Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291
Expires: 6-30-2025
See PRA statement on page 6.

FDA USE ONLY

Mfr report #	1723170-2025-12345
UF/Importer Report #	
Exemption/Variance #	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-JAN-1900.

A. PATIENT INFORMATION

1. **Patient Identifier** *(In confidence)*
NONE

2. Age
☐ Year(s) ☐ Week(s)
☐ Month(s) ☐ Day(s)

or Date of Birth *(e.g., 01-Jan-1900)*

3. **Sex:** Enter the patient's sex at birth *(the sex that a person has or was assigned to at birth).*
☐ Male
☐ Female

SECTION REMOVED

4. **Weight**
☐ lb
☐ kg

5. **Ethnicity** *(Check one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

6. **Race** *(check all that apply)*
☐ American Indian/Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian/ Other Pacific Islander
☐ White

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. **Type of Report** *(check all that apply)*
☐ Adverse Event
☒ Product Problem *(e.g., defects/malfunctions)*

2. **Outcome Attributed to Adverse Event** *(check all that apply)*
☐ Death – Date of death *(01-JAN-1900):*
☐ Life-threatening
☐ Hospitalization (initial or prolonged)
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. **Date of Event** *(01-JAN-1900)*
21-Feb-2025

4. **Date of this Report** *(01-JAN-1900)*
03-Mar-2025

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see instructions

(continued on next page)

5. **Describe Event or Problem**

Medtronic received information regarding a navigation system being used outside of a procedure. It was reported that upon powering on a navigation system in the usual operating room, a burning smell was immediately noticed, followed by smoke coming from the back of the unit. It was noted that the system subsequently lost power upon powering down, and the Uninterrupted Power Source (UPS) did not maintain power. There was no patient involved.

6. **Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*	**Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*

Additional comments

been returned to Medtronic for analysis. Codes B17, C20, and D15 are applicable. Multiple Annex were coded - A1002: Applicable to a burning smell that was noticed, followed by smoke coming from the back of the unit. A0708: Applicable to the Uninterrupted Power Source (UPS) not maintaining power. A0719: Applicable to the system losing power upon powering down. Medtronic submits this report to comply with FDA regulations 21 CFR Parts 4 and 803. Medtronic has made reasonable efforts to provide as much relevant information as is available to the company as of the submission date of this report. This report does not constitute an admission or a conclusion by FDA, Medtronic, or its employees that the device, Medtronic, or its employee caused or contributed to the event described in the report. Any required fields that are unpopulated are blank because the information is currently unknown or unavailable. Medtronic will submit a supplemental report if additional relevant information becomes known.

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, tobacco product use, alcohol use, and liver/kidney problems, etc.)*

C. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. **Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--

NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

2. **List Medical Product and Treatment Given at the Same Time of the Event and Date** *(Do not include treatment for initial event)*

3. **Dose or Amount**	**Frequency**	**Route**
	--	--
Unit	**Other Frequency**	**Other Route**
--		

4. **Treament Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on *(e.g., 01-Jan-1900)*	Therapy stopped on *(e.g., 01-Jan-1900)*	Dose Reduced *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ Yes ☐ No ☐ Doesn't apply

SUSPECT PRODUCT #2

1. **Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--

NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

2. **List Medical Product and Treatment Given at the Same Time of the Event and Date** *(Do not include treatment for initial event)*

3. **Dose or Amount**	**Frequency**	**Route**
Unit --	**Other Frequency**	**Other Route**

4. **Treament Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on *(e.g., 01-Jan-1900)*	Therapy stopped on *(e.g., 01-Jan-1900)*	Dose Reduced *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ Yes ☐ No ☐ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**	2a. **Common Device Name**	2b. **Procode**
StealthStation™ S8 system	NEUROLOGICAL STEREOTAXIC INSTRUMENT	HAW

3. **Manufacurer Name, City and State**

Medtronic Navigation, Inc 826 Coal Creek Circle Louisville, CO, 80027, UNITED STATES

4. **Model #**	**Lot #**	**Catalog #**
9735669		9735669

Expiration Date *(01-JAN-1900)*	**Serial #**

Unique Device Identifier *(UDI)* **#**

5. **Operator of Device**	6a. **If Implanted, Give Date** *(01-JAN-1900)*	6b. **If Explanted, Give Date** *(01-JAN-1900)*
☐ Health Professional ☐ Patient/Consumer ☒ Other OHP		

7a. **Is this a single-use device that was reprocessed and reused on a patient?**	7b. **If yes, enter the name and address of the reprocessor**
☐ Yes ☒ No	

8. **Was this device ever serviced by a third-party servicer?**	9. **Is this Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☐ No ☐ Unknown	☐ Yes ☒ No ☐ Returned to manufacturer on *(01-JAN-1900)*

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Product Name	Therapy Start Date *(01-JAN-1900)*	Therapy End Date *(01-JAN-1900)*
1. SEE H11....		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

E. INITIAL REPORTER

1. **Name and Address**

Last Name	First Name
UNK	UNK

Address

City	State/Province/Region	ZIP/Postal Code	Country
	UNITED STATES		--

Phone # Email

2. **Health Professional?**	3. **Occupation** *(Select from list)*	4. *Initial reporter also sent report to FDA*
☐ Yes ☐ No	--	☐ Yes ☒ No ☐ Unknown

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One**
☐ User Facility ☐ Importer

2. **User Facility/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(01-JAN-1900)*

7. **Type of Report**

8. **Date of This Report** *(01-JAN-1900)*

9. **Approximate Age of Device**

10. **Adverse Event Problem** *(Refer to coding manual)*

Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code

11. **Report Sent to FDA?**
(If Yes, enter date (01-JAN-1900))
☐ Yes ☒ No

12. **Location Where Event Occurred**
☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other *(Specify)*
☐ Home ☐ Outpatient Diagnostic Facility
☐ Hospital ☐ Nursing Home

13. **Report Sent to Manufacturer?**
(If Yes, enter date (01-JAN-1900))
☐ Yes
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office** *(and Manufacturing Site for Devices)* **or Compounding Outsourcing Facility**

Name	Email Address	Phone Number
John Doe	JD@medtronic.com	1 (763) XXX-XXXX

Address
MNAV 8200 Coral Sea Street NE MVS21 Mounds View, MN, 55112, UNITED STATES

Compounding Outsourcing Facility 503B?
☐ Check box if applicable

Outsourcing Facility

2. **Report Source** *(check all that apply)*
☐ Foreign ☐ Literature ☒ Health Professional ☒ Company Representative
☐ Study ☐ Consumer ☐ Use Faciltiy ☐ Distributor/Importer ☐ Other *(Please list)*

3. **Date Received by Manufacturer** *(01-JAN-1900)*
21-Feb-2025

4. **NDA #**	**ANDA #**	**IND #**	**BLA #**	**PMA/510***(k)* #

Check all that apply:
☐ Combination product ☐ Pre-ANDA ☐ Pre-1938 ☐ OTC ☐ Compounded Product

5. **If IND/Pre-ANDA, Give Protocol #**

6. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 15-day ☐ Periodic ☐ Follow-up #
☐ 7-day ☒ 30-day ☒ Initial

7. **Adverse Event Term***(s)*

8. **Manufacturer Report Number**
1723170-2025-12345

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** *(check all that apply.)*
- ☐ Death
- ☒ Malfunction
- ☐ Serious Injury
- ☐ Summary Report
  No. of events summarized

2. **If Follow-up, What Type?**
- ☐ Correction
- ☐ Additional Information
- ☐ Response to FDA Request
- ☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
- ☐ Yes
- ☒ No

4. **Device Manufacture Date** *(01-JAN-1900)*
05-Apr-2023

5. **Labeled for Single Use?**
- ☒ Yes
- ☐ No

6. **Adverse Event Problem** *(Refer to coding manual)*

Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code
4582	2645	3010, 4019, 4030	420, 423, 498

Type of Investigation	Investigation Findings	Investigation Conclusions
4114	3221	4315

7. **If Remedial Action Initiated, Check Type**
- ☐ Recall
- ☐ Relabeling
- ☐ Patient Monitoring
- ☐ Repair
- ☐ Notification
- ☐ Modification/Adjustment
- ☐ Replace
- ☐ Inspection
- ☐ Other:

8. **Usage of Device**
- ☐ Initial Use of Device
- ☒ Reuse
- ☐ Unknown

9. **If action reported to FDA under 21 USC 360i(g), list correction/ removal reporting number:**

10. **Related Report Number**

11. **Additional Manufacturer Narrative**

Continuation of D10: Section D information references the main component of the system. Other relevant device(s) are: Product ID: 9 735787, Serial/Lot #: -, UBD: unknown, UDI#: unknown ; Product ID: 9735773, Serial/Lot #: -, UBD: unknown, UDI#: unknown ; Product ID: 9735784, Serial/Lot #: -, UBD: unknown, UDI#: unknown ; Product ID: 9735787, Serial/Lot #: -, UBD: unknown, UDI#: unknown H3, H6: No products have

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