Arthrex GmbH | Erwin-Hielscher-Str. 9 | D-81249 München

Clinic / CompanyPosition / Department
Title First name Last name
Street
Zip Code City

your contact
Jane Doe

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Field Safety Notice

Reference: R546

Purpose

This voluntary Field Safety Notice (FSN) is to inform you about a Field Safety Corrective Action (FSCA) for the AR-9800 Synergy RF Console.

The Arthrex Synergy^{RF} System, when used with an Apollo^{RF} Ablation Device (Probe), is intended for use as a complete system in the resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures. Specifically, the ablation devices, electrosurgical generator and their accessories are used for arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, foot and ankle.

Products affected by the issue

Product Name	Part No.	Affected devices
SYNERGY^{RF} CONSOLE	**AR-9800**	**All devices at Rev. 6 or below**

Description of the issue

Upon initial power up of the AR-9800 there is a potential, with some electrical services, that an inrush current may occur. If this inrush current is to occur, there is a possibility that the circuit breaker trips. If the breaker trips, resetting the circuit breaker will be required to restore power. Other devices connected to the same electrical circuit would experience a temporary power outage until the circuit breaker is reset or the devices are connected to another power circuit.

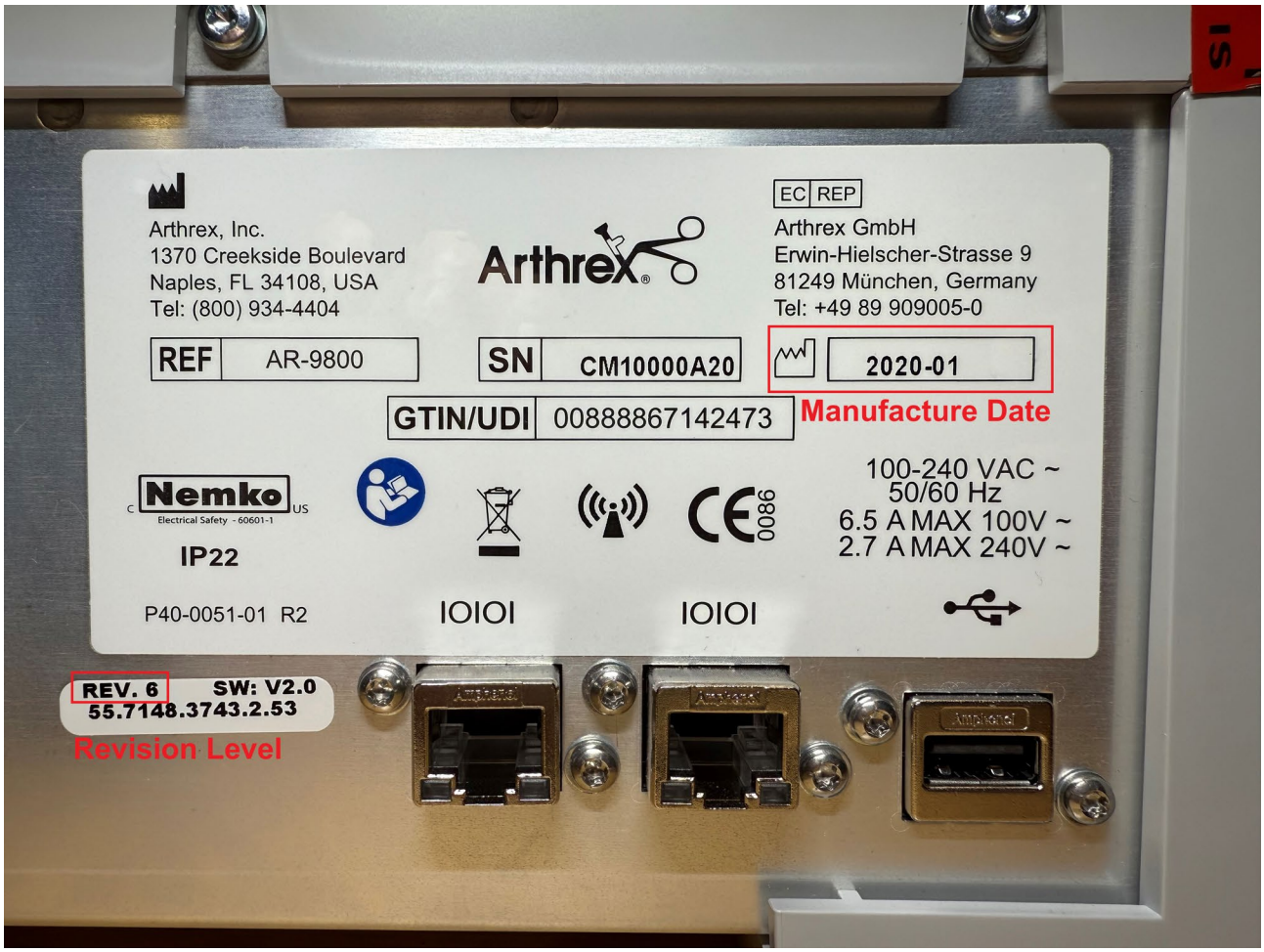
Arthrex has identified 77 occurrences of complaints reporting breakers tripping for devices at Rev. 6 or below. The reported events have never resulted in harm to patients, users or third parties. Although no harm has been reported, it was determined that if a failure occurs, the worst potential outcome would be a failure to complete a procedure.

To resolve this issue, an Arthrex employee will replace the current T8A fuses with new F4A fuses and relabel the device with new fuse specifications.

New label

Actions to be taken by the addressee of this notice

1. Immediately identify the indicated AR-9800 you have in your control.
   The affected devices can be identified via a label on the back of the device that indicates the revision level (see picture below). If the revision level label is not present, the device should be considered affected if the manufacturing date is prior to July 2020. The manufacturing date is indicated on the main label on the back of the device.



2. The affected devices must only be used on a dedicated electrical circuit until an Arthrex employee has performed the necessary field correction.

3. Please fill out the “Arthrex customer’s response form” located on the last page of this document and return it to vigilance@arthrex.de.

4. After receiving your response form, Arthrex will reach out to you to schedule an appointment to correct the affected devices.

Transmission of this Field Safety Notice

Please forward this Field Safety Notice (FSN) to all those who need to be aware of it within your organization or to any organization where the potentially affected devices have been transferred.

The relevant National Competent Authorities have been advised of this voluntary recall.

Contact information

Product Surveillance GmbH:
Sarah Merkle
Manager Vigilance & Product Surveillance
Phone +49 89 90 90 05 52 40
E-Mail: vigilance@arthrex.de

Product-specific questions:
Michael Böhm
Senior Product Manager Imaging & Resection
Phone +49 89 90 90 05 41 12
E-Mail: michael.boehm@arthrex.de

Sincerely,

Sarah Merkle
Manager Vigilance & Product Surveillance

Arthrex GmbH
Oskar-von-Miller-Str. 6
85235 Odelzhausen
Phone: +49 89 90 90 05 52 40
Fax: +49 89 90 90 05 52 01
Email: vigilance@arthrex.de

Arthrex customer's response form

Field Safety Notice

Reference: R546

Return To	
To	**Arthrex GmbH** Product Surveillance Oskar-von-Miller-Str. 6 85235 Odelzhausen Germany
Email	vigilance@arthrex.de
Fax	+49 89 90 90 05 52 01

From	
Facility Name	
Address **City**	
Name	
Title	
Phone	

Please complete the form as follows and return it by fax or email to the addressee above:

☐ The following affected products are in our stock

Part Number	Serial Number(s)	
AR-9800		

☐ The products in question of the field safety notice are not in our stock and use anymore

Date Signature