Maxtec, LLC

April 20, 2023

URGENT FIELD SAFETY NOTICE

Handi+ (Oxygen Analyzer)

Internal Recall Reference number: RC-2023-001

Dear Device Customer/Distributor,

This document serves as a notice stating that Maxtec, LLC is initiating a Field Safety Corrective Action (FSCA) as per the Medical Devices Vigilance System (MEDDEV 2.12/1 rev 7) for the identified serial numbers and reference numbers of our hand-held oxygen analyzer, the Handi+. **The type of FSCA is a Device Recall.**

The Handi+ Oxygen analyzer is used by healthcare professionals to spot check oxygen levels delivered by medical oxygen delivery equipment and respiratory care systems. *The device's intended use does NOT include continuous monitoring.*

There have been NO reports of serious injuries and/or deaths due to the failure mode associated with this recall.

Reason for Device Recall

During a complaint investigation it was confirmed that an assembly configuration error occurred which impacts the digital read out on the Handi's display. The digital read out of the display on the affected Handi+ does not show oxygen concentration. Instead, the display shows a value of 100 minus the oxygen concentration level analyzed. This will result in the analyzer failing its initial calibration prior to use.

Affected Product

Maxtec Handi+ family affected reference numbers are R218P12-001, R218P12-004, R218P12. See *table 1 on page 4* of this notice for affected serial numbers and lot numbers.

Only the serial numbers, associated lot numbers and product reference (part numbers) identified within this notice are affected.

Risk:

The Instructions for Use (IFU) supplied with each Handi + requires that the unit be calibrated prior to use. The problem is easily detectable during this step and would result in a failed calibration, precluding use, therefore the defective product is ***not likely*** *t*o cause adverse health consequences.

Identifying Recalled Product

Review your Handi+ Analyzers to determine if it is impacted by locating the reference number (REF) and serial number (SN) on the device label and comparing it to *Table 1 on page 4* of this notification.

Picture is for reference only. Private Labeled products may differ cosmetically however location of label containing serial number is consistent.

If your Handi+ is unopened and in its original kit packaging, you may identify impacted product by locating the reference number (REF) and lot number (LOT) on the packaging label and comparing it to T*able 1 on page 4* of this notification.

Special Instructions for Distributors

- Immediately stop distributing and quarantine all recalled product.
- Perform a count of recalled products in inventory. Complete the enclosed Medical Device Recall Response form and return it to the contact listed. **Return the attached recall response form even if no recalled product is in inventory.**
- Email Quality@maxtec.com and you will be assigned an RMA number and given instructions on how to return the recalled product.
- Please DO NOT return recalled products without an RMA assigned via this process. Do not include with any other product returns.
- Send a copy of this recall package to all other secondary customers and end users.

End Users (Hospitals, Acute Care Centers, and Others)

- Perform a count of recalled products in inventory. Complete the enclosed Medical Device Recall Response form and return it to the contact listed. **Return the attached recall response form even if no recalled product is inventory.**

- Email Quality@maxtec.com and you will be assigned a Return Material Authorization number and given instructions on how to return the recalled product.

- Please DO NOT return recalled products without an RMA assigned via this process. Do not include these returns with any other product returns.

Contact Information

If you have questions regarding the recall, please contact our Quality or Customer Service team.

- Sidra Hankins, VP Of Quality Assurance and Regulatory Affairs shankins@maxtec.com
- Charly Duffy, Director of Quality cduffy@permapure.com
- Maxtec, LLC Quality Distribution Email : quality@maxtec.com
- Call Maxtec via our toll-free number at (800) 745-5355

Table 1 Recalled Product – Model Handi+

Reference (Part Number) Number	Model	Manufacturing Date	Serial Numbers	Lot Numbers (External Kit Packaging)
R218P12-001	Analyzer, Handi+ International	January 2023	JA22599001 HM29699016 JA22599002 HM29699017 JA22599003 HM29699018 JA22599004 HM29699019 JA22599005 HM29699020 JA22599006 HM29699021 JA22599007 HM29699022 JA22599008 HM29699023 JA22599009 HM29699024 JA22599010 HM29699025 JA22599011 HM29699026 JA22599012 HM29699027 JA22599013 HM29699028 JA22599014 HM29699029 JA22599015 HM29699030 HM29699001 HM29699031 HM29699002 HM29699032 HM29699003 HM29699033 HM29699004 HM29699034 HM29699005 HM29699035 HM29699006 HM29699036 HM29699007 HM29699037 HM29699008 HM29699038 HM29699009 HM29699039 HM29699010 HM29699040 HM29699011 HM29699041 HM29699012 HM29699042 HM29699013 HM29699043 HM29699014 HM29699044 HM29699015 HM29699045 HM29699046	JA22599 HM29699
R218P12-004	Handi+, Check & Go Disposeable Drive 18580	January 2023	5M2301491039 5M2301491040 5M2301491041 5M2301491042 5M2301491043 5M2301491044	5M2301491

			5M2301491045 5M2301491046 5M2301491047 5M2301491048 5M2301491049 5M2301491050	
R218P12	Analyzer, Handi+ Medical	May 2020	FD73399001 FD73399002 FD73399003 FD73399004 FD73399005 FD73399006 FD73399007 FD73399008 FD73399009 FD73399010 FD73399011 FD73399012 FD73399013 FD73399014 FD73399015 FD73399016 FD73399017 FD73399018 FD73399019 FD73399020 FD73399021 FD73399022 FD73399023	FD73399

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Handi+ April 2023 Recall Reference No. RC-2023-001

On behalf of my organization, I acknowledge receipt of and have read and understand the recall instructions provided in the April 20, 2023, letter.

Yes ☐ No ☐

Organization	
Response Completed by Name	
Title	
Email	
Telephone No.	
Date	
Signature	

Any adverse events associated with recalled product?

Yes ☐ No ☐

If yes, please explain:

Affected Stock:

If you have **No affected stock**, tick this box ☐

If you have affected stock, please complete the details in the following table.

Affected Product Information Table			
Reference Number	Serial Numbers(s)	Lot Number(s)	Quantity of Units Isolated awaiting RMA Instructions
R218P12			
R218P12-001			
R218P12-004			

Has your organization supplied the affected product to any other organization?

No ☐

Yes ☐ and I have forwarded the recall information on _____*(date)* via_____ (*method)*

OR

Yes ☐ and I would like Maxtec to contact them (please supply an attachment with the organization name, contact information and affected product distributed)

Return Completed forms by mail or email to:

Name	Charly Duffy
Organization	Maxtec, LLC
Address	2305 S 1070 W, West Valley City, UT 84119 USA
Email	quality@maxtec.com
Subject of Email	Maxtec Recall Reference Number: RC-2023-001
Phone Number	Office 732-244-0010 Mobile 732-575-3651