Quanta System	Customer Complaint	MOD 8.2.2-01 Rev02

Section to be filled by Quanta System

Complaint Number		Received by	
RMA Nr. (if any)		Received on	

COMPLAINANT DATA

Complainant (Distributor/Agent) name and address *

Complainant case identification (i.e. internal report number):

Reported by (Distributor/Agent contact person)

Phone/email (Distributor/Agent)

HOSPITAL / CLINIC DATA

Name and address of the hospital/clinic

Name of the initial reporter at the hospital/clinic

Phone of the hospital/clinic initial reporter

Event date (if available)

Date notified to the complainant (Distributor/Agent) *

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PRODUCT AND PROBLEM DATA

Product Family

Product Model

Serial Number / Lot *

Q.ty *

Part Number

UDI

Software/hardware version

Error Code(s)

Reported Issue (select one) *

Temporary Error	Minor anomalies not impacting on functionalities	Aesthetic defects / missing components
Wear damages	Product completely impossible to use	Functional / Performance impacting issues

Product Effect (select one) *

Product Impossible to use anymore	Component / Subsystem impossible to use anymore	Product usable but with reduced performance or usability
Product usable after component replacement	Product usable after technical intervention / service	Product normally usable, no performance or usability impact

Problem Description *

Timing of the Problem (select one) *

☐ As received from Quanta	During First Quality Control Incoming Inspection	Unknown / no timing reported
☐ During demo without patient	During first installation	During maintenance
☐ Patient there-just before treatment	During treatment on patient	Patient there- after treatment

Patient Involvement (select one) *

No involvement or consequences	Delay in AESTHETIC / DERMATOLOGIC treatment (without consequences)	Delay in SURGICAL treatment (without clinical consequences)
Limited/trivial damages that would heal within short timing	Reversible cosmetic damage	New or prolonged hospitalization of the patient
Trivial impairment or damage to a body structure or function	Medical or surgical intervention needed to preclude permanent impairment of a body function or damage to a body structure	Permanent irreversible impairment of a body function or permanent damage to a body structure
Life threatening Injury-Illness	Death	Unknown / no patient involvement reported
Other - Please Specify below		