Monday, December 13, 2021

RE: MEDICAL DEVICE FIELD SAFETY CORRECTION (FDA CLASS III)

Dear valued Inogen customer, distributor or economic operator,

This letter is to inform you that we identified an error on the shipping label on some of our products. **This issue does NOT affect the fit, form or function of the medical device and accessories and does NOT introduce any new risk to the patient pertaining to the safety and performance of the medical device and accessories.**

At this time, we are issuing an FDA Class III Field Safety Correction. This letter shall inform you of the products impacted and the actions (if any) that need to be taken.

Reason for this product advisory notice

This Field Safety Correction had been initiated due to missing information on the product's packaging label located on the outside of the shipping carton. This packaging label lists all component(s) inside the carton but does not affect the products within the shipping carton.

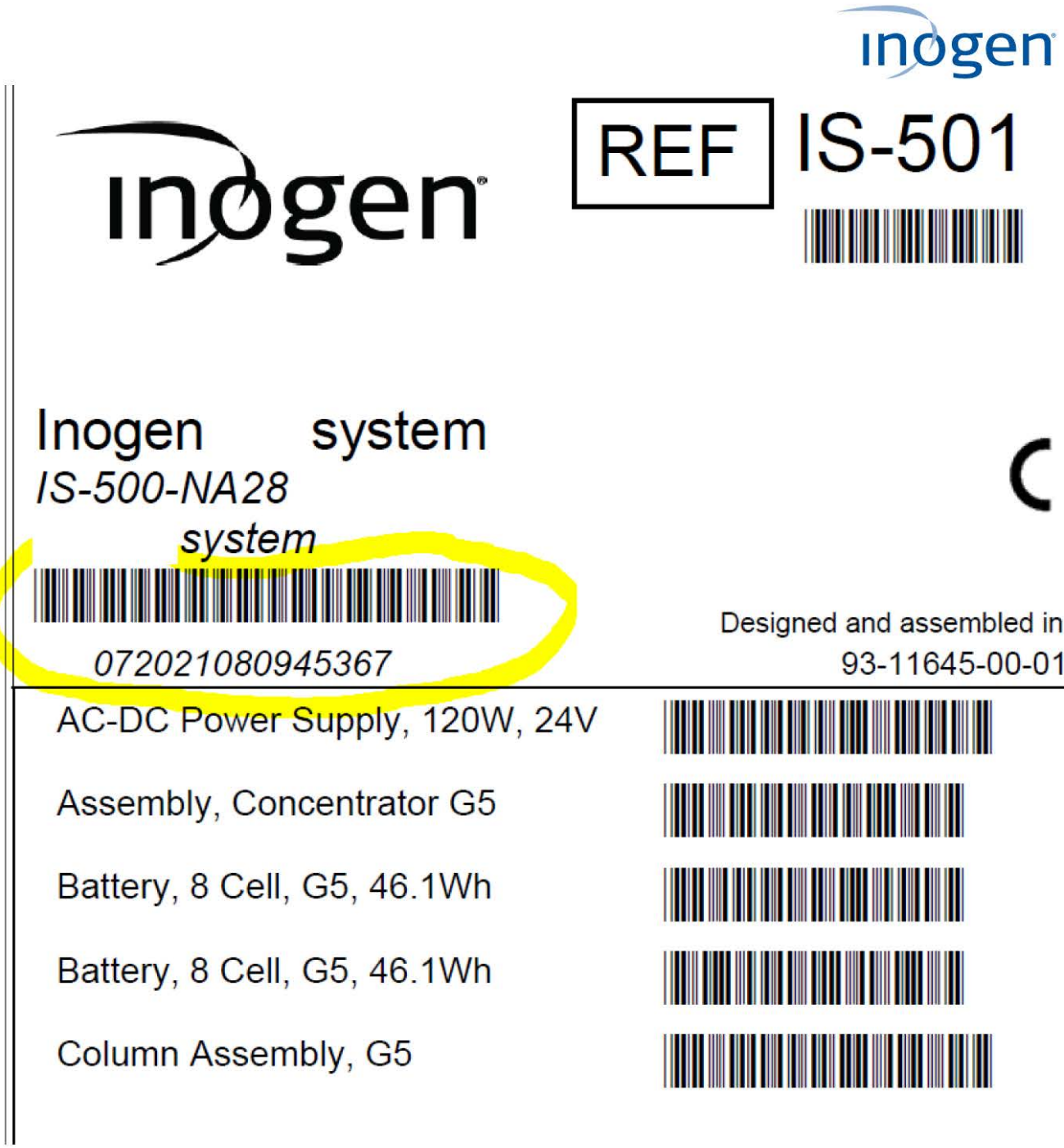
Products impacted

The following Inogen products shipped between **November 20th, 2021,** and **December 6th, 2021,** are impacted by the Field Safety Correction.:

- TAV Tidal Assist Ventilator
- Inogen One G3 Portable Oxygen Concentrator
- Inogen One G4 Portable Oxygen Concentrator
- Inogen One G5 Portable Oxygen Concentrator
- Inogen-at-Home Stationary Concentrator
- Corresponding accessories: Batteries, Battery Chargers, AC Power Supplies, DC Power Supplies, Column Replacements

Master Serial Numbers impacted: See Appendix A

See Below highlighted example of MSN number location for tracing.



Action required for affected product

1. Please inspect your inventory upon receipt of this letter to determine whether theMSN number of any of your inventory matches any of the affected MSN number ranges listedbelow
2. If your inventory contains one or more of the MSN numbers listed, quarantine any units at your distribution center by segregating them from the unaffected inventory within 3-5 days.
3. You will receive a labeling kit to over-label the packaging label. Please follow the instructions included with the kit to correct all affected inventory.
4. For affected units that have already been distributed to customers, no further action is required at this time.
5. You can expect to receive your kits for relabeling the week of December 20th, 2021.

In addition to these steps, we also need you to confirm you've received this notice and will comply with the procedures. **Please complete the enclosed form (Appendix B) and send it to within 48 hours of receipt at Complaints@inogen.net.**

We appreciate your help in correcting this issue. If you have questions, please call the B2B Sales Support Center at 1 ((855)-631-2438.

[redacted]

Appendix A: Affected Master Serial Numbers (MSN)

MSN numbers impacted from 112021103825545- 12062111312526258

Appendix B – Distributor Return Response Form

MEDICAL DEVICE ADVISORY NOTICE (FDA CLASS III)

Please complete this form and email it to Inogen Customer Care email Complaints@inogen.net within 10 business days.

☐ I have read and understand the instructions provided in this letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

Customer name	[mail merge that information here]
Name (print)	
Name (signature)	
Title	
Email address	

Appendix C: Frequently Asked Questions

Is this notification a recall?
There are many types of recalls. This notice pertains to a **corrective notice** "recall". In this type of recall, product is NOT being recalled from the field. We want to make it clear that you **do not need to send back affected packaged products.**

The FDA defines a recall as "a method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration (FDA)". Most recalls are voluntarily done by manufacturers. There are 3 levels of recall. A Class 3 recall involves a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Can my patients continue to use their Inogen devices?
Yes. This correction letter does not impact the fit, form or function of the medical device and accessories; only the packaging. Your customers may continue to use their device as usual.

When will I receive the labelling kit?
The labelling kit was included with this notice. If you did not receive it or have misplaced it, please contact customer care at 1 (877) 466-4364.

Do you need proof that I have over-labeled affected devices?
We do not require photo evidence. However, you are required to send back the distributor return response form in Appendix B.

Should I stop shipments in route?
No. No further action is required at this time.