

Urgent Field Safety Notice

Parker 500
ID 111011AHE
Risk of Electric Shock

Date: 2011-10-13

Attention: All users of Parker 500 Bath system
All use must stop immediately and the tub/bath
must be disconnected from the mains electrical
supply.

Details on affected devices:
All Parker 500 Baths, Model numbers AL2xxx-xx
with serial numbers according to appendix A,
FSN111011 Affected units list.

Description of problem

An incorrect routing of a mains supply cable may allow for the supply cable to be cut by the high/low actuator yoke. A cut mains supply cable may cause an electrified framework leading to the risk of serious injury or death.

Advice on action to be taken by the user:

All use must stop immediately and the tub/bath must be disconnected from the mains electrical supply.

Tub must be quarantined pending correction.
The correction involves re-routing or replacement of the mains supply cable.

Please contact your local ArjoHuntleigh representative to schedule a service call.

Transmission of Field Safety Notice (if appropriate)

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected device have been transferred.



Contact reference person:

John Wennborg,
QA & RA Manager

or

Anna Fabisch Fors,
Group Complaint Handler/ Vigilance
Coordinator

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We regret any and all inconveniences that this FSN may cause; however we ask that you please see this preventive action as extended resident safety vigilance. Please contact your local ArjoHuntleigh representative or yours truly should you have additional questions or comments in this matter.

The signature below confirms that the appropriate Regulatory Agencies have been notified



John Wennborg, Eslöv 2011-10-13



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FSN 111011AHE
Affected units list

October 12
2011

This is the comprehensive list of all Parker 500 baths affected by this Field Safety Corrective Action

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FSN 111011AHE affected units per country

Australia

Model	Serial #'s	Qty
AL23010-EU	1109001348	1
	1109001481	1
Grand Total		2

Austria

Model	Serial #'s	Qty
AL21010-EU	1108001070	1
	1109000752	1
	1110000054	1
Grand Total		3

Belgium

Model	Serial #'s	Qty
AL20000-EU	1109000230	1
AL20010-EU	1109001448	1
	1110000213	1
AL21001-EU	1108000669	1
AL21010-EU	1108001092	1
AL22000-EU	1109000738	1
	1109000757	1
AL22010-EU	1109001364	1
AL24010-EU	1107000031	1
	1108000739	1
	1108000754	1
	1108000756	1
	1108000806	1
	1108000836	1
	1108000911	1
	1109000001	1
	1109000193	1
	1109000203	1
	1109000915	1
	1109001290	1
	1109001301	1
	1110000083	1
	1110000094	1
	1110000238	1
	1110000266	1
AL24110-EU	1108001069	1
	1108001082	1
AL25010-EU	1110000086	1

AL26010-EU	1108000472	1
	1108000561	1
	1109001266	1
AL27010-EU	1106000973	1
	1107000047	1
	1108000398	1
	1108000693	1
	1108000755	1
	1108000825	1
	1109000127	1
	1109001372	1
AL27110-EU	1108000967	1
	1109000268	1
	1109001486	1
	1109001497	1
Grand Total		43

Canada

Model	Serial #'s	Qty
AL21010-CA	1109000623	1
AL24000-CA	1109000855	1
	1109000867	1
AL24010-CA	1109000497	1
	1109000499	1
	1109000511	1
	1109000535	1
	1109000569	1
	1109000599	1
	1109000604	1
AL26010-CA	1109001249	1
AL27000-CA	1109000350	1
AL27010-CA	1109000848	1
	1109000880	1
	1109001232	1
AL27110-CA	1109000480	1
Grand Total		16

France

Model	Serial #'s	Qty
AL20010-EU	1109000601	1
	1109000722	1
AL24010-EU	1109001035	1
AL27010-EU	1108000532	1
	1108000563	1
	1109000082	1
	1109000294	1
	1109000912	1
	1109001221	1
AL27110-EU	1108000607	1
	1108000631	1
	1108000660	1
	1108000926	1
	1109000402	1
	1109000705	1
	1109001177	1
Grand Total		16

Germany

Model	Serial #'s	Qty
AL20000-EU	1106000905	1
	1106000922	1
	1108001098	1
	1109000049	1
	1109000200	1
	1109000222	1
	1109000328	1
	1109000333	1
	1109000347	1
	1109000625	1
	1109000759	1
	1109000970	1
	1109000971	1
	1109001076	1
	1109001091	1
	1109001113	1
1109001282	1	
AL20001-EU	1105000397	1
AL20002-EU	1110000192	1
AL20106-EU	1108000915	1
AL21000-EU	1109001013	1
AL24000-EU	1110000179	1
AL26000-EU	1107000150	1
	1107000167	1
AL26116-EU	1109001187	1
AL27000-EU	1109001014	1

AL27002-EU	1109001170	1
	1110000130	1
	1110000131	1
AL27110-EU	1109000052	1
Grand Total		30

Great Britain

Model	Serial #'s	Qty
AL20000-GB	1109000669	1
	1109000841	1
AL20010-GB	1109000668	1
	1110000053	1
AL21000-GB	1109001326	1
	1109001490	1
	1109001496	1
AL21001-GB	1110000250	1
AL21010-GB	1109000240	1
	1109000606	1
	1109001036	1
	1109001064	1
	1109001275	1
	1109001343	1
	1109001349	1
AL23010-GB	1109000602	1
	1109000637	1
AL25011-GB	1109000696	1
Grand Total		18

Italy

Model	Serial #'s	Qty
AL20000-EU	1109000371	1
	1109000373	1
AL24010-EU	1109000106	1
	1109000755	1
AL27010-EU	1108000668	1
AL27111-EU	1109000407	1
	1109000412	1
	1109000456	1
	1109000537	1
Grand Total		9

Netherlands

Model	Serial #'s	Qty
AL21010-EU	CAT04	1
	CAT05	1
	CAT09	1
	CAT10	1
AL27010-EU	1107000098	1
	1109000118	1
AL27110-EU	1109001114	1
Grand Total		7

Switzerland

Model	Serial #'s	Qty
AL20000-EU	1110000281	1
	1110000287	1
AL26010-EU	1109000038	1
AL27100-EU	1109000199	1
Grand Total		14

In all 148 +11 units have been distributed from Arjo Hospital Equipment, many are still in ArjoHuntleigh possession (in transit or in warehouses) due to the Parker 500 being a new product. The +11 are units used for in-house training, verifications or tradeshow and are all in AHE possession.

[Redacted]
John Wennborg
[Redacted]