

Subject: Compella- Exposed AC Power Conductors

Commercial name and details of the affected product:

Product	Model	Manufacturing Dates
Compella™ Bariatric Bed System	P7800A	All beds manufactured
Compella Therapy Air Supply Unit	P7810A	All Air Supply units manufactured

FA Number: FA-2021-12-003-BAT-008

Type of action:

Advisory Notice

Date:

Description of the problem

Over the lifespan of the Compella Bed and Compella Air Supply Unit their respective powers cord can become damaged due to improper storage. Hillrom has become aware of complaints related to exposed AC power conductors due to cut or damaged power cords.

Potential risk

The resulting damage may cause the power conductors to be exposed, thereby creating a risk of shock from the power mains. Where proper intended use practice is followed, i.e cables are stored correctly during transport of the bed; no such damage will occur to the power cords.

Recommendations to mitigate the risk:

Please follow the instructions outlined within the user manual for the Compella Bed and Compella Air Supply Unit.

Compella Bariatric Bed

To help prevent personal injury and/or equipment damage, before you transport the bed, make sure that the power cord, hoses, and other equipment are correctly stowed.

There are two blue hooks on the inside of the head-end frame to stow the power cords for transport. Wrap the cords around the hooks so that they do not drag on the floor. (Fig 1.)

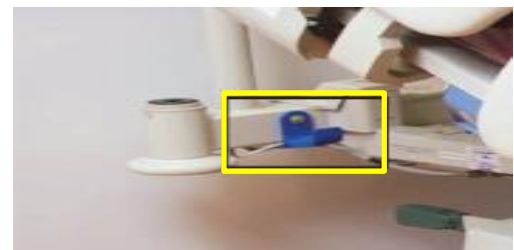


Fig. 1- Compella Cord Hooks.

- Compella Air Supply Unit

Before you transport the bed, remove the air supply unit from the footboard. Failure to do so could cause equipment damage.

1. Turn the air supply unit Off.
2. Unplug the air supply unit from the AC power source.

NOTE:

The air surface will stay inflated during transport. To help with lateral transfers, Max Inflate the surface before you disconnect it from the AC power; the surface will then stay firm.

3. Unplug the power cord from the air supply unit.
4. Use the magnets on the power cord to keep the power cord attached to the metal frame of the bed and off the floor. (Fig 2)

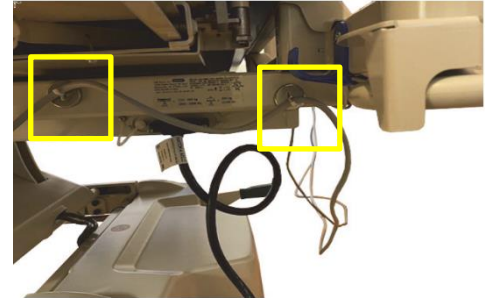


Fig. 2- Power Cord Magnets

NOTE:

Make sure that the magnets do not interfere with the movement of the foot end section when the foot section is lengthened or shortened.

5. Disconnect the three color-coded air hoses from the patient left-hand side of the air supply unit.
6. Lift the unit and its hoses over the footboard and set the unit and hoses on the foot or side section of the bed.
7. At the head end of the bed, unplug the power cords for both the bed and the air supply unit. Use the blue cord hooks at the head section to store cords during transport.
8. Put the brake/steer pedals in the Steer or Neutral position as necessary.
9. Transport the patient.

If you identify exposed wires on your power cords/transformers, do NOT make physical contact with it. Switch off the plug at the wall and contact your Biomedical/Clinical Engineering department.

Actions to be taken by end user:

Please follow our recommendations to mitigate the risk and please share with potential users in your organization as a reminder to follow the instructions for proper handling techniques. Please inspect your power cords upon receipt of this notification. If a power cord is damaged, please contact Technical Support to arrange to have it replaced. Complete the attached response form and return to HillromBAT008OUS@sedgwick.com within 2 weeks.

Actions to be taken by distributors:

Please share with your end users, complete the attached response form and return to HillromBAT008OUS@sedgwick.com within 2 weeks. Contact HillromBAT008OUS@sedgwick.com to receive an electronic copy of this notification and response form for onward distribution.

Transmission of this Notice:

Please ensure this notice is circulated to all appropriate personnel. This may include, but is not limited to:

• A&E departments	• In-house maintenance staff
• Adult intensive care units	• IV nurse specialists
• All Maternity wards & Clinics	• Medical directors
• Biomedical engineering staff	• Nursing executive directors
• Clinical governance leads	• Theatres
• Day case theatres	• Pediatric intensive care units
• EBME departments	• Risk managers

• Equipment stores & Libraries	• Supplies managers
• Health and safety managers	

Contact reference person:

If you have any questions regarding this notice, please contact Hillrom Technical Support.

Market Region Country	Phone Number	Technical Support Email
Austria	(+ 43) 2 243 285 50	service.dach@hillrom.com
Germany	(+ 49) 2 0149869500	service.dach@hillrom.com
Switzerland	(+ 41) 8 48 811530	service.dach@hillrom.com
Netherlands	(+ 31) 347 323 532	service.nl@hillrom.com
Belgium		service.be@hillrom.com
Spain	(+ 34) 9 36856000	asistencia@hillrom.com
Italy	(+ 39) 02 950541	assistenza.tecnica@hillrom.com
France	(+ 33) 0 820 012345	sav@hillrom.com
Sweden	(+ 46) 20-781030	ordernordic@hillrom.com
UK/Ireland	(+ 44) 1530 562176	UKTechSupport@hillrom.com
Eastern Europe Countries	Contact your Local Hillrom Distributor	
Middle East & Africa	Contact your Local Hillrom Distributor	
India Sub Continent	Contact your Local Hillrom Distributor	

Hillrom considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading this important notification.

Yours sincerely,



Director Quality

Response Form

Subject: Compella- Exposed AC Power Conductors (FA-2021-12-003-BAT-008)

It is important that you return this form/receipt as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information and return this Response Form within **2 weeks**.

Hillrom account number (if known): _____

Name of the facility: _____

Address of the facility: _____

City: _____ Zip: _____ Country: _____

Facility Contact Person Name: (print) _____

Signature: Date: ____/____/____

Title: _____ Phone: _____

Email: _____

Check actions taken:

We have reviewed and understand the attached **Advisory Notice**

Yes No

Results from the inspection of our product inventory show we have:

- We do not have the affected products.
 We have affected products. Quantity _____

For Distributors Only: I confirm I have shared this notice with our end users:

Yes No

Comments

Response form shall be returned to HillromBAT008OUS@sedgwick.com within 2 Weeks.