

## FIELD CORRECTION NOTICE

### Alpha Active 3, 4 & 5 medical pump

**Date:** 2021-FEB-16

**Product Issue:** Power cable damage

**Affected Product:** Alpha Active 3, Alpha Active 4 & Alpha Active 5 medical pump

**Affected Serial No.:** Please see attached Customer Response Form

**Resolution:** Power cable replacement

**Field Correction Notice:** FCN-SUZ-004-2020

**Pages:** 2 & Customer Response Form



**Dear Customer,**

Our records indicate that you may have one or more Arjo Alpha Active 3, Alpha Active 4 and/or Alpha Active 5 pump(s) within your facility(ies). This letter is to inform you of an action that Arjo intends to take on those device(s) to enhance the power cable's resistance to unintentional damage.

Each pump is equipped with a mains power cable allowing the device to be plugged into a power socket. This enables the pump to provide pressure injury prevention therapy into the mattress.

Arjo has investigated customer complaints where mains cables have been damaged accidentally or through miss-use (i.e. incorrectly stowed). Although the mains cables on the Alpha Active models listed have been tested to, and comply with IEC60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*, and are fit for purpose, the investigation has identified ways of mitigating possible damage by increasing the cable wall thickness and incorporating an improved grommet.

Although Arjo acknowledges that there are many situations that could lead to unintentional damage such as incorrect stowage, we would like to assure you that any such failures reported to Arjo did not involve any serious health consequences.

Therefore we intend to provide you, free of charge, with a mains power cable with a thicker wall which will also incorporate an improved grommet.

We would like also to emphasize that the product must always be used according to information, cautions and warnings provided in the Instruction for Use (IFU) as they firmly prevent from the damage.

### **Next Steps**

1. Verify whether you possess any Alpha Active 3, Alpha Active 4 or Alpha Active 5 pumps and ensure that all caregivers and users are made aware of this Field Correction Notice (FCN).
2. Check carefully the condition of the power cable and all electrical connections for signs of damage and excessive wear. Make sure that the cable is disconnected from a power socket beforehand. If any damage is observed, remove the device from use and contact Arjo.
3. The device can remain in use as long as the cable is not frayed or worn and secured properly from being caught or entrapped in a bed mechanism as advised in the Instruction for Use.
4. Complete and sign the enclosed Customer Response Form and return this form to your local Arjo office. Once returned, Arjo will contact a designated facility representative listed on the Customer Response Form to schedule the service visit and retrofit all devices at your facility.

Note: if your facility has sold or moved the affected pump, please include the new facility's information in the Customer Response Form.

We regret any inconvenience that this Field Correction Notice may cause, however we greatly appreciate your understanding as we take actions to ensure the satisfying quality of our products.

### **Additional Comment**

If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo at +65 6202 7367 or via email at Michael.Perez@arjo.com.

## Customer Response Form

### FIELD CORRECTION NOTICE FCN-SUZ-004-2020

**Reference: Alpha Active 3, 4 & 5 medical pump – Power cable damage**

Our records indicate that the Alpha Active 3, Alpha Active 4 and/or Alpha Active 5 medical pump(s) listed below was/were delivered to your facility.

Please verify if you have any of the listed devices (table on page 2) and complete the information below.

**Record the total number of affected devices currently located at your facility here → \_\_\_\_.**

Please mark the appropriate boxes below:

- We have read the Alpha Active 3, 4 & 5 Field Correction Notice and we understand the communication and the required actions.

**If marked: please provide information where the affected devices are physically located now.**

#### Field Correction Notice Receipt and Customer Response Form Completion

<b>Current Facility Name</b>	Best Contact Sdn Bhd		
<b>Contact Name / Title</b>	Lee Hock Siang		
<b>Full Address</b>	No.13-12, Jalan Jalil Perkasa 13 Aked Esplanad, Bukit Jalil Kuala Lumpur, 57000 Malaysia		
<b>City, State/Province, Zip/Post Code</b>	Kuala Lumpur		
<b>Phone Number</b>	012-535 6113	<b>Fax:</b>	
<b>E-Mail Address</b>	leehs@bestcontact.com.my		
<b>Signature</b>		<b>Date:</b>	

- We have sold/moved our Alpha Active 3, 4 & 5 pump(s) to another facility.

**If marked: please provide new facility information below.**

<b>New Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Full Address</b>			
<b>City, State/Province, Zip/Post Code</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address</b>			
<b>Signature:</b>		<b>Date:</b>	

- We have read the Alpha Active 3, 4 & 5 pump(s) Field Correction Notice and we confirm that the affected device(s) at our facility has/have been already decommissioned/withdrawn from use.

**PLEASE RETURN YOUR COMPLETED FORM TO:  
MAIL**

Arjo South East Asia Pte. Ltd.  
31 Kaki Bukit Road 3  
#05-06/07 Techlink Lobby B  
Singapore 417818

**CONTACT**

Michael.Perez@arjo.com  
Tel: +65 6202 7367  
Fax: +65 6747 0994

**Alpha Active 3, 4 & 5 pump(s) delivered to your facility:**

NO.	SERIAL NO.	FACILITY		ROOM / FLOOR / WARD (enter a location)
		CURRENT OR NEW (mark a correct one)		
1	648314113	CURRENT	NEW	BCM
2	1900059928	CURRENT	NEW	BCM
3	1900059929	CURRENT	NEW	BCM
4	1900059930	CURRENT	NEW	BCM
5	1900059931	CURRENT	NEW	BCM
6	1900059932	CURRENT	NEW	BCM
7	1900059933	CURRENT	NEW	BCM
8	1900059934	CURRENT	NEW	BCM
9	1900059935	CURRENT	NEW	BCM
10	1900059936	CURRENT	NEW	BCM
11	1900059937	CURRENT	NEW	BCM
12	1900059938	CURRENT	NEW	BCM
13	1900059939	CURRENT	NEW	BCM
14	1900059940	CURRENT	NEW	BCM
15	1900059941	CURRENT	NEW	BCM
16	1900059942	CURRENT	NEW	BCM
17	1900059943	CURRENT	NEW	BCM
18	1900059944	CURRENT	NEW	BCM
19	1900059945	CURRENT	NEW	BCM
20	1900059946	CURRENT	NEW	BCM
21	1900059947	CURRENT	NEW	BCM
22	1900059948	CURRENT	NEW	BCM
23	1900059949	CURRENT	NEW	BCM
24	1900059950	CURRENT	NEW	BCM
25	1900059951	CURRENT	NEW	BCM
26	1900059952	CURRENT	NEW	BCM
27	1900059953	CURRENT	NEW	BCM
28	1900059954	CURRENT	NEW	BCM
29	1900059955	CURRENT	NEW	BCM
30	1900059956	CURRENT	NEW	BCM
31	1900059957	CURRENT	NEW	BCM
32	1900059958	CURRENT	NEW	BCM
33	1900059959	CURRENT	NEW	BCM
34	1900059960	CURRENT	NEW	BCM
35	1900059961	CURRENT	NEW	BCM
36	1900059962	CURRENT	NEW	BCM
37	1900059963	CURRENT	NEW	BCM
38	1900059964	CURRENT	NEW	BCM
39	1900059965	CURRENT	NEW	BCM
40	1900059966	CURRENT	NEW	BCM
41	1900059967	CURRENT	NEW	BCM
42	1900059968	CURRENT	NEW	BCM
43	1900059969	CURRENT	NEW	BCM
44	1900059970	CURRENT	NEW	BCM
45	1900059971	CURRENT	NEW	BCM
46	1900059972	CURRENT	NEW	BCM
47	1900059973	CURRENT	NEW	BCM
48	1900059974	CURRENT	NEW	BCM
49	1900059975	CURRENT	NEW	BCM
50	1900059976	CURRENT	NEW	BCM
51	1900059977	CURRENT	NEW	BCM

NO.	SERIAL NO.	FACILITY CURRENT OR NEW (mark a correct one)		ROOM / FLOOR / WARD (enter a location)
52	1900059978	CURRENT	NEW	BCM
53	1900059979	CURRENT	NEW	BCM
54	1900059980	CURRENT	NEW	BCM
55	1900059981	CURRENT	NEW	BCM
56	1900059982	CURRENT	NEW	BCM
57	1900059983	CURRENT	NEW	BCM
58	1900059984	CURRENT	NEW	BCM
59	1900059985	CURRENT	NEW	BCM
60	1900059986	CURRENT	NEW	BCM
61	1900059987	CURRENT	NEW	BCM
62	1900059988	CURRENT	NEW	BCM
63	1900059989	CURRENT	NEW	BCM
64	1900059990	CURRENT	NEW	BCM
65	1900059991	CURRENT	NEW	BCM
66	1900059992	CURRENT	NEW	BCM
67	1900059993	CURRENT	NEW	BCM
68	1900059994	CURRENT	NEW	BCM
69	1900059995	CURRENT	NEW	BCM
70	1900059996	CURRENT	NEW	BCM
71	1900059997	CURRENT	NEW	BCM
72	1900059998	CURRENT	NEW	BCM
73	1900059999	CURRENT	NEW	BCM
74	1900060000	CURRENT	NEW	BCM
75	1900060001	CURRENT	NEW	BCM
76	1900060002	CURRENT	NEW	BCM
77	1900060003	CURRENT	NEW	BCM
78	1900060004	CURRENT	NEW	BCM
79	1900060005	CURRENT	NEW	BCM
80	1900060006	CURRENT	NEW	BCM
81	1900060007	CURRENT	NEW	BCM
82	2000012930	CURRENT	NEW	BCM
83	2000012931	CURRENT	NEW	BCM
84	2000012932	CURRENT	NEW	BCM
85	2000012933	CURRENT	NEW	BCM
86	2000012934	CURRENT	NEW	BCM
87	2000012935	CURRENT	NEW	BCM
88	2000012936	CURRENT	NEW	BCM
89	2000012937	CURRENT	NEW	BCM
90	2000012938	CURRENT	NEW	BCM
91	2000012939	CURRENT	NEW	BCM
92	2000012940	CURRENT	NEW	BCM
93	2000012941	CURRENT	NEW	BCM
94	2000012942	CURRENT	NEW	BCM
95	2000012943	CURRENT	NEW	BCM
96	2000012944	CURRENT	NEW	BCM
97	2000012945	CURRENT	NEW	BCM
98	2000012946	CURRENT	NEW	BCM
99	2000012947	CURRENT	NEW	BCM
100	2000012948	CURRENT	NEW	BCM
101	2000012949	CURRENT	NEW	BCM
102	2000012950	CURRENT	NEW	BCM
103	2000012951	CURRENT	NEW	BCM
104	2000012952	CURRENT	NEW	BCM
105	2000012953	CURRENT	NEW	BCM
106	2000012954	CURRENT	NEW	BCM
107	2000012955	CURRENT	NEW	BCM
108	2000012956	CURRENT	NEW	BCM
109	2000012957	CURRENT	NEW	BCM

NO.	SERIAL NO.	FACILITY CURRENT OR NEW (mark a correct one)		ROOM / FLOOR / WARD (enter a location)
		CURRENT	NEW	
110	2000012958	CURRENT	NEW	BCM
111	2000012959	CURRENT	NEW	BCM
112	2000012960	CURRENT	NEW	BCM
113	2000012961	CURRENT	NEW	BCM
114	2000012962	CURRENT	NEW	BCM
115	2000012963	CURRENT	NEW	BCM
116	2000012964	CURRENT	NEW	BCM
117	2000012965	CURRENT	NEW	BCM
118	2000012966	CURRENT	NEW	BCM
119	2000012967	CURRENT	NEW	BCM
120	2000012968	CURRENT	NEW	BCM
121	2000012969	CURRENT	NEW	BCM