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Department: Customer Service

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Your reference

• Your correspondence dated

• Our reference

• Date

QM700017105

2021-10-29

Emergency safety notice

Affected product: HF surgical generator 400 kHz
Product number: 2260001 / 2260002

Product number:	Serial number:
2260001	SN00111
	SN00115
	SN00116
	SN00117
	Sn00118
2260002	SN00131
	SN00135

Our reference no.: QM 700017105

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to a potential defect on the HF surgical generator 400 kHz. According to our records, you operate the potentially affected product. The procedure for preventing the defect is set out in this letter.

This affects HF surgical generators 400 kHz with product label 2260001 or 2260002 and software version 1.4.4 or lower.

The problem

In rare cases, using the auto-start and / or auto stop function may lead to device error 0233, which causes the HF current to be deactivated immediately. While error 0233 is present, the HF surgical generator cannot be operated and must be restarted.



Unless a suitable measure to prevent this is put in place, procedures may be delayed or not carried out at all. We want to pre-empt this situation by implementing this measure.

Until Richard Wolf is able to provide an appropriate solution, the affected HF surgical generators must not be used in conjunction with the auto-start and / or auto stop function. Therefore, please do not use them with this function until further notice.

Measures to be taken by the addressee

Read through both this letter and the attached reference documents (see list of attachments) and keep them on file until the measure has been implemented.

Please follow the steps below:

1. Check your stock of HF surgical generators 400 kHz with product labels 2260001 and 2260002. If you find an HF generator that may be affected, check the device software version in the Service menu. Affected generators will have software version 1.4.4 or lower.
2. Within your organization, make sure that all users of the product referred to here and any other persons who require this information have been made aware of this emergency safety notice. If you have passed on this product to third parties, please forward a copy of this notice and inform the contact person stated below accordingly.
3. Make sure that this notice is retained within your facility until all the in-house measures required have been implemented.
4. To verify that you have received this emergency safety notice, we require you to return the enclosed **response form by November 10, 2021**. You can send this to us **via e-mail to FSCA700017105@richard-wolf.com**. We also ask that you complete this form even if you no longer have the product in stock. In doing so, you will be confirming receipt of this safety notice and you will not receive any further reminders from Richard Wolf.
5. Please inform Richard Wolf GmbH of any other adverse events.

Richard Wolf will get in touch with you as soon as a solution is available.
The relevant national authorities have been informed of this **emergency safety notice**.

Your contact for

Questions concerning safety:

Mr. Marco Bruxmeier
Head of Quality Engineering Department

Tel.: +49 7043 35 4011
E-mail: FSCA700017105@richard-wolf.com

Questions concerning the procedure:

Mr. Thilo Musikant
Head of Customer Service Department and
Service Center

Tel.: +49 7043 35 4189
E-mail: thilo.musikant@richard-wolf.com

Please accept our apologies for any inconvenience caused by this measure. On behalf of Richard Wolf GmbH, thank you in advance for your support in ensuring its timely implementation.

Yours faithfully,

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Attachments:
Response form