



URGENT FIELD SAFETY NOTICE

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# FMI 14018

To: Director of Orthopedic dept/Physicians/Gynecologist
Risk Manager/Hospital/ Clinic Administrator
Director of Biomedical Engineering

RE: **Achilles EXP II 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 EXP II systems were shipped with European Power Cords to non-European countries where three pin plugs are required for protective earth connection.

**Safety
Issue #2**

Certain Achilles EXP II systems were shipped with 125V rated power cords (type B plug) to Thailand, Peru, and Brazil, where the mains voltage could be greater than 200V.

These two issues could lead to an electric shock. There have been no reported injuries as a result of these issues.

**Safety
Instructions
#1**

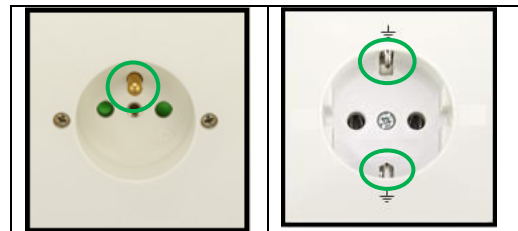
You may continue to use your system after following the instructions below:

- Inspect the power cord set used on your Achilles EXP II system and ensure its compatibility with your wall socket.
- Use the European 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 Europe 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: European Plug
(shipped with systems)



Figure 2: Use European Plug ONLY
with these Wall Sockets



**Safety
Instructions
#2**

For certain systems in Thailand, Peru, and Brazil, 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 EXP II 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 Thailand, Peru, Brazil



**Affected
Product
Details**

Achilles EXP II Systems with power cords.
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,

A handwritten signature in black ink, appearing to read "JDennison". The signature is fluid and cursive, with a large initial "J" and "D".

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

A handwritten signature in black ink, appearing to read "JHersh". The signature is fluid and cursive, with a large initial "J" and "H".

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Appendix

List of Affected Achilles EXP II System IDs

| | | | | |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| 0002973787 | 083033060004714 | 083033200051511 | 083033600013313 | 083033826615818 |
| 0004093369A | 083033060006713 | 083033200056111 | 083033600018813 | 083033826803515 |
| 0004094504 | 083033060010512 | 083033200056112 | 083033600022312 | 083033827377117 |
| 0004221356 | 083033060015812 | 083033200058912 | 083033600036213 | 083033827551817 |
| 0004227285 | 083033060018613 | 083033200075911 | 083033600074613 | 083033840005212 |
| 0004270582 | 083033060033614 | 083033200089915 | 083033600078213 | 083033840005214 |
| 0004293265 | 083033060054612 | 083033200111512 | 083033600118811 | 083033840073811 |
| 0004293266 | 083033060060511 | 083033200111612 | 083033600305814 | 083033840079911 |
| 0004666133 | 083033060077313 | 083033200114013 | 083033600308914 | 083033840127812 |
| 0004683261 | 083033060116913 | 083033200119613 | 083033600310612 | 083033840138814 |
| 0828330134 | 083033060122114 | 083033200123414 | 083033600315312 | 083033843586115 |
| 0828330138 | 083033060146216 | 083033200132313 | 083033600328113 | 083033843866715 |
| 0828330139 | 083033060805718 | 083033200134113 | 083033600328814 | 083033848564317 |
| 0828330140 | 083033061893415 | 083033200413212 | 083033600713216 | 083033849597117 |
| 0828330141 | 083033062334115 | 083033200413213 | 083033601103318 | 083033849647918 |
| 0828330144 | 083033062894915 | 083033201027813 | 083033602796819 | 083033860530313 |
| 0828330145 | 083033064096615 | 083033201395016 | 083033603907817 | 083033862421418 |
| 0828330146 | 083033067190115 | 083033202082516 | 083033604253619 | 083037021677015 |
| 0828330147 | 083033067550017 | 083033202420018 | 083033605898313 | 083037800089413 |
| 0828330154 | 083033100005114 | 083033203573317 | 083033606417016 | 083433NZM60865 |
| 083007000119514 | 083033100119011 | 083033203825416 | 083033608097917 | 083433NZM60866 |
| 083007200053216 | 083033100119513 | 083033204181617 | 083033800003016 | 083433NZM60867 |
| 083033000004814 | 083033100125113 | 083033204843015 | 083033800026315 | 083433NZM61499 |
| 083033000026116 | 083033100310614 | 083033205334417 | 083033800028114 | 083433NZM61500 |
| 083033000050714 | 083033100312414 | 083033206326116 | 083033800039015 | 083433NZM61501 |
| 083033000051714 | 083033100361215 | 083033208786416 | 083033800057014 | 083433NZM61705 |
| 083033000063215 | 083033102960516 | 083033208912415 | 083033800067415 | 083433NZM61708 |
| 083033000072316 | 083033103243719 | 083033209500216 | 083033800072415 | 084333NZM60678 |
| 083033000078211 | 083033106956916 | 083033210043715 | 083033800073812 | 084333NZM60679 |
| 083033000078311 | 083033107350016 | 083033215334817 | 083033800073813 | 084333NZM60680 |
| 083033001891715 | 083033107492116 | 083033217746817 | 083033800120613 | 084333NZM60681 |
| 083033003790018 | 083033107697716 | 083033240005414 | 083033800126713 | 084333NZM60682 |
| 083033005474718 | 083033108445616 | 083033240011713 | 083033800447317 | 084333NZM60683 |
| 083033020013512 | 083033200004914 | 083033240014914 | 083033801896017 | 084333NZM60685 |
| 083033022064019 | 083033200005314 | 083033240125212 | 083033803475515 | 084333NZM60691 |
| 083033024506616 | 083033200008115 | 083033242601015 | 083033805645617 | 084333NZM60695 |
| 083033027274616 | 083033200011613 | 083033242601215 | 083033820001712 | 0856330062 |
| 083033029349617 | 083033200026115 | 083033280005014 | 083033820003012 | 0856330064 |
| 083033040039513 | 083033200027813 | 083033280057814 | 083033820007713 | 0856330065 |
| 083033040051413 | 083033200034613 | 083033280154712 | 083033820008611 | 0856330066 |
| 083033040069511 | 083033200037811 | 083033600007414 | 083033824098815 | 0856330068 |
| 083033040074313 | 083033200038111 | 083033600013113 | 083033825001516 | 0856330072 |
| 083033040163117 | 083033200042815 | 083033600013213 | 083033825003516 | 0856330073 |

| | | | | | |
|----------------|---------------|----------------|-------------|------------|------------|
| 0856330074 | 1553BD0002 | 1573UL0501 | A6165904 | ACH+62432 | SA2250XR04 |
| 0856330092 | 1553BD0003 | 1573UL0502 | A6170801 | ACH+62497 | SA2250XR05 |
| 0856330104 | 1553BD0005 | 1573UL0503 | A6183401 | ACH+62504 | SA2251XR02 |
| 085633NzM60545 | 1553BD0006 | 1573ULNzM61706 | A6240601 | ACH+62691 | SA2251XR03 |
| 085633NzM61071 | 1553BD0007 | 1573ULNzM61707 | A6240701 | ACH+62849 | SA2307XR01 |
| 085633NzM61167 | 1553BD0009 | 20146RAD04 | A6240702 | ACH+62978 | SA2401XR01 |
| 085633NzM61188 | 1553BD0010 | 5973BD0004 | A6240801 | ACH+63684 | SA2403XR01 |
| 085633NzM61189 | 1553BD0011 | 5973BD0008 | A6240901 | AE1223XR13 | SA2403XR02 |
| 085633NzM61190 | 1553BD0012 | 5973BD0022 | A6266401 | AE1223XR14 | SA2498XR01 |
| 085633NzM61191 | 1553BD0013 | 5973UL0622 | ACH+12858 | AE1223XR15 | SA2498XR02 |
| 085633NzM61192 | 1553BD0014 | 6073UL0084 | ACH+12859 | AE1223XR17 | SA2498XR03 |
| 085633NzM61193 | 1553BD0015 | 6073ULNzM61186 | ACH+60618 | AE1223XR18 | SA2498XR04 |
| 085633NzM61196 | 1553UL0002 | 803943BD02 | ACH+60651 | AE1223XR19 | ZA2700LUN1 |
| 085633NzM61199 | 1553UL0062 | 83092797174 | ACH+60652 | AE1223XR20 | ZA2952RX01 |
| 085633NzM61450 | 1553UL0063 | 83092797268 | ACH+60823 | AE1223XR21 | |
| 085633NzM61467 | 1553UL0171 | 83092797366 | ACH+60824 | AE1223XR22 | |
| 085633NzM61468 | 1553UL0172 | 83165358352 | ACH+60828 | AE1223XR23 | |
| 085633NzM61590 | 1553UL0208 | A195945617 | ACH+61101 | AE1223XR24 | |
| 085633NzM61593 | 1553UL0209 | A5108285 | ACH+61106 | AE1368RX01 | |
| 085633NzM61595 | 1553UL0210 | A5649020 | ACH+61107 | AE1370XR01 | |
| 085633NzM61597 | 1553UL0211 | A5945703 | ACH+61131 | AE1424XR01 | |
| 085633NzM61599 | 1553UL0212 | A5945704 | ACH+61133 | AE1424XR02 | |
| 085933NzM60672 | 1553UL0213 | A5945705 | ACH+61138 | AE1434RX02 | |
| 085933NzM60673 | 1553UL0214 | A5945706 | ACH+61141 | AE1486XR01 | |
| 085933NzM60674 | 1553UL0215 | A5945707 | ACH+61303 | AE1500RX01 | |
| 085933NzM60965 | 1553UL0217 | A5945708 | ACH+61304 | AE1500RX02 | |
| 085933NzM60967 | 1553UL0265 | A5945709 | ACH+61305 | AE1507RX01 | |
| 085933NzM60971 | 1557UL0101 | A5945710 | ACH+61306 | AE1507RX02 | |
| 085933NzM61228 | 1557UL0102 | A5945711 | ACH+61572 | AE1636RX01 | |
| 085933NzM61233 | 1557UL0103 | A5945712 | ACH+61573 | CH+60825 | |
| 085933NzM61234 | 1557UL0192 | A5945713 | ACH+61574 | IE1026LU03 | |
| 085933NzM61235 | 1573AW0016BD1 | A5945714 | ACH+61575 | IE1515LU01 | |
| 085933NzM61236 | 1573BD0011 | A5945715 | ACH+61576 | IL4263US24 | |
| 085933NzM61237 | 1573BD0018 | A5945716 | ACH+61577 | JO4113US01 | |
| 085933NzM61238 | 1573BD0019 | A5945717 | ACH+61578 | KW1110US01 | |
| 085933NzM61239 | 1573BD0020 | A5945718 | ACH+61579 | LB1434US01 | |
| 085933NzM61240 | 1573BD0022 | A5945719 | ACH+61580 | LB1434US02 | |
| 10003RAD06 | 1573BD0025 | A5945720 | ACH+61583XX | LB1463US01 | |
| 10709RAD01 | 1573BD0027 | A5945721 | ACH+61729 | MU1012US05 | |
| 10711RAD01 | 1573BD0028 | A5950303 | ACH+61915 | MU1012US06 | |
| 10728RAD01 | 1573BD0032 | A5952501 | ACH+62103 | NG1126LC07 | |
| 10920BMD01 | 1573BD0041 | A6096704 | ACH+62107 | QA1059US01 | |
| 10920BMD02 | 1573UL0500 | A6165903 | ACH+62149 | SA2250XR03 | |



**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# 14018.

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:
Recall14018@ge.com

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

