



ABEX MEDICAL SYSTEM Sdn. Bhd.

Co. Registration No. 198101007945 (74062-D)

1. Medical device field corrective action notification form.

FIELD CORRECTIVE ACTION NOTIFICATION FORM			
Type of Field Corrective Action (FCA)	<input type="checkbox"/> Return <input checked="" type="checkbox"/> Modification	<input type="checkbox"/> Exchange <input type="checkbox"/> Destruction	<input type="checkbox"/> Specific Advice
Establishment Particulars			
Name of company	Abex Medical System Sdn Bhd		
Company address	Lot 2-6, Jalan SU/6A, Lion Industrial Park, Section 26, 40400 Shah Alam, Selangor Darul Ehsan, Malaysia.		
Contact person name	Mr Wan Muhammad Hafis		
Job title	QA/RA Executive		
Tel No.	03-5191 6633	Fax No.	03-5191 3988
Email Address	muhdhafis@abexmedical.com.my		
Medical Device Details			
Medical device name	Elekta Synergy, Precise Digital Accelerator, Elekta Infinity, Versa HD		
Medical device intended use	Treatment of cancer		
MDA Registration No. <i>(if device is registered)</i>	GC73830983018, GC227501186818, GC23765696518, GC76319499317		
Model No.	N/A		
Serial No.	N/A		
Lot/Batch No.	N/A		
Accessories/Associated medical devices affected <i>(if any)</i>	N/A		
Manufacturer name	ELEKTA LIMITED		
Manufacturer address	LINAC HOUSE FLEMING WAY CRAWLEY, WEST SUSSEX		
AR/Distributor/Importer and contact details	DISTRIBUTOR: ABEX MEDICAL SYSTEM SDN BHD Lot 2-6, Jalan SU/6A, Lion Industrial Park, Section 26, 40400 Shah Alam, Selangor Darul Ehsan, Malaysia.		
FCA Proposed Plan and Action			
FCA planned by establishment	FCA Notice : 200-06-103-090 CITB external interlock check : Check the connections to the CITB for the customer required external interlocks and confirm with the customer that they are correct. Update the calibration values to enable the External Terminate and Room Doors 3 inputs (software interlocks) which have been disabled by default in the calibration. Test the external interlocks. Scope : All Digital Accelerator		