

Richard Wolf GmbH • Postfach 11 64 - 65 • 75434 Knittlingen, Germany

Department: Customer Service
Administrator: Thilo Musikant

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Your reference • Your correspondence dated • Our reference • Date
QM700023919 04.12.2024

Emergency safety notice

Affected products:

Product number: **100505** **PIEZOWAVE 2 CONTROL UNIT**
 100506 **PIEZOWAVE 2 CONTROL UNIT**
 3000501 **LITHOTRIPTOR 3000PLUS**
 80414 **SWISS PIEZOCLAST**

Our reference no.: **QM 700023919**
Actor ID/SRN: **DE-MF-000007048**

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to a potential defect.

According to our records, you operate the potentially affected product. The procedure for rectifying the defect is set out in this letter.

Material	Serial number	
100505	1101046992	1101083383
	1101046993	1101083384
	1101046994	1101083386
	1101046995	1101083387
	1101046996	1101083389
	1101046997	1101083390
	1101046998	1101083391
	1101046999	1101083392
	1101047000	1101083393
	1101083376	
	1101083377	
	1101083378	
	1101083379	
	1101083381	

Material	Serial number			
100506	1101050738	1101056400	1101060106	1101069953
	1101050739	1101056401	1101060107	1101069954
	1101050740	1101056402	1101060108	1101069955
	1101050741	1101056403	1101060109	1101069956
	1101050742	1101058299	1101060110	1101069957
	1101050743	1101058300	1101060111	1101069958
	1101050744	1101058301	1101063948	1101069959
	1101050745	1101058302	1101063949	1101069960
	1101050746	1101058303	1101063950	1101069961
	1101050747	1101058304	1101063951	1101070783
	1101050748	1101058305	1101063952	
	1101050749	1101058306	1101063953	
	1101050750	1101058307	1101063954	
	1101050751	1101058308	1101063955	
	1101050752	1101058309	1101063956	
	1101050753	1101058310	1101063957	
	1101050754	1101058311	1101063958	
	1101050755	1101058312	1101063959	
	1101050756	1101058313	1101063960	
	1101050757	1101058314	1101063961	
	1101056384	1101058315	1101063962	
	1101056385	1101058316	1101063963	
	1101056386	1101060092	1101063964	
	1101056387	1101060093	1101063965	
	1101056388	1101060094	1101063966	
	1101056389	1101060095	1101063967	
	1101056390	1101060096	1101069943	
	1101056391	1101060097	1101069944	
	1101056392	1101060098	1101069945	
	1101056393	1101060099	1101069946	
	1101056394	1101060100	1101069947	
	1101056395	1101060101	1101069948	
	1101056396	1101060102	1101069949	
1101056397	1101060103	1101069950		
1101056398	1101060104	1101069951		
1101056399	1101060105	1101069952		

Material	Serial number
3000501	1101063795
	1101070633
	1101084682

Material	Serial number	
80414	1101043704	1101052735
	1101043705	1101052736
	1101043706	1101052737
	1101043707	1101052738
	1101043708	1101052739
	1101043709	1101052740
	1101043710	1101052741
	1101043711	1101052742
	1101043712	1101052743
	1101049431	1101052744
	1101049432	1101052745
	1101049433	1101052746
	1101049434	1101052747
	1101049435	1101052748
	1101049436	1101052749
	1101049437	1101052750
	1101049438	1101052751
	1101049439	1101052752
	1101049440	1101052753
	1101049441	1101052754
	1101052727	1101052755
	1101052728	1101052756
	1101052729	1101052757
	1101052730	1101052758
	1101052731	1101052759
	1101052732	1101052760
	1101052733	1101052761
1101052734		

The problem

Richard Wolf has discovered that a capacitor from a particular production batch may fail after a number of surge voltages in a short period of time. If this happens, no further use is possible. The defective capacitor may produce smoke and a burning smell. The medical device is designed so that only self-extinguishing materials are used. Consequently, there is no risk of fire outside the medical device.

We want to pre-empt this situation by implementing this measure.

No patient injuries have been reported to Richard Wolf to date.

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 inventory for the material and serial numbers listed above.
2. In the event of defect of the capacitor as described, turn off the system, disconnect the device from the power supply, take it out of service immediately, and get in touch with your contact at Richard Wolf. If necessary, the institution's emergency procedures must be followed.
3. 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 persons stated below accordingly.
4. Make sure that this notice is retained within your facility until all the in-house measures required have been implemented.
5. To verify that you have received this emergency safety notice, we require you to return the enclosed **response form by December 16, 2024**. You can send this to us **via e-mail to FSCA700023919@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.
6. Please inform Richard Wolf GmbH of any adverse events.

Richard Wolf or our authorized service partner will contact you after receiving the response letter to arrange an appointment for the inspection and replacement of the circuit board.
The relevant national authorities have been informed of this **emergency safety notice**.

Your contact for

Questions concerning safety:

Mr. Martin Senger
Head of Quality Engineering Department

Tel.: +49 7043 35 4011
E-mail: FSCA700023919@richard-wolf.com

Questions concerning the procedure:

Mr. Thilo Musikant
Director Customer Service, Maintenance and Repair

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,
Richard Wolf GmbH

p.p. Martin Senger
Head of Quality Engineering Department

p.p. Thilo Musikant
Director Customer Service, Maintenance and Repair

Attachments:
Response form