

Date: 20.08.2020


Urgent Field Safety Notice MD11 / MD30

For Attention of: Users and Distributors of MD11 and MD30

Contact details of local representative

Nouvag AG
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Urgent Field Safety Notice (FSN) MD11 / MD30
Production according to expired EMV Standard 60601-1-2 Edition 3


1. Information on Affected Devices	
1.	<p>1. Device Type</p> <p>The MD11 and MD30 is a mobile motor system with an integrated infiltration pump for oral surgery and implantology</p> <div style="text-align: center;">  </div>
1.	<p>2. Commercial name(s)</p> <p>Motor System MD11 Motor System MD30</p>
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>MD11 control unit: +ENOU33350H MD11 sets: +ENOU200308 +ENOU20260D +ENOU20270E +ENOU20280F</p> <p>MD30 control unit: +ENOU33300C MD30 sets: +ENOU200409 +ENOU20050A +ENOU20070C +ENOU20160C</p>

1.	<p>4. Primary clinical purpose of device(s)*</p> <p>The MD 30 in combination with a motor and corresponding handpiece or contra angle (separate medical device) is used primarily in dental implantology. The device can also be used for microsurgical applications as well as in oral and maxillofacial surgical procedures. The device is designed for drilling, milling and sawing bone as well as for screw insertion into bone. An integrated peristaltic pump is provided in order to cool the rotating instruments so that damage to tissue can be prevented.</p>																																							
1.	<p>5. Device Model/Catalogue/part number(s)</p> <p>MD11 control unit and sets: 3335; 2003; 2026; 2027; 2027m; 2028 MD30 control unit and sets: 3330; 2004; 2005;</p>																																							
1.	<p>6. Affected serial or lot number range</p> <p>MD11:</p> <table border="1" data-bbox="296 832 866 1290"> <thead> <tr> <th>Qty</th> <th>SET SN</th> <th>UNIT SN</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>1661S1908R</td> <td>0658U1902R</td> </tr> <tr> <td>1</td> <td>3547S2004R</td> <td>6974U1912R</td> </tr> <tr> <td>1</td> <td>3253E1903R</td> <td>5906U1811R</td> </tr> <tr> <td>1</td> <td>5599E1904R</td> <td>5942U1811R</td> </tr> <tr> <td>1</td> <td>2697S1909R</td> <td>0656U1902R</td> </tr> <tr> <td>1</td> <td>0780S2002R</td> <td>6956U1912R</td> </tr> <tr> <td>1</td> <td>1903S2003R</td> <td>6967U1912R</td> </tr> </tbody> </table> <p>MD30:</p> <table border="1" data-bbox="292 1389 861 1672"> <thead> <tr> <th>Qty</th> <th>SET SN</th> <th>UNIT SN</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>9774E1901R</td> <td>2405U1803R</td> </tr> <tr> <td>1</td> <td>9775E1901R</td> <td>2411U1803R</td> </tr> <tr> <td>1</td> <td>5561S1911R</td> <td>1228U1908R</td> </tr> <tr> <td>1</td> <td>2441E1903R</td> <td>9163U1901R</td> </tr> </tbody> </table>	Qty	SET SN	UNIT SN	1	1661S1908R	0658U1902R	1	3547S2004R	6974U1912R	1	3253E1903R	5906U1811R	1	5599E1904R	5942U1811R	1	2697S1909R	0656U1902R	1	0780S2002R	6956U1912R	1	1903S2003R	6967U1912R	Qty	SET SN	UNIT SN	1	9774E1901R	2405U1803R	1	9775E1901R	2411U1803R	1	5561S1911R	1228U1908R	1	2441E1903R	9163U1901R
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2 Reason for Field Safety Corrective Action (FSCA)	
2.	<p>1. Description of the product problem</p> <p>The devices MD 11 and MD 30 do not comply with the latest harmonized EMC standard (60601-1-2, Edition 4). The devices only comply with the expired Edition 3 and were not adapted to the new standard.</p>
2.	<p>2. Hazard giving rise to the FSCA</p> <p>The device might interfere with other electrical devices. The MD11 and MD30 could disturb the function of devices nearby or could itself be disturbed by them.</p>
2.	<p>3. Probability of problem arising</p> <p>Little to no probability of problems arising. The device still complies with the previous Edition 3 EMC standard (IEC 60601-1-2:2007). With the harmonization of the EMC standard Edition 4 (IEC 60601-1-2:2014) the acceptable ranges of electromagnetic interference is now smaller and thus not successfully achieved by the device.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>none</p>

3. Type of Action to mitigate the risk	
3.	<p>1. Action To Be Taken by the User</p> <p> <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p>

	<p>Device must be returned to the following address:</p> <p>Nouvag AG St. Gallerstrasse 23-35 CH-9403 Goldach Switzerland</p> <p>Tel: +41 71 846 66 91 info@nouvag.com</p>	
3.	2. By when should the action be completed?	Immediately
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, As soon as possible
3.	<p>4. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Device modification on manufacturing site</p>	

4. General Information	
4.	1. FSN Type New
4.	2. For updated FSN, reference number and date of previous FSN N/A
4.	3. For Updated FSN, key new information as follows: N/A
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Nouvag AG
	b. Address St. Gallerstrasse 23-25, CH-9403 Goldach
	c. Website address www.nouvag.com
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4.	6. Name/Signature Mehdi Zadehnour, COO
	

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Please fill in the customer/ distributor reply form and send it to us before the defined deadline at: vigilance@novvag.com