Medtronic

URGENT FIELD SAFETY NOTICE

Endoflip v1.0 System, Endoflip System v1.0 Refurbished, and DL Endoflip v1.0, all serial numbers

Notification

Product Information		
Product Description	**Manufacturer's Product Number**	**GTIN**
Endoflip v1.0 System	EF-100	05391530810050 10884521809307
Endoflip v1.0 System Refurbished	RFG-EF100	05391530810166 10884521808096
DL Endoflip v1.0 System	DLEF-100	10884521786684

May 2026

Medtronic Reference: FA1538
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Risk Manager/ Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is initiating a field action regarding the devices listed within the product information table above.

Issue Description:

The Windows operating system of the EF-100 module has reached end-of-life (EOL) due to a software limitation that restricts the recording of catheter usage-years to a range between 2010 and 2025. This affects the internal system clock, which will prevent the unit from recognizing Endoflip™ and Esoflip™ catheters after 01-January-2026, causing them to appear as expired.

Up until 23-April-2026, Medtronic has received 54 complaints related to this error. No patient harm has been reported, and as the error occurs prior to patient interaction, none is expected, though there may be a delay in treatment.

We understand that some customers have not yet upgraded to the new EF-300 system and may choose to continue using legacy systems beyond the EOL date of 31-December-2025. Our engineering team has identified a possible solution that may allow users to adjust the internal system

clock and extend EF-100 usability beyond 01-January-2026. However, please note that this solution is not guaranteed to work on all EF-100 units.

Prior to Medtronic's acquisition, legacy Endoflip units were manufactured with a variety of software versions. These versions may affect your ability to reset the internal system clock, and unfortunately, Medtronic does not have historical records indicating which legacy systems contain software packages that prevent updating the clock.

System Use Recommendations:

We recommend that customers who continue to use legacy EF-100 systems consult their biomedical staff for assistance in adjusting the internal clock. Instructions for this process are enclosed with this notification. As the product has reached end-of-life and end-of-service, Medtronic Technical Services is unable to assist in resetting the internal clock.

The user is advised that effects of the data change workaround are seen in exported files. When a USB drive is inserted into the EF-100 system, the SAVE button is enabled to record raw data. For each procedure, a folder is generated and is automatically deleted when the next procedure begins. The folder name includes the Patient ID, the date (YYMMDD format), and the time (HH:MM). All files generated within this folder include the Patient ID in their filenames. The live data file contains raw data with time stamps. These timestamps will reflect the system date, which, under the Date Change Workaround, will be set to 2020.

Customer Actions:

- Customers may use the EF-300 system, if they have one.
- Post this notice in all care environments where the affected products are used, to maintain awareness of this issue.
- Share this notice with all relevant personnel within your organization, and with any organization to which the affected product listed in the Product Information table above has been transferred or distributed.

Additional information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

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Sincerely,

Local / OU manager

Enclosed:

- Attachment A: Affected Units List
- Endoflip Internal Clock Reset Instructions

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Attachment A: Affected Units

GTIN	Manufacturer's Product Number	Serial Number
05391530810050	EF-100	0191203602
10884521809307	EF-100	M191231902

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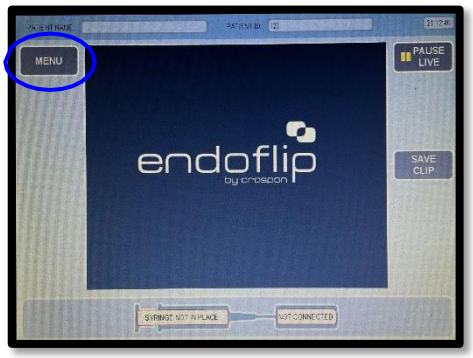
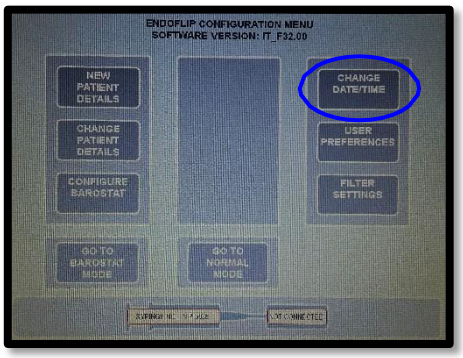
Quick refence guide for resetting internal system clock of EF-100

System error: Catheters expired, (not recognized), after January 1st, 2026.

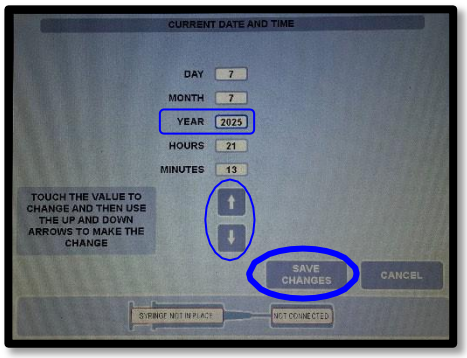
1. Turn Endoflip™ system on; wait for approximately 30 seconds for initialization screen to appear.
2. On the **initialization screen**, select and press the MENU button to navigate to Endoflip **Configuration Menu screen**.
3. On the Endoflip **Configuration Menu screen**, select and press the CHANGE DATE/TIME button to navigate to the **Current Date and Time screen**.
4. On the **Current Date and Time screen**, select and press the YEAR field.
5. Use the UP or DOWN arrows to adjust the YEAR field to 5 years prior, (i.e. from 2025 to 2020). *Note: keep the "DAY", "MONTH", "HOUR" and "MINUTE" accurate.*
6. Press the SAVE CHANGE button.
7. Power off the Endoflip™ system, switch on back panel.
8. Power on the Endoflip™ system, switch on back panel.
9. On the **Initialization screen**, select and press the Menu button to navigate to Endoflip **Configuration Menu screen**.
10. Confirm modified YEAR has been saved.
11. Return to the **Initialization screen**, proceed with normal catheter, pre-check and use.



Initialization Screen



Configuration Menu Screen



Current Date and Time Screen