



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

27/09/2019

GEHC Ref# 14019

To: Director of Orthopedic dept/Physicians/Gynecologist
Risk Manager/Hospital/ Clinic Administrator
Director of Biomedical Engineering
Chairman Medical Board
Relevant Head of Departments for hospital

RE: Achilles Express and Achilles Insight Systems with incorrect power cords shipped - Potential for electric shock

*This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.
Please retain this document for your records.*

Safety Issue #1

Certain Achilles Express and Achilles Insight systems were shipped with European CEE-7/7 Type Power Cords to countries where three protruding pin plugs are required for protective earth connection. This issue could lead to an electric shock. There have been no reported injuries as a result of this issue.

Safety Instructions #1

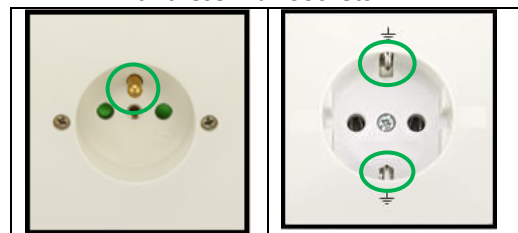
You may continue to use your system after following the instructions below:

- Inspect the power cord set used on your Achilles Express or Achilles Insight system and ensure its compatibility with your wall socket.
- Use the European CEE 7/7 Type plug shown in Figure 1 only with the two wall sockets shown in Figure 2. The protective earthing connection will not be established with any other socket.
- Do not use any adapters with your plug or wall socket.
- If you have a CEE 7/7 Type plug and a wall socket other than that shown in Figure 2, discontinue use of your system. Your power cord set will be replaced with the correct power cord. Destroy the incorrect power cord to ensure it is not used.

Figure 1: CEE -7/7 Type Plug
(shipped with systems)



Figure 2: Use CEE-7/7 Plug ONLY
with these Wall Sockets



**Safety
Issue #2**

Applicable only to countries Peru, Philippines and Thailand. Certain Achilles Express and Achilles Insight systems were shipped with 125V rated power cords (type B plug) to these countries where the mains voltage could be greater than 200V. This issue could lead to an electric shock. There have been no reported injuries as a result of this issue.

**Safety
Instructions
#2**

For certain systems in Peru, Philippines and Thailand, a power cord type B plug rated at 125V, as shown in Figure 3, was shipped. The mains voltage in these countries could be greater than 200V and, as a result, this plug should not be used. If you are located in one of these three countries with mains voltage greater than 200V and have the plug shown in Figure 3, disconnect your Achilles Express or Achilles Insight system from your facility's power supply, and discontinue use of your system. Your power cord set will be replaced with correct power cord. Destroy the incorrect power cord to ensure it is not used.

Figure 3: Type B plug DO NOT USE in Peru, Philippines, Thailand



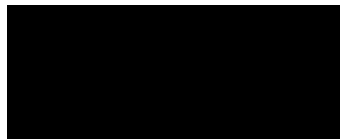
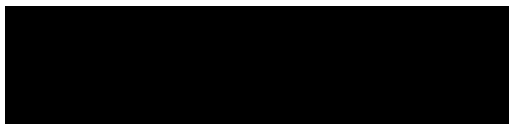
**Affected
Product
Details**

Achilles Express and Achilles Insight systems with power cord.
See attached Appendix for a list of system ID numbers.

**Product
Correction
Contact
Information**

GE Healthcare will send you the correct replacement power cord set at no cost to you.

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.



Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

Laila Gurney
Senior Executive, Global Regulatory and Quality
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Appendix

List of Affected Achilles Express and Achilles Insight systems IDs

11235RAD01	834334047	847334076	853330097	853330212	853330299	853330385	856330050
2644078	834334048	853330024	853330107	853330215	853330300	853330386	856330051
2651516	834334054	853330025	853330108	853330216	853330301	853330387	856330052
2693419	834334055	853330027	853330137	853330217	853330309	853330388	856330053
2738051	834334056	853330028	853330138	853330218	853330310	853330389	856330055
2798401	834334057	853330029	853330139	853330219	853330311	853330390	856330056
2815867	834334058	853330030	853330140	853330223	853330312	853330391	856330057
2858452	834334059	853330031	853330141	853330228	853330320	853330392	856330069
2876988	834334060	853330032	853330142	853330229	853330321	853330394	856330070
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A5141812	A5985201	ACH+12932	AE1224XR01	IQ1287US02	SA2344XR01



GE Healthcare

GEHC Ref# FMI 14019

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice and required actions to be taken GEHC Ref# 14019.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:

Recall14019@ge.com

You may obtain this e-mail address through the QR code below:

