

Customer name & address

**Field Safety Corrective Action – Urgent Safety Information
Quickie Q 700-UP M & Quickie Q700-UP F**

Your reference, your letter from

Our reference, our letter from

Phone
+49 7253/980-0

Date
2020-04-06

Dear Ladies and Gentlemen


The safety of our customers is a top priority for Sunrise Medical. As part of our quality assurance processes, we continuously monitor our internal processes and our products in the market.

We have received a market feedback that there has been a short circuit and a smoldering cable. The cause was a non-approved cable attachment. The affected wheelchairs have to be reworked in the field, we kindly ask you for your support to perform this.

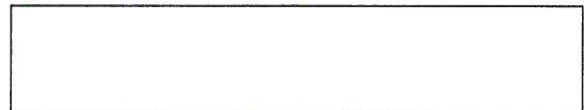
In order to keep the effort as low as possible, we have enclosed in this letter additional information in the form of; an urgent safety information (FSN), the necessary quantity of cable attachment including assembly instructions, and the reply form.

We really regret the inconvenience and apologize for it. We know that we act in the interests of our quality-focused dealers and all wheelchair users. We want to thank you for the implementation of this philosophy and look forward to further cooperation.

Best regards



Head of Sales



Quality & Regulatory Director

Sunrise Medical GmbH

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Sitz: Malsch/Heidelberg
Handelsregister Mannheim HRB-Nr.: 727105
Gerichtsstand: Heidelberg
Geschäftsführer: Bernd Krebs

Bankverbindung:
Commerzbank Mannheim
Kto.: 666 116 900 - BLZ: 670 400 31
IBAN: DE 78670400310666116900
BIC-Code: COBADEFF670

Urgent safety information***Power Wheelchairs Quickie Q700-UP M & Quickie Q700-UP F***

Sender: Sunrise Medical GmbH, Kahlbachring 2-4, D-69254 Malsch / Heidelberg / Germany

Addressee: All customers who have received a product from the relevant batch.

Identification of the affected medical products:

All customers who have received a wheelchair from the relevant batch will be informed in writing. The affected medical products can be clearly identified using the serial number. It only affects wheelchairs produced between 2019-02-19 and 2019-02-28 and between 2020-01-28 and 2020-04-01.

The following serial numbers are affected at your company:

Description of the problem including the cause which has been identified:

During the assembly process, a non-approved cable attachment has been assembled. As a result, the cable can be pinched, which in an unfavorable case could lead to a short circuit and to a smoldering cable.

What measures must be taken by the addressee?

The non-approved cable attachment must be replaced with an approved cable attachment. The required parts and installation instructions are included with this information. Please confirm the exchange of the cable attachment with the approved version with the return form by post, fax or email by May 31, 2020.

Distribution of the information described here:

Please make sure that, within your organisation, all users of the products mentioned above and other individuals who need to be informed are made aware of this urgent safety information. In the event that you have passed the products onto a third party, please send them a copy of this information or advise us accordingly.

Please retain this information at least until the measures have been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent safety information".

Contact person:**Sunrise Medical GmbH**

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BIC-Code: COBAEFF670

Reply by Post:

Sunrise Medical GmbH
Regulatory
Kahlbachring 2- 4
D-69254 Malsch

Reply by Fax:

Fax: +49 7253 980 111
Fax: +49 7253 980 305

Reply by Mail:

Regulatory@sunrisemedical.de

Urgent safety information

Customer number: _____

Customer name: _____

Serial number: _____

The rework of the above Quickie Q700-UP M / Quickie Q 700-UP F has been completed.

The rework of the above Quickie Q700-UP M / Quickie Q 700-UP F has not been completed

because of _____

Date

Signature / stamp

Name in letters

Sunrise Medical GmbH

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Serial number	Serial number	Serial number
203190617689348	203200523516003	203201024515768
203190517583295	203200423284047	203201124612459
203190617689069	203200623683921	203200523515990
203190517598916	203200623647511	203201124748248
203190717763213	203200623684039	203200723989447
203190717764650	203200623656903	203201024484747
203190617647916	203200523565551	203201124696387
203190617702080	203200623809491	203200723955263
203190617687511	203200623793714	203201124696314
203190617722186	203200623746943	203200623731185
203190517582685	203200723874452	203201124696773
203190617647518	203200623712410	203201124724587
203190717801780	203200723927001	203200924306554
203190617701833	203200523548953	203201024484757
203190617648820	203200824078184	203201024449766
20319071777271	203200723955482	203201124696250
203190717764252	203200623731185	203201224835884
203190717777097	203200724006147	203201024484762
203190517567746	203200724005920	203201224835979
203190817856511	203200723926894	203201324996345
203190817844531	203200723989466	203201224898134
203200323086961	203200924264317	203201224835873
203200223041460	203200824167181	203201224927243
203200423304937	203200924264318	203201024544012
203200423284035	203200824182745	203200523516026
203200423396723	203201024449903	203200924360755
203200423282846	203200924362908	203200222916860