Incident Report Form for Customer

Incident Report

In case of an incident due to our products, please fill in this form and return it via email (incident@besa.de).

Please note that you shall no longer use, or alter the device causing the incident. (E.g. do not update the software, or uninstall it from the device it was used with on time of the incident.)

Definition of Incident

(Source: Regulation (EU) 2017/745 on medical devices (MDR)):
'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect

Report submitted by:	
Name:	
Title:	
Institution:	
Working Department:	
Address:	
Street	
City	
Country	

Contact: (Email/Phone/Fax)	
Mobile (voluntary):	

Incident information:

Incident observed by: (Fill in if different from person above)	
Date of incident:	
Name of device causing the incident:	
Version number of device causing the incident:	
BESA License Key ID:	

Nature and classification of incident:

Provide a comprehensive description of the incident, including: (1) what went wrong with the device (if applicable)	

(2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/ birth defects; indirect harm; no serious outcome)	
Serious incident? ('serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat)	Incident can be rated as a SERIOUS incident: ☐ No: no serious incident according to definition ☐ Yes: death of a patient, user or other person ☐ Yes: temporary or permanent serious deterioration of a patient's, user's or other person's state of health ☐ Yes: serious public health threat
Number of patients / people involved:	
Operator of device at the time of the incident:	☐ Health care professional ☐ Neuroscience professional ☐ Lay user

Additional space to report, if required:	

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Change History (valid revision number)

Version	Effective Date
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