USER MANUAL

teleCARE IP Multi Medical Alarm Module

ascom

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CE NIMA-G4E
NIMA-W4E

CE 2460 NIMA-G4D

Contents

1 Intended Use

Intended Use

The Multiple Medical Alarm (MMA) module (item numbers NIMA-G4E and NIMA-W4E), in combination with specific Room controller software, is intended to interface with medical devices using relay closure circuits (“primary medical devices”), the Ascom Messaging System and the teleCARE IP nurse call system, in order to provide a secondary means of automated visual and/or audible annunciating and displaying of patient alarm information to healthcare professionals, via display devices (class I).

The MMA (item number NIMA-G4D) is also, in combination with specific Room Controller (NIRC3), Room Controller software, and corridor lights (NICL2), intended to interface with primary medical devices approved for communication of alarm conditions, 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 MMA does not replace or alter the behavior of the primary medical devices. When used for indication of alarm conditions, the MMA does not modify, change or add information to the alarm condition.

The MMA 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 MMA is not intended to be used for diagnostic purposes or to come in physical contact with patients.

The MMA 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

Read instructions.

Applicable to: NIMA-G4D.

Note: Label can be found on top of the NIMA-G4D module.

See 4.3 Class IIb labels, page 6

Read instructions.

NIMA-G4E

NIMA-W4E

NIMA-G4D

Waste Electrical and Electronic Equipment Directive (WEEE Directive)

Primary medical device connect.

Primary medical device intentional disconnect.

Primary medical device connections

1: High priority

2: Medium priority

3: Low priority

4: Low priority

3 MDD/MDR Compliancy

3.1 MDD/MDR Class I compliancy

The NIMA-G4E and NIMA-W4E are MDD/MDR Class I compliant devices. The NIMA-x4E is a teleCARE IP nurse call system peripheral device, based on the single switch module and is available in grey (NIMA-G4E) or white (NIMA-W4E).

The NIMA-G4E and NIMA-W4E are designed to be used in combination with the bedside module (NIBM2), the medical rail socket (NIMS2) or the pull cord module (NIPC) version 2.23 or later. It offers the secure medical alarm function, unintentional disconnect alarm and line break detection. The multi medical alarm module is connected to the NIBM2, NIMS2 or NIPC by a modular interconnection cable.

3.2 MDD Class IIb compliancy

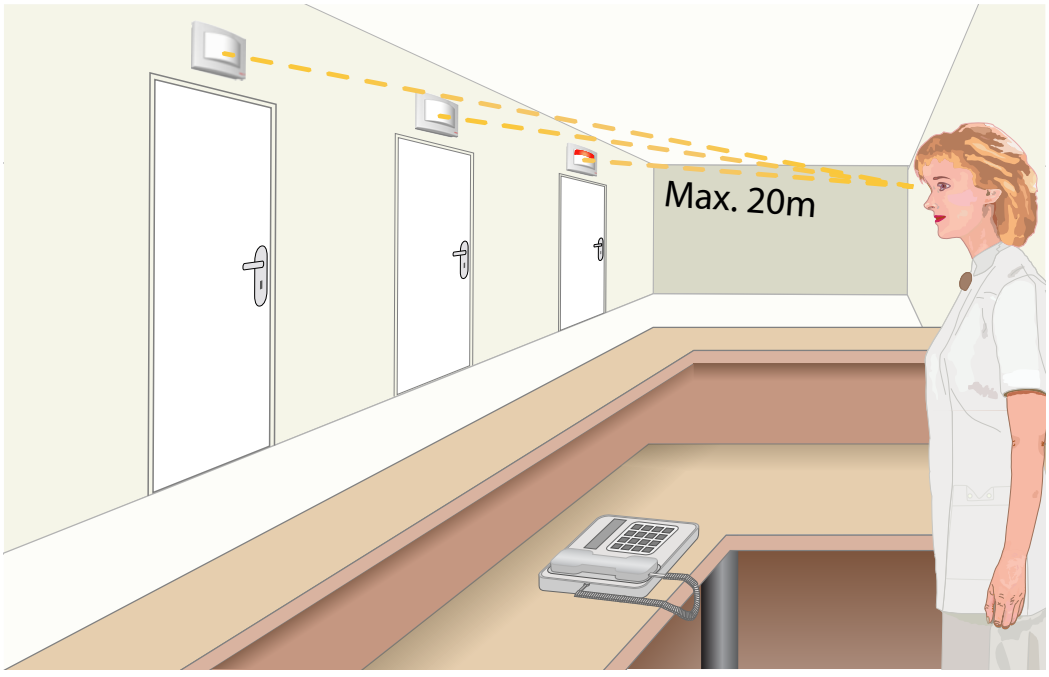
The NIMA-G4D is an MDD Class IIb compliant device. The NIMA is a teleCARE IP nurse call system peripheral device, based on the single switch module and is available in grey only.

An MDD class IIb compliant system is formed by using the NIMA-G4D in combination with the bedside module (NIBM2) or the medical rail socket (NIMS2) version 2.23 or later. The multi medical alarm module is connected to the NIBM2 or NIMS2 by a modular interconnection cable. A corridor lamp (room controller NIRC3 or corridor lamp NICL2) 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 EN60101-1-8 (red, yellow, cyan or yellow).

IMPORTANT: *It is mandatory to use the corridor lamp (NICL2 or NIRC3 lamp) at the entrance of locations (rooms) where NIMA 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 NIMA to corridor lamp	< 1s
Peripheral lost signalling of NIMA to corridor lamp	< 1s
Reboot of Room Controller (NIRC3) and restoring of signalling on corridor lamp	< 90s

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	Continuous

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 10.6 “Supervision” on page 17, page 20 for detailed information on how to proceed when the supervisor continues to flash for more than 90 seconds.

3.3 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.

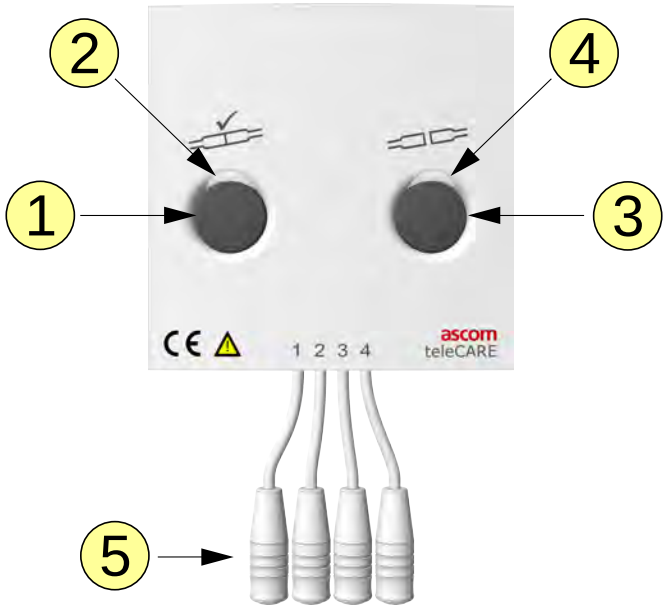
Anyone who becomes aware of any event involving death or serious deterioration of health and an Ascom medical device, or if it appears the Product may have contributed to a death or injury, or if there is a perceived Product malfunction that could contribute to death or injury, or if a customer expresses 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 the report.

If any regulatory body or competent authority provides written notice to an end user, or reseller / distributor with respect to inquiries about, or investigates 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.

4 Multi Medical Alarm Module (NIMA) Components

4.1 NIMA Module



1. Test Alarm Button
2. LED (Multi-color)
3. Disconnect Button
4. LED (Green)
5. Four inputs for the Multi Medical Alarm Cable
   1: High Priority
   2: Medium Priority
   3: Low Priority
   4: Low Priority

4.2 Class I labels

NIMA-G4E

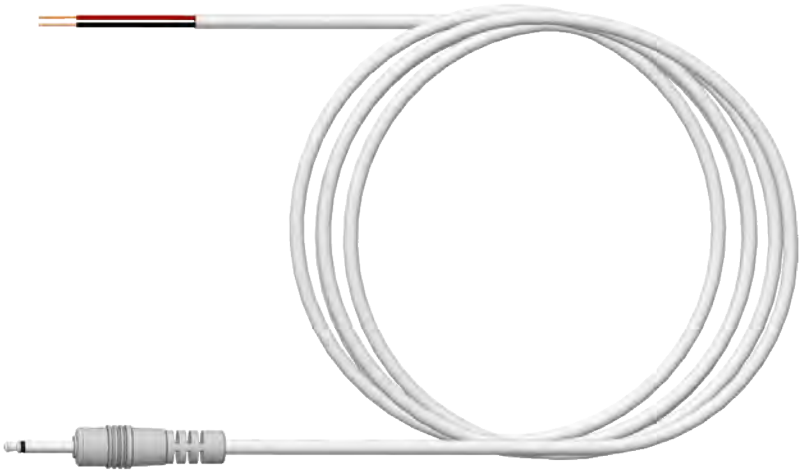
NIMA-W4E

4.3 Class IIb labels

NIMA-G4D

NIMA-G4D Example:

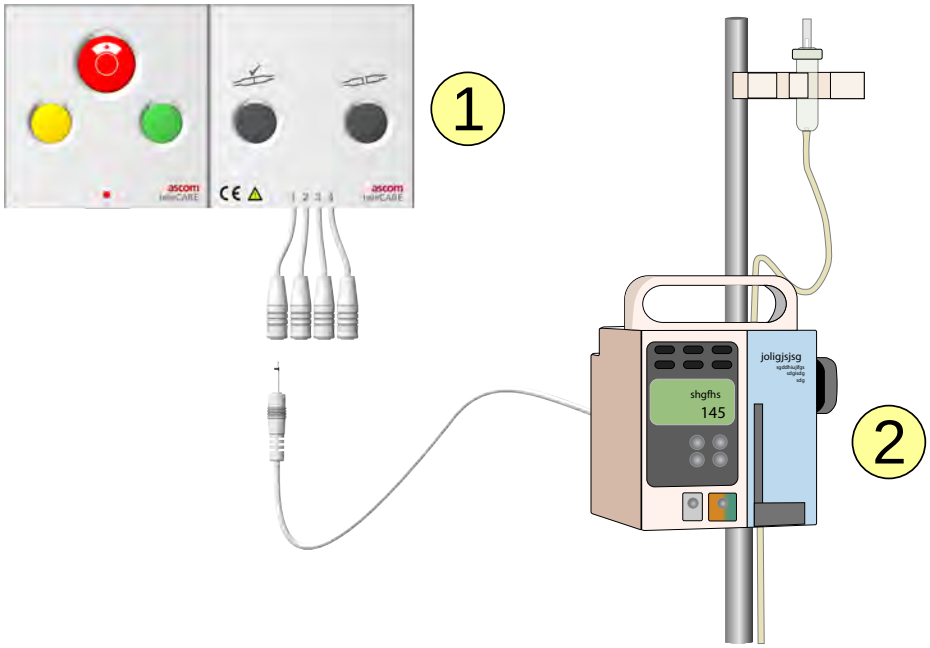
4.4 Medical Alarm Cable



IMPORTANT: *In order to fulfill the requirements of EN 60601-1-8, the use of the MMA Alarm Cable (660393) is mandatory in order to connect primary medical devices to the NIMA and also an end of line (EOL) resistor must be connected across the alarm contacts of the medical device to monitor the continuity of the electrical connection to the NIMA module.*

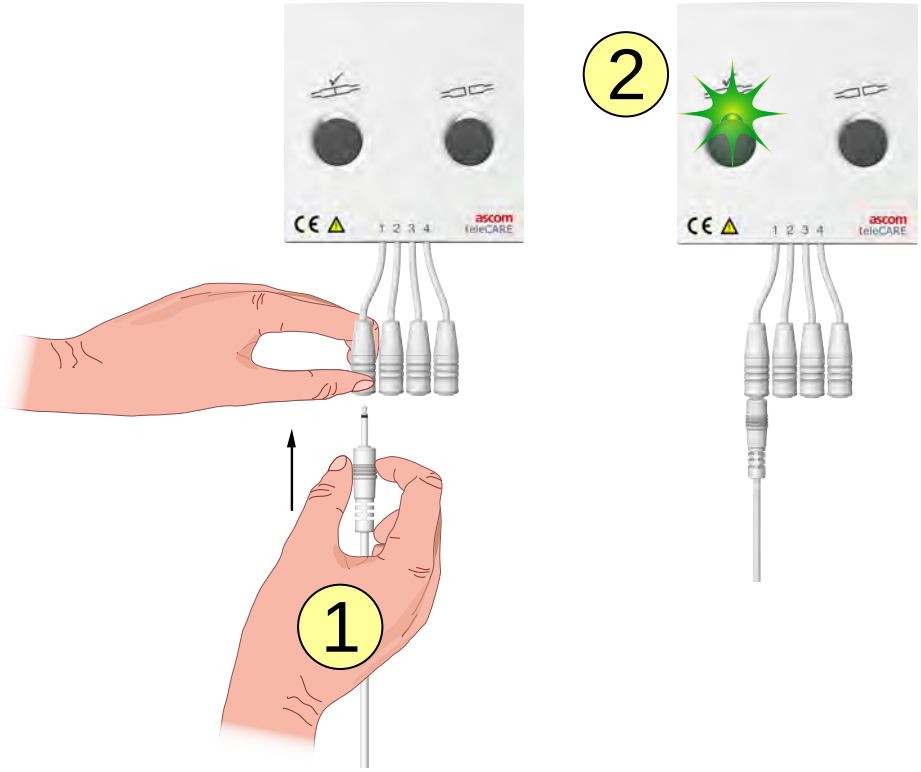
5 Preparations

When installing the NIMA-G4D make sure that an Ascom representative connects the medical alarm cable 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 “Peripherals” chapter of the Installation Guide (TD92609EN) under section “Multi Medical Alarm Module (NIMA)”.



1. Multi Medical Alarm Module — NIMA
2. Primary Medical Device

6 Connecting the Multi Medical Alarm Cable

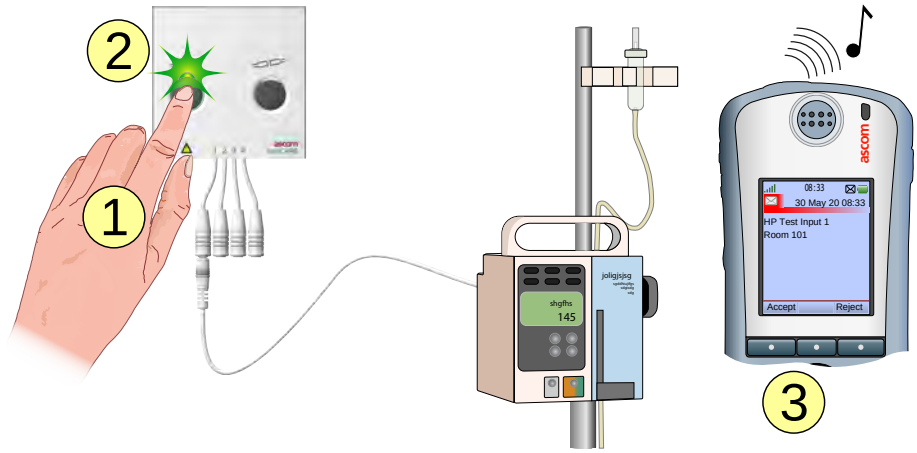


1. Insert the multi medical alarm cable into one of the four inputs depending on the messaging priority.
   1: High priority
   2: Medium priority
   3: Low priority
   4: Low Priority
2. The multi-color LED above the (left) test button will flash (green) 1, 2, 3 or 4 times depending on the amount of primary medical devices that are connected to the multi medical alarm module.

   Primary Medical Device Connections

   1
   2
   3
   4

7 Perform the Medical Alarm Test

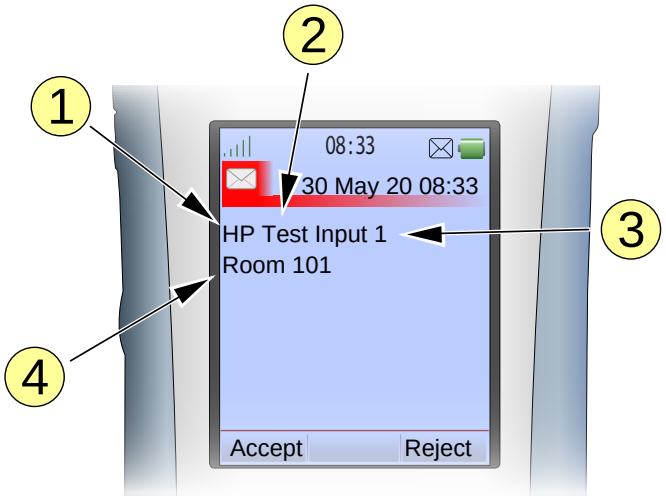


1. Press and hold the test button of the multi medical alarm module.
2. The multi-color LED above the test button will flash (green) 1, 2, 3 or 4 times to indicate how many primary medical devices are connected.
3. If the teleCARE IP system includes messaging an alarm test message will be sent for each primary medical device that is connected to the multi medical alarm module.

- Release the test button to stop the test alarm(s).

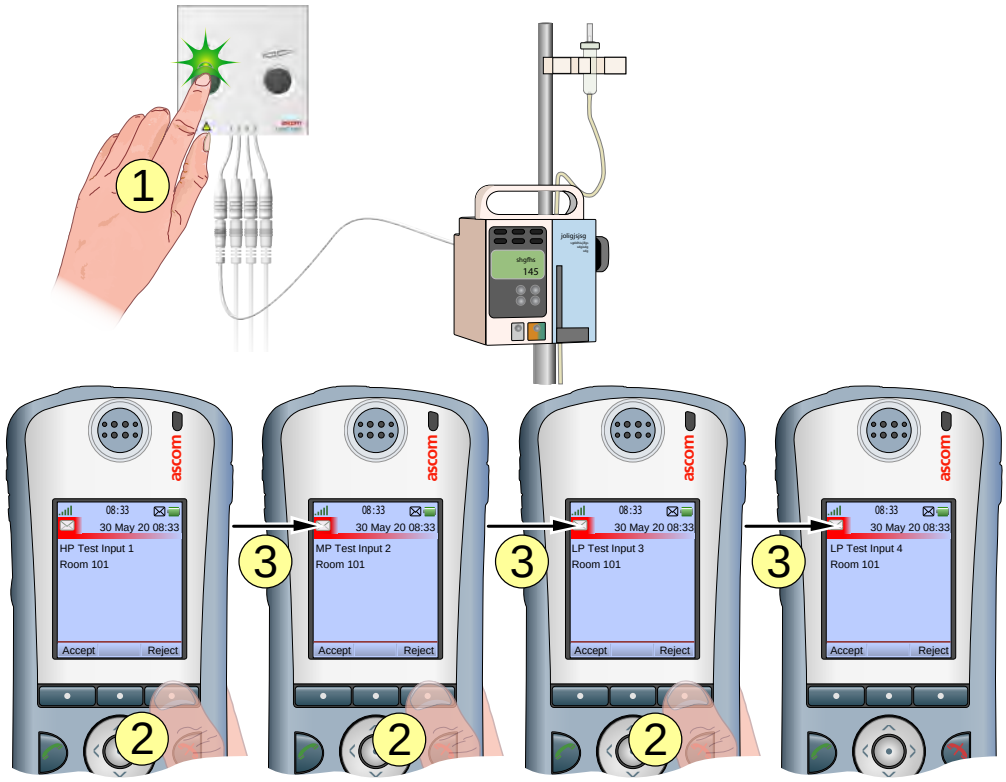
IMPORTANT: *Only put the primary medical device into operation if a correct test message has been received on the display device.*

An example of a test message is displayed below.



1. Priority:
   HP = High
   MP = Medium
   LP = Low
2. Alarm Type
3. Alarm Input
4. Location of the multi medical alarm module

7.1 Test Alarm Handling



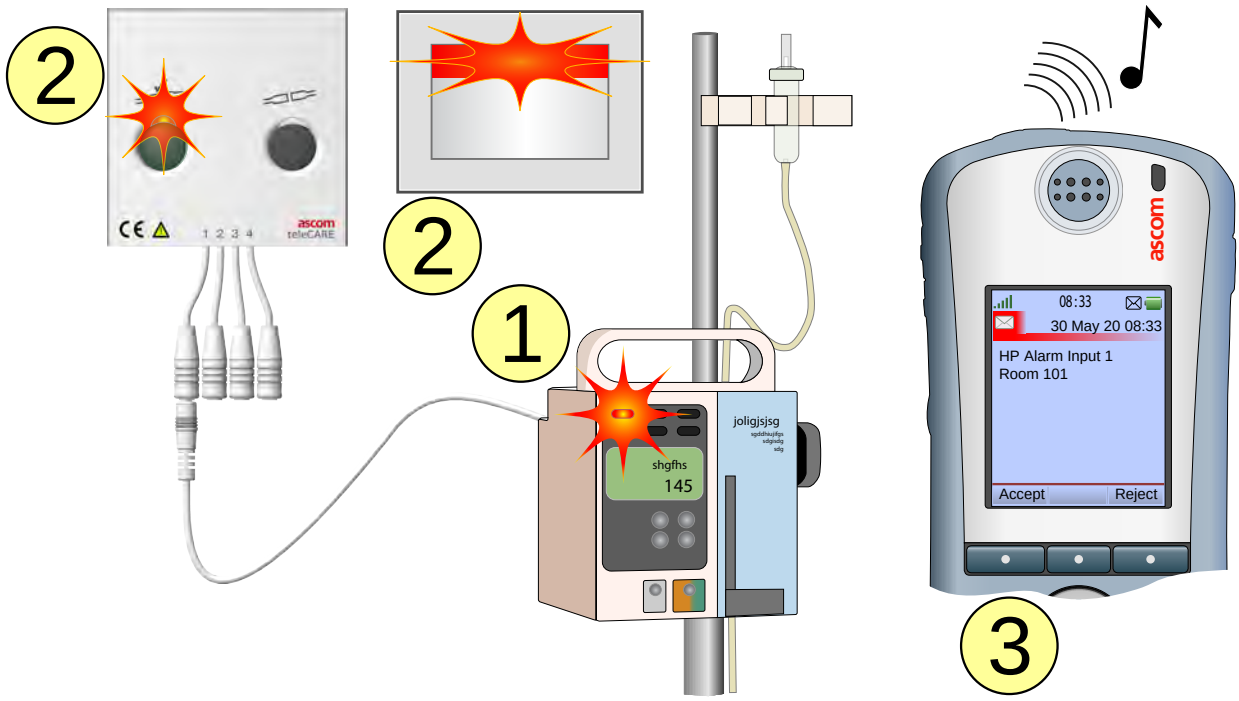
To see if all the test alarms have been received on the display device when two or more primary medical devices are connected:

1. Press and hold the test button on the multi medical alarm module for the entire procedure.
2. Press the “Reject” button up to 3 times for every test message received.
3. The next test message should appear on the display.

When pressing the test button not all test messages may arrive on the display device you are carrying, this is depending on the responsibility which is based on the priority of the alarm and the configuration of the system.

- Release the test button to stop the test procedure.

8 Medical Alarm



1. The primary medical device activates a medical alarm.
2. The multi-color LED above the test button 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.

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.

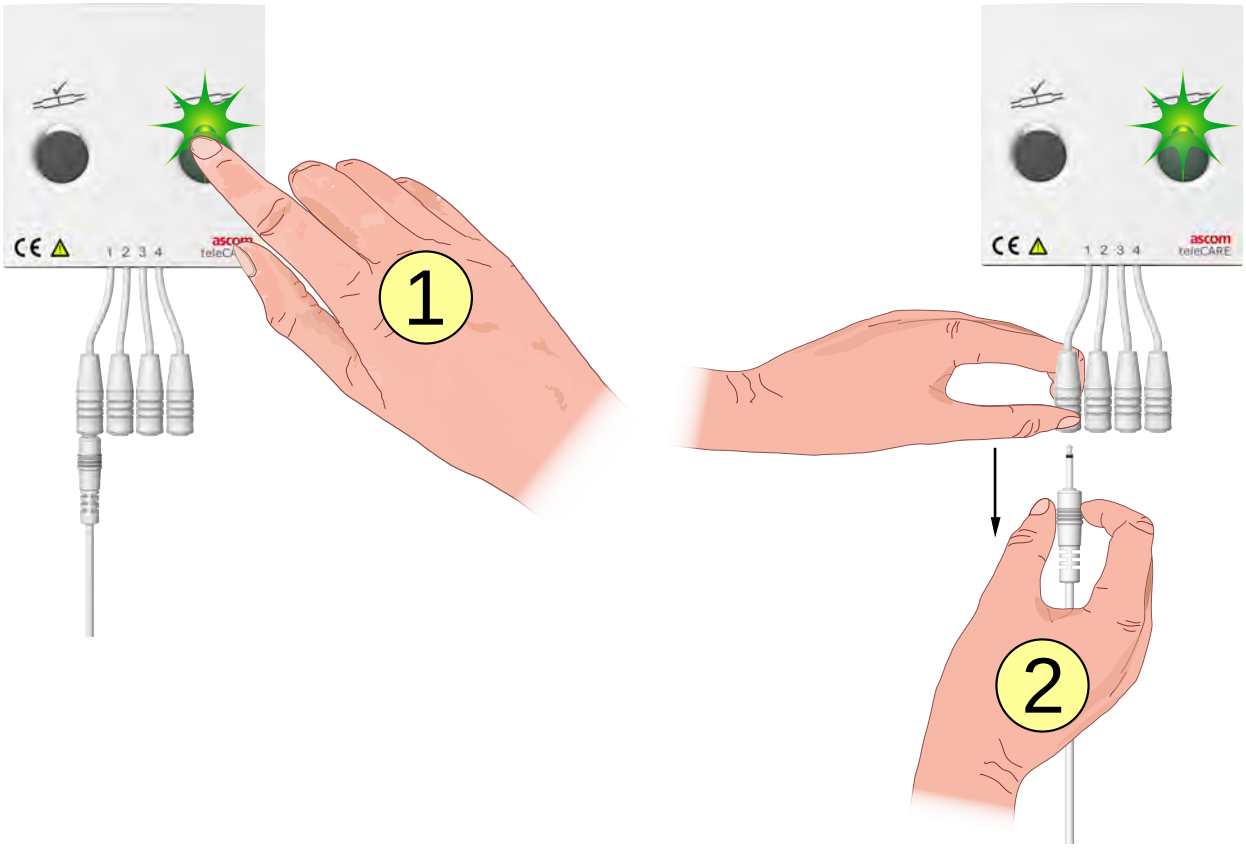
- Cancelling the alarm condition at the primary medical device will reset the medical alarm call at the multi medical alarm module and cancel the medical alarm call.

8.1 Medical Alarm Priority

When two or more alarm calls are active at the same time, the multi-color LED above the test button will show the flashing pattern of the highest priority alarm call. Solving the cause of the highest priority alarm call will cancel the alarm and the LED will show the flashing pattern of the next alarm call with the highest priority.

9 Intentional Disconnection of a Primary Medical Device

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



1. Press the “Disconnect” button on the right (green LED on).
2. Within 3 seconds remove the plug of the primary medical device you want to disconnect from the multi medical alarm module.

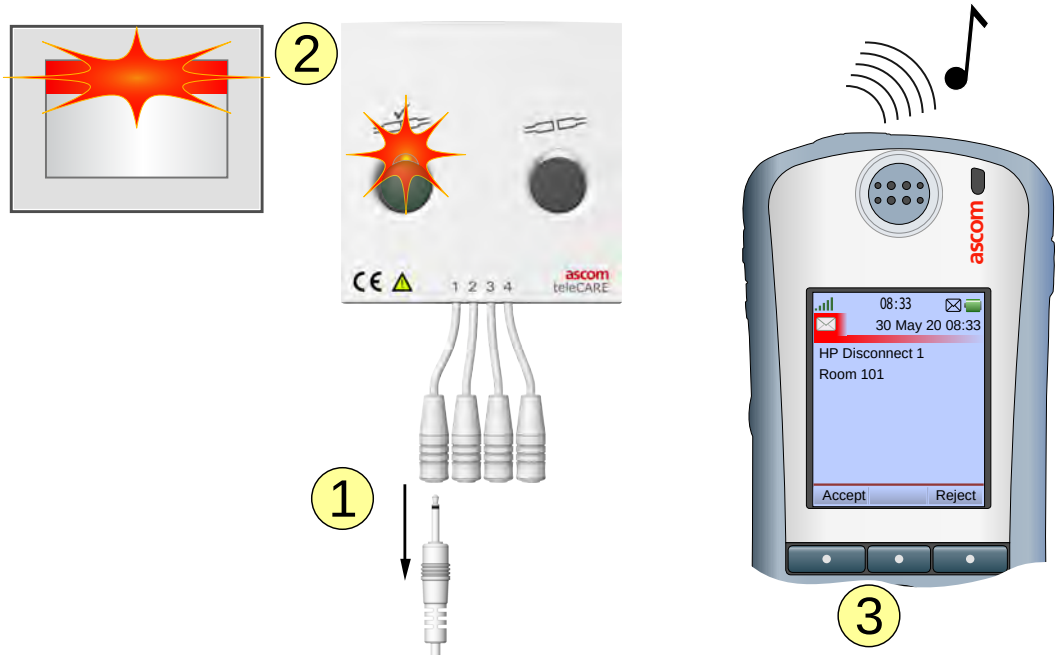
- If you disconnect a primary medical device when the green LED is off (after 3 seconds), a disconnect alarm will be generated.

10 Fault Conditions

10.1 Unintentional Primary Medical Device Disconnection

A primary medical device can get disconnected unintentionally by the plug being pulled out of the multi medical alarm module or a poor connection on the primary medical device.

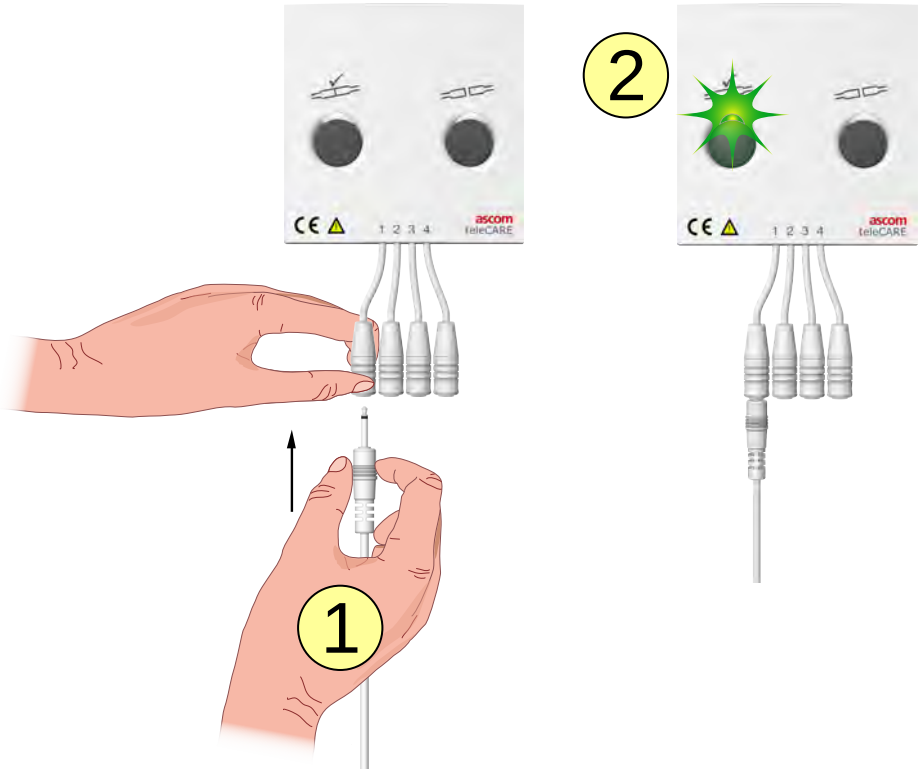
10.1.1 Unplugged from the Multi Medical Alarm Module



1. One of the plugs attached to a primary medical device gets unplugged from the multi medical alarm module.
2. The multi-color LED above the test button 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.

Reconnecting an Unintentionally Unplugged Primary Medical Device



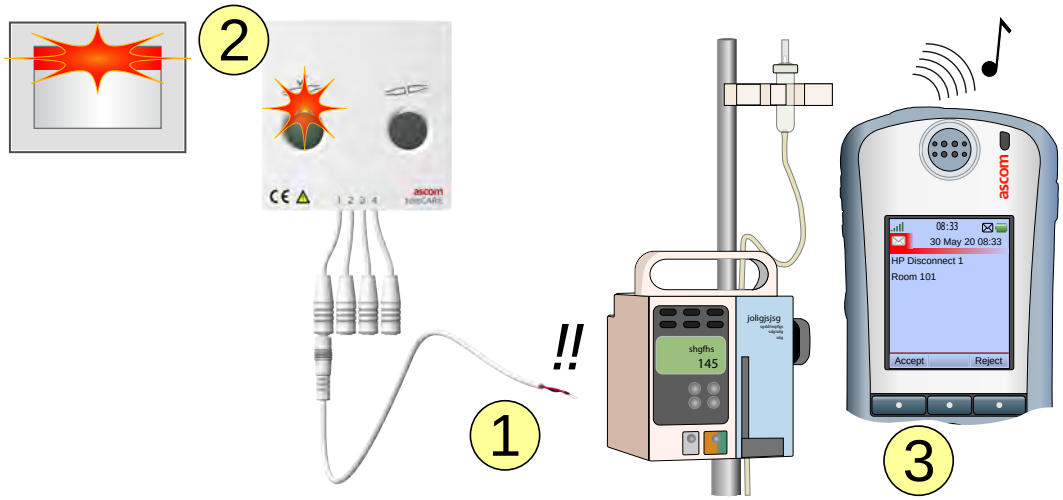
1. Reconnect the multi medical alarm cable to the required input.
2. The medical disconnect alarm is cancelled automatically and the multi-color LED above the test button will flash (green) 1, 2, 3 or 4 times to indicate how many primary medical devices are connected.

   Primary Medical Device Connections

   1 ▬
   2 ▬ ▬
   3 ▬ ▬ ▬
   4 ▬ ▬ ▬ ▬

- When connecting or reconnecting a multi medical alarm cable, make sure to always perform the medical alarm test sequence before putting the primary medical device into operation, see 7 “Perform the Medical Alarm Test” on page 8, page 9.

10.1.2 Disconnected from the Primary Medical Device



1. The multi medical alarm cable gets disconnected from the primary medical device by a loose contact or a cable break.
2. The multi-color LED above the test button and the 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.

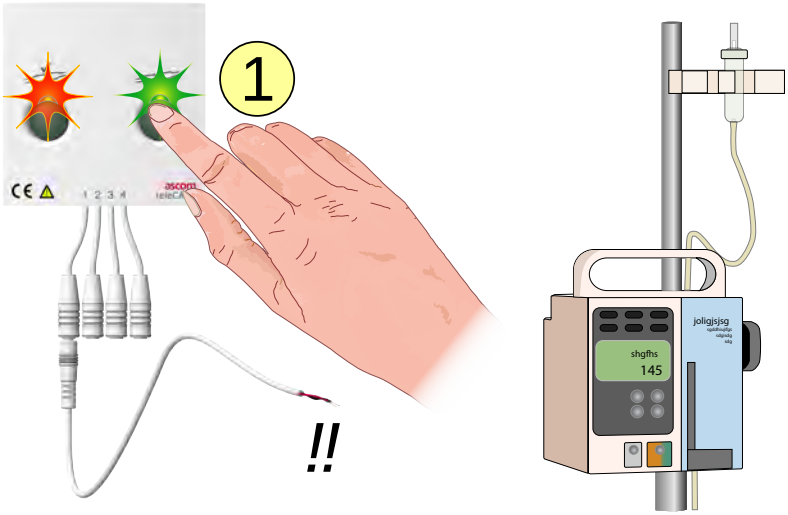
3. If the teleCARE IP system includes messaging, a disconnect alarm message will be sent to the messaging device of the relevant nurse depending on the alarm priority.

Contact Qualified Technical Personnel

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

10.1.3 Cancel a Disconnect Alarm

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

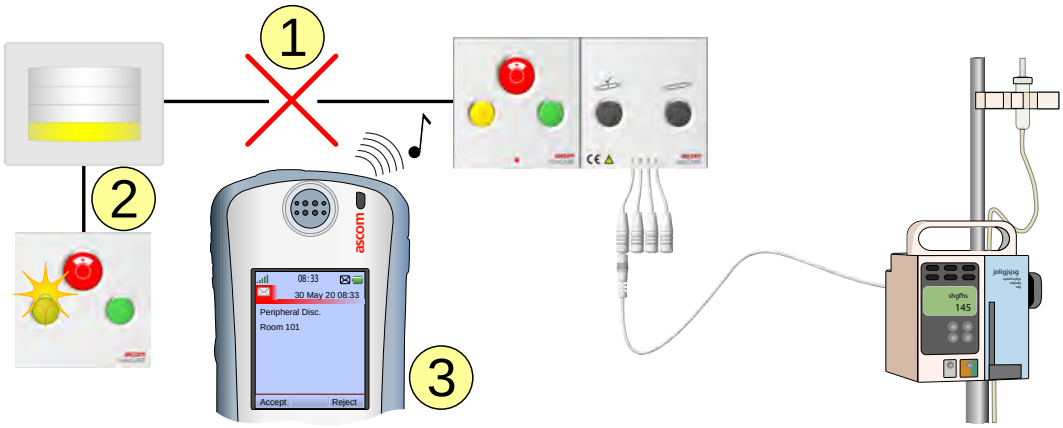


To cancel a disconnect alarm:

1. Press and hold the “Disconnect” button on the multi medical alarm module for four seconds.

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 multi medical alarm module.*

10.2 Multi Medical Alarm Module Failure



1. The multi medical alarm module fails to operate (broken, disconnected)
2. The status of the multi medical alarm module is constantly monitored by the module it is connected to. When the module breaks down or the interconnection cable breaks, the linked doorside module and 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 multi medical alarm 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 multi medical alarm module.*

10.3 Lifespan of the Multi Medical Alarm Module

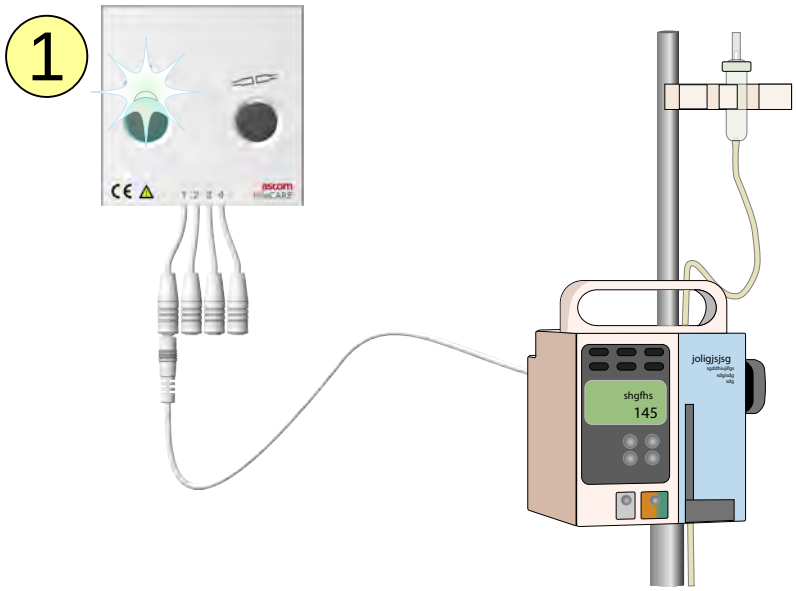
Due to the wear and tear of the alarm input connectors as a result of the connection of primary medical devices to the alarm connectors of the multi medical alarm module, the lifespan of an alarm input connector is guaranteed for up to 5000 connections.

The multi medical alarm module will count the number of connections for all four alarm inputs. When an alarm input reaches the 5000 limit it will be marked as being a worn input and a “Replace module” message will be sent to the assigned technical personnel.

The input will still function normally but a proper connection to the primary medical device cannot be guaranteed. When continuing to use the worn input, the assigned technical personnel will receive a “Replace module” message for every 20 connections that are made to the worn input.

Once a “Replace module” message has been sent it is advised to replace the module as soon as possible. When continuing to use the multi medical alarm inputs that have not reached the limit, be sure to decommission the worn input.

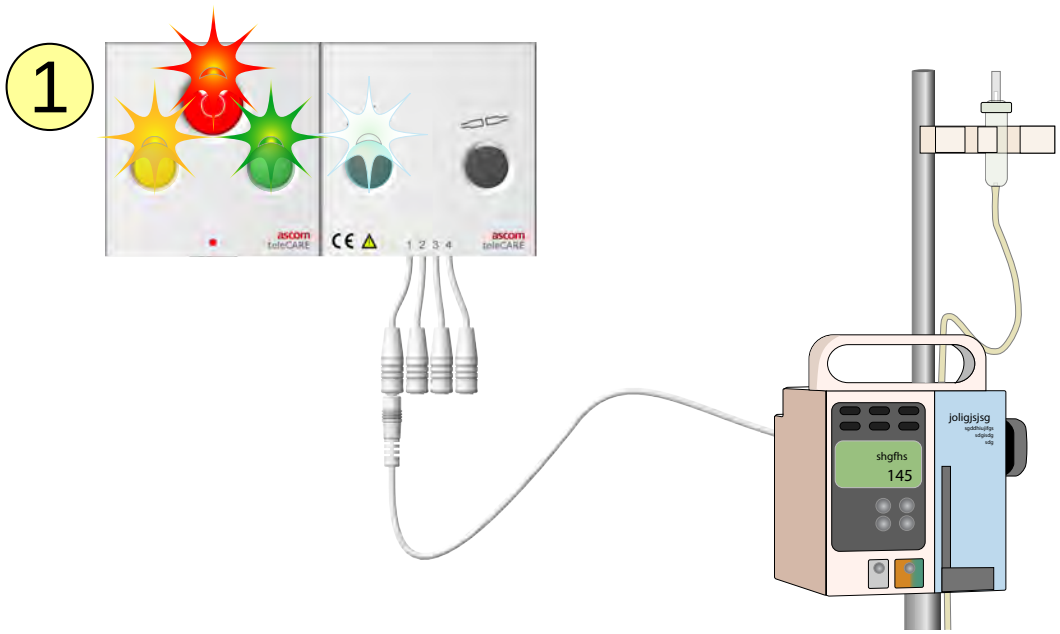
10.4 Multi Medical Alarm Module Configuration Error



1. The multi-color LED above the test button will flash white if the system configuration for the multi medical alarm module is wrong, not existing or during a start up of the system.

10.5 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 right before a power failure occurs. When the power returns and the system has been restarted, the status of the medical alarm will be restored.



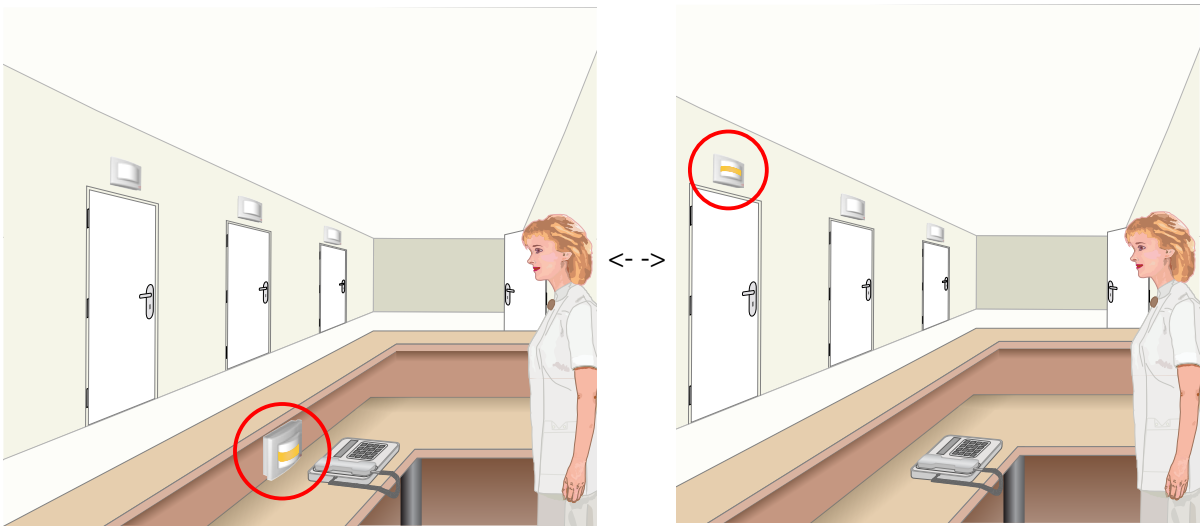
1. When the power returns, the multi color LED above the left button of the multi medical alarm module and all the LEDs on the bedside module will start flashing to indicate that the startup procedure is in progress.

IMPORTANT: *Always perform the medical alarm test procedure after a system restart, see* *7 Perform the Medical Alarm Test, page 9*.

10.6 Supervision

System supervision is part of a teleCARE IP system that includes multi medical alarm 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.

11 Document History

Version	Date	Description
F		• Document History added. • MDD Class I compliancy updated to “MDD/MDR”. See 3 MDD/MDR Compliancy, page 3 • Added reporting of incidents. See 3.3 Vigilance and reporting incidents, page 4 • Images updated: Text and tables that were displayed on top of images have been removed from the images and placed below, as part of the normal text flow in order to improve the “exporting for translation” capabilities.

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