

FIELD CORRECTIVE ACTION NOTIFICATION FORM			
Type of Field Corrective Action (FCA)	<input type="checkbox"/> Return	<input type="checkbox"/> Exchange	<input type="checkbox"/> Specific Advice
	<input checked="" type="checkbox"/> Modification	<input type="checkbox"/> Destruction	
Establishment Particulars			
Name of company	Technology Medical Associate 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	DRYPRO SIGMA		
Medical device intended use	Processing high quality and stable images using advanced image Interpolation processing Intechnology.		
MDA Registration No. <i>(if device is registered)</i>	GMD42528502718A		
Model No.	N/A		
Serial No.	017243, 017245, 017263		
Lot/Batch No.	N/A		
Accessories/Associated medical devices affected <i>(if any)</i>	DEFECT PART : A4A9AF1873 (CABLE, STEPPER MOTOR, 3 PHASE)		
Manufacturer name	KONICA MINOLTA, INC.		
Manufacturer address	1 SAKURA-MACHI, HI NO-SHI, TOKYO, JAPAN.		
AR/Distributor/Importer and contact details	Distributor: Technology Medical Associate Sdn Bhd Lot 2-6, Jalan SU/6A, Lion Industrial Park, 40400 Shah Alam Selangor Darul Ehsan, Malaysia.		
FCA Proposed Plan and Action			
FCA planned by establishment	<p>A defect was found in the cable between MCS and ET in 165 units of DRYPRO SIGMA which produced in this March and April. Therefore, replace the cable when installation or a service call.</p> <p>There are no associated safety issues. Konica will provide countermeasure cables to the companies or dealers to which the object machines have been shipped.</p> <p>Regarding the replacing procedure, refer to attached "Procedure of replacing defective cable between MCS and ET.pdf".</p> <p>The number of affected units in Malaysia are 3, as per Serial No. above. All affected units are in storage. Thus, Notification to customer is not needed.</p>		