Medtronic

Cardiac Rhythm Management

Increased Potential for Reduced Energy or No Energy Delivered During High Voltage Therapy When Programmed AX>B

Regional Field Corrective Action Plan

(based on Revision A of global plan)

Plan developed by

Name	Title	Signature & Date
Katrina Joyce Sajonas	Senior Quality Systems Specialist	DocuSigned by:  Signer Name: Katrina Joyce Sajonas Signing Reason: I am the author of this document Signing Time: 10 May 2023 | 19:34 CDT 950BD91B0D2F4334A8BC4881A24BBF92

FCA Package Approval (Denotes approval of FCA Plan and all communication documents)

Name	Title	Signature & Date
Chloe Tan	**QARA Director** Mainland and Island Southeast Asia	DocuSigned by:  Signer Name: Chloe Tan Signing Reason: I approve this document Signing Time: 11 May 2023 | 09:06 SGT 90D0724C9B1C402A99B286449A1644B8

Change History Information

Revision	Change History
A	Original approved Field Corrective Action Plan.

1. Executive Summary

The purpose of this document is to outline the intended Regional Field Corrective Action (FCA) plan for initiating communications to consignees, programmer update, software updates, IFU update, and completing effectiveness checks for Blackwell, Polaris and EV-ICD devices due to a potential for intermittent-reduced-energy shock when Programmed AX>B. If a future global plan revision does not impact any of the countries in Mainland and Island Southeast Asia, revision of the regional plan will not be required. Refer to the global plan for these changes.

A Product Hold Order is not recommended to manage this issue in the field.

CAPA # 584229 was opened. Risk assessment details are available in Blackwell, Polaris and EV-ICD Unintended Conductive Pathways in Device Connectors document # D00809908.

CAPA # 566141 was also opened. Risk assessment details are available in Pacing Impedance Measurement Drop Following High Voltage Therapy in Blackwell and EV-IC Devices document # D00673437.

Global product quantities affected by this issue and those in scope of this FCA are shown below:

Device Status Description	Global Qty
Total distributed affected devices in scope of this field action	816,312
Total affected devices within Medtronic control and not in scope of this field action	135,382
Total affected devices released from manufacturing	951,694

Note: The affected device population will increase as inventory currently in Medtronic control and newly manufactured devices are distributed. Waves of communication will occur quarterly for newly distributed affected devices to newly identified customers until IFU update and all SmartSync tablets and 2090 / Encore programmers have been updated or reconciled as part of this field action. All devices will be updated via the same FCA strategy.

See section 2.4 for additional scope details.

2. Background

2.1. Device Description and Intended Use

Blackwell and Polaris products are Implantable Cardioverter Defibrillators (ICDs) that automatically detect and treat episodes of ventricular fibrillation, ventricular tachycardia, fast ventricular tachycardia, and bradyarrhythmia. Some devices can also provide cardiac resynchronization therapy, including sequential biventricular pacing (CRT-D devices). The Polaris devices feature Bluetooth wireless technology.

EV-ICD investigational products Medtronic Models DVEX2E4 (Pilot) and DVEX3E4 (Pivotal, United States Continued Access, Japan Study) are single chamber, extravascular implantable cardioverter defibrillators (ICDs). It is a magnetic resonance (MR) conditional, multiprogrammable cardiac device that monitors and regulates the patient's heart rate. It provides ventricular tachyarrhythmia detection and therapy, post-shock pacing, and prolonged pause detection and therapy (Pause Prevention pacing). The device also provides diagnostic and monitoring features to assist with system evaluation and patient care. The EV-ICD system is intended to provide ventricular anti-tachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients who are indicated for an ICD and who do not have symptomatic bradycardia.

2.2. Problem Description and Technical Summary

Medtronic is notifying health care professionals of the increased potential for significantly reduced-energy or no energy delivery during high voltage (HV) therapy (typically 0-12J output) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a glassed feedthrough.

ISSUE DETAILS:

There is an increased potential for a reduced- or no-energy HV therapy in the AX>B configuration when all the following conditions are met:

- The device has a glassed feedthrough (manufactured after July 2017).
- There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
- An unintended current pathway forms within the void created by the insulation separation, capable of conducting high levels of current during HV therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger. This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. SCP events may also be lead related; for both lead-related and device-related unintended current pathways, the defibrillation waveform is truncated early in the energy delivery sequence, resulting in reduced or no energy being delivered (~0-12J).

With current field programming, devices with a glassed feedthrough may experience increased risk (projected to be 0.02% at 5 years) for reduced- or no-energy output during HV therapy. In some cases, a persistent 50% drop in all pacing lead impedances may be displayed; lead function, however, is not affected.

Complaint Summary:

Through 10 April 2023, 27 devices with glassed feedthroughs have been identified as experiencing a reduced or no-energy HV therapy (0.003% out of 816,000 distributed devices). Of these, 26 were in devices with an AX>B delivered pathway. Based on an analysis of patients with a glassed feedthrough device and with a history of HV therapy, the observed rate for this issue is 0.03%.

Note: The focus of this FCA is related to the increased potential for a reduced- or no-energy HV therapy. Given this focus, the complaint information (27 events) is limited to devices that were confirmed to have experienced device-related reduced- or no-energy HV therapy events from the glassed feedthrough devices. As part of the CAPA investigations, additional analysis was conducted on historical devices with an alternative (brazed) feedthrough design dating back to 2012. These historical events were used to support the modeling of future (projected) device-related reduced energy events. While the CAPA investigations also revealed that a device could experience a 50% drop in pacing lead impedances (LID events), and that this behavior is an indicator that a device is susceptible to future reduced-energy HV therapies, LID events are included in the modeling and risk assessments for this issue. But LID events that did not also have a corresponding reduced-energy shock are not included in the 27 complaints. These complaints occurred in the United States (25), Australia (1) and India (1)

Root Cause Investigation Summary:

The root cause for device related first-phase SCP events, the sequence of events and the physics of failure remains under investigation. Based on the investigation to date, potential contributors to a first-phase SCP events are:

- The feedthrough design type
- The feedthrough pin with the presence of delamination, and
- The HV therapy programming pathway (e.g. AX>B)

Additional Root cause: Blackwell devices:

As documented in CAPA 566141, the root cause of the lead impedance drop is related to a rare electrical disruption (likely an electrical arc event due to an unintended conductive pathway), causing a non-typical reset of the L404 integrated circuit (IC).

During our investigation, a broader analysis was conducted to determine the incidence of device related reduced- or no-energy HV therapy events outside of the above population, with implants dating back to 2012. Using these historical observed events, projected rates for this population of devices is 0.002% at five (5) years and 0.006% at nine (9) years. This analysis identified two deaths from the historical population in which there was evidence suggesting a device-related reduced- or no-energy HV therapy occurred.

Risk Analysis Summary:

Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.

The risk associated with this issue is in Zone 3 for the potential of catastrophic harm due to inadequate tachyarrhythmia therapy for the Blackwell, Polaris, and EV-ICD devices with either a glassed or brazed feedthrough (both overall and high voltage therapy populations).

2.3. Actions to be taken

This FCA will be broken into Phases and includes Waves of communication.
Phase - A new activity that is added to the plan (e.g. communication, product/software availability notification, etc.) for which new evidence for effectiveness is required.
Wave - Pre-planned iterations of an existing communication directed to new consignees as the result of affected product continuing to be distributed. For tracking purposes, the initial communication is considered Wave 1

Phase I: Initial communication to consignees of the issue.

- A voluntary FCA will be implemented to communicate the issue to all consignees who have received affected product according to Medtronic records. See 3.1 Consignee Communications for details.
- Consignees (i.e.: physicians or accounts) will be asked to confirm receipt of FCA notification.
- Waves of communication will occur quarterly for newly distributed affected devices to newly identified customers until the IFU is revised and all SmartSync tablets and 2090 / Encore programmers have been updated or reconciled as part of this field action. Confirmation is required.
- Waves of Supplemental Notification communication will occur monthly until April 2024 for newly identified SCP events. The Supplemental Notification is considered courtesy. If the consignee is newly identified, confirmation is required. The supplemental query is based on US server and affects US, Canada, and ANZ.
- EV ICD, pre-market clinical study devices are exempt from communication waves. All Clinical Study Principal Investigators will receive the initial communication.
- A Principal Investigator (PI) Letter will be provided to impacted Clinical Study PIs. This is for pre-market studies only and does not impact post market studies.
- For cases where a physician, other than the initial implanting physician (e.g. following physician), is subsequently identified as treating a patient with an affected device, Medtronic will send the same communications as was sent for initially identified implanting physicians. These newly identified physicians will receive communications as part of next wave scheduled.

Phase II: SmartSync programmer and 2090/Encore programmer software updates availability communication.

- To be updated with details of the actions based on final software release schedule.
- Global planning team to reconvene in June 2023 to assess reportability of Blackwell software update.

Additional Medtronic Actions:

- Update Instructions for Use.
- Update applicable Medtronic website (PPeSource).
- Field representatives may assist customers with the timely return of the customer signed Customer Confirmation Form.
- Other associated Corrective/Preventive Actions established in associated CAPAs.
- Ongoing CareLink monitoring to end April 20244) for field events related to SCP events. Supplemental letter will be provided to identified Physicians monthly if no associated complaint has been filed.

2.4. Distributed product in scope of this FCA by Country and Quantity

The global scope of this FCA includes products listed below:

Product Description	CFN	Global Quantity
ICD-DR DDBB1D1 EVERA XT IS1/DF1 US	DDBB1D1	2179
ICD-DR DDBB1D4 EVERA XT IS1/DF4 US	DDBB1D4	522
ICD EVERA XT DR GOLD CTD	DDBB1D4G	1
ICD-DR DDBB2D1 EVERA XT IS1/DF1 INTL	DDBB2D1	2282
ICD-DR DDBB2D4 EVERA XT IS1/DF4 INTL	DDBB2D4	727
ICD-DR DDBC3D1 EVERA S IS1/DF1 GLOB	DDBC3D1	5176
ICD-DR DDBC3D4 EVERA S IS1/DF4 GLOB	DDBC3D4	4056
ICD-DR DDMB1D1 EVERA MRI XT US DF1	DDMB1D1	22484
ICD-DR DDMB1D4 EVERA MRI XT IS-1/DF4 US	DDMB1D4	61404
ICD-DR DDMB2D1 EVERA MRI XT OUS DF1	DDMB2D1	8626
ICD-DR DDMB2D4 EVERA MRI XT IS-1/DF4 INT	DDMB2D4	35877
ICD DDMB2D4 EVERA MRI DR XT DF4 OUS EIFU	DDMB2D4	84
ICD-DR DDMC3D1 EVERA MRI S OUS/US DF1	DDMC3D1	10878
ICD-DR DDMC3D1 EVERA MRI S OUS DF1	DDMC3D1	25
ICD-DR DDMC3D4 EVERA MRI S IS-1/DF4 GLOB	DDMC3D4	37502
ICD DDMC3D4 EVERA MRI DR S DF4 OUS EIFU	DDMC3D4	45
ICD-DR DDMD3D1 PRIMO MRI	DDMD3D1	3800

ICD-DR DDMD3D1 PRIMO MRI OUS	DDMD3D1	1
ICD-DR DDMD3D4 PRIMO MRI	DDMD3D4	11239
ICD-DR DDME3D1 MIRRO MRI	DDME3D1	2831
ICD-DR DDME3D4 MIRRO MRI	DDME3D4	8219
ICD COBALT XT DR MRI IS1 DF1	DDPA2D1	2748
ICD DDPA2D1G COBALT XT DR MRI DF1 GOLD	DDPA2D1G	3
ICD COBALT XT DR MRI IS1 DF4	DDPA2D4	22114
ICD DDPA2D4G COBALT XT DR MRI DF4 GOLD	DDPA2D4G	6
ICD COBALT DR MRI IS1 DF1	DDPB3D1	1941
ICD COBALT DR MRI IS1 DF4	DDPB3D4	11645
ICD CROME DR MRI IS1 DF1	DDPC3D1	487
ICD CROME DR MRI IS1 DF4	DDPC3D4	2018
CRT-D DTBA1D1 VIVA XT IS1/DF1 US	DTBA1D1	1473
CRT-D DTBA1D1G DF1 VIVA XT US GOLD CTD	DTBA1D1G	1
CRT-D DTBA1D4 VIVA XT IS1/DF4 US	DTBA1D4	661
CRT-D DTBA1Q1 VIVA QUAD XT IS4/DF1 US	DTBA1Q1	373
CRT-D DTBA1QQ VIVA QUAD XT IS4/DF4 US	DTBA1QQ	981
CRTD VIVA QUAD XT CUST PARY GOLD	DTBA1QQPG	14
CRT-D DTBA2D1 VIVA XT IS1/DF1 INTL	DTBA2D1	4354
CRTD DTBA2D1G VIVA XT IS1 DF1 OUS GOLD	DTBA2D1G	8
CRT-D DTBA2D4 VIVA XT IS1/DF4 INTL	DTBA2D4	2904
CRT-D DTBA2Q1 VIVA QUAD XT IS4/DF1 INTL	DTBA2Q1	1132
CRT-D DTBA2QQ VIVA QUAD XT IS4/DF4 INTL	DTBA2QQ	2931
CRT-D VIVA QUAD XT GOLD CTD	DTBA2QQG	1
CRT-D DTBB1D1 VIVA S IS1/DF1 US	DTBB1D1	207
CRT-D DTBB1D4 VIVA S IS1/DF4 US	DTBB1D4	182
CRT-D DTBB1Q1 VIVA QUAD S IS4/DF1 US	DTBB1Q1	123
CRT-D DTBB1QQ VIVA QUAD S IS4/DF4 US	DTBB1QQ	193
CRT-D DTBB2D1 VIVA S IS1/DF1 INTL	DTBB2D1	1076
CRT-D DTBB2D4 VIVA S IS1/DF4 INTL	DTBB2D4	435
CRT-D DTBB2Q1 VIVA QUAD S IS4/DF1 INTL	DTBB2Q1	7
CRT-D DTBB2QQ VIVA QUAD S IS4/DF4 INTL	DTBB2QQ	523
CRT-D DTBC2D1 BRAVA IS1/DF1 INTL	DTBC2D1	7921
CRT-D DTBC2D4 BRAVA IS1/DF4 INTL	DTBC2D4	3355
CRT-D DTBC2Q1 BRAVA QUAD IS4/DF1 INTL	DTBC2Q1	1754
CRT-D DTBC2QQ BRAVA QUAD IS4/DF4 INTL	DTBC2QQ	7994
CRTD DTMA1D1 CLARIA MRI US DF1	DTMA1D1	11794
CRTD DTMA1D4 CLARIA MRI US DF4	DTMA1D4	12291
CRTD DTMA1Q1 CLARIA MRI QUAD US DF1	DTMA1Q1	8602
CRTD DTMA1QQ CLARIA MRI QUAD US DF4	DTMA1QQ	58706

CRTD DTMA2D1 CLARIA MRI OUS DF1	DTMA2D1	3570
CRTD DTMA2D4 CLARIA MRI OUS DF4	DTMA2D4	4593
CRTD DTMA2Q1 CLARIA MRI QUAD OUS DF1	DTMA2Q1	1658
CRTD DTMA2QQ CLARIA MRI QUAD OUS DF4	DTMA2QQ	23220
CRTD DTMA2QQ CLARIA MRI QUAD CRTD OUS	DTMA2QQ	3
CRTD DTMB1D1 AMPLIA MRI US DF1	DTMB1D1	3005
CRTD DTMB1D4 AMPLIA MRI US DF4	DTMB1D4	2767
CRTD DTMB1Q1 AMPLIA MRI QUAD US DF1	DTMB1Q1	2173
CRTD DTMB1QQ AMPLIA MRI QUAD US DF4	DTMB1QQ	10370
CRTD DTMB2D1 AMPLIA MRI OUS DF1	DTMB2D1	6536
CRTD DTMB2D4 AMPLIA MRI OUS DF4	DTMB2D4	8526
CRTD DTMB2D4 AMPLIA MRI CRTD OUS	DTMB2D4	49
CRTD DTMB2Q1 AMPLIA MRI QUAD OUS DF1	DTMB2Q1	4767
CRTD DTMB2QQ AMPLIA MRI QUAD OUS DF4	DTMB2QQ	28092
CRTD DTMB2QQ AMPLIA MRI QUAD CRTD OUS	DTMB2QQ	80
CRTD DTMC1D1 COMPIA MRI US DF1	DTMC1D1	664
CRTD DTMC1QQ COMPIA MRI QUAD US DF4	DTMC1QQ	2519
CRTD DTMC2D1 COMPIA MRI OUS DF1	DTMC2D1	10197
CRTD DTMC2D4 COMPIA MRI OUS DF4	DTMC2D4	11374
CRTD DTMC2D4 COMPIA MRI CRTD OUS	DTMC2D4	1
CRTD DTMC2QQ COMPIA MRI QUAD OUS DF4	DTMC2QQ	31882
CRTD DTMC2QQ COMPIA MRI QUAD CRTD OUS	DTMC2QQ	2
CRTD COBALT XT HF MRI IS1 DF1	DTPA2D1	4151
CRTD DTPA2D1G COBALT XT HF QUAD OUS	DTPA2D1G	5
CRTD DTPA2D1PX COBALT XT HF QUAD OUS	DTPA2D1PX	3
CRTD COBALT XT HF MRI IS1 DF4	DTPA2D4	4914
CRTD COBALT XT HF QUAD MRI IS4 DF1	DTPA2Q1	2669
CRTD COBALT XT HF QUAD MRI IS4 DF4	DTPA2QQ	27788
ICD COBALT XT HF QUAD OUS	DTPA2QQG	9
CRTD COBALT HF MRI IS1 DF1	DTPB2D1	2884
CRTD COBALT HF MRI IS1 DF4	DTPB2D4	2968
CRTD COBALT HF QUAD MRI IS4 DF1	DTPB2Q1	1878
CRTD COBALT HF QUAD MRI IS4 DF4	DTPB2QQ	15427
CRTD CROME HF MRI IS1 DF1	DTPC2D1	462
CRTD CROME HF MRI IS1 DF4	DTPC2D4	476
CRTD CROME HF QUAD MRI IS4 DF1	DTPC2Q1	404
CRTD CROME HF QUAD MRI IS4 DF4	DTPC2QQ	2142
ICD-VR DVAB1D1 VISIA AF US IS1/DF1	DVAB1D1	425
ICD-VR DVAB1D4 VISIA AF US DF4	DVAB1D4	240
ICD-VR VISIA AF XT OUS IS1/DF1	DVAB2D1	71

ICD-VR VISIA AF XT OUS DF4	DVAB2D4	12
ICD-VR VISIA AF S US/OUS IS1/DF1	DVAC3D1	176
ICD-VR VISIA AF S US/OUS DF4	DVAC3D4	194
ICD-VR DVBB1D1 EVERA XT IS1/DF1 US	DVBB1D1	16
ICD-VR DVBB1D4 EVERA XT DF4 US	DVBB1D4	4
ICD-VR DVBB2D1 EVERA XT IS1/DF1 INTL	DVBB2D1	1354
ICD-VR DVBB2D4 EVERA XT DF4 INTL	DVBB2D4	447
ICD-VR DVBC3D1 EVERA S IS1/DF1 GLOB	DVBC3D1	6821
ICD-VR DVBC3D4 EVERA S DF4 GLOB	DVBC3D4	5296
ICD-VR DVEX2E4 EV ICD OUS EV4	DVEX2E4	21
ICD-VR DVEX3E4 EV ICD EV4 PIVOTAL	DVEX3E4	289
ICD-VR DVFB1D1 VISIA AF MRI US DF1	DVFB1D1	12099
ICD-VR DVFB1D4 VISIA MRI AF US DF4	DVFB1D4	34350
ICD-VR DVFB2D1 VISIA AF MRI XT OUS DF1	DVFB2D1	4546
ICD-VR VISIA MRI AF XT OUS DF4	DVFB2D4	15381
ICD-VR DVFC3D1 VISIA AF MRI S OUS/US DF1	DVFC3D1	5622
ICD-VR VISIA MRI AF S US/OUS DF4	DVFC3D4	16244
ICD-VR DVMB1D4 EVERA MRI XT DF4 US	DVMB1D4	20
ICD-VR DVMB2D1 EVERA MRI XT OUS DF1	DVMB2D1	2310
ICD-VR DVMB2D4 EVERA MRI XT DF4 INTL	DVMB2D4	6463
ICD DVMB2D4 EVERA MRI VR XT DF4 OUS EIFU	DVMB2D4	14
ICD-VR DVMC3D1 EVERA MRI S OUS/US DF1	DVMC3D1	6522
ICD-VR DVMC3D1 EVERA MRI S OUS DF1	DVMC3D1	3
ICD-VR DVMC3D4 EVERA MRI S DF4 GLOB	DVMC3D4	25041
ICD DVMC3D4 EVERA MRI VR S DF4 OUS EIFU	DVMC3D4	17
ICD-VR DVMD3D1 PRIMO MRI	DVMD3D1	5215
ICD-VR DVMD3D4 PRIMO MRI	DVMD3D4	14270
ICD-VR DVME3D1 MIRRO MRI	DVME3D1	3851
ICD-VR DVME3D1 MIRRO MRI OUS	DVME3D1	1
ICD-VR DVME3D4 MIRRO MRI	DVME3D4	14989
ICD COBALT XT VR MRI IS1 DF1	DVPA2D1	2000
ICD COBALT XT VR MRI DF4	DVPA2D4	9325
ICD COBALT VR MRI IS1 DF1	DVPB3D1	1930
ICD COBALT VR MRI DF4	DVPB3D4	7048
ICD CROME VR MRI IS1 DF1	DVPC3D1	510
ICD CROME VR MRI DF4	DVPC3D4	2031
Grand Total		**816312**

Rationale for Scope of this FCA: Medtronic will be notifying all Implanting Physicians of the potential for reduced or no energy delivery during high voltage (HV) therapy (typically 0-12J output) in a subset (glassed

feedthrough) of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). A courtesy notification will also be sent to Risk Managers at affected sites in the US only. The programming recommendations apply to all devices with a glassed feedthrough design.

Product scope (affected serial numbers) is documented in D00941104 an D00941116.

The table below provides an overview of the distribution and inventory status for affected units in scope of this FCA (notification) on 02 Apr 23.

The table below provides an overview of the distribution and inventory status for affected units in scope of this FCA (notification) on 02 Apr 23.

Country	Active Implant	Sold*	Consigned	Total	Number of Consignees
Bangladesh	1	257	0	258	6
Brunei Darussalam	0	230	23	253	6
Cambodia	0	1	0	1	1
Guam	2	1	2	5	1
Indonesia	0	235	0	235	2
Malaysia	0	1,630	109	1,739	58
Myanmar	0	41	0	41	1
Nepal	0	110	0	110	3
Philippines	2	440	27	469	48
Singapore	1	1,016	79	1,096	37
Sri Lanka	0	177	0	177	3
Thailand	2	4,237	208	4,447	107
Viet Nam	0	375	0	375	3
Grand Total *	**8**	**8750**	**448**	**9206**	**276**

Note: Number of consignees by country will be finalized at time of FCA closure.

Product affected by this issue and identified as in Medtronic Control is not in scope of FCA communications and is listed in the table below as of 02 Apr 23.

Country	Warehouse (WH)	Internal	Inactive	Scrapped Prior to FCA	Vendor	Trunk Stock	Grand Total
Bangladesh	29	0	0	8	0	0	37
Indonesia	5	1	1	1	0	0	8
Malaysia	74	5	93	15	0	8	195
Philippines	80	13	63	0	0	1	157
Singapore	348	24	559	94	21	0	1,046

Thailand	358	0	202	25	0	0	585
Viet Nam	2	0	0	0	0	0	2
Grand Total *	**896**	**43**	**918**	**143**	**21**	**9**	**2030**

Clinical:

Study Name	Principal Investigators
EV ICD	49

Rationale for Scope of this FCA: Documented in Appendix K: Clinical Assessment. Number of PIs by will be finalized at time of FCA closure.

3. Communication Plan

FCA communication documents, included as attachments and approved with this plan, are:

- Consignee Notification & Confirmation Form
- Supplemental Letter (CareLink identified patients)
- MDT Rep Confirmation Form (UTC)
- Internal Q&A
- Patient Letter Template
- Waves for Newly Identified Physicians Cover Letter

3.1. Consignee Communications

3.1.1. Regional Consignees

- Medtronic will send the Consignee Notification and Customer Confirmation Form (or equivalent record) via a regionally approved method (e.g., courier, registered mail, hand delivery) to each listed consignee.
- For countries that follow EU MDR: The SRN will be noted in the consignee notification. The devices in scope of this field action are MDD devices therefore UDI is not available or relevant and will not be provided in consignee notification.
- Distributors are responsible for forwarding the Urgent Medical Device Correction Letter to those consignees to which they have distributed (forwarded) impacted product.
- Follow-up communications to consignees (with assistance from field representatives as necessary) will be made until all Customer Confirmation Forms (or equivalent record) have been received, or three unsuccessful attempts to obtain the signed confirmation certificate are documented.
- **CareLink Monitoring:** Physicians with patients identified through CareLink as having an SCP event that does not have an associated complaint on file will be sent the Supplemental Letter. Medtronic will identify new patients and notify physicians on a monthly basis starting May 2023 through April 2024,

newly identified Physicians will be asked to confirm receipt of notification. Previously identified Physicians are not required to confirm.

- **Waves:** Waves of communication will occur quarterly for newly distributed affected devices to newly identified customers until the IFU is revised, all SmartSync tablets and 2090 / Encore programmers have been updated or reconciled as part of this field action. Confirmation is required.

Initial Notification:

Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
Implanting / Current Following Physicians with patients with affected devices – confirmation required	Consignee Notification & Confirmation Form Patient Letter Template	11-May-2023	Hand delivery / Email / regionally approved method	Local Sales & Marketing
Risk Managers will receive as a courtesy – confirmation not required	Consignee Notification	11-May-2023	Hand delivery / Email / regionally approved method	Local Sales & Marketing

CareLink Monthly Monitoring:

Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
CareLink Following Physicians with patients with affected devices, and who have a patient Identified in CareLink as having an SCP event, but with no complaint on file	Supplemental Letter (CareLink identified patients)	Monthly beginning May 2023 and ending April 2024	Hand delivery / Email / regionally approved method	Local Sales & Marketing

Quarterly Waves of Newly Distributed:

Recipient/ Audience	Document Description	Distribution Dates	Distribution Method	Communication Owner
Newly Identified Implanting / Following Physicians with patients with affected devices – confirmation required	Consignee Notification (All Cobalt/Crome models) & Confirmation Form Patient Letter Template Waves for Newly Identified Physicians Cover Letter	Quarterly beginning June 2023 and ending when the IFU is revised and all SmartSync tablets and 2090 / Encore programmers have been updated has been fully deployed. Tentatively scheduled for December 2025.	Hand delivery / Email / regionally approved method	Local Sales & Marketing
Risk Managers will receive as a courtesy – confirmation not required	Consignee Notification (All Cobalt/Crome models)		Hand delivery / Email / regionally approved method	Local Sales & Marketing

Phase II:

- To be updated by global

3.2. Regulatory Body Communications

Note: See section 5.4 *FCA Plan Execution* for regulatory reporting actions.

3.2.1. U.S. FDA Reporting

This FCA has been determined to be reportable according to CFR 21 CFR 806 as it was initiated (1) to reduce a Risk to Health posed by the device; or (2) To remedy a violation of the act caused by the device which may present a Risk to Health. This FCA will be reported to the FDA Division office using 115-F367 within 10 working days of the date when this Global FCA plan is approved or the date immediate action is authorized, whichever occurs first. Status reports will be submitted to the FDA using 115-F369, *806 Status and Closure Report* as required.

3.2.2. Regional Regulatory Body Reporting

This FCA will be reported to local regulatory authorities as required or applicable, per country requirements.

4. FCA Effectiveness Check Methods

International Effectiveness Check Methods:

Each region or country is required to execute customer communication and effectiveness check methods in alignment with the global plan and in accordance to local regulatory requirements. Additional regional plans may be developed that further outline actions required for completing FCA activities.

5. Field Action Plan Activity and Timing

5.1. Prepare for FCA Plan Execution

This section outlines activities to prepare for distribution of FCA documents and FCA plan execution.

Activity	Responsible	Plan Date dd-mmm-yyyy
Complete draft of Regional FCA plan/documents and submit for review/approval (as applicable)	Regional FCA Coordinator	Upon Global Plan Approval
Review/approve Regional FCA plan(s) (as applicable)	QARA Director for ISEA and MSEA	Upon Global Plan Approval
Finalize Consignee lists and prepare communication documents	Regional FCA Coordinator	Upon Global Plan Approval
Share approved FCA information internally across functions listed in section 2.5 *Note: Ensure alignment with the FCA strategy*	Regional FCA Coordinator	Upon Global Plan Approval
Conduct conference call(s) / PowerPoint presentation with impacted countries	Regional FCA Coordinator	No sooner than 09-May-2023

5.2. FCA Plan Execution (Including Closure)

This section outlines FCA plan execution activities with owners and plan dates.

Phase 1:

Activity	Responsible	Plan Date dd-mmm-yyyy
Report to local regulatory authority (if applicable)	Country RA	*within the required timeline of local regulations*
Initiate customer communications and confirmations, including special accounts.	Local Sales & Marketing	11-May-2023 *or starting on the date approved by your local regulatory authority, whichever comes later*
CareLink Monthly Monitoring: **Preparation Activities –** 1. Provide scope (bounding) of all affected products manufactured (Product/Model No. and name, UPN/GTIN, Serial Numbers, Lot Numbers with quantities) of FCA to Global FCA Coordinator	OU Quality	Monthly beginning May 2023 and ending 30-April-2024. See date detail in **CareLink Monthly Monitoring Wave Dates Table**
CareLink Monthly Monitoring: **Preparation Activities –** 2. Finalize and Reconcile scope: a) Identifying affected product locations and devices within scope of FCA notifications. Create reconciled item list and consignee list. b) Check for other Healthcare Organization contractual business requirements for FCA notifications and take appropriate action (e.g. Kaiser Healthcare) c) Distribute reconciled item list to impacted countries	OU Quality / FCA Scoping Team, Regional FCA Coordinator, Local Sales & Marketing	See date detail in **CareLink Monthly Monitoring Wave Dates Table**
CareLink Monthly Monitoring: **Preparation Activities –** 3. Initiate Communications	Local Sales & Marketing	See date detail in **CareLink Monthly Monitoring Wave Dates Table**

Activity	Responsible	Plan Date dd-mmm-yyyy
Quarterly Waves: 1. Provide scope (bounding) of all affected products manufactured (Product/Model No. and name, UPN/GTIN, Serial Numbers, Lot Numbers with quantities) of FCA to Global FCA Coordinator	OU Quality	Quarterly and ending when the IFU is revised and all SmartSync tablets and 2090 / Encore programmers have been updated has been fully deployed. See date detail in **Quarterly Wave Dates Table**
Quarterly Waves: 2. Finalize and Reconcile scope: a) Identifying affected product locations and devices within scope of FCA notifications. Create reconciled item list and consignee list. b) Check for other Healthcare Organization contractual business requirements for FCA notifications and take appropriate action (e.g. Kaiser Healthcare) c) Distribute reconciled item list to impacted International regions on US CareLink Server and cc: OU Quality and Anne Smith	OU Quality / FCA Scoping Team, Regional FCA Coordinator, Local Sales & Marketing	See date detail in **Quarterly Wave Dates Table**
Quarterly Waves: 3. Initiate communications	Local Sales & Marketing	See date detail in **Quarterly Wave Dates Table**
Newly identified physicians list to be provided to scoping team.	FCA Execution Team	Following bounding schedule in Quarterly Waves schedule. See date detail in **Quarterly Wave Dates Table**

Activity	Responsible	Plan Date dd-mmm-yyyy
Second communication attempt mailing or other	Local Sales & Marketing	See date detail in **CareLink Monthly Monitoring Wave Dates Table** and **Quarterly Wave Dates Table**
Third communication attempt	Local Sales & Marketing	See date detail in **CareLink Monthly Monitoring Wave Dates Table** and **Quarterly Wave Dates Table**
Confirmation of Customer Communication completed (see Effectiveness Checks/Closure Criteria)	OU Quality / Regional FCA Coordinator	See date detail in **CareLink Monthly Monitoring Wave Dates Table** and **Quarterly Wave Dates Table**

Phase II:

Activities and due dates for Phase II will be updated based on IFU, SmartSync tablets and 2090 / Encore programmers release schedule.

Activity	Responsible	Plan Date dd-mmm-yyyy
IFU Revision Complete	Rob Musto	30-Sept-2023*
Availability of SmartSync tablets and 2090 / Encore programmers Updates	Rob Musto	Beginning 1-Sept-2023*
Second letter to Risk Manager advising of revised IFU and availability SmartSync tablets and 2090 / Encore programmers Updates	Local Sales & Marketing	Beginning 1-Oct-2023*
SmartSync tablets and 2090 / Encore programmers Updates Complete	Local Sales & Marketing	02-Sep-2025
Country/Region Closure Forms due upon confirmation– all affected Countries/Regions	SSC QA	15-May-2026*
Confirm FCA Status reporting aligns with Country/Region closure form	SSC QA	24-May-2026*

* If an extension was initiated / an update was made by global, refer to the latest revision of the global plan for this FCA.

CareLink Monthly Monitoring Wave Dates Table:

Wave	Bounding Provided (No later than)	Finalize and Reconcile Scope	1st Attempt (Beginning)	2nd Attempt (No later than)	3rd Attempt (No later than)	Confirmation of Customer Communication completed
Initial (Wave 1)	24-APR-2023	26-APR-2023	11-MAY-2023	10-JUL-2023	30-AUG-2023	28-Sep-2023
Wave 2	24-MAY-2023	31-MAY-2023	07-JUN-2023	2-AUG-2023	27-SEP-2023	31-Oct-2023
Wave 3	23-JUN-2023	28-JUN-2023	10-JUL-2023	30-AUG-2023	25-OCT-2023	23-Nov-2023
Wave 4	21-JUL-2023	26-JUL-2023	02-AUG-2023	27-SEP-2023	22-NOV-2023	28-Dec-2023
Wave 5	21-AUG-2023	23-AUG-2023	30-AUG-2023	25-OCT-2023	20-DEC-2023	18-Jan-2024
Wave 6	22-SEP-2023	25-SEP-2023	29-SEP-2023	22-NOV-2023	17-JAN-2024	15-Feb-2024
Wave 7	20-OCT-2023	23-OCT-2023	30-OCT-2023	20-DEC-2023	14-FEB-2024	14-Mar-2024
Wave 8	20-NOV-2023	22-NOV-2023	27-NOV-2023	17-JAN-2024	13-MAR-2024	11-Apr-2024
Wave 9	18-DEC-2023	20-DEC-2023	22-DEC-2023	14-FEB-2024	10-APR-2024	09-May-2024
Wave 10	19-JAN-2024	22-JAN-2024	24-JAN-2024	13-MAR-2024	8-MAY-2024	06-Jun-2024
Wave 11	16-Feb-2024	17-FEB-2024	21-FEB-2024	10-APR-2024	05-JUN-2024	04-Jul-2024
Wave 12	21-Mar-2024	23-MAR-2024	28-MAR-2024	8-MAY-2024	10-JUL-2024	08-Aug-2024
Wave 13	18-Apr-2024	22-APR-2024	25-APR-2024	5-JUN-2024	31-JUL-2024	03-SEP-2024

Quarterly Waves Dates Table:

Wave	Bounding Provided (No later than)	Finalize and Reconcile Scope	1st Attempt (Beginning)	2nd Attempt (No later than)	3rd Attempt (No later than)	Confirmation of Customer Communication completed
Initial (Wave 1)	07-APR-2023	05-MAY-2023	11-MAY-2023	06-JUN-2023	04-JUL-2023	07-NOV-2023
Wave 2	19-JUL-2023	26-JUL-2023	02-AUG-2023	03-SEP-2023	01-OCT-2023	03-DEC-2023
Wave 3	11-OCT-2023	18-OCT-2023	25-OCT-2023	26-NOV-2023	17-DEC-2023	23-JAN-2024
Wave 4	10-JAN-2024	17-JAN-2024	24-JAN-2024	27-FEB-2024	26-MAR-2024	23-APR-2024
Wave 5	27-MAR-2024	03-APR-2024	10-APR-2024	14-MAY-2024	11-JUN-2024	16-JUL-2024
Wave 6	19-JUN-2024	26-JUN-2024	06-JUL-2024	06-AUG-2024	10-SEP-2024	15-OCT-2024
Wave 7	11-SEP-2024	18-SEP-2024	25-SEP-2024	22-OCT-2024	26-NOV-2024	17-DEC-2024
Wave 8	04-DEC-2024	11-DEC-2024	18-DEC-2024	14-JAN-2025	11-FEB-2025	18-MAR-2025
Wave 9	26-FEB-2025	02-MAR-2025	12-MAR-2025	15-APR-2025	13-MAY-2025	17-JUN-2025
Wave 10	21-MAY-2025	28-MAY-2025	04-JUN-2025	08-JUL-2025	05-AUG-2025	16-SEP-2025
Wave 11	13-AUG-2025	20-AUG-2025	27-AUG-2025	23-SEP-2025	21-OCT-2025	25-NOV-2025
Wave 12	05-NOV-2025	12-NOV-2025	19-NOV-2025	16-DEC-2025	13-JAN-2026	17-FEB-2026

6. Closure Criteria

6.1. FCA Activities Completion Criteria:

- Confirmation that 100% identified customers were notified of the issue and/or despite three documented attempts, customer was not located or did not provide a response (documented on Country/Region Closure Form).
- [Phase II activity] Confirmation that 100% identified customers were notified of revised IFU, SmartSync tablets and 2090 / Encore programmers Updates.
- [Phase II activity] 100% of Required SmartSync tablets and 2090 / Encore programmers Updates are complete or rationale documented for unable to complete.
- 100% of Country/Region Closure Forms are completed and returned to RS.CFQFCA@medtronic.com.