



Control of the measuring function of the H₂-breath test device
LactoFAN2

Dear customer,

To ensure the measuring function of the LactoFAN2, we recommend a weekly quality control using control samples if patients are examined during the calendar week.

Control and calibration materials must not be identical.

You can order a corresponding test gas with 20 ppm H₂ from us under article number **HV-Lacto-TG**.

Procedure



Press the Settings key to display the settings screen.

If necessary, the PIN for accessing the settings will be requested.



Press the "Start Quality Control" button and follow the on-screen instructions.

For firmware versions earlier than 2.26, which do not yet have an integrated test routine, please proceed as follows:

1. Start a measurement.
2. Select a currently unused patient memory location.
3. Create a new table for measurements if necessary.
4. Confirm the selection.



...



5. If an error message is displayed, cancel the operation. Proceed as described on page 3 "If an error occurs".



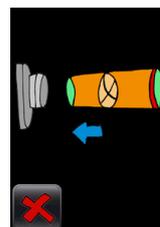
6. Select ' - - ' (no measuring protocol)



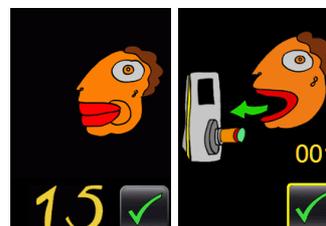
7. Now screw the regulator for calibration gas onto the test gas cylinder as you are used to during the calibration process.



8. Insert the reducer into the mouthpiece flange.



9. Wait until the air hold countdown is over.



10. Now open the outlet valve so far that the ball floats at least at the lowest mark.



11. Wait 20 seconds and close the outlet valve.



12. Confirm the end of the measuring process.



13. Wait until the LactoFAN2 has found the final measured value.

If the device displays the buttons to confirm or cancel, the control value has been found (large numbers).



14. Record the value according to your internal documentation requirements or use the quality assurance checklist in the appendix.

15. Quit the measurement.



16. Remove the reducing connector.

Evaluation

The value should be consistent with the information on the bottle label with an accuracy of $\pm 10\%$ or 2 ppm (whichever is the greater).

The tolerance indicated on the test gas label must be included.

Example for test gas 20ppm $\pm 5\%$ tolerance:

Acceptable reading= 20ppm ± 2 ppm Accuracy ± 1 ppm Test gas tolerance = 17...23ppm

If the control value exceeds this tolerance or an error message is displayed, the device should not be used for measurements of patient samples until the cause of the deviation has been determined and corrected.

If an error occurs

Proceed as described in the instructions for use on page 20.

If necessary, recalibrate the device.



You can download the current version of the instructions for use from

<https://fan-gmbh.de/en/portfolio/lactofan2/>.

If you have further questions do not hesitate to contact as usual by phone at +49 (0) 341-244500 or by e-mail at fan@fan gmbh.de.

Best regards,
Your FAN team.