



## FIELD ACTION NOTICE

Date

Customer Name  
Customer Address  
City, State Zip

Dear Aribex Customer:

This letter is to inform you of a potential concern related to NOMAD handsets and is part of our ongoing commitment to deliver best-in-class products and customer support. Thank you for being a loyal Nomad customer. We value your business and appreciate you reading this field action letter to ensure that your Nomad is properly cleaned.

Aribex has recently learned that it is possible some owners and/or operators of the NOMAD Pro/Pro 2 Handheld X-ray System are still not following the manufacturer recommended cleaning and maintenance procedures and adhering to warnings for the NOMAD Pro/Pro 2 handsets. Improperly cleaning the device can lead to liquid ingress into the handset and cleaning agents coming in contact with the battery pack can displace some of the solder on the internal circuit board, thereby short-circuiting the internal board and the internal battery pack of the NOMAD Pro/Pro 2 handsets. The short circuit could cause the handset to malfunction and even cause the handset to overheat, smoke, and/or melt, rendering them unusable. There is also potential for surrounding material to be damaged if it is in contact with the handset at the time of the handset malfunction.

These failures should not occur when proper cleaning methods are followed by the operator. As a reminder, enclosed is the current Operator Manuals for the NOMAD Pro/Pro 2. Please refer to Section 2 to review warnings and proper cleaning of the NOMAD Pro/Pro 2 as outlined below:

- Warning: Do not spray disinfectant or cleaners directly on the NOMAD Pro/Pro 2, handsets, charging cradle or AC power supply. The connecting areas are open to ingress and damage to your device may result.
- Routinely use a non-acetone based disinfectant wipe (according to chemical manufacturer's recommendations) to disinfect the exterior surfaces of the NOMAD Pro/Pro 2 and the handset in between use on each patient.
- Leave the handset connected to the NOMAD Pro/Pro 2 and wipe down all surfaces of the device.
- Unplug the charging cradle before cleaning.
- NOMAD Pro/Pro 2, the handsets, the charging cradle, and the AC power supply are not designed to be subjected to any kind of sterilization procedure.

In addition, Aribex has enclosed a supplemental warning label to be adhered to the handset as an additional reminder of proper cleaning and disinfection techniques. Please use a non-acetone disinfectant wipe to clean the handset and do not spray liquid cleaners on the device. Peel the self-adhering backing from the enclosed label and press firmly to adhere to the handsets as depicted below:

Figure 1: “Do Not Spray” Sticker and NOMAD Handset

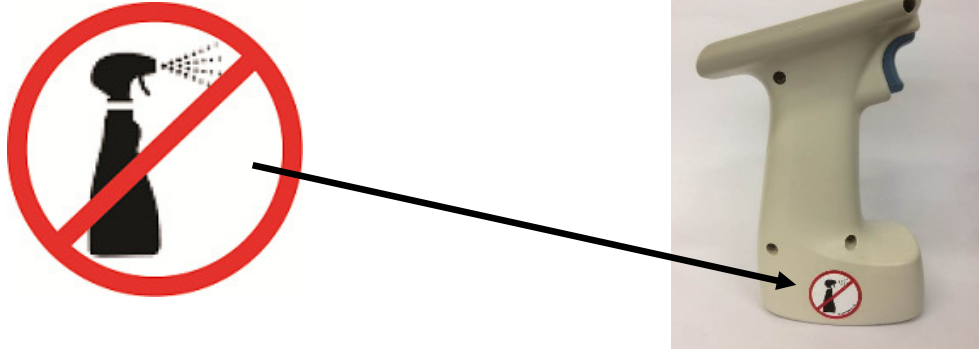


Figure 2: Handset showing signs of heavy cleaning fluid



As an Aribex customer, if you have concerns that your NOMAD Pro/Pro 2 has not been cleaned to manufacturer's instructions above, please contact Aribex Customer Care at 1-844-293-3620 or [nomadregulatory@aribex.com](mailto:nomadregulatory@aribex.com). Our Customer Care team will help determine your eligibility to receive a replacement handset at no charge. Replacement handset orders will be shipped out in order of receipt.

Please review and complete the attached Field Action Acknowledgement Form and mail the original attached Field Action Acknowledgement Form to Aribex in the enclosed self-addressed stamped envelope. You can also fax the form to Aribex, attention Erika Martin, at (704) 587-7250 or e-mail it to Erika Martin at [nomadregulatory@aribex.com](mailto:nomadregulatory@aribex.com).

Customer Actions Requested:

1. Place "Do Not Spray" stickers on your handsets.
2. Return completed Field Action Acknowledgement Form to Aribex.
3. If current handset(s) was not cleaned in a manner consistent with manufacturer's instructions, call Aribex Customer Care to determine your eligibility for a replacement handset(s) at no charge.

Contact Guide:

Inquire about a replacement(s) handset: 1-844-293-3620 or email [nomadregulatory@aribex.com](mailto:nomadregulatory@aribex.com).  
Questions regarding this letter: 1-844-293-3620.

Sincerely,

A handwritten signature in cursive script that reads "Erika Martin".

Erika Martin  
Sr. Regulatory Affairs Manager



Customer Name  
Customer Address

## **FIELD ACTION ACKNOWLEDGEMENT FORM**

### **Product Description Table**

<b>Model Number</b>	<b>Serial Number(s)</b>	<b>Device labeled? Yes / No</b>	<b>Replacement handset(s) ordered? Yes/No</b>

- ☐ ***We acknowledge receipt of the Aribex Field Action Notice letter (Check box). Please print your name, sign, and date this form indicating acknowledgement of the Aribex Field Action Notice then return this form to Aribex as instructed below.***
- ☐ ***We acknowledge receipt of the Aribex manuals and labels (Check box). Please print "Yes" or "No" in the "Device Labeled" column indicating if the label was attached to the handset.***

\_\_\_\_\_  
Contact Person (Please Print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Please return this form in the enclosed prepaid envelope to:

**Aribex**  
**11727 Fruehauf Drive**  
**Charlotte, NC 28273**  
**Attention: Erika Martin**

***You can also fax this form to Erika Martin at 704-587-7250 or e-mail to  
erika.martin@kavokerrgroup.com***