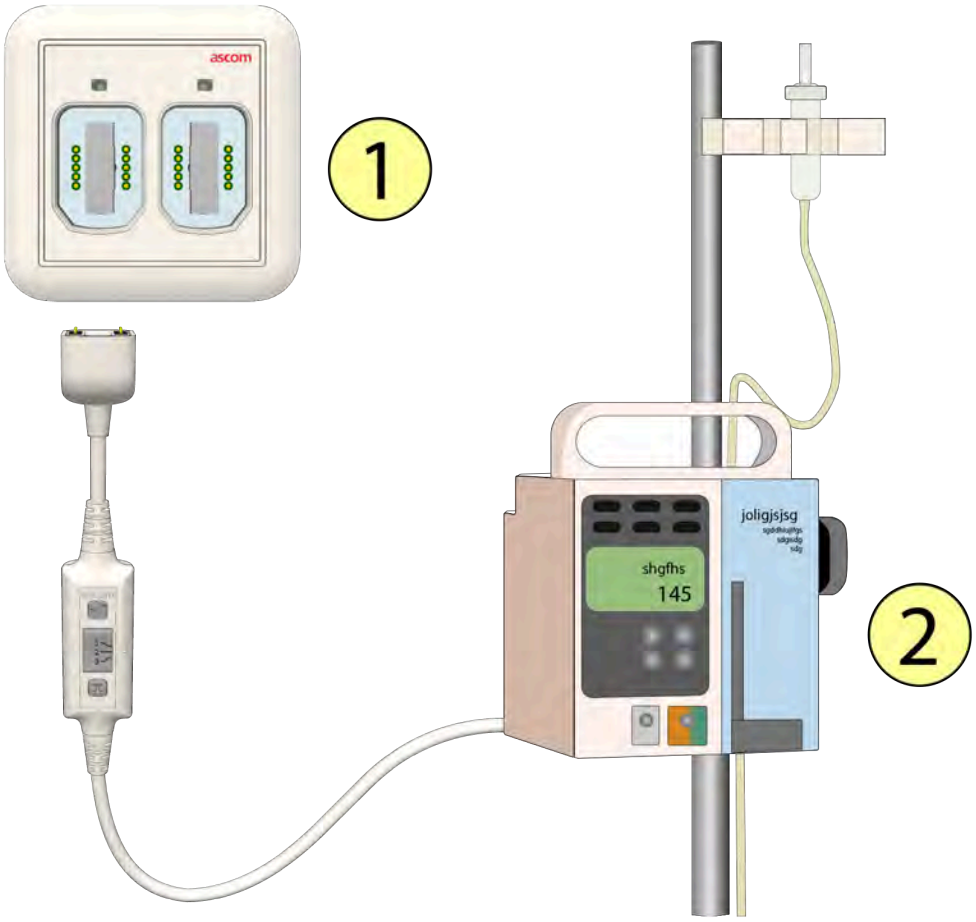
The module NUMI2A-HE and the Medical Device Cable NUMDC-H comply with the relevant standards for electronics and can be safely disposed of as electronic waste at the end of the life cycle. See the data sheet TD 93435EN for applicable regulatory compliance.

5.7 Risk assessment

Extensive risk assessments for the NUMI2A-HE module and the NUMDC-H Medical Device Cable have been performed and will be provided upon request.

6 Preparations

When installing the NUMI2A-HE make sure that an Ascom representative connects the medical device cable NUMDC-H and the End-of-Line resistor to the primary medical device (connector). The Ascom representative should consult the hospitals qualified biomedical or medical engineer regarding the technical details of the medical device. Detailed instructions can be found in the NUMDC-H Medical Device Cable - Installation Sheet (P/N PM000203A).

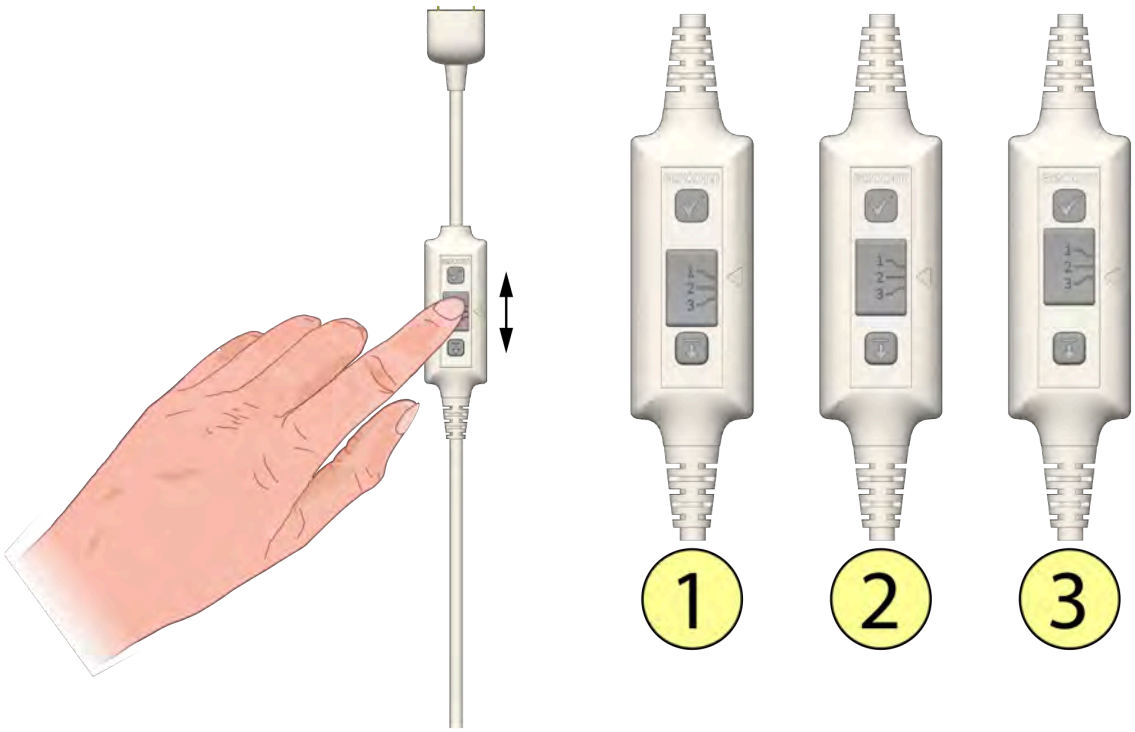


1. External Input Module - NUMI2A-HE
2. Primary Medical Device

7 Selecting the Required Medical Alarm Priority

Before connecting the medical device cable (NUMDC-H) to the External Input Module (NUMI2A-HE) first set the required medical alarm priority using the priority slider on the medical device cable.

Slide the priority slider to:



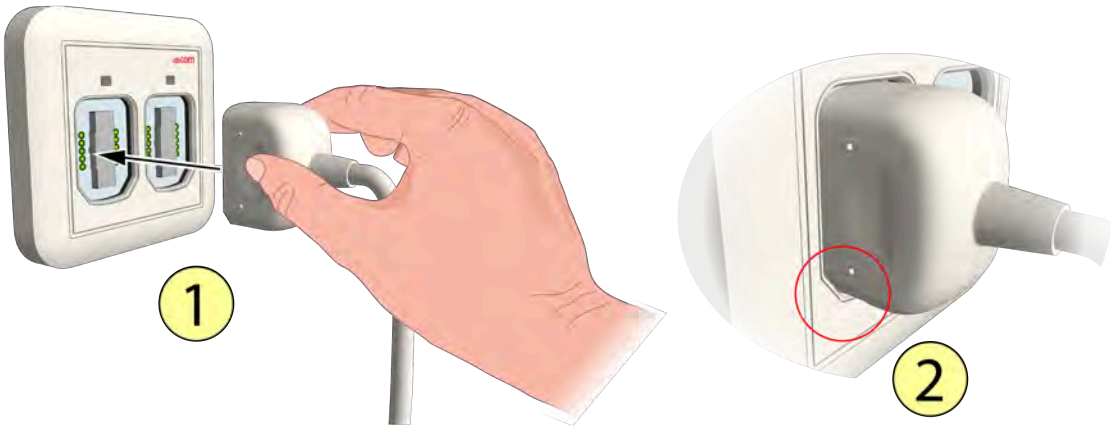
1. High Priority.
2. Medium Priority.
3. Low Priority.

You cannot change the medical alarm priority when the cable is plugged into the SafeConnect socket. Be sure to remove the cable from the socket before changing the medical alarm priority. Changing the medical alarm priority while plugged in will cause a `disconnect alarm`.

In case of an unintentional or accidental change of the priority setting, the `disconnect alarm` can be cancelled by sliding the Priority Select Slider to its original setting. Disconnecting the cable is not necessary.

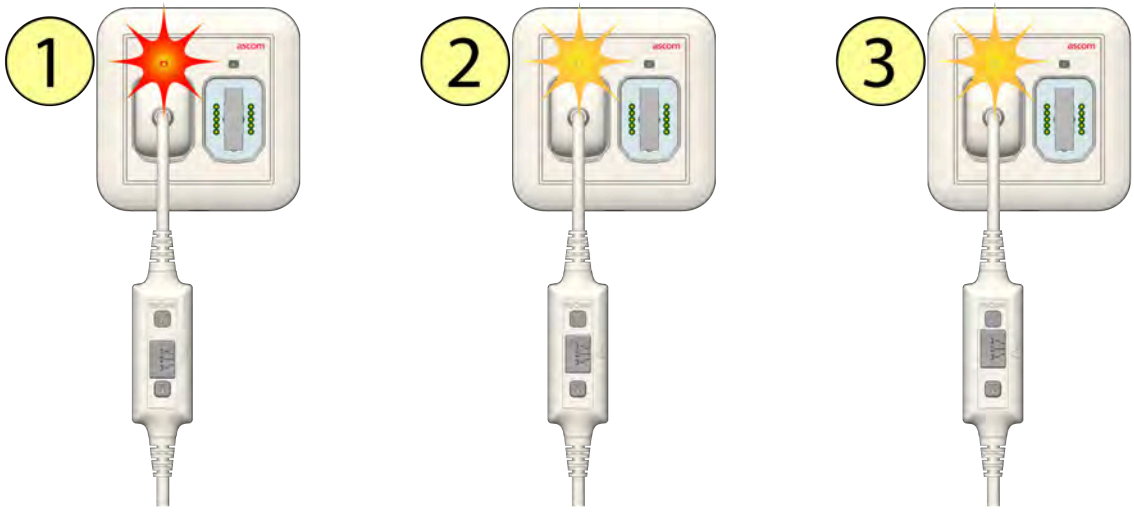
8 Connecting the Medical Device Cable

When the required priority is selected on the medical device cable, you can plug the cable into one of the two SafeConnect sockets of the External Input Module.



1. Plug the cable into one of the two available sockets.
2. To ensure a proper connection, pay attention to the orientation of the SafeConnect plug and be aware that the plug is able to fit into the socket only one way.

When correctly connected, the LED above the SafeConnect socket will light up for three seconds with the color associated to the medical alarm priority selected on the medical device cable.



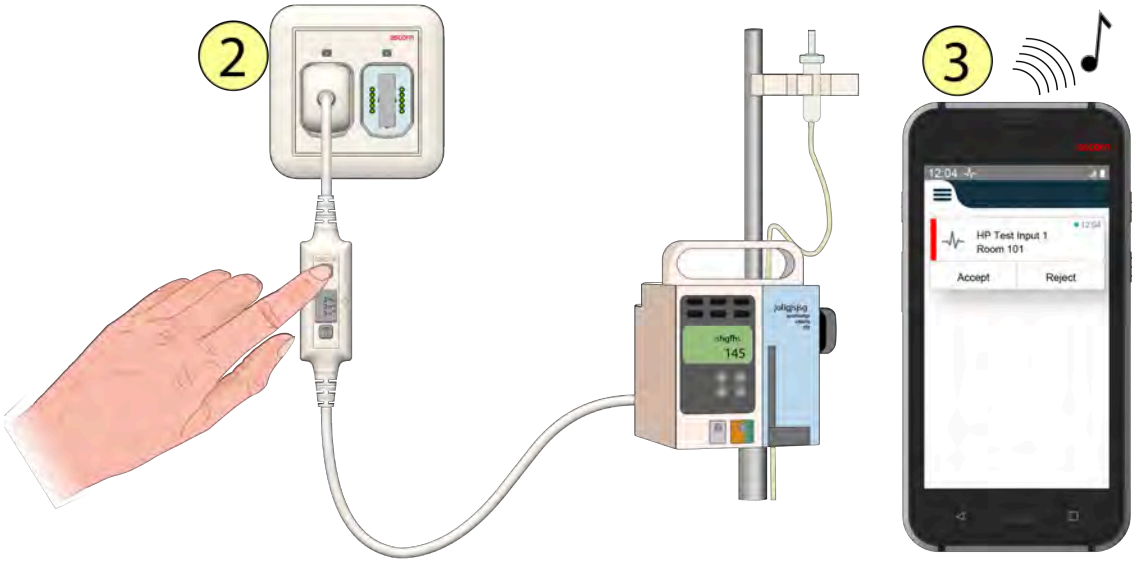
1. LED color `Red` - High priority selected.
2. LED color `Yellow` - Medium priority selected.
3. LED color `Yellow` - Low priority selected.

After three seconds the LED dims to its back-lit level.

You cannot change the medical alarm priority when the cable is plugged into the SafeConnect socket. Be sure to remove the cable from the socket before changing the medical alarm priority. Changing the medical alarm priority while plugged in will cause a `disconnect alarm`.

When connecting or reconnecting a medical device cable, make sure to always perform the medical alarm test sequence before putting the primary medical device into operation, see 9 Perform the Medical Alarm Test, page 14.

9 Perform the Medical Alarm Test

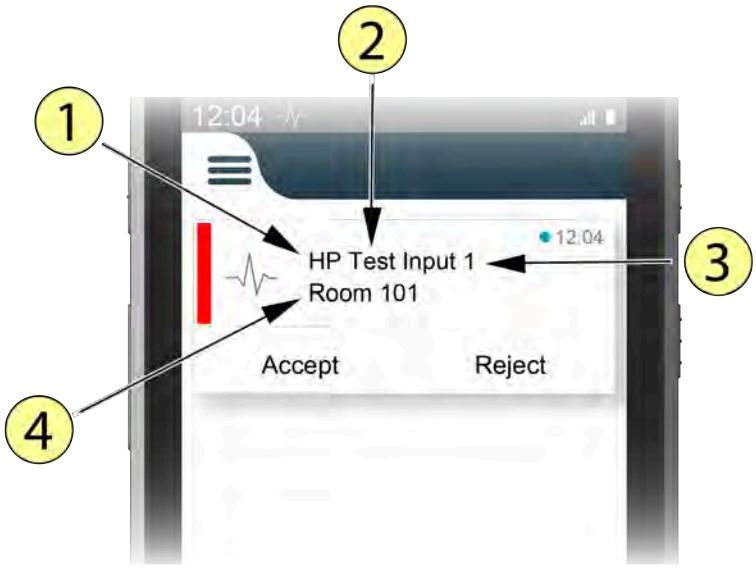


1. Press and hold the test button of the medical device cable.
2. The LED above the SafeConnect socket will light up according the priority color and flashing pattern of the selected priority.
3. If the teleCARE IP system includes messaging, a medical alarm test message will be sent to the associated signaling or display device.

- Release the test button to stop the test alarm.

IMPORTANT: *Only put the primary medical device into operation if a correct alarm test message has been displayed on the corridor light for the room/bed, and test message has been received on the display device if applicable.*

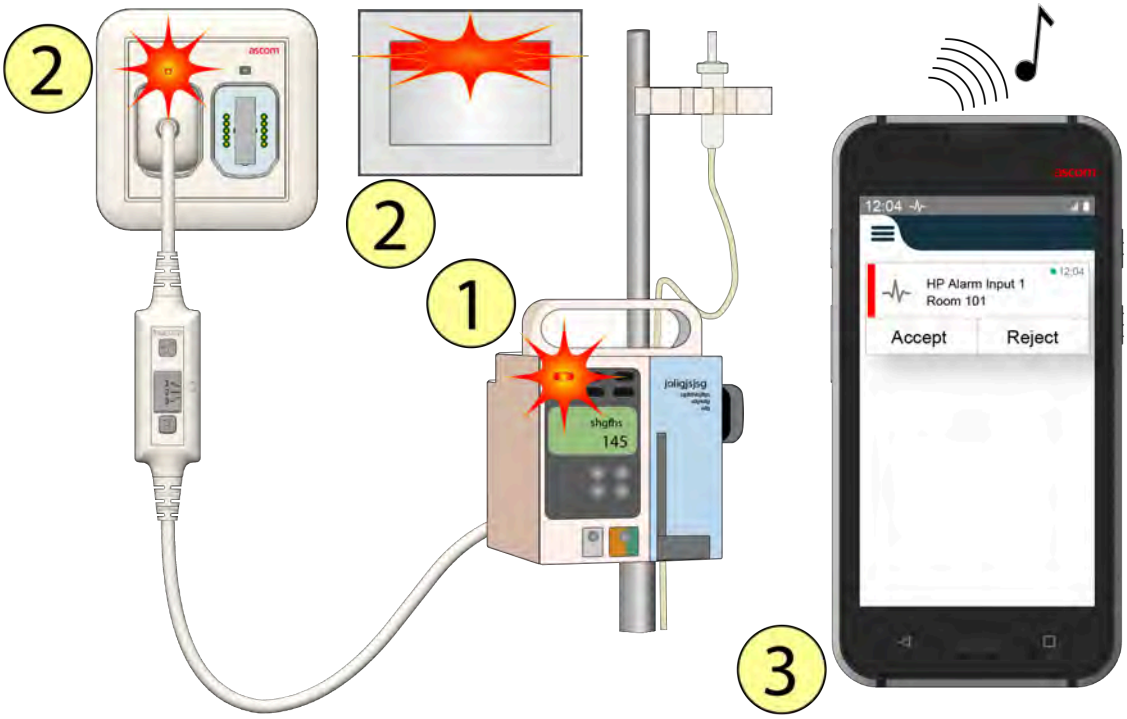
An example of a test message is displayed below.



1. Priority:
   HP = High.
   MP = Medium.
   LP = Low.

2. Alarm Type.
3. SafeConnect socket number.
4. Location of the External Input Module.

10 Medical Alarm



1. The primary medical device activates a medical alarm.
2. The LED above the SafeConnect socket and the LEDs in the room controller / corridor lamp will show:
   - Fast flashing red for high priority alarms.
   - Slow flashing yellow for medium priority alarms.
   - Constant yellow for low priority alarms.

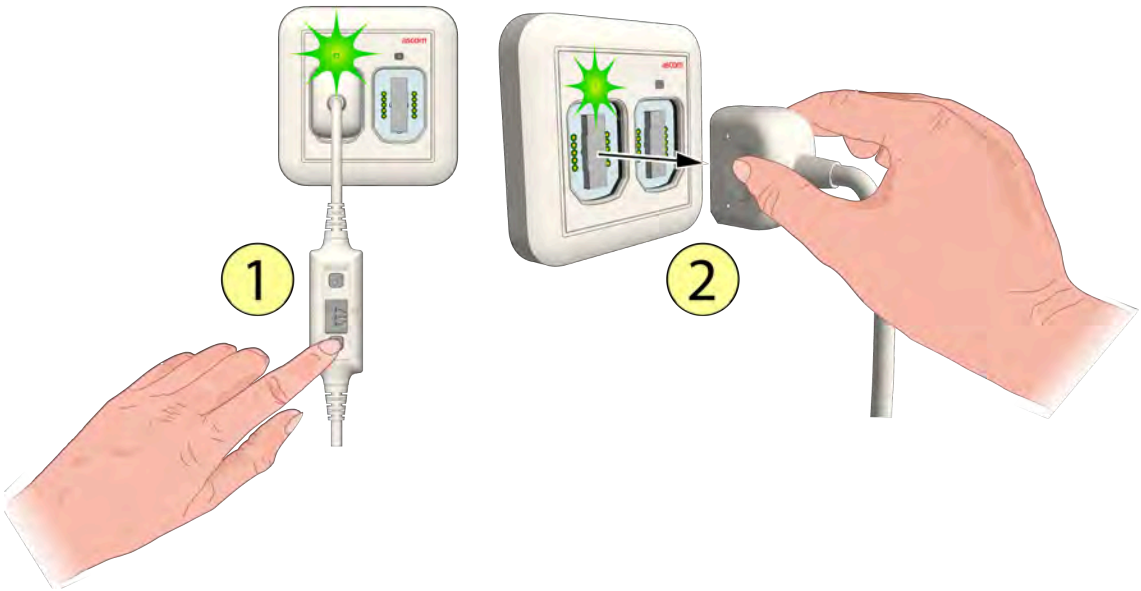
Priority	Alarm Indications
High	
Medium	
Low	

3. If the teleCARE IP system includes messaging, an alarm message will be sent to the display device of the assigned clinical personnel depending on the alarm priority.

- Cancelling the alarm condition at the primary medical device will reset the medical alarm call at the External Input Module and cancel the medical alarm call. A medical alarm is a persistent alarm and therefore it cannot be cancelled remotely through a messaging device or by a linked doorside module.

11 Intentional Disconnection of a Primary Medical Device

This is the correct way to disconnect a Primary medical device.



1. Press the `Disconnect` button of the medical device cable until the socket's LED illuminates green.
2. Within three seconds remove the plug of the primary medical device you want to disconnect from the External Input Module.

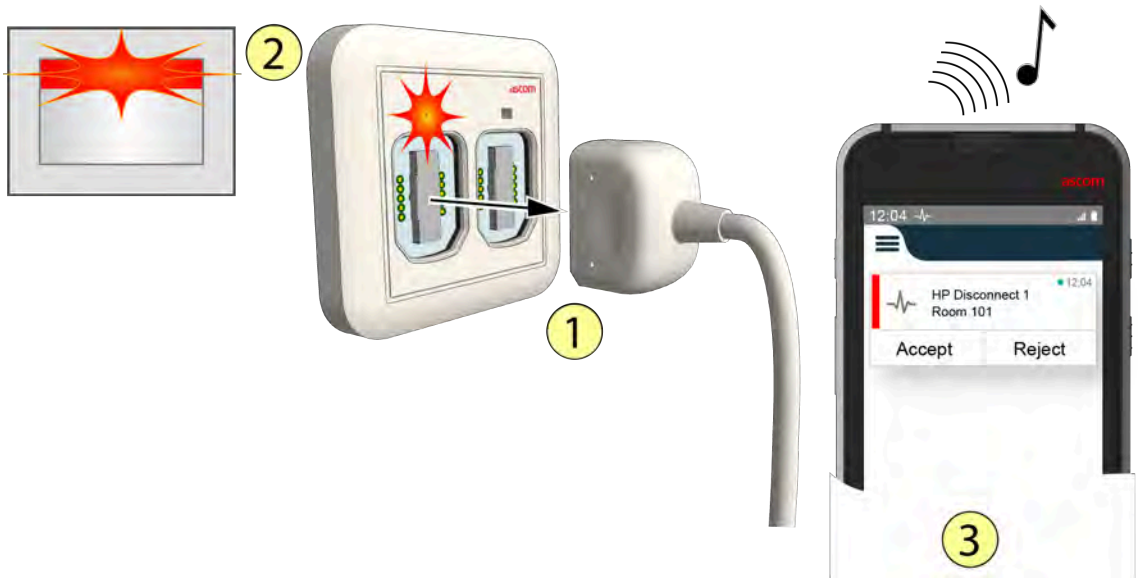
If you disconnect a primary medical device when the green LED is off (after 3 seconds), a disconnect alarm will be generated. Reconnect the medical device cable to cancel the disconnect alarm, for details refer to, Reconnecting an Unintentionally Unplugged Primary Medical Device, page 19

12 Fault Conditions

12.1 Unintentional Disconnection of a Primary Medical Device

A primary medical device can get disconnected unintentionally by the plug being pulled out of the External Input Module.

12.1.1 Unplugged from the External Input Module

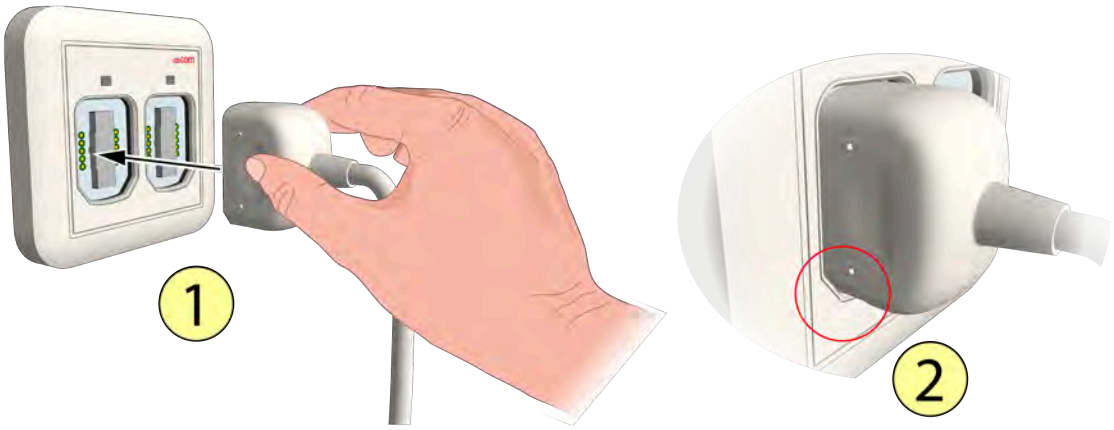


1. One of the plugs attached to a primary medical device gets unplugged from the External Input Module.
2. The LED above the SafeConnect socket and the LEDs in the room controller / corridor lamp will show:
   - Fast flashing red when a high priority input gets disconnected.
   - Slow flashing yellow when a medium priority input gets disconnected.
   - Constant yellow when a low priority input gets disconnected.

3. If the teleCARE IP system includes messaging, a disconnect alarm message will be sent to the messaging device of the relevant nurse depending on the alarm priority.

Plug the cable back into the SafeConnect socket to clear the disconnect alarm.

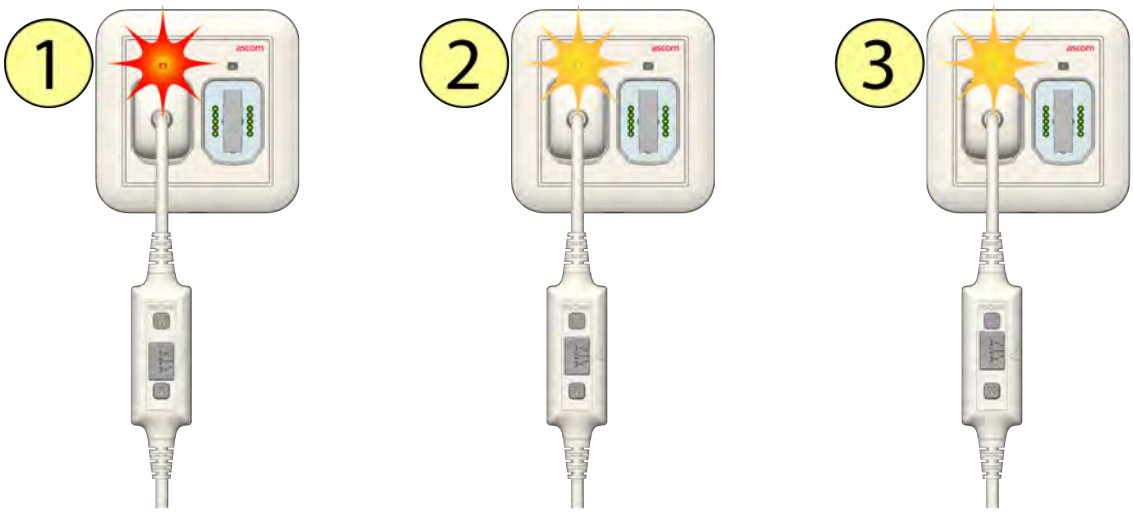
Reconnecting an Unintentionally Unplugged Primary Medical Device



1. Reconnect the medical device cable.

The medical disconnect alarm is cancelled automatically and the LED above the SafeConnect socket will light up for three seconds with the color associated to the medical alarm priority selected on the medical device cable.

Do not change the priority of the medical device cable when reconnecting it to the External Input Module, otherwise the disconnect alarm will not be cancelled.

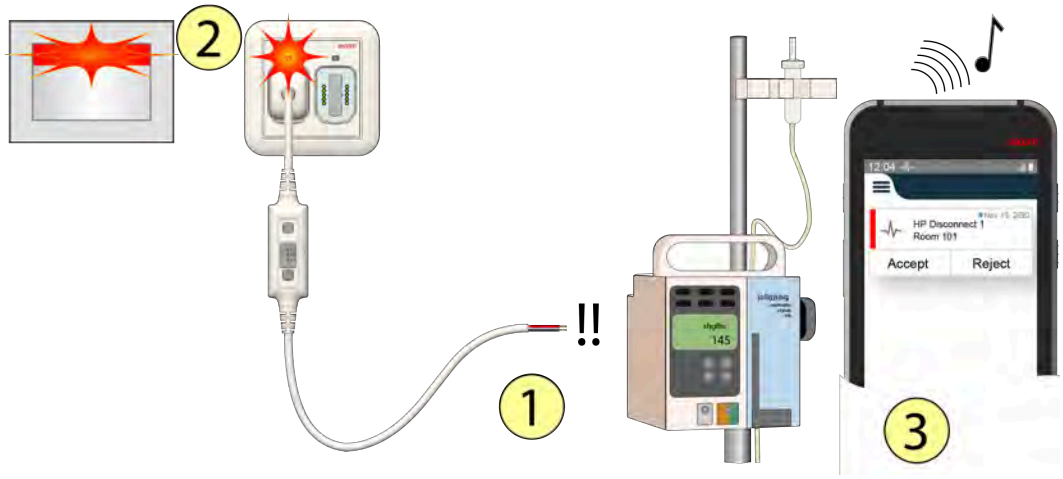


1. LED color `Red` - High priority selected.
2. LED color `Yellow` - Medium priority selected.
3. LED color `Yellow` - Low priority selected.

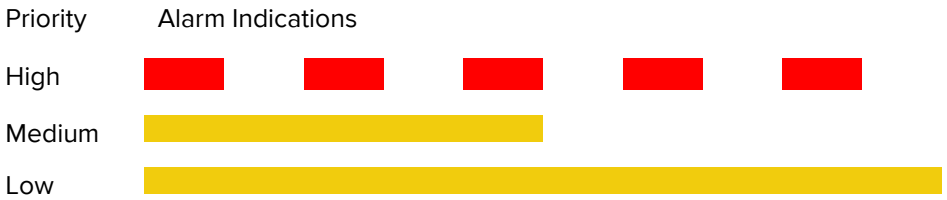
After three seconds the LED dims to its back-lit level.

When connecting or reconnecting a medical device cable, make sure to always perform the medical alarm test sequence before putting the primary medical device into operation, see 9 Perform the Medical Alarm Test, page 14.

12.1.2 Disconnected from the Primary Medical Device



1. The medical device cable gets disconnected from the primary medical device by a loose contact or a cable break.
2. The LED above the SafeConnect socket and the LEDs in the room controller / corridor lamp will show:
   - Fast flashing red when a high priority input gets disconnected.
   - Slow flashing yellow when a medium priority input gets disconnected.
   - Constant yellow when a low priority input gets disconnected.



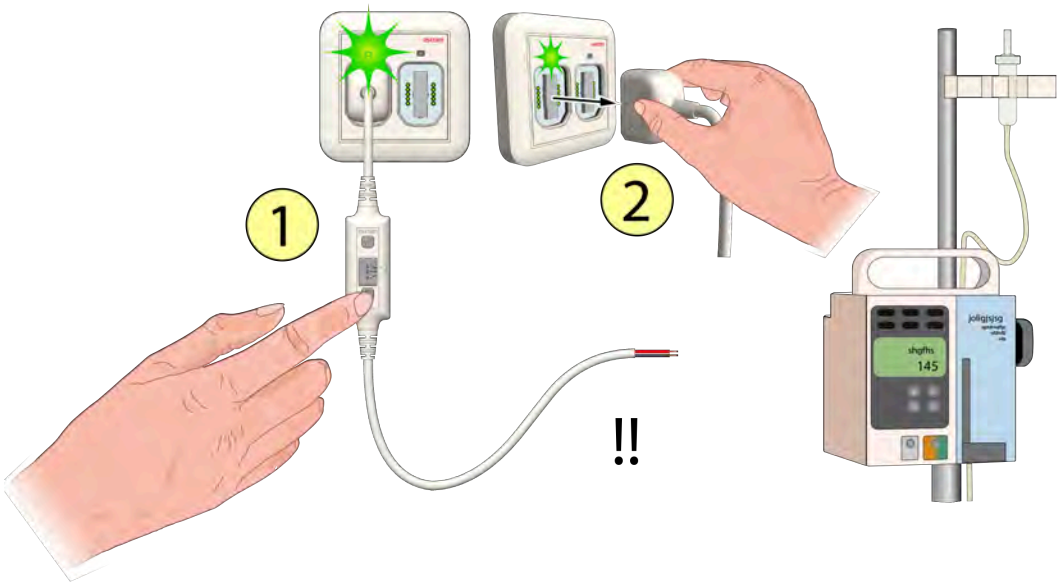
3. If the teleCARE IP system includes messaging, a disconnect alarm message will be sent to the messaging device of the relevant nurse depending on the alarm priority.

Contact Qualified Technical Personnel

Contact qualified technical personnel in order to reconnect the medical device cable to the primary medical device.

12.1.3 Cancel a Disconnect Alarm

If it is not possible for the user to reconnect the medical device cable to the primary medical device, the user can still cancel the disconnect alarm using the `Disconnect` button of the medical device cable.



To cancel a disconnect alarm and remove the medical device cable from the External Input Module:

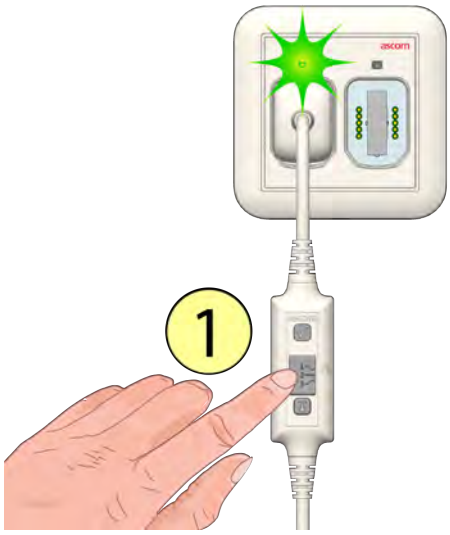
1. Press the `Disconnect` button of the medical device cable (green LED on for three seconds).
2. Within three seconds remove the plug, of the medical device cable that got disconnected from the primary medical device, from the External Input Module.

IMPORTANT: Make sure to switch off the primary medical device according to the manufacturers medical device procedure, since the primary medical device alarms will no longer be distributed by the External Input Module.

An Ascom representative should be contacted to repair or replace the medical alarm cable and test the proper functioning of the cable.

12.1.4 Cancel a Disconnect Alarm after Unintentional Priority Change

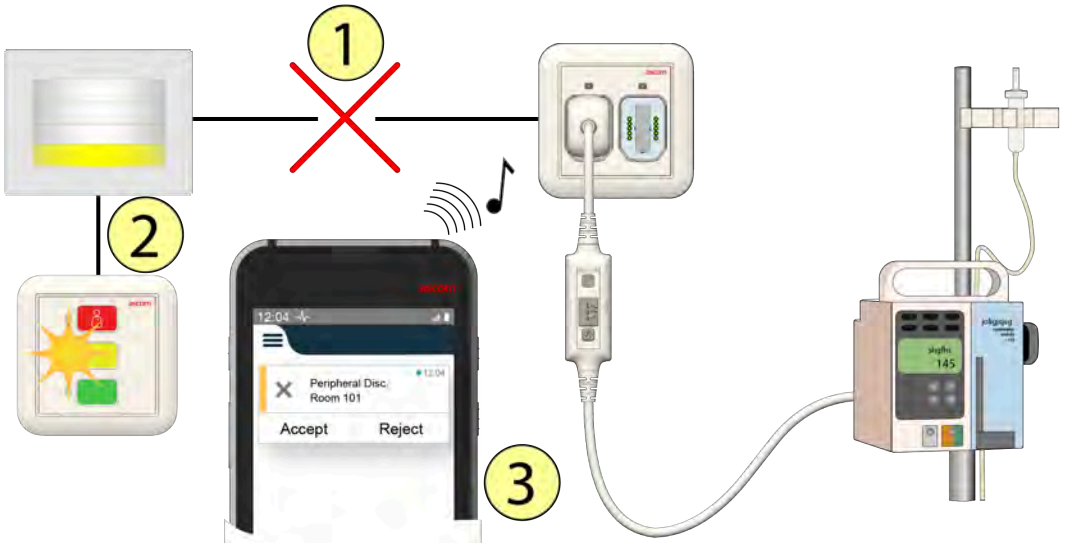
If the user unintentionally or accidentally changes the priority on the NUMDC cable, a `disconnect alarm` is generated. To restore the normal operation, the user must shift the Priority Select Slider to its original position.



To cancel a `disconnect alarm` due to an unintentional or accidental priority change:

1. Slide the Priority Select Slider to its original position/priority. Disconnecting the cable is not necessary.

12.2 External Input Module Failure



1. The External Input Module fails to operate (broken, disconnected).
2. The status of the External Input Module is constantly monitored by the room controller (NIRC4) it is connected to. When the module breaks down or the interconnection cable breaks, the linked doorside module and room controller / corridor lamp will show a special yellow flashing pattern to indicate that the peripheral is disconnected.

   Peripheral Disconnect flashing (Repeated)

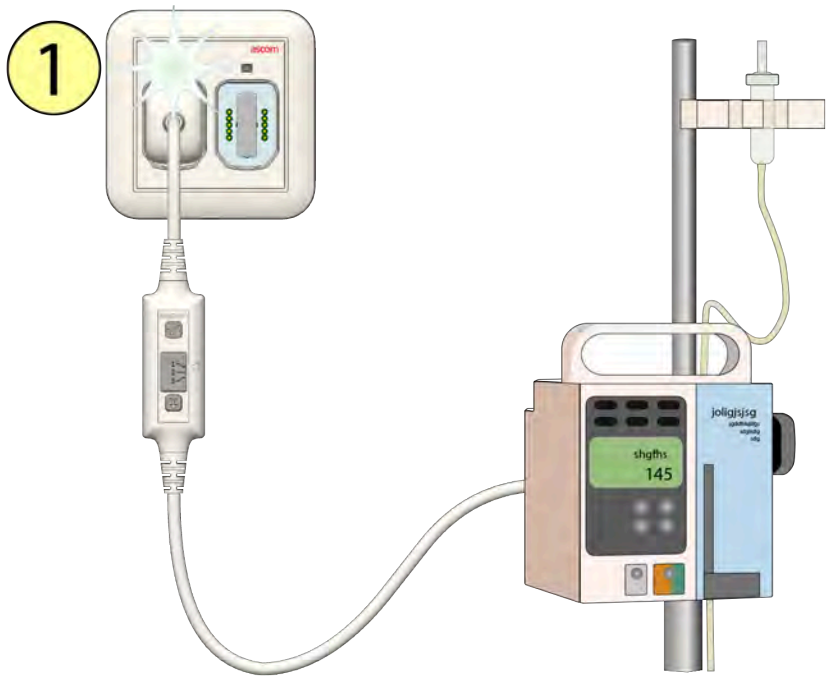
   
3. If the teleCARE IP system includes messaging, a peripheral disconnect message will be sent to the display device of the responsible person.

Device failures can only be solved by qualified technical personnel.

IMPORTANT: *Do not connect primary medical devices to a disconnected External Input Module and take proper actions for the primary medical devices that are already connected, since the primary medical device alarms will no longer be distributed by the External Input Module.*

Contact the service organization in order to get the module repaired or replaced by an Ascom representative.

12.3 External Input Module Configuration Error

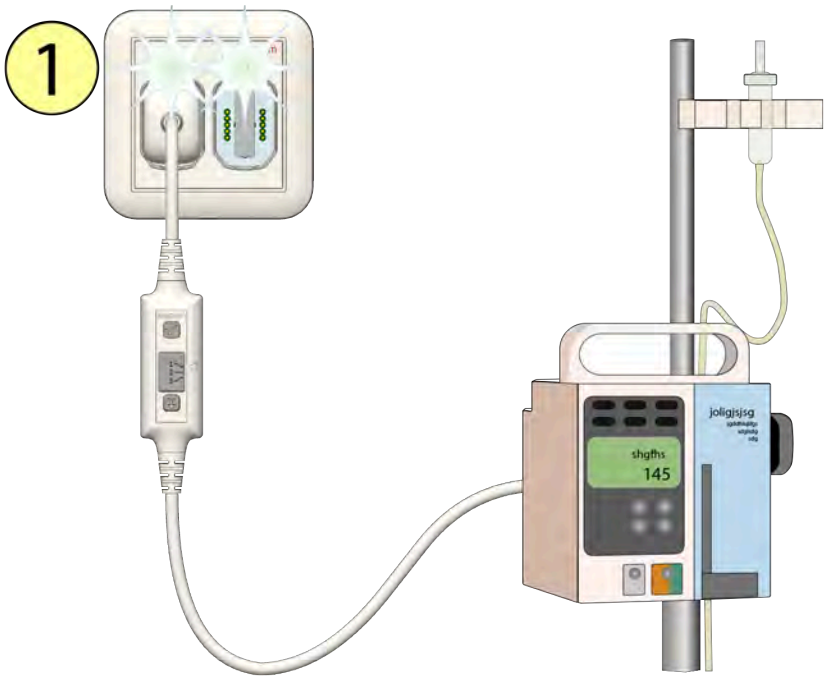


1. When connecting the medical device cable, the LED above SafeConnect socket will flash white for 3 seconds if the system configuration for the External Input Module is wrong or not existing.

   No or wrong configuration flashing - white (3 seconds)

12.4 Power Failure

The teleCARE IP system will restart automatically when the power returns after a power failure. The status of an active medical alarm call will be saved. When the power returns and the system has been restarted, the status of the medical alarm will be restored.



1. When the power returns and the NUMI2A-HE is identified by the system, the LEDs above the SafeConnect sockets will illuminate white for 3 seconds, after which the status of the medical alarm(s) will be restored.

IMPORTANT: *Always perform the medical alarm test procedure after a system restart, see* *9 Perform the Medical Alarm Test, page 14**.*

12.5 Supervision

System supervision is part of a teleCARE IP system that includes External Input Modules. With supervision a dedicated room controller will act as the supervisor, the supervisor constantly monitors all connected modules inside an assignment area. The supervisor will inform the user whenever connection problems occur on the LAN network or on one of the room busses connected to the individual room controllers inside the assignment area.

The room controller that acts as the supervisor must be clearly visible to staff members. This can be a dedicated room controller installed at the nurse station desk, or a room controller mounted above the door of a patient room that is directly visible from the nurse station desk.

	Supervisor Flashing Patterns															
Peripheral disconnect	■		■		■		■									
LAN disconnect	■		■		■		■		■		■		■		■	

When one of these flashing patterns appear on the supervisor corridor lamp, immediately contact qualified technical personnel in order to solve the problem.

13 Document History

Version	Date	Description
A	03 June 2021	First Release.
B	09 December 2021	California Proposition 65 Warning added. See 3 Caution and Notes, page 3 Updated text for “Vigilance and reporting incidents”. See 4.2 Vigilance and Reporting Incidents, page 5 Removal of Class I references. Removal of MDD references.
C	03 January 2022	Updated CE definition. See 2 Symbols, page 2 UDI—DI table added. See 4 MDR Compliance, page 4 Updated Intended Purpose. See 1 Intended Purpose, page 1 Removed unused labels. See 2 Symbols, page 2 Changed label graphic. See 5.2 Class IIb labels, page 8
C2	28 June 2022	CH REP - Swiss Authorization Representative information added. See CH REP - Swiss Authorization Representative information, page 2
D	03 April 2024	Added warning for professional users. See 3 Caution and Notes, page 3
E	26 May 2024	Added paragraph for unintentional/accidental priority slider change. See 12.1.4 Cancel a Disconnect Alarm after Unintentional Priority Change, page 22 Added a note to “Selecting the Required Medical Alarm Priority” in the case of an unintentional or accidental priority change. See 7 Selecting the Required Medical Alarm Priority, page 12
F	08 October 2024	Updated the regulatory standard to EN60601–1–8. See 4.1 MDR Class IIb compliance, page 4

Ascom (Sweden) AB

Grimbodalen 2

SE–417 49 Göteborg

Sweden

Phone +46 31 55 93 00

www.ascom.com

TD 93433EN / 08 October 2024 / Ver. F