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Complaint Questionnaire

FM 7.2-001 EN

Revision: 4

Dear Sir/Madam,

thank you for your message. We are sorry to hear about the dissatisfaction with one of our products. In order to proceed with your enquiry as quickly as possible, we will need further information from you. Therefore, we have to ask you to complete below questionnaire in detail and return it to service@inomed.com and qm@inomed.com soon as possible. Following your reply, we will be able to process your complaint and respond in a timely manner.

Thank you for your time and understanding.

Contact details									
Facility / Office or Hospital name:									
Street:									
ZIP-code/city:			Country:						
Surname, first name:									
Phone number:									
E-Mail:									
Details to product idea	ntification								
Article number / REF:						□ Software			
SN / LOT:									
Software-version: To be filled in if a cross has been set for 'Software' above.									
1. Fault description Please describe the fault in as m If possible and where available,	•		h as pictures,	log entries ar	nd log files.				
2. When did the fault	occur?				Date:				
☐ during transport		at procedure prep	aration	☐ durin	ng reprod	cessing			
\square during unpacking		during the proced	ure	□ rema	remarks:				
3. How often does the	error occu	r?							
□ always	□ i	ntermittent		□ one-t	time				
□ after min Remarks:	□ 8	after h		□ daily	ca	/x times			



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4. Please describe the procedure in as much detail as possible								
Wich devices (including third-party devices such as RF generators) and accessories were used (if applicable, small schematic with								
electrode placement)? What type of procedure was it and during which action did the fault happen?								
5. Information about reusable accessories								
How many application cycles have the accessories already been used? Please let us know the reprocessing parameters used.								
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6. Have patients, users or third parties been harmed?								
□ Patient □ User □ Third □ Nobody was harmed								
If someone has been injured, please describe the damage:								
7. Was the procedure cancelled or extended as a result of the complaint?								
☐ Cancellation of the procedure ☐ Extension of the procedure ☐ No impact								
□ Further/new treatment/surgery If yes, which one:								
8. Was the complaint already reported to the authorities?								
□ No □ Yes								
If yes, case number / name of authority:								
Will the device / accessories be returned to inomed Medizintechnik?								
□ Yes □ No, remarks:								

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Note:

Please mark the returned goods so that it is clear that it is a complaint and that it can be recognised if it is contaminated. Please do not sterilise disposable products before sending them in.

Return address:

inomed Medizintechnik GmbH

Attn: Service-Department

Im Hausgrün 29

79312 Emmendingen

Customer:			
Date, signature:			