PHILIPS

Form, Customer Complaint

Control# 114-0300.03/12

Complete ALL information until "STOP" and if directed to complete AE section(s)
Refer to instructions on page 13

A. SOURCE DETAILS

Date of Event/Occurrence:		Date Philips IGT-O Notified:	
Date Distributor was Notified:		Date Communicated to Site Complaint Unit [SCU]/PMS:	
Source:	☐ Customer ☐ Distributor ☐ Philips Representative	**Distributor Company Name:** (when "Distributor" is selected)	
Observed Case? (If Philips Representative)	☐ Yes ☐ No		
Source Name:		Prefix:	☐ Mr. ☐ Mrs. ☐ Ms. ☐ Miss ☐ Dr. ☐ Prof.
Source Phone Number:		**Source Email Address:**	
Is this part of a study? (If part of a study, please complete the entire gray section)	☐ No ☐ Yes	**Study Name:**	
		Patient Identifier for Study:	
		When did this occur?	☐ Initial ☐ Follow-up

B. CUSTOMER DETAILS

Customer ID:		Facility Contact Name:	
Facility Name:		Contact Department:	
Facility Address:		Contact Phone:	
Facility City:		**Contact Email :**	
Facility State:		Physician Name:	
Facility Zip Code:		**Physician Phone:**	
Customer Country:		**Physician Email:**	
Customer Letter Requested?	☐ Yes ☐ No	**Physician Specialty:**	

C. PRODUCT DETAILS

Product Name:		Product Model #:	
Product Lot/Batch #:		Product Serial/Sequence #:	
Software Version:		Product/component returning?	☐ Yes ☐ No

Was the device known to have been exposed to blood borne pathogens (Ex. HIV, HepB, HepC)?	☐ Yes, therefore no product is returning ☐ No	If the device was not exposed to blood borne pathogens, will product/ component be returning?	☐ Yes, RMA to be assigned ☐ No, discarded ☐ No, lost at customer site
Concomitant Devices: (Other 3PNC/Volcano/Philips devices used with the suspect device)			

D. PROCEDURE/PATIENT DETAILS

What was the nature of the complaint?
(Detailed description of the issue/event including timeline, sequence of events, contributing factors)