



2016/05/20

Field Safety Notice (FSN) regarding Miris Human Milk Analyzer

Dear customer and user of Miris Human Milk Analyzer (HMA),

We are contacting you regarding an incident report filed to the Swedish Medical Products Agency. The incident concerned inaccurate programming of an HMA used for nutritional analysis of human milk. The error was found only at analysis on the instrument's calibration for unhomogenized milk, where the protein levels were overestimated.

Miris takes this incident very seriously. Without further investigation of each instrument we are unable to rule out that no other instruments are also affected by the error, which may lead to incorrect nutrition of preterm infants. **Therefore, Miris recommends users to stop using the HMA for fortification purposes in nutritional care of pre-term infants until the instrument has been controlled and validated by Miris staff.**

All models of the HMA with six buttons and containing application software version 2.10 or later are affected by a planned field safety corrective action.

Miris will, at no extra cost, visit users who are using the HMA in nutritional care of pre-term infants, for validation/control of their HMA in order to ensure safety and correctness of the instrument.

For those users who are using the HMA in research or for other purposes, Miris will offer guidance and support to validate and if needed correct the instrument.

If you have questions please contact Kristina Medin, +46 70 870 07 75, kristina.medin@miris.se or your local Miris distributor.

Please confirm by returning e-mail and without delay, that you have received this information. We kindly ask you to also specify how your instrument is used:

- fortification purposes in nutritional care of preterm infants
- research purposes
- other purposes (please describe)
- the instrument is unused

Please distribute this letter to all concerned personnel at your workplace and also to those in your network who may be affected. Miris will, with the highest priority, plan the visits together with the local distributor in your region and will let you know of any concrete plans as soon as possible.

Miris apologizes for any inconvenience, we are doing our utmost to handle the situation and to limit the effects on your work.

A handwritten signature in blue ink, appearing to read 'Kristina Medin', written over a horizontal dashed line.

Kristina Medin
Dir. Sales & Marketing
Miris AB

A handwritten signature in blue ink, appearing to read 'Elin Hallén', written over a horizontal dashed line.

Elin Hallén
Dir. QA/QC
Miris AB