



NSpiro



USB-Spirometer

Instructions for Use of NSpiro Calibration

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|----------|------------|
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1. Calibration – General Informations

Norav Medical GmbH in accordance with the ATS and ERS recommends that a calibration of a Spirometry device is performed daily using a calibrated 3L syringe. Alternatively it is possible to use a calibrated 1L or 2L syringe.

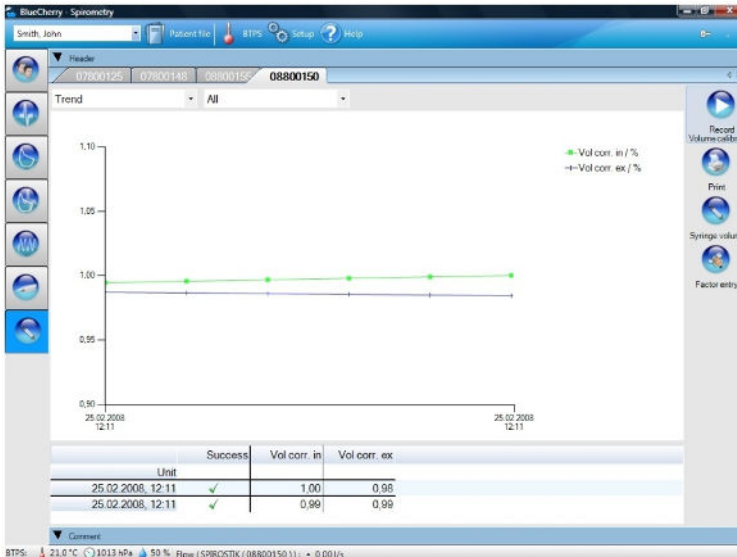


Always ensure any calibration syringe is checked and re-calibrated regularly in order to ensure accurate system calibration.

The flow sensors manufactured by Norav Medical GmbH are pre calibrated and very precise. Therefore it should not be necessary to calibrate after replacing the flow sensor.

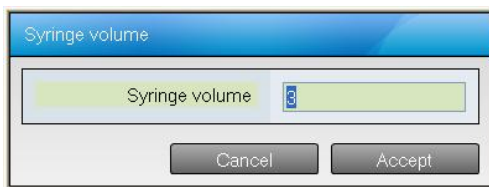
1.1 The Calibration Window

Selecting the **“Calibration”** button in the left selection area, the following calibration window will appear:



The User can choose between **“Volume Calibration”** and **“Flow linearity”**. In the Volume calibration the measured volume is checked and corrected by using the exact known volume of the hand pump. In contrast during the flow linearity, the linearity of the flow sensor is checked at different flow rates.

Please ensure that the set pump volume and the volume of the used hand pump are the same. For that click the **“Syringe volume”** button of the right selection area.



As an alternative it is possible to set the system for the used flow sensor by entering of character string. For that click the „**Input factors**“ of the right selection area.



Enter flow calibration factors

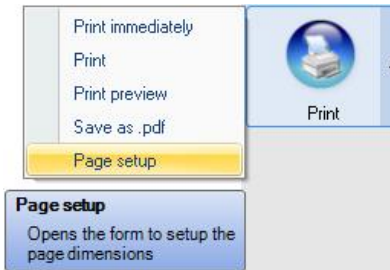
Factors (yellow stickers) K K

Cancel Accept

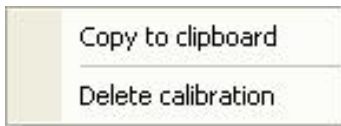
The calibration code for each sensor is printed on the package (right picture) or on the sensor (left picture), as illustrated. The reading must be from left to right.



Using the **“Print”** button of the right selection area can print the performed calibrations.



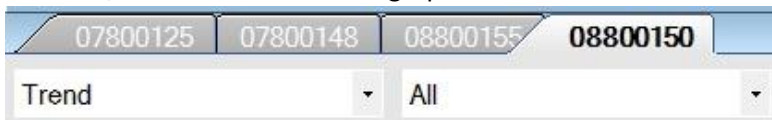
Using the right mouse button in the graph area can open a popup-menu with additional useful functions.



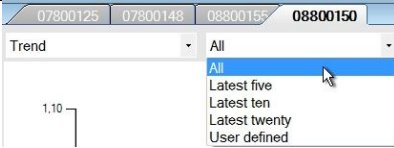


“Copy to clipboard” means copying the graphs in a cache within Microsoft Windows. This content can then be made available to other programs using the copy/paste function.

By clicking the “Delete calibration” window another window will be displayed where the user has to select the calibration he wants to delete.

Additional buttons and pull-down menus, which offer the following functions, are located above the graph area:

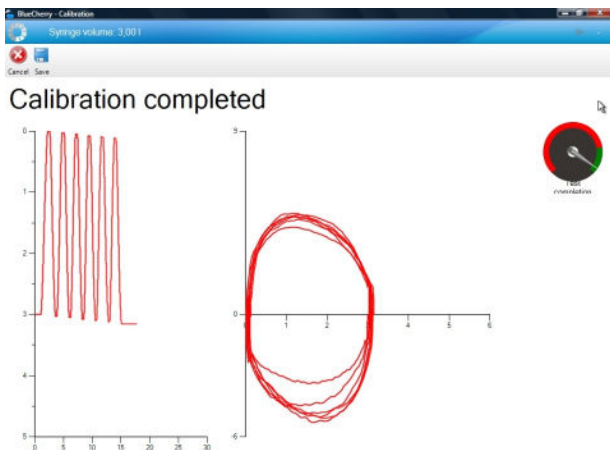


| Button | Meaning |
|---|--|
|  | Serial no of NSpiro. For each unit calibrated a new tab will be shown. |
|  | Select between trend graph and single calibration graph. |
|  | Select which calibrations will be shown in the graph area. |



Before starting the calibration procedures ensure that the flow sensor is securely connected to the calibration syringe, and the syringe piston is pushed completely in to its stop point.

1.2 Volume Calibration

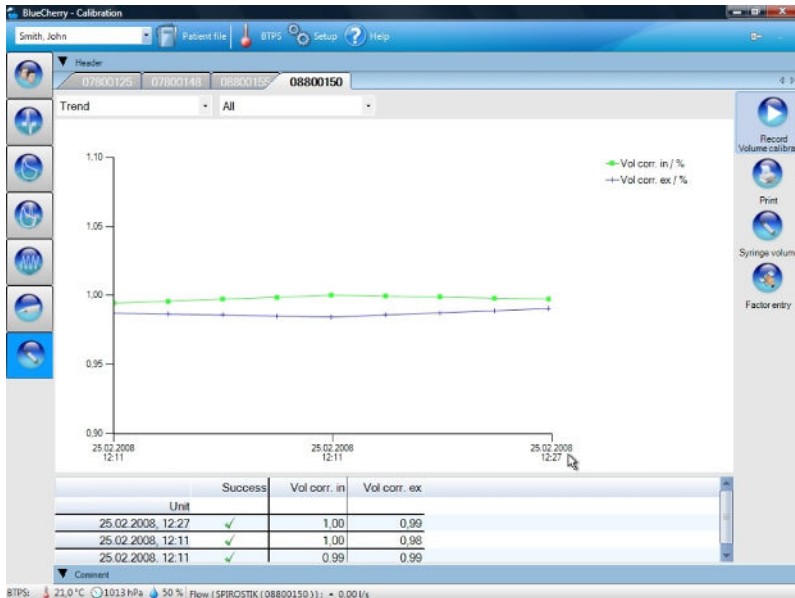
Clicking the **“Record”** button in the right hand selection area will start the volume calibration. Pump the syringe piston regularly in order to calibrate the device. Always ensure the piston is pushed and pulled completely to its stop to ensure constant pump volume.



During the calibration procedure the following icons are available.

| Button | Meaning |
|---|--|
|  | Cancel calibration. All data will be lost. |
|  | Stop and save calibration. |

When calibration is completed and saved, the user will be returned to a trend graph of the recent calibrations.



NSpiro checks automatically if a calibration is valid. Valid calibrations will be shown with a green tick in the column **“Success”**. Invalid calibrations will show a red cross.

A valid calibration must fulfil the following quality criteria:

- Vol corr. In and Vol corr. Ex between 0,90 and 1,10
- Difference between Vol corr. In and Vol corr. Ex less than 3%



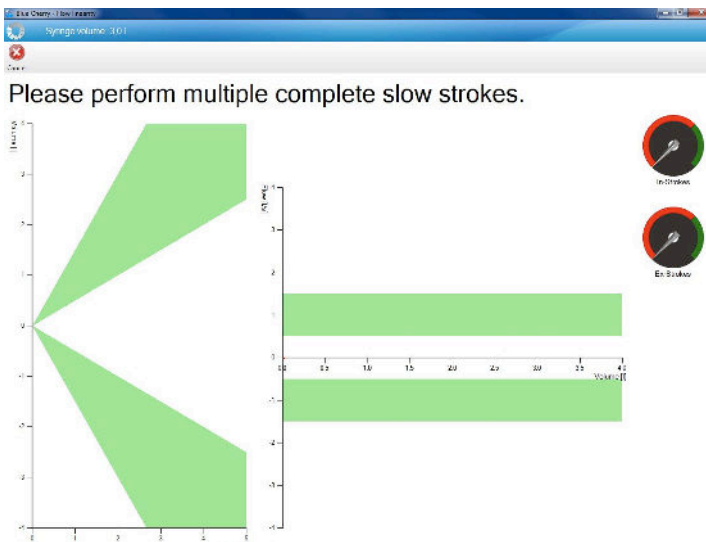
A Flow sensor that shows invalid calibration must be replaced. The last valid calibration will always be used for the measurements.

1.3 Flow Validation



In accordance with ATS and ERS recommendations, Norav Medical GmbH recommends a weekly validation check of the spirometry system using a calibrated 3L syringe.



The linearity check starts after selecting the **“Record”** button from the right section area. The following window will appear:



The software will check flow linearity in 3 different flow ranges.

| Range | Flow in [L/s] |
|--------|---------------|
| Low | 0,5 – 1 |
| Medium | 2 – 4 |
| High | 5 – 7 |

During validation check procedure the following icons will be shown:

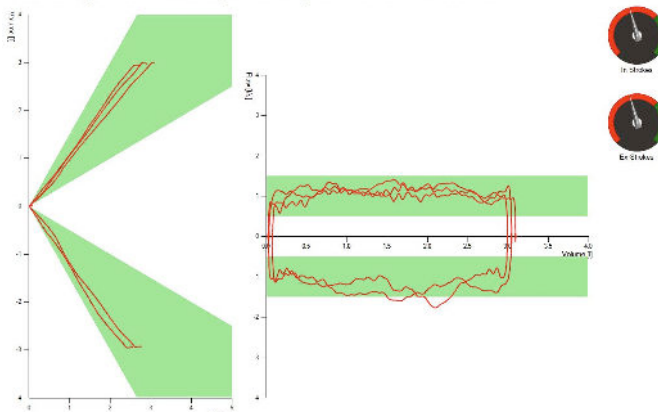
| Button | Meaning |
|---|--|
|  | Cancel linearity check. All data will be lost. |
|  | Stop and save calibration check |

1.3.1 Flow validation at low flows

Begin now to pump evenly and slowly. A pump stroke should last approximately 6 seconds. Always ensure that the pump stroke is complete by moving the syringe completely to its stop point this will ensure a constant pump volume is used. The calibration curves should lie within the marked green ranges if not adapt pump speed accordingly.



Please perform multiple complete slow strokes.



As soon as sufficient pump strokes lie within the given range the software will automatically move to the next stage.

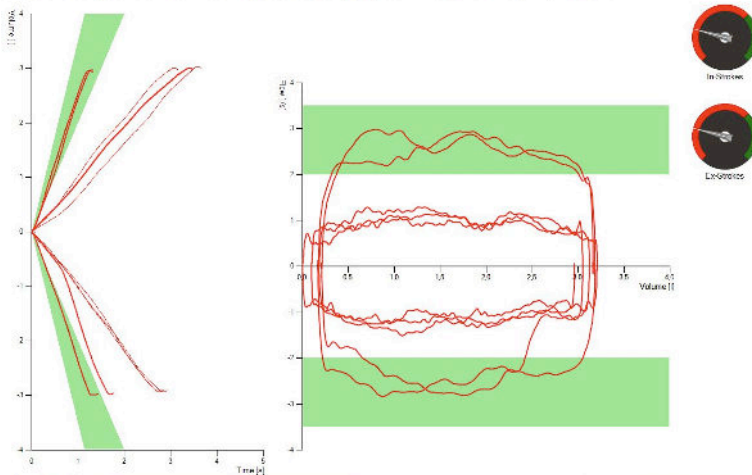
1.3.2 Flow validation at medium flows

When the stage changes begin to pump evenly at a medium speed. A pump stroke should last approximately 1 second. Always ensure that the pump stroke is complete by moving the syringe completely to its stop point this will ensure a constant pump volume is used.

The calibration curves should lie within the marked green ranges if not adapt pump speed accordingly.



Please perform multiple complete medium strokes.



As soon as sufficient pump strokes lie within the given range the software will automatically move to the next stage.

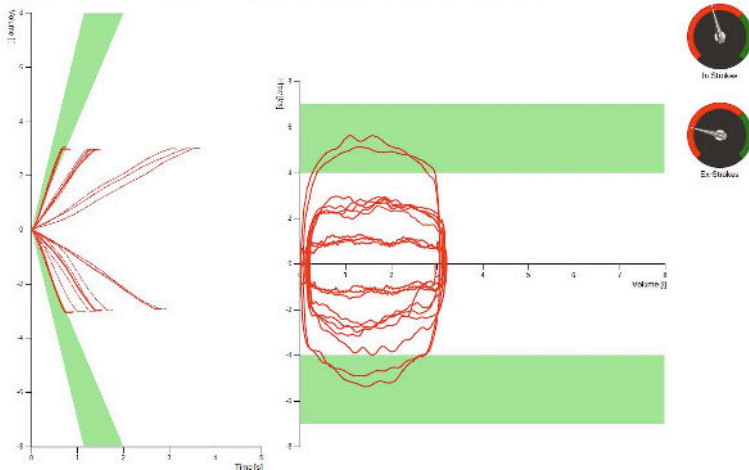
1.3.3 Flow validation at high flows

Finally when the stage changes again begin to pump evenly at a fast speed. A pump stroke should last approximately 0.5 seconds. Always ensure that the pump stroke is complete by moving the syringe completely to its stop point this will ensure a constant pump volume is used.

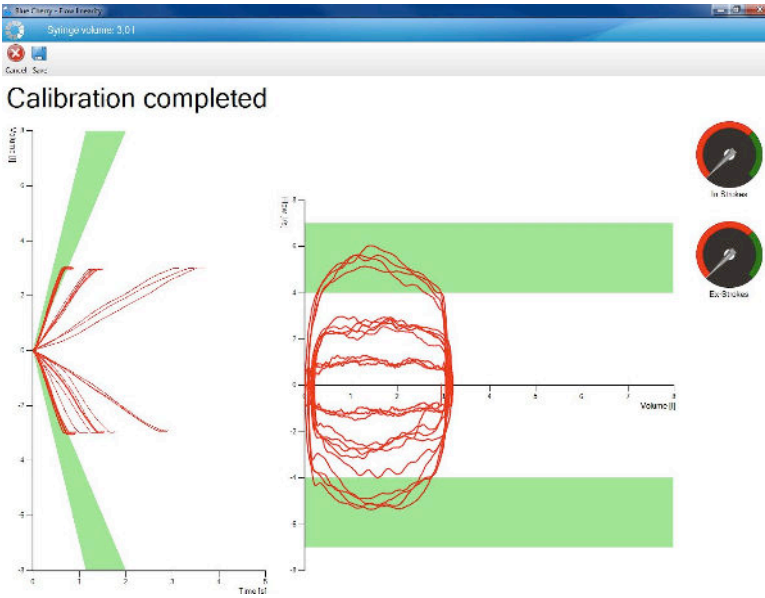
The calibration curves should lie within the marked green ranges if not adapt pump speed accordingly.



Please perform multiple complete fast strokes.

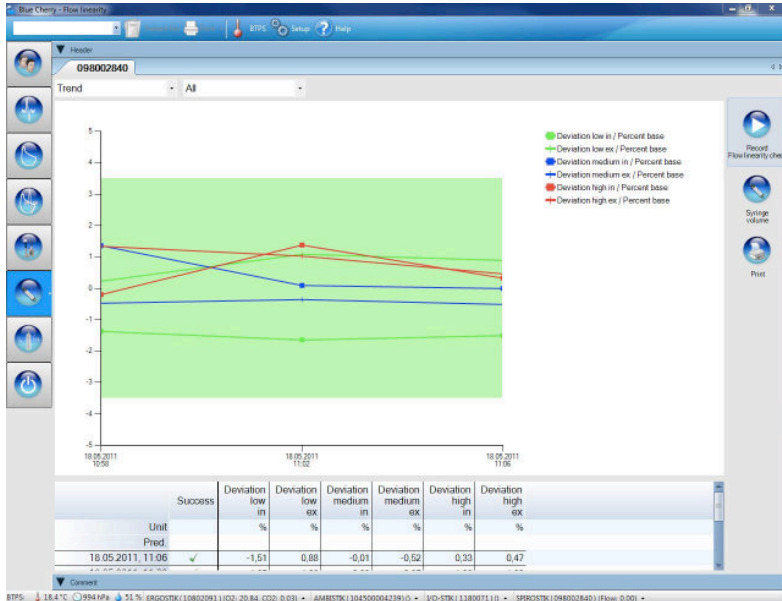


As soon as sufficient Pump strokes lie within the given range the program will display the following screen, click **“Save”** to record the values and end the flow validation.



1.3.4 After the flow validation

Once the validation check procedure is complete, NSpiro will show a trend of all the validation checks that have been performed.



Selecting the **“Trend”** drop down menu allows the view to be changed from the trend graph to the individual validation manoeuvres.

The program for the linearity checks determines automatically the linearity deviation. NSpiro applies the ATS/ERS criteria to the linearity validation which says any error must not exceed $\pm 3.5\%$ this range is shown by the coloured section in the graph. Valid linearity checks will show a green tick in the successful column, Invalid tests show a red cross.