NOT APPLICABLE IN THE UNITED STATES OR CANADA

Subject: FIELD SAFETY NOTICE – Unresponsive Touchscreen After Power-On in Clearway 2 Devices

FSN Reference number:	CAPA-291 / 6.6.2-2025-086126
FSN Date:	28 October 2025
Affected Product:	Clearway 2 Mechanical Insufflation-Exsufflation (MI-E) Device (REF 232000)
Affected units:	Devices manufactured between 01 November 2023 and 23 March 2025 (serial number between 20234937 and 202511779), and devices repaired between 01 November 2023 and 23 March 2025, with firmware version 3.0.0 or earlier.
Manufacturer:	Breas Medical Ltd.

Dear valued Healthcare Provider,

A limited number of Clearway 2 devices may exhibit an unresponsive touchscreen after power-on, prior to starting treatment. The device cannot be operated while this condition prevails. The device may still be switched off using a long press of the power button.

This issue has been linked to two causes:

1. A firmware defect in firmware versions 3.0.0 or earlier. The defect was already corrected in firmware version 3.1.0, released in January 2025.
2. A supplier defect in earlier revisions of touchscreens, used in Clearway 2 devices manufactured or serviced between 01 November 2023 and 23 March 2025.

It has come to our attention through reports from users that the inability to start the treatment may affect patients where alternative treatments are not available, as required in the Instructions for Use. Breas Medical wants to ensure that healthcare providers are aware of the potential for unresponsive touchscreen in affected devices, and how to respond if it occurs.

Please forward this notice to all relevant staff within your organization and, where applicable, to any customers and users to whom you have supplied potentially affected devices.

IMPORTANT: Please acknowledge receipt of this notice by completing and returning the attached Response Form within 30 (thirty) days.

User Action Required

- Devices not experiencing touchscreen issues can continue to be used. The issue, when present, only prevents device start-up and does not affect delivery of therapy once the device is operating. Only use the device for its Intended Use and always adhere to the general user precautions in the Instructions for Use.
- If an unresponsive touchscreen occurs, users should first attempt to power the device off, then on again. If this does not resolve the issue, users should contact their Breas Medical authorized service workshop to arrange for a repair.
- Patients who, after clinical assessment, are deemed at elevated risk of hospital admission or serious deterioration of health without access to a functioning MI-E device may require additional equipment and/or alternative airway clearance methods.
- Healthcare providers should test the function of touchscreen on their Clearway 2 devices, and update the device to firmware version 3.1.0 or later, during the next scheduled annual check, and no later than twelve (12) months, in accordance with the Clinician's Manual.
- Authorized service workshops must request replacement touchscreens from Breas Medical, with information about serial numbers of affected devices.

Intended Use and General User Precautions:

The Clearway 2 airway clearance device assists patients in loosening, mobilizing, and clearing secretions, as well as promoting lung volume recruitment by Mechanical Insufflation-Exsufflation (MI-E). The device can be used by adult or paediatric patients that have compromised secretion clearance and/or a reduced ability to cough effectively.

The device can be used for MI-E in both invasively and non-invasively ventilated patients as well as patients who are self-ventilating. The device may be used either with a facemask, mouthpiece, or with a suitable adapter to a patient's endotracheal (ET) or tracheostomy tube (MI-E only).

General User Precautions in the Clearway 2 Instructions for Use include:

- Clearway 2 must only be used under the direction and prescription of a physician, respiratory therapist, or other qualified persons.
- If the patient is using the Clearway 2 outside the hospital environment, there should always be a trained caregiver administering the therapy and to monitor the patient during and after therapy is carried out.
- When using the Clearway 2, suction and emergency resuscitation equipment shall be available.
- Monitor the device while in use and stop providing treatment if the device malfunctions. Do not use the Clearway 2 in the event of suspected damage to the

device, unexplainable or sudden pressure, performance or sound changes during operation, or if the delivered air from the Clearway 2 is abnormally hot or emits an odour.

How to Identify the Date of Manufacture and Serial Number

The date of manufacture and serial number are printed on the Clearway 2 device label which is affixed to the back panel (rear) of the device.

If you require assistance or further information, please contact your distributor of the Clearway 2 device, your local Breas representative or Breas technical support at techsupport@breas.com.

Sincerely,

Steve Birchall

Therapy Area Director, Airway clearance

Breas Medical

Field Safety Notice Response Form

Please complete and return this form within 30 (thirty) days using one of the following methods:

1. Submit electronically via website: https://forms.office.com/e/4xQJwvTC3D
2. E-mail the completed form to: fsn@breas.com

1. Field Safety Notice (FSN) information	
FSN Reference number:	CAPA-291
FSN Date:	28 October 2025
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2. Respondent Details (* mandatory fields)		
Organization/Company Name*		
Address*	Line 1:	
	Line 2:	
	Postcode:	
	City:	
	Country:	
Contact Name*		
Title or Function		
Telephone number*		
Email*		

3. Actions taken (* mandatory fields)		
3.1	*I confirm that we have received, read and understood this Field Safety Notice.	☐ **YES**
3.2	*We have forwarded this information to relevant staff and customers.	☐ **YES** ☐ **NO, please explain:**
3.3	*We have Clearway 2 devices affected by this FSN.	☐ **YES** ☐ **NO**
3.4	*If YES on 3.3: We have identified and instructed affected users to follow the instructions in this FSN.	☐ **YES** ☐ **NO, please explain:**
3.5	*If YES on 3.3: We will test the function of touch screens, replace affected touchscreens and update the firmware of affected devices within 12 months in accordance with this FSN.	☐ **YES** ☐ **NO, please explain:**
Print Name to confirm*.		
Date *		