

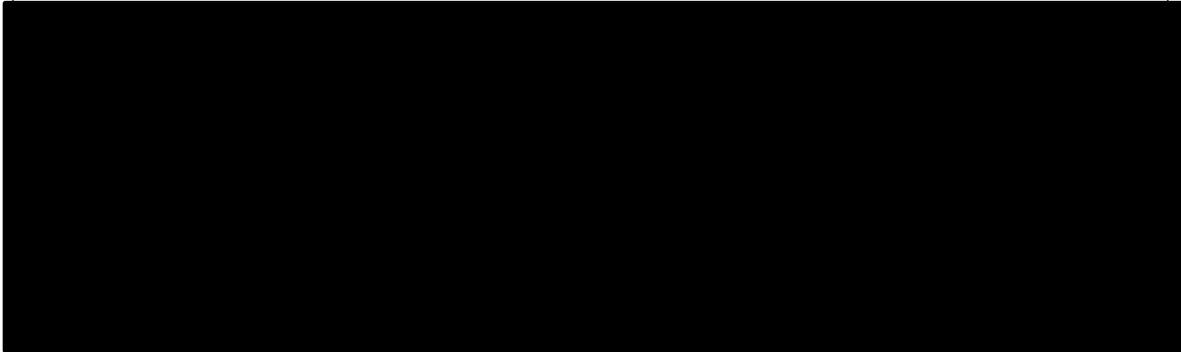
FSN Ref: 2a\_01\_FSN\_0420  
FSCA Ref: 2a\_01\_FSCA\_0420

Date: 2020-04-23

**Urgent Field Safety Notice (FSN)**  
**Dringender Sicherheitshinweis**  
**SpeedSurg control unit**

For Attention of: Affected users and distributors

Contact details



## Urgent Field Safety Notice (FSN)

### Dringender Sicherheitshinweis

### SpeedSurg control unit

#### Information on Affected Devices

##### Device Type

Control unit for driving an electronic motor for drilling and sawing on bones, as well as for shaving treatment in the ENT area or head and neck surgery.



##### Commercial name

SpeedSurg control unit

##### Primary clinical purpose of device

Micro drill and shaver system that drives an electronic motor (accessory) for drilling and cutting bones and for shaver treatment in the field of ENT or head and neck surgery.

##### Device Model/Catalogue number

78CU80-EN    78CU80-DE    78SS80-SET-DE    78SS80-SET-EN

##### Description of the product problem

A faulty electrical component has been found during routine quality assurance tests. In this regard, no device defect or patient injury has occurred.

Nevertheless, as a precautionary measure we would like to inform you that when the power switch is turned off, the mains cable may carry more electricity after being pulled out of the socket than is permitted by the specifications of the standard EN 60601-1.

**For some devices, this may cause a considerable risk of electric shock by touching the contacts that become free when the device is disconnected from the power supply.**

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### Affected serial number range

3627U1903R	4487U1608A	6914U1905R	7309U1812R	8402U1906R
3628U1903R	4498U1608A	6915U1905R	7310U1812R	8403U1906R
3629U1903R	4631U1706R	6916U1905R	7311U1812R	8404U1906R
3630U1903R	4640U1706R	6917U1905R	7312U1812R	8407U1906R
3631U1903R	4642U1706 R	6918U1905R	7313U1812R	8408U1906R
3632U1903R	4650U1706R	6919U1905R	7314U1812R	8409U1906R
3634U1903R	4651U1706R	6920U1905R	7315U1812R	8410U1906R
3635U1903R	4652U1706R	6921U1905R	7316U1812R	8411U1906R
3636U1903R	4653U1706R		7318U1812R	8412U1906R
3637U1903R	4656U1706R		7319U1812R	8414U1906R
3638U1903R	4658U1706R		7320U1812R	8417U1906R
3639U1903R	4662U1706 R		7755U1906R	8420U1906R
3640U1903R	4664U1706R		7756U1906R	8421U1906R
3641U1903R	4666U1706R		7757U1906R	9869U1907R
3643U1903R	4667U1706R		7758U1906R	9874U1907R
3644U1903R	4668U1706R		7759U1906R	9875U1907R
3645U1903R	4669U1706R			
3646U1903R				
3647U1903R				
3648U1903R				
3649U1903R				
3650U1903R				
3651U1903R				

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## Reason for Field Safety Corrective Action (FSCA)

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### Background on Issue

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The mains-filter capacitor is intended to ensure that interference voltages from the power supply network can be filtered out. In the case of some SpeedSurg control units, this capacitor has been mistakenly positioned in an unfavourable position. Thus after switching off the unit using the power switch on the back of the housing the capacitor continues to be supplied with a higher mains voltage than the specifications of the EN 60601-1 standard allow, but the electricity can no longer flow into the device. The capacitor can hold the current for up to one week after disconnection from the power source.

As soon as the mains cable is removed from the socket and the external and neutral conductors of the earthed plug on the mains cable are touched simultaneously by the user, the capacitor discharges, current flows and a corresponding electric shock occurs. Disconnecting the mains plug while the control unit is switched on will immediately discharge the capacitor into the unit, so that there is no risk of electric shock during this procedure.

### Hazard giving rise to the FSCA

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A voltage flashover will not occur if the power plug is removed from the socket. The amount of the voltage drop is theoretically calculated to be at up to 360V.

Theoretical calculation:

$$\begin{aligned} \text{Mains voltage} &= 230 \text{ V} \\ I_{\text{Peak}} &= U_{\text{Peak}} / R_{\text{Body}} \quad R_{\text{Body}} \approx 1000 \Omega \text{ (frequently assumed value)} \\ I_{\text{Peak}} &= 357.8 \text{ V} / 1000 \Omega \\ I_{\text{Peak}} &\approx \underline{358 \text{ mA}} \end{aligned}$$

$$\begin{aligned} \text{Mains voltage} &= 115 \text{ V} \\ I_{\text{Peak}} &\approx \underline{179 \text{ mA}} \end{aligned}$$

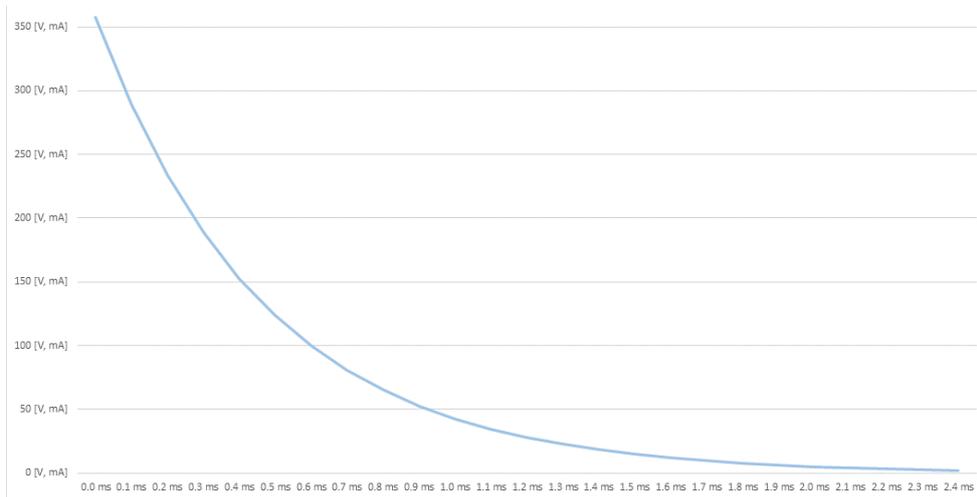
$$\begin{aligned} \text{Mains voltage} &= 100 \text{ V} \\ I_{\text{Peak}} &\approx \underline{156 \text{ mA}} \end{aligned}$$

In a random check using a multimeter, voltages above +300 volts or below -300 volts could not be detected, but several times values above +200 volts or below -200 volts and often in between were measured.

An alternating current  $I \leq 358 \text{ mA}$  can be potentially fatal. However, the present decreasing voltage does not originate from a constant current source, but quickly discharges itself in the body, so that a potentially life-threatening situation is very unlikely to occur.

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Assumed time course of voltage [V] and current [mA] (with theoretically maximum possible initial voltage of 357.8 V and a body resistance of approx. 1000 Ω) when touching the plug contacts immediately after pulling the plug from the socket:



### Predicted risk to users

Patients are not affected by this hazard.

Users may suffer a low-voltage accident when pulling the mains plug.

Possible side effects:

Cramping of the musculature

Cardiac effects

Nervous system disorders

Thermal incidents

Secondary injuries (e.g. fall)

### Type of Action to mitigate the risk

#### Action To Be Taken by the User

Identify Device     Quarantine Device     Return Device     Destroy Device

On-site device modification/inspection

Follow patient management recommendations

Take note of amendment/reinforcement of Instructions For Use (IFU)

Other

None

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### List of measures

1. Please check if there are products with the listed serial numbers in your stock.
2. Users should discontinue the use and distribution of the affected products and immediately quarantine these products.
3. As a distributor: Forward this safety information to all customers who have received a product affected by this safety information.
4. If you have products affected by this safety information in your inventory, please contact SPIGGLE & THEIS Medizintechnik GmbH Customer Service at



Customer Service will then issue you with a return number.

5. Return all affected products to SPIGGLE & THEIS Medizintechnik GmbH immediately. Please complete Appendix 1 and return it to the fax number or e-mail address below.

### How to disconnect the devices from the power supply without risk

**If the device is still connected to the power supply, the following applies:**

1. First switch ON the device at the device power switch, switch position "I" (please leave already switched on devices switched on).
2. As soon as the unit is visibly switched ON, please unplug the power cord of the still ON(!) unit from the power outlet.
3. After 1 second the faulty capacitor is discharged.

**If the device has just been disconnected from the power supply and the device power switch has been switched off beforehand, please observe the following:**

1. If the unit has just been disconnected from the power supply, please do not touch the contacts of the power supply connection!
2. Self-discharge of the faulty capacitor can take up to a week.
3. The capacitor of the unit disconnected from the power supply can be safely discharged in seconds via the low-resistance transformer by switching the mains switch to the switch position "I" (ON).

**The Competent (Regulatory) Authority of your country has been informed about this communication to customers.**

**List of attachments/appendices:**

Annex 1

**Name/Signature**



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Annex 1

## Customer Reply Form

### RECALL – Speedsurg Control Unit

Please fill out this customer reply form completely and send it back to us immediately via fax: +49(0)2206 9081-13 or Email: [vigilance@spiggle-theis.com](mailto:vigilance@spiggle-theis.com)

Please tick the box that applies to you and complete the following fields.

<input type="checkbox"/> We hereby confirm that we have received the Field Safety Notice information (FSN) and that the contents have been read and understood. We further confirm that we have <b>NO</b> affected products in our organization's inventory.	<input type="checkbox"/> We confirm that we have received the Field Safety Notice information (FSN) and that the contents have been read and understood. We further confirm that we either <b>DO HAVE</b> affected products at our organization's inventory or have distributed them to end customers. All measures requested by the FSN are completed. All affected products have been quarantined and the products with the serial numbers listed below will be returned.  Return Number: _____
<b>Product Code*</b>	<b>Serial Number</b>
<ul style="list-style-type: none"> <li>• Please enclose a copy of this <b>completed customer reply form</b> with the return shipment.</li> <li>* If you return more than 8 products, please list the numbers in an attachment.</li> </ul>	

<b>Institution Name</b> (e.g. name of hospital, distributor)	
<b>Institution Address</b>	
<b>Telephone Number/ Fax</b>	
<b>Email Address</b>	
<b>Form filled in by</b>	
_____	_____
Name (in block letters)	Signature, Date

Many thanks for your kind support.