Instruction:

Please fill in this report and send it by e-mail to the address below. **Make sure not to submit any identification of patient/end user if they are EU citizens.** If a product return is requested, return the product (and its package, if available) clearly marked with the assigned RGA number to ATOS MEDICAL AB for investigation. Thank you for your cooperation!

ATOS MEDICAL AB Att: Complaint Investigator Kraftgatan 8 SE-242 35 Hörby SWEDEN	Telephone: Int.+46 (0)415-198 00 Telefax: Int.+46 (0)415-198 98 Web: www.atosmedical.com Email: **complaint.se@atosmedical.com**	Complaint Registration number/ Return Goods authorization number filled in by ATOS MEDICAL AB: **RGA no**.

Reporter contact information

Distributor or subsidiary:	Complainant:	
Contact person:	Hospital (if applicable):	
Address: E-mail:	Address: E-mail:	
Country:	Country:	
Tel:	Tel:	MBI No (US only):

Customer relation

Warranty product given to customer? ☐ **Yes** ☐ **No**	Is follow-up requested by customer? ☐ **Yes** ☐ **No**

Product

Ref No:	Product name:	Lot or Serial No:
Manufacturer: Atos Medical AB ☐ Other (3PP): ☐		Complaint Quantity:

Event info

NOTE! Complaints must be forwarded to ATOS MEDICAL AB without delay, due to vigilance reporting requirements.

Date when **company representative** was made aware of event (by mail, phone call, personal meeting etc):	
Date when the event occurred (per information received from customer):	
Country where the event happened:	

Did the event lead to death or serious injury? ☐ **No** ☐ **Yes** (Describe in detail below) Was medical intervention required? ☐ **No** ☐ **Yes** (Describe in detail below) Any residual adverse effect on patient? ☐ **No** ☐ **Yes** (Describe in detail below)	Patient injured, frightened or experienced discomfort ☐ (Describe in detail below) or Product complaint only ☐
How long has the **actual** product been used by patient?	Has the product been used according to instructions? ☐ **Yes** ☐ **No**
Has the patient/user experienced this problem previously? ☐ **Yes**, if so when? ☐ **No**	Is the product available for examination? ☐ **Yes** ☐ **No** Are products from same lot/carton available? ☐ **Yes** ☐ **No**

Have other products/medicines been used together with the product?

If so, please list here

Event description

Please include a detailed description of what is considered wrong with the product and/or what happened to the patient. Feel free to uses as many pages as necessary. The more information the better.

Initial reporter within organization: