

Medtronic Representative Confirmation Form / Unable to Obtain Customer Confirmation Form

URGENT: MEDICAL DEVICE CORRECTION

**Induction of ventricular arrhythmia during Sphere-9™ catheter radiofrequency ablation
in patients with Biotronik ICDs**

Model Number	Product Name	Basic UDI Number	GTIN
AFR-00001	Sphere-9™ Catheter	0763000B000262284	OUS: 00763000871734; 00763000973384; 00763000973513; 00763000811341; 00763000911515; 00763000963675 US: 00763000871741; 00763000973391; 00763000973506

Account name: _____
 Account Number: _____
 Contact person at account: _____
 City, State or Province: _____
 Country: _____

This form is for use by Medtronic Representatives to document communication attempts, to consignee and/or complete additional actions, as applicable, for field corrective action (e.g. IFU updates).

Please see important guidelines on how to fill out this form correctly at the bottom; non-compliant forms **will be rejected**.

Please tick only one (1) of the boxes below to indicate the status of communication with the account, customer or physician:

By signing this form, I confirm that:

- The customer listed above has received the Urgent Medical Device Correction letter/Urgent Field Safety Notice.

<input type="checkbox"/> verbally	<input type="checkbox"/> during a site visit (the FSN was hand delivered to the customer)
	<input type="checkbox"/> through a phone call Date acknowledged (dd-mmm-yyyy): _____ Name of acknowledging person: _____ Job title: _____
<input type="checkbox"/> via email	Provide copy of email acknowledgment (applicable per local requirements)

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- Despite multiple attempts, Medtronic was unable locate or reach successfully the <account> listed above / obtain a signed consignee confirmation.

Please document all confirmation attempts in the table below (and add communication evidence). These attempts must be made in accordance with regional requirements using various contact methods.

Attempt	Date DD/MM/YYYY	Communication method	Individual Contacted Name and Title
1		<input type="checkbox"/> Telephone <input type="checkbox"/> Site Visit <input type="checkbox"/> Email <input type="checkbox"/> Other_____	Name: Title:
2		<input type="checkbox"/> Telephone <input type="checkbox"/> Site Visit <input type="checkbox"/> Email <input type="checkbox"/> Other_____	Name: Title:
3		<input type="checkbox"/> Telephone <input type="checkbox"/> Site Visit <input type="checkbox"/> Email <input type="checkbox"/> Other_____	Name: Title:

- I confirm that multiple attempts were not necessary because:

Tick this box if one of the following reasons applies. Then tick the appropriate sub-reason below.

- Account is no longer in business

- Refused to sign

Details:

As a Medtronic Representative, I certify that the information on this form is, to the best of my knowledge, complete and accurate.

Medtronic Representative Name (Print): _____

Medtronic Representative Title (Print): _____

Medtronic Representative Signature (Ink): _____

Date (DD/MM/YYYY) _____

Please send this completed form (or questions) via email to Medtronic at rs.seandfplusfca@medtronic.com

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Important Guidelines:

Confirmation Forms are an FCA document and **MUST** be completed properly following good documentation practices for quality including:

- One form per Account.
- 3 documented attempts (depending on country) using at least 2 different methods must be included if the account/physician was unable to be reached.
- Evidence for contacting the account via email / (phone)call / messaging apps such as copy of the email or screenshots of call logs or messages must be attached in this form (applicable per local requirements).
- There should be at least 7 calendar days from first attempt to the last attempt to conform to regulator expectation of good faith attempts
- All sections of the form must be completed
 - o Account information (top of the form) must be fully completed including physician name, physician account and address (If available, as applicable per local requirements).
 - o Box checked (where required/applicable).
 - o Please provide as much detail as is available
 - o Person completing the form must sign by hand in ink or via DocuSign/Adobe fill (depending on local requirement) and sign signature. **(Simply typing a name in the signature field is NOT ACCEPTABLE)**
- Errors must be corrected with a single line strike through, initials, date, and error explanation. **NO white out, completely blacking out text, etc.**

Completed forms can be returned electronically. If submitting electronically, it is acceptable to scan using a smart phone or tablet. Image of the form must be good quality **(information cannot be cutoff, blurry, illegible).**