FIELD SAFETY NOTICE – nGenuity CO2 MONITORS manufactured since 2024
Serial # starting with: 424, 125, 225, 325, 425, 126, 226, 326, 426

21 CFR Part 806 – No Mandatory Return Required – Action If Alarm Occurs

FIELD SAFETY NOTICE: nGenuity Patient Monitor – CO2 Section

Important Information About Your Monitor's CO2 Monitoring Function

Criticare Technologies, Inc.
333 Strawberry Field Rd.
Suite 11
Warwick, RI 02886, (800) 486-3849, www.criticare.com

May 22, 2026

Dear Valued Customer,

We are writing to inform you of an important matter affecting all nGenuity patient monitors equipped with CO2 (capnography) monitoring. Please read this notice carefully and keep it for your records. No immediate action is required today, but we ask that you be aware of the information below.

WHAT IS THIS NOTICE ABOUT?

We have identified a manufacturing process error that may affect some CO2 subassemblies in nGenuity monitors. When this happens, your monitor displays a "Checkline Error" alarm at device startup.

WHAT HAPPENS IF MY MONITOR HAS THIS PROBLEM?

- ✓ Your monitor will display a clear "Checkline Error" alarm on the CO2 section at startup.
- ✓ The monitor does not produce incorrect or misleading CO2 readings – it stops and tells you.
- ✓ No patient is placed at risk by an alarming unit – you will know before the procedure begins.
- ✓ No patient injuries have been reported across all known complaints related to this issue.

DOES MY MONITOR HAVE THIS PROBLEM RIGHT NOW?

Most monitors do not show this alarm – out of approximately 4,400 CO2-equipped monitors in the field, fewer than 2% have been reported with this issue. Of these, this notice specifically covers those manufactured since 2024 (approximately 1,200 units), where the failure rate is highest. Customers with earlier units may also contact us with any concerns. You may never see this alarm on your unit. However, we want every customer to know what to do if it does occur.

There is no external inspection that can predict whether your unit will develop this issue. The monitor itself will alert you if a problem develops, by displaying the Checkline Error alarm at startup.

IS THERE A RISK TO MY PATIENTS?

The risk to patients from this issue is considered very low, for two reasons:

- The alarm appears at device startup/set-up.
- ADA guidelines generally require CO2 monitoring for sedation procedures. If your monitor cannot provide CO2 readings, it is recommended that you not proceed.

No patient injuries or adverse events have been reported in connection with this issue across the entire complaint history.

WHAT SHOULD I DO RIGHT NOW?

No action is required today unless your monitor is currently displaying a Checkline Error alarm. We recommend the following:

1. Be aware of the Checkline Error alarm. If it appears on your CO2 section at startup, follow the steps in the next section.
2. Verify your backup plan. Confirm that your practice has access to an alternate CO2 monitoring source. This is good practice regardless of this notice.
3. Keep this notice. Retain this letter and note your unit's serial number for your records.
4. Contact us if you have questions. Our service team is available at (800) 486-3849 and can answer any questions about your specific unit.

CHECK THIS FIRST – BEFORE CALLING FOR SERVICE

If your monitor displays a Checkline Error alarm, please check the following before contacting us:

- Are you using an AUTHORIZED sample line? Non-authorized or third-party sample lines can cause the same Checkline Error alarm as a hardware failure.
- Authorized sample lines are available from Criticare Technologies at www.criticare.com.
- If switching to an authorized sample line clears the alarm, no service is required. Please note the incident and contact us so we can log it for our records.
- If the alarm persists with an authorized sample line, contact our service team.

WHAT TO DO IF THE CHECKLINE ERROR ALARM APPEARS

If your monitor displays "Checkline Error" on the CO2 section at startup:

1. Do not attempt to bypass or override the alarm.

2. It is recommended that you not use this monitor for sedation procedures requiring CO2 monitoring.
3. Contact our service team immediately: (800) 486-3849 or service@criticare.com.
4. We will arrange priority service.
5. A loaner monitor may be available at no charge depending on availability, while your unit is being serviced.

OUR COMMITMENT TO YOU

We have already corrected the manufacturing process, and all new monitors are built under the validated corrected process.

For monitors already in the field, we are making the following commitments:

- **Priority service for any unit displaying the Checkline Error alarm.**
- Enhanced monitoring of field complaints, with a commitment to escalate our response if the situation changes.

VOLUNTARY INSPECTION OPTION

If you would like your unit proactively inspected, even if it is not currently showing any alarm, we are happy to arrange that. Contact our service team at (800) 486-3849 or service@criticare.com to schedule a voluntary inspection.

HOW TO CONTACT US

Website Service Request (preferred) WWW.CRITICARE.COM
Email: service@criticare.com
Voluntary Inspection: www.criticare.com
Reference Number: 3012238587 05/22/2026 001-c

We sincerely apologize for any concern this notice may cause. Patient safety is our first priority, and we are committed to supporting you fully through this corrective action. Please do not hesitate to contact us at any time.

Sincerely,

John Haefele
VP/GM
Criticare Technologies, Inc.
(800) 486-3849 | john@criticare.com

This notice is being provided pursuant to 21 CFR Part 806 in connection with a voluntary field safety corrective action. All nGenuity monitors with CO2 option manufactured since 2024 are included in this notice.