



# URGENT: MEDICAL DEVICE RECALL

June 4, 2010

This recall applies to all SonaMed Clarity devices.

Attention: Director of Maternal Child Health and Risk Manager

This communication follows up on a detailed notification Natus recently forwarded to you in late April. The purpose of this letter is to inform you of a **product recall** pertinent to all SonaMed Clarity devices. Natus is forwarding this letter to you because its records indicate that your user location has purchased one or more SonaMed Clarity Systems.

Natus' previous communications to you in writing in October 2008 and April 2010 regarded its concerns about whether the Clarity device could be lawfully used to comply with FDA-related requirements and other pertinent professional guidelines/standards for newborn infant hearing screening. In summary, such notices indicated that the above-referenced SonaMed devices:

1. have **not** been cleared by FDA as an "automated" screener;
2. **cannot** lawfully be used by anyone other than "audiologists or trained health care professional knowledgeable of audiometers and skilled in their use";
3. are **not** supported by any published or otherwise appropriately documented sensitivity and specificity rates for the detection of hearing impairment in newborns and, therefore, there exists no "clear scientific rationale" or "evidence" – as both FDA and the JCIH require – for even a professional to make the required choices pertinent to selecting parameters and establishing screening test criteria; and
4. do **not** and **cannot** conform to the JCIH recommendation that newborn hearing screening devices incorporate an automated statistical method for determining pass/refer rates.

Given these findings, Natus had no choice but to conclude that no adequate basis exists – even when the user manual is followed – for a reasonable and informed professional to make the choices called for above or to have any confidence in the automated screening information resulting from use of the Clarity system. Accordingly, Natus further concluded that the Clarity devices should no longer be used.

Given that the above-referenced SonaMed Clarity devices cannot perform as intended or as reasonably expected, Natus is undertaking a **voluntary recall** to stop and prevent further use of the devices. This will ensure that such devices will not result in a failure to identify – in a timely and adequate manner – newborn infants with hearing loss, or cause delay in necessary intervention, or cause possible injury.

Natus apologizes in advance for any inconvenience this recall may cause. Natus is committed to providing the highest quality products and services to our customers and their patients. Natus, the leader in newborn hearing screening, certainly recognizes the need for your facility to continue screening without interruption. For that reason, we are providing on loan at no-charge handheld screener(s) to facilities that do not have alternate screening devices. Please contact our Technical Service group at 800-272-8075 to discuss this loaner device option. Natus hopes our commitment to our customers and to universal hearing screening is clearly evident with the offer of this loaner device.

In order to successfully complete this recall, Natus needs your cooperation. Specifically, Natus requests that you:

1. stop using the SonaMed Clarity devices,
2. disable the screening function of your Clarity system(s) by returning to Natus, in the enclosed pre-addressed return envelope, either of the two below-referenced (and pictured) probes you may possess and have used in screening:
  1. TPI-830- 8-pin ear probe, or the
  2. TPI-815- 7-pin ear probe



TPI-815 7-pin ear probe

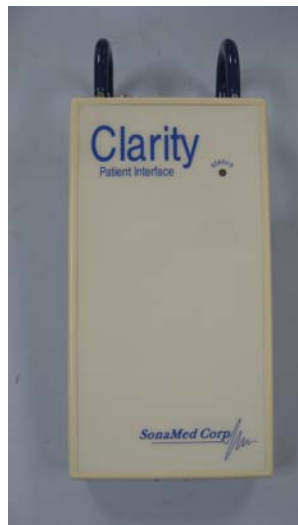
TPI-830 8-pin ear probe

Please be sure to return all 7- or 8-pin probes for **all** of your Clarity systems;  
and

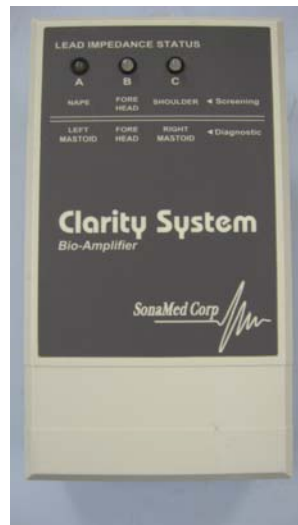
3. complete the attached “Device Recall Reply Form” and return it in the enclosed already addressed and stamped envelope.

Natus recognizes that local medical and other record retention and reporting requirements apply to all patient results that have been generated as of this date via screening use of the Clarity. Such requirements are, of course, still continuing. Thus, in order for you to retain access to these records, the Clarity PC should be retained along with the:

1. TPI-820- Patient Interface Module or PIM 2000, or the
2. TPI-800- Bio Amp



TPI-820 Patient Interface Module or PIM 2000



TPI-800- Bio Amp

Return of the 7- or 8- pin probes to Natus will not adversely affect the procedures to access your data on your device-related PC.

If you would like to archive the data which the Clarity device(s) produced in a non-proprietary format, such as PDF, please contact Natus Technical Support at 1-800-272-8075. Natus can provide you with an optional CD and instructions to enable you to transfer the above-referenced data for long term storage.

Remaining components of the Clarity device may be dispositioned per your facility procedures.

Please note that effective this date, Natus will no longer provide service, parts, supplies, or technical support for any screening use associated with the Clarity System. As noted above, Natus will continue to support the need to archive and retrieve information contained in the Clarity PC.

Again, Natus sincerely apologizes for any inconvenience this recall may cause your facility.

If you have any questions concerning any aspect of this recall notice, please call Natus Technical Support at 1-800-272-8075.

Thank you in advance for your timely attention to and cooperation in completing this recall.

Sincerely,

A handwritten signature in cursive script, appearing to read "Martha Kadas", with a horizontal line extending to the right.

Martha Kadas  
Director, Regulatory Affairs and Quality  
Assurance