

Urgent Field Safety Notice

AquaC UNO H (F00003546) – Risk of defective crimp connection on the protective conductor

Date: August 28th, 2020

To whom it may concern

During regular quality inspections within Fresenius Medical Care of AquaC UNO H devices we discovered incorrectly crimped connectors on the main protective earth conductor. During device movement there is a risk that the crimp connector becomes loose. Should the phase or neutral conductor connections also become loose, there is the possibility that the cables touch the housing, leading to the transfer of electrical energy and the risk of electric shock.

The use of a non-qualified-crimping tool in the production line was identified as cause for the above described risk. All affected devices had passed the internal mandatory electrical safety test at the end of the production line and during installation at the customer site, confirming that crimp connector was still attached at this point and that the crimp connection created by this tool initially was correct. However, this connection may become or has become loose at a later timepoint due to device movement or vibrations.

Therefore, affected devices should be handled with care, avoiding unnecessary or sudden movements. Until the crimp connector has been checked and if needed replaced by a Fresenius Medical Care representative, careful use is advised.

Until now, no incidents with the described issues have been reported to Fresenius Medical Care.

Per our records you received one or more of the AquaC UNO H device(s) with the possibly affected serial numbers (see included table below for the list of devices).

AquaC UNO H (F00003546) - Possibly affected serial numbers							
0CHS3904	0CHS3913	0CHS3943	0CHS4001	0CHS4034	0CHS4120	0CHS4137	0CHS4178
0CHS3905	0CHS3914	0CHS3944	0CHS4002	0CHS4112	0CHS4129	0CHS4138	0CHS4179
0CHS3906	0CHS3915	0CHS3945	0CHS4003	0CHS4113	0CHS4130	0CHS4171	0CHS4180
0CHS3907	0CHS3916	0CHS3946	0CHS4004	0CHS4114	0CHS4131	0CHS4172	0CHS4181
0CHS3908	0CHS3917	0CHS3947	0CHS4029	0CHS4115	0CHS4132	0CHS4173	0CHS4184
0CHS3909	0CHS3883	0CHS3948	0CHS4030	0CHS4116	0CHS4133	0CHS4174	
0CHS3910	0CHS3884	0CHS3949	0CHS4031	0CHS4117	0CHS4134	0CHS4175	
0CHS3911	0CHS3885	0CHS3950	0CHS4032	0CHS4118	0CHS4135	0CHS4176	
0CHS3912	0CHS3942	0CHS3951	0CHS4033	0CHS4119	0CHS4136	0CHS4177	

Fresenius Medical Care (UK & Ireland) Limited

Please excuse the inconvenience caused by this matter. A Fresenius Medical Care representative will contact you to arrange an appointment; it is not mandatory that you contact us first to ensure a quick and comprehensive processing.

Please forward this Urgent Field Safety Notice to those in your organization who require this information.

Should you have any questions, please feel free to get in touch with us:

Name: Tom Spencer
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Sincerely yours



Antony Mazzei
Managing Director
Head of FMC NephroCare | UK & Ireland



Tim Wheeldon
Managing Director
Head of FMC UK & Ireland

Fresenius Medical Care (UK & Ireland) Limited

Customer Reply Form

Affected Device: AquaC UNO H (F00003546)
Identifier: SO-2020-1516
FSCA: Risk of defective crimp connection on the protective conductor

Customer Name: _____
Facility Name: _____
Facility Address: _____
City, State: _____
Country Postal Code: _____

Please complete for regulatory effectiveness check:

I confirm receipt of the Field Safety Notice and that I read and understood its content:	
Signature:	_____
Print Name:	_____
Date:	_____

Please return this form before 4/9/2020, to the following address:

- Email the signed form to vigilanceUK@fmc-ag.com

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