

Hillrom. Accella™ Therapy Mattress Instructions for Use

P006783A-P006788A-P006789A P006790A-P006791A-P006792A P006793A-P006794A









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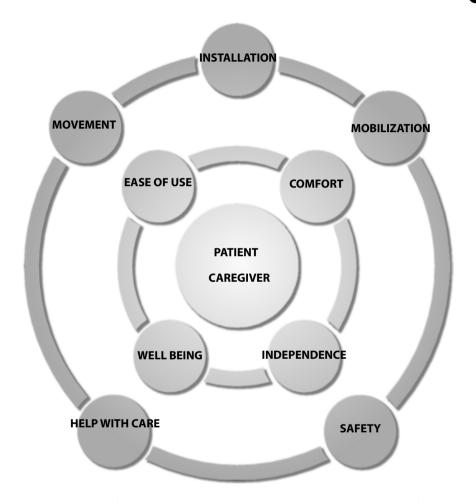
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Destination and Specifications

Structure of the Manual and Symbols Definition



For every type of use, Hillrom $^{\text{m}}$ mattresses provide patients with optimal comfort and greater independence for a feeling of well-being that is conducive to a swift recovery. They are also easy to use for caregivers.

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Understanding the Symbols

Symbol	Description		
①	Highlights special information or explains important instructions.		
	WARNING This symbol indicates that the failure to follow the associated recommendation can put the patient or the user in danger, or damage the equipment.		
	CAUTION This symbol indicates that the failure to follow the associated recommendation can result in damage to the equipment.		
	Tip		
	Risk of falling		
	Caught hazard warning		
D	Risk of crushing an upper limb		
HAZ- COS:	Chemical Hazard Warning		
7	Electric Shock Hazard		
	Biological danger		

Safety and Usage Tips

Intended Use

This device benefits are phase I to phase IV pressure ulcers prevention and treatment help.

Indications

It is suitable for low to very high-risk patients, within the recommended patient weight limits of 30 to 160 kg on the standalone mattress and between 40 and 160 kg on the version combined with the Accella™ bed or Progressa™ bed, in order to achieve valuated clinical performance in all the usual positions of the adjustable head section.

It can be used as a mattress in the following environments, as defined in the standard IEC 60601-2-52:

- application environment 1 (acute care);
- application environment 2 (short-term care in hospitals or other medical establishments);
- application environment 3 (long-term care in medical establishments);
- application environment 5 (outpatients or ambulatory care).

The device is not designed to come into direct contact with damaged skin and must to be used with a sheet between the patient's skin and the surface of the mattress.

(i) In accordance with the NPUAP/EPUAP directives', Hill-Rom recommends that the condition of each patient be regularly checked. For patients with special needs, Hill-Rom recommends the use of the most suitable I-mmersion™ Therapy system. Caregivers are responsible for taking this decision, in accordance with modern care practices.

Contraindications



This device must not be used with patients:

- with medullary lesions, for any other unstable fractures, a medical examination is necessary to determine whether the use of the device is appropriate.
- with atypical anatomy;
- suffering from cervical or trans-bone traction.

Intended Users

The Accella™ Therapy mattresses are designed to be used by Qualified Staff for patient care from several care application environments.

^{1.} NPUAP / EPUAP - Prevention and treatment of Pressure Ulcers - Quick Reference Guide, 2019

Identifying the models

Certain mattress models, certain features or accessories may be available or not, depending on the destination country. These features are identified with an asterisk (*) and the accessories or the additional parts are identified by two asterisks (**).

Model	Description
P006783A* P006790A*	Accella™ Therapy mattress
P006788A* P006791A* P006794A*	Accella™ Therapy MCM™ mattress
P006789A* P006792A*	Accella™ Therapy MCM™ mattress (combined with Hill-Rom® 900 Accella™ bed)
P006793A*	Accella™ Therapy MCM™ mattress (combined with Progressa™ bed)

The mattress P006783A or P006788A or P006790A or P006791A or P006794A is a standalone mattress controlled by a wired remote control, also available as an accessory (see page 49).

The mattress P006789A or P006792A is combined with the Hill-Rom® 900 Accella™ bed and is controlled using the bed interface.

The mattress P006793A is combined with the Progressa™ bed (P7500A without StayInPlace™ function) and is controlled using the bed interface.

First Use



Before using the mattress, it is essential to have a thorough understanding of this manual. This manual contains instructions for general use and maintenance and guarantees improved safety. Caregivers must have access to this manual.

Caregivers must be informed of the risks that may be encountered in the use of electric devices.

Product training can be provided on demand.



When using the mattress with medical devices (accessories), the user must ensure that safety and conformity requirements are met.

Before using the device for the first time or when removing from storage:

- check the condition and conformity of the electrical system with the applicable safety standards;
- Connect the device to the mains power supply (See "Complying with Electrical Safety Standards" on page 5);
- Allow access to the wall outlet to disconnect the mattress when needed;
- Make sure that all the functions of the device are in good conditions of operation;
- make sure that the device and the care environment are in a good state of hygiene (See "Disinfecting" on page 44);
- check the safe positioning of the device in its working environment (see "Before Placing the Patient on the Device" on page 19).

Preventing Risks



Improper use of the device can result in risks for the patient or the user. The following recommendations must be read and followed.



In view of the multitude of models of frames and siderails, and for safety reasons, Hill-Rom advises that all necessary precautions must be taken, especially with regard to the height of the siderails and the dimensions of the mattress support platform. If this device is used on a bed with siderails that are less than 22cm above the mattress, patients must not be left unattended.

For safety reasons, it is advisable to use the lock-out functions of the bed in the following situations:

- During all interventions on the patient or the device (e.g.: examinations, transfers, maintenance):
- when the patient is in an unusual condition or behaves abnormally (e.g.:excited, confused, disoriented, obsessive, old or of a weak constitution).

Properly trained medical staff should determine how the device should be used and the required level of monitoring or constraint.

It is imperative to observe the practices relating to the safety of caregivers. Special attention must be taken when redistributing the load application points, since there is a danger that the bed will tip when the chassis is moved.

The impermeability of the surface and its therapeutic qualities may be compromised by holes made by needles or any other perforations in the cells of the mattress. Caregivers must be informed in order to avoid any tears in the cells of the mattress caused by needles.



Notice to Users and/or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Complying with Electrical Safety Standards

The mains power supply must comply with following standards:

- NF C15-100 and NF C15-211 (France);
- International Electrotechnical Commission (IEC) 60364 for other countries.

Check that the supply voltage of the device shown on the identification label matches the voltage of the establishment's mains power system (See "Locating the Identification Labels of the Device" on page 14).



The device should be connected to a power system equipped with a maximum 30 mA earth leakage circuit breaker, in compliance with IEC 60364-5-53.



Connect the device to the nearest wall plug in order to leave the shortest possible length of cable on the floor to avoid any risk of crushing.





(i) For the mattress P006789A* or P006792A* (combined with the Accella[™] bed) and P006793A* (combined with the Progressa[™]

bed), refer to the bed's manual for the recommendations on connections.

In compliance with standards relating to electromagnetic interference for medical devices, this product does not interfere with other medical devices nor is it susceptible to interference when combined with other medical devices that also comply with the electromagnetic standards in place.

However, some devices, particularly older ones that do not comply with the electromagnetic compatibility standards, may undergo interference or may themselves interfere with the functionality of this device.

Using accessories or cables other than those specified, with the exception of cables sold by the device manufacturer, as replacement parts for internal components, may result in an increase of emissions or a reduction of the device's immunity.

The users of such devices are responsible for ensuring that any malfunctions will not endanger the patient or any other person.

When intravascular or intracardiac connections are in use, the electric potentials of all the unprotected metal parts of the appliance and the bed need to be equalized.



This label indicates that **oxygen tents must never be used** and that only the use of nasal tubes and oxygen masks is authorized. For reasons of safety, masks and tubes should always be kept at a higher level than the mattress support platform.

Complying with Conditions for Transport, Storage and Use

Symbol	Features	Use	Transport/storage ^a
Temperature		+10°C to +40°C	-30°C to +50°C
<u></u>	Hygrometry	30% - 85%	20% - 85%
\$••	Atmospheric pressure	700 mbar - 1060 mbar	700 mbar - 1060 mbar

a. Applicable only if the device is stored in its original packaging.

The device is designed for indoor use only. When used at 40°C,

the temperature of the applied part can reach 43°C. The electrical medical device must be used at an altitude of 3000 m or lower.



The device must be stored in its original packaging:

- protected against light and damp;
- At least 10 cm above floor level to prevent fluid ingress:
- protected against dust:
- outside passageways.

Never stack more than 5 mattresses.

Referring to Technical Specifications

Specifications are subject to change.

Essential performances of the device

The Accella[™] Therapy is a therapeutic mattress. It has two operating modes: continuous low pressure (CLP) and alternating low pressure (ALP), with permanent regulation of the pressure by the I-mmersion[™] sensor in both modes.

Control pendant*

Front View of the Control Pendant



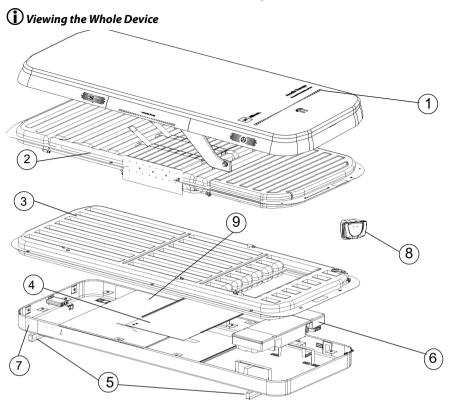
Characteristics	Description
Dimensions	12x17x9 cm / 4.8x6.77x3.54"
Weight	0.445 kg / 0.98 lb
Protection index offered by the covers (IEC 60529)	IP21: Protected against access to dangerous parts with fingers and splashes of water

Only the original connector should be connected to the device.

Therapeutic Mattress

Characteristics	Desc				
Model	P006783A- P006788A- P006789A	P006790A- P006791A- P006792A	P006793A- P006794A		
Dimension (inflated)	203x92x21.5 cm	203x92x21.5 cm / 80x35.5x8.5"			
Weight	~ 17.5 kg / ~ 37	.5 lb	•		
Voltage	220-240V	120V	220-240V		
Frequency	50 Hz	60 Hz	50 Hz		
Apparent power ALP & CLP modes Initial inflation	32 VA 146 VA	32 VA 146 VA	32 VA 146 VA		
Maximum energy consumption	13 Wh	13 Wh	13 Wh		
Operation of the device	Continuous				
Upper cover (applied part of the device)	Polyurethane coating on Polyamide material, low- friction, stretchable in both directions, breathing, bacteriostatic; fungistatic and antimicrobial; can be wiped and washed.				
Volume of the device: in ALP or CLP regulation mode	<55dB(A)				
Alarm: Sound pressure (ISO 3744)	44.6 dB(A)				
Electric shock protection	Class II				
Class according to IEC 60601-1	Type BF applied parts protected against defibrillation shocks (labeled 1 and 8 page 11)				
Protection against inflammable anesthetic mixtures	Not for use with flammable anesthetics.				
= 250Kg	The safe working load is the maximum permissible load that can be applied, above which the mattress may be damaged. Safe Working Load is the technical limit of patient weight that can be applied after which a damage may occur on the mattress.				
Degree of protection provided by the cover (CEI 60529)	IP24: protection against splashes of water.				
Battery: Time to fully charge	24 hours				
Battery life with CPR/patient exit alarm/low pressure alarm	2 hours				
Patient support battery life	8 hours				

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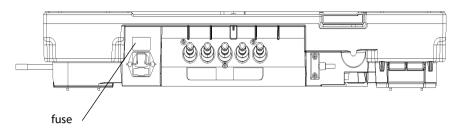
Item	Name
1	Upper cover
2	Therapeutic Mattress with 5 Zones: Head zone (3 bladders) Back zone (6 bladders) Sacrum zone (8 bladders) Thigh zone (2 bladders) Heel Zone (11 bladders)
3	Bottom Cover
4	I-mmersion™ sensor
5	Straps (Accella™ Therapy) or knobs (Progressa™)
6	Technical box
7	Bottom cover
8	Control pendant*
9	X-ray bag

Understanding the Symbols on the Device

Symbols on the Upper Cover

	Do not walk on or run over the power cord
	Adjust the straps
ŤŤ	Foot end
	Zone for notes
I-mmersion Therapy ♦ ♦ • • • • • • ♦ ♦ ♦ ♦	Always install the mattress so that the (I-mmersion $\mbox{\ensuremath{^{TM}}}$) Therapy text is visible
000	Seat cushion
000000000000000000000000000000000000000	X-ray bag
00000000000000000000000000000000000000	MCM™
	Safe Working Load

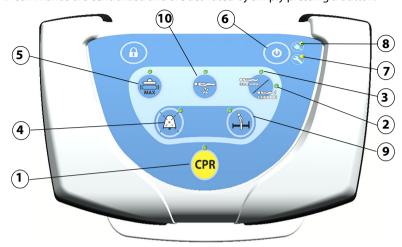
Symbols on the Technical Box



250V T 1,6A lcu: 1500A	220-240VAC : 5*20 time delayed 1.6A fuse-lcu=1,500A
250V T 1,6A	120VAC :
lcu: 1500A	5*20 time delayed 2A fuse-lcu=1500A

Symbols on the Control Pendant*

All commands are centralized and are activated by simply pressing a button.



	Buttons and indicator lights						
	Symbol	Description		Symbol	Description		
1	CPR	CPR activated: Green	6	(b)	On/Off Button		
2		Continuous low pressure (CLP) mode activated: Green	7	3	Malfunction/service alarm: yellow and intermittent audi- ble alarm		
3		Alternating low pres- sure (ALP) mode activated: Green	8	3	Mains power present after pressing the On/Off button: Green Mains Power Fault Alarm: yel- low and intermittent audible alarm		
4		Inhibit/suspend the alarms activated for 10 minutes: Green	9		Bed exit monitor activated: Green Bed exit alert: Green flashing and continuous audible sig- nal		
5	MAX MAX	Maximum inflation activated for 20 minutes (P-Max): Green	10		MicroClimate Management (MCM™)* activated: Green		

Symbols on the labels

•••	Manufacturer	IP24	Cover protected against access to dangerous parts with fingers and splashes of water
REF	Device reference ^a	┤↑	Type BF applied parts pro- tected against defibrillation shocks
SN	Serial number		Class II device
\sim	Alternating Current	C E 0459	Medical Device conformity mark
<u>^</u>	General safety sign		Temperature limits
	Refer to the Instructions for Use.	***	Atmospheric pressure limits
	DO NOT DISCARD Obey local recycling rules	<u>%</u>	Hygrometry limits
	Interior use		Fuse
	No Oxygen Tent		Date of manufacture
UDI	Unique Device Identifica- tion	MD	Medical Device

a.The device part number contains the following information: P+6 figures = model,

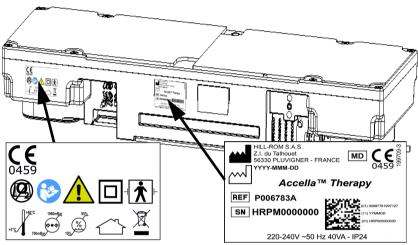
⁻ A = device version letter

See "Locating the Identification Labels of the Device" page 14

Locating the Identification Labels of the Device

On the technical box

To identify the device model REF and its serial number SN:





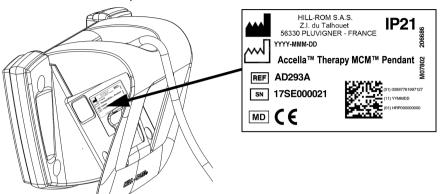
220-240V ~50 Hz 40VA - IP24





On the Control Pendant

The label showing the conditions of use and specifications of the device is located on the rear of the control pendant.



Refer to "Symbols on the labels" page 13 for details of the symbols.

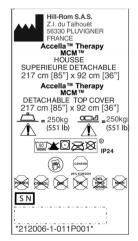
Accessing to the Upper and BottomCovers Identification Labels

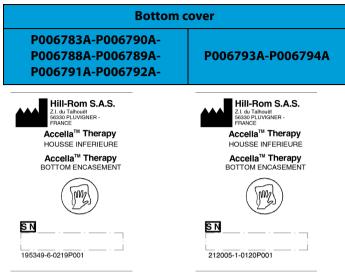
Open the zip fastener on the device





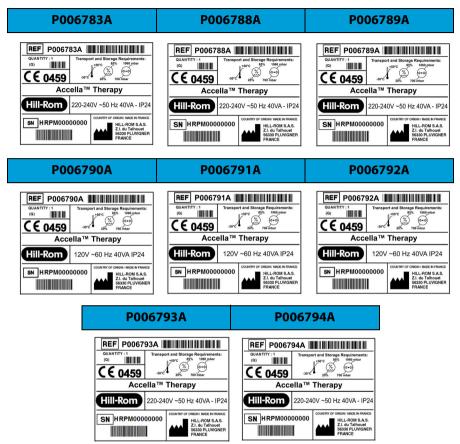






See details of the symbols for cleaning and disinfection in the "Disinfecting and Servicing" page 41 section.

Checking the Model of the Device on the Packaging Label



See symbols in paragraph "Complying with Conditions for Transport, Storage and Use" page 6)

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Installing the Patient

Before Placing the Patient on the Device

Assess the various risks, including but not limited to the following (incomplete list containing risks related to reasonably foreseeable misuse):

- risk of entrapment;
- potential falls from the bed:
- patient in state of confusion;
- patient's learning ability;
- persons lacking the mental capacity to recognize risky actions;
- unauthorized persons.

Install and use for the first time must be done in accordance with these instructions.

Checking the Compatibility of Bed Frames and Mattresses

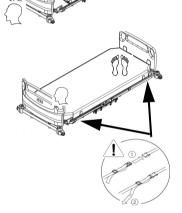
The bed / mattress / siderails combination (and in particular their respective dimensions) must be examined in order to make sure that it meets the requirements of the IEC 60601-2-52 standard and the "Hospital Bed Safety Workgroup" guide, and that the resulting combination does not alter the performance of the devices, their safety nor their usability.

Check that there are no overly large spaces on the sleep surface, especially by the I-mmersion™ sensor, that could compromise the efficacy of the therapeutic functions.

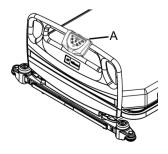
Installing the Device

Standalone version

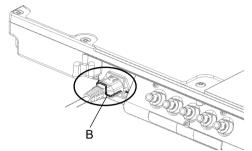
- Unpack the control unit and the mattress.
 Take care not to damage them when unpacking.
- Check that all the components are present and correct, and that the power cord is not damaged.
- 3. Place the rolled up mattress on the top of the bed at head foot end and unroll it.
- 4. Check that the symbol \(\frac{1}{2} \) on the cover is at the foot of the bed.
- 5. Attach the mattress using the straps at the head and foot ends.
- 6. Adjust the length of the straps to safely secure the mattress.



- 7. Make sure that the device is correctly installed and securely attached, and in particular that it is well centered on the sleep surface and pushed tightly against the foot board to avoid the danger of entrapment.
- Make sure that the attachments do not become entangled in the moving parts of the bed chassis, such as actuators, CPR handles, etc. With articulated chassis, make sure that the straps of the device are only attached to the mobile head and foot sections and NOT to the main fixed chassis.
- 9. Attach the control pendant to the footboard of the bed using the handle attachment (A).



10. Open the zip fastener of the upper cover on the left at the foot of the bed. Pass the cord through the hole in the middle on the left-hand side and put the power cord under the lower mattress and the connector as shown below, making sure that it is secured by the safety clamp (B).



Check that the clamps of the power supply cord are attached to the main frame, and not to articulated parts, such as the head or foot sections, and close the cover. Failure to follow this recommendation could result in damage to the equipment.



Take care not to damage the power cord when moving the bed. Failure to follow this recommendation could result in corporal injury.

- 11. Connect the power cord to the wall outlet.

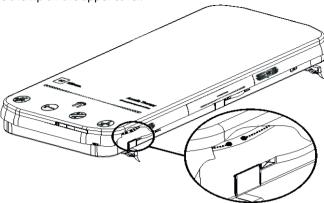
 Ensure that the wall outlet is freely accessible after installation of the device.
- 12. Make sure the CPR button is not pressed (CPR indicator light off).

 The mattress inflates as soon as it is switched on and automatically switches to the ALP / MCM™* mode at the end of the initialization cycle. The mattress takes approximately 20 minutes to inflate.



- 13. Do not place the patient on the mattress during the initial inflation phase and until the ALP mode activation. The operator must check that all the zones of the mattress are fully inflated before installation.
- 14. For small patients, center the sacrum on the I-mmersion™ Therapy zone marked on the mattress cover.
- The control pendant continuously diplays the status of the device.

15. Close the zip on the upper cover.



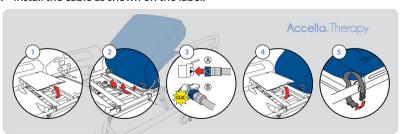
Placing a cotton sheet on the mattress will improve patient comfort and make it easier to administer care



It is advisable not to place any waterproof materials (e.g., drapes) on mattresses with the MCM™ function, as doing so would reduce the performance of the function.

Version combined with the Accella™ bed

- 1. Unpack the control unit and the mattress. Take care not to damage them when unpacking.
- 2. Check that all the components are present and correct, and that the power cord is not damaged.
- 3. Place the rolled up mattress on the top of the bed at the head end and unroll it.
- 4. Check that the symbol on the cover is at the foot of the bed.
- 5. Fold in two at the head end.
- 6. Remove the hard surface of the thigh section.
- 7. Install the cable as shown on the label.



8. Connect the plug to the bed connector (it clicks into place).

- 9. Install the hard surface of the thigh section.
- 10. Attach the mattress using the straps in the center on the thigh section.
- 11. Unfold the mattress.
- 12. Adjust the length of the straps to securely attach the mattress.





- 13. Make sure that the mattress is correctly installed and securely attached, and in particular that it is well centered on the sleep surface and pushed firmly against the foot board to avoid the danger of entrapment.
- 14. Connect the bed power cord to a wall outlet.
- 15. Press Mattress on the CGI
- 16. Press Start.
- The mattress switches to initialization mode. A beep sounds after 20 minutes, indicating that the mattress is operational.



- 18. The status of the mattress switches to ON in the default mode. The ALP and MCM™ modes are active.
- 19. Do not place the patient on the mattress during the initial inflation phase before the ALP / MCM™ mode is activated. The operator must check that all the zones of the mattress are fully inflated before installation.
- 20. For small patients, center the sacrum on the I-mmersion™ Therapy zone marked out on the mattress cover.
- Placing a cotton sheet on the mattress will improve patient comfort and make it easier to administer care.



It is advisable not to place any waterproof materials (e.g., drapes) on mattresses with the MCM™ function, as doing so would reduce the performance of the function.

Version combined with the Progressa™ bed

- Unpack the control unit and the mattress.
 Take care not to damage them when unpacking.
- Check that all the components are present and correct, and that the power cord is not damaged.

- 3. Place the rolled up mattress on the top of the bed at the head end and unroll it.
- 4. Check that the symbol on the cover is at the foot of the bed.
- 5. Fold in two at the head end.
- 6. Connect the plug to the bed connector (it clicks into place).
- 7. Attach the mattress using the knobs in the center on the head section.
- 8. Unfold the mattress.
- 9. Make sure that the mattress is correctly installed and securely attached, and in particular that it is well centered on the sleep surface and pushed firmly against the foot board to avoid the danger of entrapment.
- 10. Connect the bed power cord to a wall outlet.
- 11. The mattress switches to initialization mode. A beep sounds after 20 minutes, indicating that the mattress is operational.
- 12. The status of the mattress switches to ON in the default mode. The ALP and MCM™ modes are active
- 13. Do not place the patient on the mattress during the initial inflation phase before the ALP / MCM[™] mode is activated. The operator must check that all the zones of the mattress are fully inflated before installation.
- 14. For small patients, center the sacrum on the I-mmersion™ Therapy zone marked out on the mattress cover
- (i) Placing a cotton sheet on the mattress will improve patient comfort and make it easier to administer care.



It is advisable not to place any waterproof materials (e.g., drapes) on mattresses with the MCM™ function, as doing so would reduce the performance of the function.







Mobilizing and Securing the Patient

The CPR function and the therapeutic modes and alarms are not available when the mattress is OFF.

This device is designed for optimal therapeutic benefits when the adjustable head section is inclined to between 0° and 45°.

Raising the head of bed to 45° or higher increases the risk of pressure ulcer formation in the sacral area.

Patients are ideally positioned when their hip is aligned with the patient position indicator on the bed.

Understanding the Therapeutic Mode

The Accella™ Therapy device has two therapeutic modes: the Continuous Low Pressure (CLP) and Alternating Low Pressure (ALP), with a permanent regulation by the sensored I-mmersion™ in each of these modes.

Irrespective of the positions of the bed frame articulations, this device detects the weight and the position of the patient and automatically adjusts the pressure of the support accordingly.

The I-mmersion...Therapy also includes an alarm that is activated whenever a fault occurs in the control system. This may happen if the patient is too heavy, and about to touch the under mattress. In this case, lower the backrest until the alarm stops.

Selecting the Operation Mode

Standalone version

Continuous low pressure (CLP) mode

To select this mode, press the button



The corresponding green indicator light comes on and a beep sounds. The patient is supported at optimum low pressure under the control of the I-mmersion™ sensor.

Alternating low pressure (ALP) mode

To select this mode, press the button



The corresponding green indicator light comes on.

The patient is supported at optimum low pressure under the control of the I-mmersion™ sensor. The bladders deflate sequentially in a 2 step cycle of approximately 10 minutes.

Maximum Inflation Mode (P-Max)

To select this mode, press the button . The corresponding green light comes on.



After 20 minutes, the device automatically returns to the initial therapy mode to reduce the risks associated with non-therapy mode.

After activating the P-Max mode, it is possible to return to therapy mode previously selected by selecting the P-Max button.

Transport mode



The Accella™ Therapy device is designed to stay inflated for approximately 2 hours without power to ensure the support of the patient during transport (See "Moving the Patient on the Bed in Transport Mode" on page 33).

Locking

A lock function is available to prevent unexpected changes due to visitors.

Press (A)

to activate the lock.

All the LEDs on the remote control flash to confirm that the function is active.

If an attempt is made to activate other functions, the LEDs on the remote control flash to indicate that they are locked.

NOTE:

Only the CPR function and the alarm silence cannot be locked out.

To deactivate the lock function, press again the button





Patient exit function

This function is used to automatically detect when the patient leaves the bed. This function is helpful for night staff or during busy periods and increases patient safety.

Press the button to activate the patient monitor. The indicator light shines green.

If the patient leaves the bed, a light flashes next to the corresponding symbol and a continuously alarm sounds.

Press again the button to switch off the patient monitor.



ne patient exit function does not replace a suitable medical surveillance.



MCMTM*

The microclimate management system is activated automatically when the Accella™ Therapy device is switched on.

It can be switched off by pressing the Ventilation button on the remote control of the MCM^{TM*} module.

When the MCM™ system is active, the green light comes on.

Combined mattress

Refer to the bed's manual for the activation and control of the different therapeutic modes.

Activating the CPR

Standalone version

In emergencies, opening the CPR valve (cardiopulmonary resuscitation) quickly deflates the mattress, providing a hard surface for external heart massages.



Do not allow unqualified persons to activate this function. Ensure that no obstacles (e.g., limbs, accessories, objects, power cords) or persons are under the head section.

Press the CPR button located on the control pendant.
 The light indicator near the CPR symbol turns green.



The mattress deflates in approximately 30 seconds.

- 2. If necessary, lower the siderails and the head section of the bed, or place the bed frame in the CPR position (refer to the instructions of the bed manufacturer).
- 3. Place a CPR board under the patient, or follow the protocol of the CPR function.

Cancel the CPR

- Press on the CPR button again.
 In view of the damage that this emergency function can cause, the mattress restarts by completing an initial inflation cycle. The mattress reverts to the preceding therapeutic mode.
- 2. If necessary, place the bed frame in the appropriate position (refer to the instructions for the bed frame).

The CPR function can only be activated when the mattress is connected to the mains and is ON, and for the first 2 hours when in transport mode.

The mattress should be plugged into a wall outlet so that it inflates.

Combined mattress

Refer to the bed's manual for the activation and control of the CPR function.

X-ray cassette pouch

The head end of the mattress is equipped with a pouch for X-ray cassettes (min. height 85 cm, min. width 84 cm) to take chest X-rays.

The type of materials, the density and the thickness of the mattress, and the weight and morphology of the patient can affect the quality of the X-ray images. The best way to produce X-rays of an optimal quality is to get as close to the patient as possible. The

radiologist is responsible for deciding on the best solution to take the X-ray according to the medical target and the hospital's protocol adapted to the patient's illness.

The X-ray cassette can be installed on the left or the right of the head section, once the corresponding siderail has been lowered.





To avoid any risk of infection, the zip fastener of the cover must be closed after each use. If necessary, the X-ray cassette pouch can be cleaned and dried using the standard disinfection methods.

Understanding the Alarms

Meaning of the alarms on the standalone mattress*

Reason for sounding	Type of alarm	Time before sounding	Action to be taken by the operator
When the product starts: Calibration problem, battery missing, low battery, I-mmersion™ missing, battery charger missing.	Audible and visible	Immediate	Contact a Hill-Rom technician
Mattress leak	Audible and visible	10 min +/- 1min	Switch off the alarm and contact a Hill-Rom technician
Problem with the I-mmersion™ sensor	Audible and visible	1 min +/- 10 seconds	Switch off the alarm and contact a Hill-Rom technician
Disconnection of the I-mmersion™ sensor	Audible and visible	Immediate	Switch off the alarm and contact a Hill-Rom technician
Pressure in the mattress is too low (12 mbar +/- 20%) (4"H2O +/- 1"H2O)	Audible and visible	1 min +/- 10 seconds	Switch off the alarm and contact a Hill-Rom technician
in transport mode: Pressure in the mattress is too low (12 mbar +/- 20%) (4"H2O +/- 1"H2O)	Audible and visible	Immediate	Switch off the alarm and contact a Hill-Rom technician
Solenoid valve blocked or pressure sensor fault	Audible and visible	10 min +/- 1min	Switch off the alarm and contact a Hill-Rom technician
Supply fault.	Audible and visible	Immediate	Switch off the alarm and contact a Hill-Rom technician
Control unit disconnected	Audible and visible	Immediate	Switch off the alarm and contact a Hill-Rom technician
Fan fault	Audible and visible	Immediate	Switch off the alarm and contact a Hill-Rom technician
MCM™ pump fault	Audible and visible	Immediate	Switch off the alarm and contact a Hill-Rom technician

If one of these alarms is raised, transfer the patient to a suitable support as quickly as possible

Table of alerts

Reason for sounding	Type of alarm	Time before sounding	Action to be taken by the operator
At the end of the product initialization phase	Audible (1 beep)	Immediately, at the end of the product initialization phase	Mattress ready for use
At the start of P-Max mode	Audible (1 beep)	Immediate	Wait
At the end of P-Max mode	Audible (1 beep)	Immediately, at the end of P-Max mode	Repeat a P-Max, if necessary
Patient exit	Audible and visible	Immediate	Attend to the patient
Microcontroller fault	Audible and visible	Immediate	Switch off the alarm and contact a Hill-Rom technician ^a

a. transfer the patient to a suitable support as quickly as possible

Table of the error codes on the GCI screen (combined mattress*)

Error Code	Fault description		
1001	Mattress pressure too low.		
1002	Deflation error after deactivating the P-Max function or initial inflation		
1003	I-mmersion™ sensor fault		
1004	Pressure sensor fault (solenoid)		
1005	Pressure sensor fault (mattress)		
1006	Inflation pump problem		
1007	A solenoid remains active for more than 10 minutes		
1008	Battery charge fault		
1009	Battery fault		
1010	Battery charger fuse fault		
1011	Fan fault		
1012	MCM™ Blower fault		
1013	ALP mode fault		
1014	P-Max function fault		

Bed connected to the mains, in the event of a type 1001 or 1006 fault, the mattress will isolate the defective part. A part of the mattress will remain functional to prevent the patient from touching the sleep surface of the bed, but there is no more functional therapeutic mode. In this case, the patient should be placed on another mattress as quickly as possible and it is necessary to call a technician to make repairs.

Alarm silence

To silence alarms in case of mains power fault or malfunction, press the button.

The corresponding visual alarm remains on yellow.

The green indicator light near the symbol comes on.

The audible alarm is re-activated automatically after approximately 10 minutes. Nevertheless, it is impossible to disable the bed exit alert.

The audible alarm can be stopped again for 10-minute periods until the problem is solved. Refer to the Service Manual for more details.

Mains power fault

The audible Mains power fault alarm sounds and the corresponding yellow visual alarm comes on if the device is disconnected from mains, or in the event of a power failure

The audible and visual alarms remain active during the transport of the device. (see "Moving the Patient on the Bed in Transport Mode" page 33)

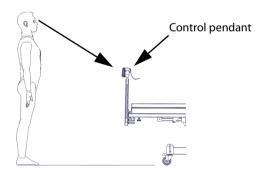
To stop the alarms, reconnect the mattress to the mains power supply, or press the button (see "Alarm silence" above).

Malfunction

The light near the symbol indicates the status of the pressure regulation device in the continuous and alternating therapeutic modes.

In case of device malfunction, or lack of pressure, the Malfunction visual alarm near the symbol changes from green to yellow.

Refer to the Accella™ Therapy device Service Manual for detailed troubleshooting instructions.



Moving the Device

Moving the Patient on the Bed in Transport Mode



The mattress must not be disconnected when the PMAX mode is active.

- 1. If the P-Max mode is active, switch it off.
- 2. Check that at least one therapeutic mode (ALP or CLP) is active.
- 3. Unplug the device from the wall socket.



Never pull on the power cable or you may damage it. A damaged power cord is an electric shock hazard.



4. The device automatically switches to transport mode and therapeutic modes are switched off. The pressure is distributed in the mattress until it is evenly inflated. The mattress remains inflated.



A backup battery maintains for 2 hours functions such:

	Standalone version	Combined with Accella™ bed	Combined with Progressa™ bed
Emergency deflate (CPR)	YES	YES	NO
Bed exit alarm	YES	NO	NO
Low pressure alarm	YES	YES	YES (audible only)

When the battery is low, the device must be connected to the mains for at least 24 hours to fully charge, otherwise the functions associated with the transport mode (range, availability CPR) are no longer guaranteed.

The mains power fault alarm sounds and the vellow indicator light comes on

5. Deactivate the audible alarm by pressing (See "Alarm silence" page 30).

(i) Audible alarm is re-activated automatically after approximately 10 minutes as a reminder that the power cord must be reconnected.

6. Safely stow the power cord.

Make sure that the cord does not drag along the ground, do not run over it when moving the bed chassis and take care not to trip up over it. Where necessary, use the attachments provided with the device.



7. Reconnect the device immediately following transport. It switches to initial inflation mode (unless the CPR mode is active or a leak is being controlled), then automatically returns to the preceding mode of operation.



If a patient whose weight is close to the SWL exits the bed, the internal pressure of the mattress may suddenly drop, causing a low safety pressure to error to occur. In this case, reconnect to the main power supply to reset the system.

Transferring the Device from One Bed to Another



Never leave the patient on the device during transfer.

Make sure that the bed chassis brakes are applied to prevent any accidental movements



Standalone version*

- 1. Activate the maximum inflate mode (and wait for 1 minute, until the mattress is firm.
- 2. Place the control pendant between the two layers of the mattress to prevent it from being damaged.
- 3. Undo the two straps that secure the mattress to the bed (at the head and foot ends).
- 4. Disconnect the power cord from the wall outlet, and place it on the mattress.
- To handle the mattress, Hill-Rom recommends the intervention of two persons.
- 5. Transfer the mattress onto the other bed.
- 6. To install the mattress on the other bed, follow the installation procedure (page 20) from step 4.

Mattress combined with the Accella™* bed

- 1. Perform steps 1 to 8 of the deflation procedure (page 37).
- Hill-Rom recommends that two people should handle the mattress.
- 2. Transfer the mattress onto the other bed chassis.
- 3. To install the mattress on the other bed, follow the installation procedure (page 22), from step 4.

Storing the Device

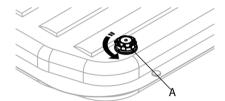


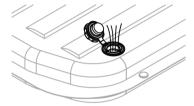
Make sure that the bed chassis brakes are applied to prevent any accidental movements.



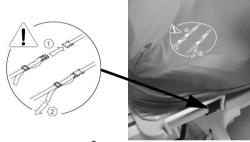
Deflating the standalone mattress*

1. Open the head end zip fastener. Unscrew and remove the deflation plug (A).





2. Undo the two straps that secure the mattress to the bed (at the head and foot ends) for the Accella™ Therapy version or the knobs for the Progressa™ version.



- 3. Activate the CPR function.
- 4. Expel as much air as possible.
- 5. Deactivate the CPR function (CPR)
- 6. Switch off the mattress using the button on the remote control.



7. Unplug the electrical power cord.



Never pull on the power cable or you may damage it. A damaged power cord is an electric shock hazard.



- 8. Starting at the foot end of the bed, roll up the mattress slowly to allow any remaining air to be expelled.
- 9. Close the deflation plug.
- 10. Close the zip fastener.

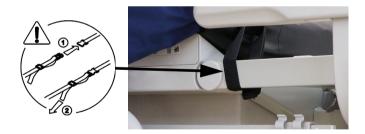
11. Use the strap on the lower cover to keep the mattress rolled up.



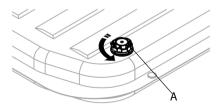
- 12. Place the rolled up mattress in a plastic bag.
- 13. Store the mattress in its original packaging or in a transport bag.

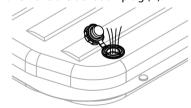
Deflate the mattress combined with the Accella™* bed

- 1. Switch off the mattress. Press stop
- 2. Wait for the end of the shutdown cycle and till the screen shows that the mattress can be disconnected.
- 3. Fold in two at the head end.
- 4. Remove the hard surface of the thigh section.
- 5. Disconnect the plug from the bed connector.
- 6. Remove the cable.
- 7. Install the hard surface of the thigh section.
- 8. Undo the two straps that secure the mattress to the bed (in the center of the thigh section).



9. Open the head end zip fastener. Unscrew and remove the deflation plug (A).





- 10. Starting at the foot end of the bed, roll up the mattress slowly to allow any remaining air to be expelled.
- 11. Expel as much air as possible.
- 12. Screw in the deflation plug.
- 13. Close the zip fastener.
- 14. Use the strap on the lower cover to keep the mattress rolled up.



- 15. Place the rolled up mattress in a plastic bag.
- 16. Store the mattress in its original packaging or in a transport bag.

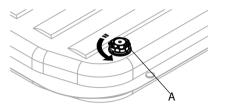
Deflate the mattress combined with the Progressa™* bed

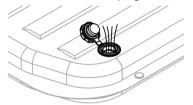
- 1. Switch off the mattress. Press stop
- 2. Wait for the end of the shutdown cycle and till the screen shows that the mattress can be disconnected.
- 3. Fold in two at the head end.
- 4. Disconnect the plug from the bed connector.
- 5. Remove the cable.
- 6. Undo the two knobs that secure the mattress to the bed (in the center of the thigh section).





7. Open the head end zip fastener. Unscrew and remove the deflation plug (A).





- 8. Starting at the foot end of the bed, roll up the mattress slowly to allow any remaining air to be expelled.
- 9. Expel as much air as possible.
- 10. Screw in the deflation plug.
- 11. Close the zip fastener.
- 12. Store the mattress in its original packaging or in a transport bag.

Disinfecting and Servicing

Cleaning and Disinfecting the Device

Complying with Safety Instructions

- Check that the brakes are applied on the bed on which the mattress is installed.
- Lock out all electrical functions.
- Disconnect the appliance and stow the power cable.
- Check that the connectors are securely connected to prevent water from entering the mattress.
- Never clean with mattress by pouring water on it, or with a high-pressure jet.
- Never use water at a temperature of more than 70°C.
- Avoid excess water on the connectors.
- Refer to the recommendations of the cleaning and disinfecting product manufacturer.
- Thoroughly dry the device before reusing it.
- Suitable individual protective equipment must be worn during the phases of the cleaning operations (blouse, gloves, eye protection, etc.).



Failure to implement one or more of these recommendations may lead to damage or deterioration, preventing use of the device and rendering the warranty void.

Controlling Infection



Insufficient cleaning=Risk of infection (biological danger)!

All parts must be kept clean at all times in order to avoid the risk of infection. All necessary precautions must be taken to eliminate all visible soiling.



The following instructions are not designed to replace more appropriate cleaning and disinfection protocols drawn up by the hygiene officer or by other bodies for your hospital in the event of particular infectious situations.

Complying with Hill-Rom Recommendations

The cleaning and disinfecting method described below applies specifically to this device and its accessories and is designed to save time and to help combat nosocomial infection more effectively.

RECOMMENDATIONS

The members of personnel must be trained in the proper cleaning and disinfection procedures.

The instructor must read the instructions carefully and follow them when the trainee is being trained. The trainee must:

- Take the time required to read the instructions and ask questions.
- Clean and disinfect the product under the instructor's supervision. During and / or
 after this process, the instructor must correct any differences between what the
 trainee did and the instructions for use.

The instructor must supervise the trainee until they are capable of cleaning and disinfecting the bed according to the instructions.



Hill-Rom recommends that the device must be disinfected before first use.

When cleaning, always check the cover for cuts, tears, cracks or snags. Never use a mattress with a damaged cover.

Using cleaning and disinfecting protocols or products other than those recommended by Hill-Rom can compromise the conformity of the device and patient safety and render the warranty null and void.

Hill-Rom recommends that the device should be disinfected before scrapping, in accordance with applicable local regulations.

(i) Cleaning and disinfection are two separate procedures.

Products to be avoided

Never use cleaning agents, detergents, degreasing agents or industrial solvents containing any of the following products in order to avoid damaging the mattress:

PHEMOL	Phenol	HCL HNØ3 H2SO4	Hydrochloric, nitric or sulfuric acids	DMF	Dimethylformamide
CRESOL	Cresol	NaOH	Soda	THE	Tetrahydrofuran

Do not use highly acidic detergents or disinfectants (pH<4).

Do not use highly basic detergents or disinfectants (pH>10).

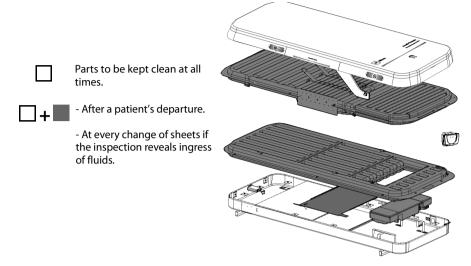
Never use abrasive cleaning products or materials, such as scouring pads or powders.

Recommended products

List of compatible products

Chemical class	Active	Maximum concentration
Chloride	Sodium hypochlorite	0.1%
Alcohol	Isopropyl alcohol	70%
Quaternary ammonium	n-Alkyl dimethyl benzyl ammonium chloride	0.44%
Quaternary ammonium chlo- rides	Didecyl dimethyl ammo- nium chloride	0.2%
Peroxide	Hydrogen peroxide	5%
Diamine	n-3-aminopropyl n-dodecyl- propane-1,3-diamine	0.13%

Cleaning and disinfection frequency of the various parts of the mattress



Cleaning and Disinfecting after the Departure of a Patient or when Changing the Sheets

Using Recommended Products

Disinfectant detergent at and recommended contact time and dilution

Cleaning



Clean the mattress with a cloth slightly dampened with hot water and a neutral detergent solution. Check that the solution does not contain any of the products to be avoided mentioned above (see "Products to be avoided" on page 42). Rinse with a wet cloth. Dry.

Cleaning Tough Stains

Quickly wipe away any traces of pharmaceutical solutions used for the patients to avoid damage to the surface.

- Remove tough stains using neutral detergents or a chlorine-based solution with a concentration less than or equal to 1,000ppm and use a soft brush.
- To eliminate hardened stains (excreta, other forms of soiling), soften them by soaking and take care to thoroughly dry the cover before putting it back on the mattress.
- Pay close attention to the straps, absorbent materials, seams, welds, complex shapes and small spaces where dirt can accumulate. It is recommended to clean and disinfect these parts twice.
- Use as many wipes as necessary to remove all the dirt.

Disinfecting

In the event of visible soiling, Hill-Rom recommends that the device should be disinfected with an intermediate disinfectant (tuberculocidal) that complies with the applicable regulations (e.g. with the requirements of directive 93/42/EEC).

For all other disinfectants:

NaCIO NaDCC C ≤ 1000 ppm	Chlorine-based solutions can be used. Concentration must be less than or equal to 1,000 ppm.
C2H5OH 25% C2H5OH	Ethanol-based solutions (alcohol) can be used. Concentration must not exceed ¼ of ethanol for ¾ of water.

Proceed with the final steps before reusing the cleaned and disinfected mattress (see "Proceed with the final steps before reusing the cleaned and disinfected device." on page 45).

Cleaning and Disinfecting at Regular Intervals or in the Event of High Risk of Contamination

Follow the same instructions as above (See "Cleaning and Disinfecting after the Departure of a Patient or when Changing the Sheets" page 43), but with the products listed below.

Using Recommended Products

 Only use compatible products and at the recommended concentrations (see "List of compatible products" on page 42)

Dry Steam Cleaning the Device

Dry steam or superheated steam contains no more than 6% of water in suspension and avoids the effects of condensation.

To avoid damage due to high pressure or an abnormal surface temperature,

take the following precautions:

- Use low pressure steam on the electric parts.
- Do not use accessories such as high pressure hoses (A) or soft non-metallic brushes (B). It is advisable to only use microfiber supports (C) on the cover, the control pendant and the mains power cable
- A B



- Avoid water and steam getting into connectors that are not in use.
- Do not brush and apply reduced pressure to labels and markings.
- Dry carefully and look for signs of water ingress.
- Test the device before reusing it.



Do not steam clean the inside parts but only the outside parts.



The upper cover can be machine-washed, but it must not always be machine-washed, as doing so will reduce the life time of the components. The upper cover should only be machine-washed if particular risks of infection occur. If this method is used, choose the wash and spin cycle with reduced mechanical action.

Proceed with the final steps before reusing the cleaned and disinfected device.

Performing the Final Steps

 Always remove all traces of the products used when washing or disinfecting the device.



Make sure that all the parts of the device are perfectly dry before installing to avoid any risk of condensation forming inside the mattress.



If the upper cover has been machine-washed, check that it is in good condition before reuse.

Servicing of the Device

Complying with Safety Instructions



Never modify this device without Hill-Rom's prior written consent.
Only facility-authorized personnel should perform maintenance.
Changes made by unauthorized personnel may result in damage to the device and/or serious injury to staff or users.

Before maintenance or servicing works:

- Ensure that the brakes are applied on the bed on which the mattress is installed;
- Lock out all electrical functions:
- Disconnect the device;
- Secure the mattress support platform and take the necessary steps to prevent movement.
- Do not work on the device when it is occupied

Refer to the Service Manual for assistance with the assembly, installation, use or maintenance of the device. Contact your local Hill-Rom representative (hillrom.com) in the event of unforeseen events or behavior.

Performing Preventive Maintenance

A Service Manual and spare parts catalog are provided with the device. The wiring diagrams, list of components, descriptions and calibration instructions can be obtained on demand from Hill-Rom After-Sales.

The frequency of inspections must be adapted to the general condition of the product and its use; for example, if the device is used by heavy patients. It is the responsibility of the facility to implement a preventive maintenance program for the device functions under its conditions of use.

The device and accessories should be inspected at least once a year to keep them in good condition and working properly.

Every 3 years, it is recommended that Hill-Rom Customer Service or a Hill-Rom-approved service provider inspects the device in order to maintain the performance and safety of the apparatus over time. The battery must be replaced during these inspections. The date of the next inspection must be recommended according to the maintenance operations and observations.

In order to benefit from optimal and rapid service when calling Hill-Rom, provide the serial number of the device for which you are calling (See "Locating the Identification Labels of the Device" page 14).

Under normal conditions of use, maintenance and services, the life time of the device is 5 years, 2 years for the cover and 3 years for the batteries.

Please refer to the service manual for more information on lifetime of wear parts and accessories.

Troubleshooting

The device is designed to adjust automatically, therefore troubleshooting is limited to a few checks.

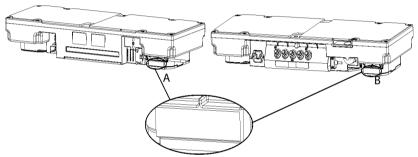


Always disconnect the device before troubleshooting.

In the event of a malfunction, press the silence alarm button to stop the audible alarm. Check the following points:

- the connection to the mains is OK;
- the power cord is not damaged;
- the sensor cable is not damaged, nor disconnected;
- the device is not damaged (torn or punctured);
- the air filter is clean. Replace the air filter every 6 months.
- Refer to the Service Manual for detailed troubleshooting instructions.

Replace the air filter (A),(B)



The air filter can be ordered separately. For more information, refer to the list of spare parts of the mattress.

Replacing the Fuse onthe Power Socket



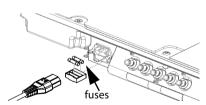
1.Switch off the control unit by pressing this button.

2. Open the zip fastener.

- 3. Remove the power cord from the connector.
- 4. Open the drawer of the fuseholder with a small screwdriver.
- Check that the new fuse matches the characteristics on the label and meets the IEC 60269-1 standard.
- 6. Replace the faulty fuse. The second fuse can be used to replace the faulty fuse. Make sure to replace it in case of use.
- 7. Securely close the drawer of the fuseholder.

Others fuses are located on the MCB. Refer to Service Manual for replacement and for verification.

If the problem is not solved, contact your local Hill-Rom representative (hillrom.com). Indicate the serial number of the device.



Complying with Warranty Conditions

The warranty for Hill-Rom's devices will be rendered null and void, in part or in total, in the event of:

- Repairs, installations, assembly, modifications or checks and tests are not conducted by the manufacturer's maintenance personnel or by personnel authorized by the manufacturer.
- The electric system does provide the conditions allowing for the use of medical appliances that comply with the standard EN 60601-1. In hospital wards in particular, the electric system does not meet the requirements applying to medical establishments:
- The device is not used in accordance with this manual.
- · Accessories are used that do not meet the requirements of this manual.

Contact your country Hill-Rom representative or go to hillrom.com to find the After-Sales Service contact details.

De-commissioning

The device and its accessories or additional parts should be cleaned and disinfected before de-commissioning.



Customers should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact Hill-Rom Technical Support for quidance on safe disposal protocols.

Do not dispose of electric and electronic equipment in the waste bin (as per directive 2012/19/EU).



Never discard the device's batteries or accumulators. They may contain substances and metals that are hazardous for the environment and health (as per Directive 2006/96/EC).

(i) Refer to the Service Manual for detailed battery replacement instructions.

The device is designed for easy dismantling so that it can be destroyed or reused in accordance with the applicable recycling regulations (e.g. electric parts, plastics, metal).

At the end of the device's life, Hill-Rom recommends that you contact a specialist in the dismantling of therapeutic mattresses or, if the device can still be used, to donate the device to a charitable organization.

Always clean and disinfect the device before shipment for dismantling or donation.

Contact your local Hill-Rom representative for more information (hillrom.com).

Additional parts

Additional parts

Transport bag**

You can order a transport and storage bag for the device.

All the additional parts can be ordered separately.

Refer to the Spare Parts List for the product part numbers.

Contact your country Hill-Rom representative or go to hillrom.com to find the After-Sales Service contact details.



Control pendant**

A control pendant can be ordered for the device.



Model	Description
AD293A**	Control pendant for mattress P006788A or P006791A (low pressure Accella™ Therapy MCM™ mattress)
AD313A**	Control pendant for mattress P006783A or P006790A (low pressure Accella™ Therapy mattress)

Correlation mattress / control pendant

	P006788A/	P006783A/	P006789A/
	P006791A/	P006790A	P006792A/
	P006794A		P006793A
AD293A	Х		Х
AD313A		Х	

All the accessories and parts can be ordered separately.

Refer to the Spare parts list for the product part numbers.

Contact your country Hill-Rom representative or go to hillrom.com to find the After-Sales Service contact details.

Compliance

CE conformity mark

The CE conformity mark applicable to class IIa Medical Devices was applied to the Accella™ Therapy mattress for the first time in 2018.



Standards

Designation
EN 60601-1: 2007 / A1: 2017
IEC 60601-1: 2005 / A1: 2012
EN 60601-1-2: 2015
IEC 60601-1-2: 2014
EN 60601-1-6: 2010
IEC 60601-1-6: 2010
EN 60601-1-8: 2007 / A1: 2013
IEC 60601-1-8: 2006 / A1: 2013
EN ISO 14971: 2012
EN ISO 10993-1: 2010
EN ISO 10993-5: 2010
EN ISO 10993-10: 2010
EN ISO 15223-1: 2016

Electromagnetic emissions compliance

Manufacturer's recommendations and declaration – electromagnetic emissions

The Accella[™] Therapy mattress is intended for use in the electromagnetic environment specified below. The customer or the user of the Accella[™] Therapy mattress device should make sure it is used in such an environment.

Emission test	Compliance	Electromagnetic environment Recommendations
RF emissions CISPR 11	Group 1	The Accella™ Therapy device only uses RF energy internally. Consequently, it only produces very weak RF emissions that are unlikely to cause interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The Accella™ Therapy device is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/flicker IEC 61000-3-3	Compliant	

Compliance with electromagnetic immunity

Manufacturer's recommendations and declaration – electromagnetic immunity

The Accella™ Therapy device is intended for use in the electromagnetic environment specified below. The customer or the user of the Accella™ Therapy device should make sure it is used in such an environment.

Immunity test	Test level IEC 60601	Compliance	Electromagnetic environment - Recommendations
Electrostatic discharges IEC 61000-4-2	\pm 8 kV on contact \pm 2 kV, \pm 4 kV, \pm 8 kV and \pm 15 kV in the air	\pm 8 kV on contact \pm 2 kV, \pm 4 kV, \pm 8 kV and \pm 15 kV in the air	The relative humidity must be at least 5%.
Fast transients in bursts IEC 61000-4-4	± 2 kV for the power supply lines ±1kV for the input/output lines (100 kHz Repetition Frequency)	± 2 kV for the power supply lines ± 1 kV for the input/output lines (100 kHz Repetition Frequency)	The quality of the main power supply must be that of a typical commercial or hospital environment.
Shock waves IEC 61000-4-5	±1 kV between line(s) ±2 kV between line(s) and earth	±1 kV between line(s) ±2 kV between line(s) and earth	The quality of the electric power supply should be the equivalent of that found in commercial or hospital environments.
Magnetic field at the frequency of the mains power supply (50/60 Hz) IEC 61000-4-8	30 A/m 60 Hz 50 Hz	30 A/m 60 Hz 50 Hz	The magnetic field at the frequency of the mains supply must be characteristic of a typical commercial or hospital environment.
Voltage Dips IEC 61000-4-11	0% U _T : 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U _T : 1 cycle 70% U _T : 25/30 cycles Single phase: at 0° (see note)	0% U _T : 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U _T : 1 cycle 70% U _T : 30 cycles Single phase: at 0° (see note)	The quality of the main power supply must be that of a typical commercial or hospital environment. If the user of the Accella™ Therapy mattress requires that the bed remain functional during outages of the mains power supply, it is advisable to power the Accella™ Therapy mattress using a UPS or a battery.
Voltage Interruptions IEC 6100-4-11	0% U _T for 250/300 cycles	0% U _T for 300 cycles	
Note: U _T is the no	minal value of the supply v	oltage applied during the	test.

Immunity test	Test level IEC 60601	Compliance	Electromagnetic environment - Recommendations
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz rms 150 kHz to 80 MHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz rms 150 kHz to 80 MHz	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	The field levels emitted by fixed RF transmitters, as determined by an electromagnetic measurement of the site*, must be below the level of compliance in each frequency band*. Interference may occur close to devices identified with the following symbol:
			((' ₄ '))

These recommendations may not apply to certain situations. The propagation of electromagnetic waves is affected by absorption and reflection due to structures, objects and persons.

- a. The field levels of fixed transmitters, such as radio telephone bases (cell/wireless) and terrestrial mobile radios, amateur radios and AM, FM and TV communication radios cannot be theoretically evaluated precisely. Site measurements are required in order to obtain the electromagnetic environment due to fixed RF transmitters. If the field level measured in the working environment of the Accella™ Therapy mattress is greater than the above applicable levels of compliance, the operation of the Accella™ Therapy mattress must be checked. If any anomalies are detected, additional measures must be taken, such as redirecting or relocating the reference equipment.
- b. The field level must be less than 3V/m above the frequency band 150 kHz to 80 MHz.

Recommended separation distances

RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer to any part of the device, including cables specified by Hill-Rom, than the recommended separation distances shown in the following table.

Otherwise, degradation of the performance of this equipment could result.

Wireless communication system	Separation distance (m)
TETRA 400 (limited to 10 W ERP*)	0.3
Public safety (460-470 MHz), GMRS 460 (limited to 5 W ERP*)	0.2
GMRS 460 (limited to 2 W ERP*)	0.1
GSM 850, GSM 900, RFID 868 MHz, TETRA 800 (limited to 2 W ERP*)	0.3
GSM 1900 (limited to 1 W ERP*)	0.2
WLAN 802.11a 5 GHz (limited to 1 W ERP*)	0.7
iDEN 820, CDMA 850, GSM 1800, CDMA 1900 (limited to 0.6 W ERP*)	0.2
FRS 460 (limited to 0.6 W EPR*), PMR 446	0.1
UMTS, DECT (limited to 0.25 W EPR*)	0.1
Bluetooth, WLAN 802.11 b/g 2450 , RFID 2450 (limited to 0.1 W EPR*)	0.1

^{*:} Effective Radiated Power.

Table 6 – Recommended separation distances between portable and mobile RF communication equipment and Accella™ Therapy device –for the Accella™ Therapy device

Recommended separation distances between portable and mobile RF communications equipment
and the
Accella™ Therapy

The Accella™ Therapy device is designed for use in an electromagnetic environment in which interference due to radiated RF is monitored. The customer or user of the Accella™ Therapy device can contribute to the prevention of electromagnetic interference by keeping the Accella™ Therapy device at the recommended distances from portable and mobile RF equipment (transmitters) as shown below, according to the maximum power output of the communication equipment.

Maximum transmitting power of	Separation distance versus the frequency of the transmitter m			
the transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
W	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	$d = [\frac{3.5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.37	0.37	0.74	
1	1.17	1.17	2.33	
10	3.69	3.69	7.39	
100	11.67	11.67	23.33	

For transmitters with a maximum transmitting power not given above, the recommended separation distance in meters (m) can be estimated by using the equation applied to the transmitter frequency, where P is the maximum transmitting power of the transmitter in Watts (W), according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies. NOTE 2: These directives cannot be applied to every situation. The propagation of electromagnetic waves is affected by absorption and reflection due to structures, objects and persons.

