



## N<sub>2</sub>MBW SOP: Spiroware 3.3.2 Supplement

Fundamental device operation and test procedure remain unchanged, however, sections of MBWN<sub>2</sub> SOP v1.1 relevant to study specific activity have been updated to reflect updated software.

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**This document is intended as a study specific supplement to, and should be used in combination with, the MBWN<sub>2</sub> Standard Operating Procedure Version 1.1, Nov 11, 2013.**

**January 27, 2023  
Version 1**

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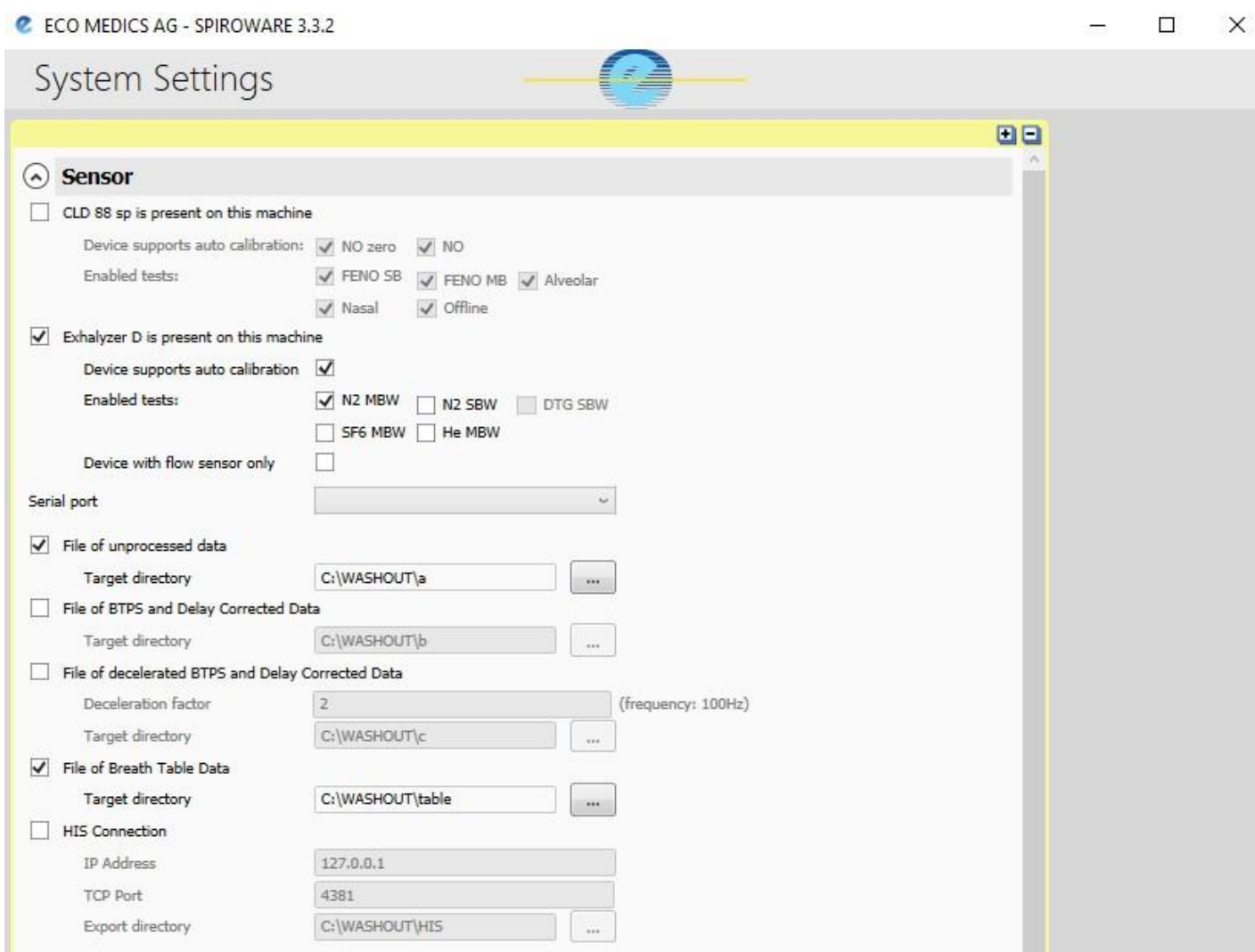
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## 1 Verify Software Settings

Corresponds to: **Sections 2.4.2.1, 2.4.2.2 and Section 5.2.1** of MBWN2 SOP v1.1, 11Nov2013

### 1.1 Confirm A-file Mapping (MBWN2 SOP section 2.4.2.1)

- It is critical that 'File of unprocessed data' is checked, and the target directory folder is correct and exists, to ensure that raw data (A-files) are saved.
- If A-files are not saved, data CANNOT be re-run to fix incorrect dead space values or signal misalignment.



## 1.2 Confirm Equipment Dead Space Volumes (MBWN2 SOP section 2.4.2.2)

- Volumes measured during MBW (tidal volume and FRC) are corrected for the technical (or equipment) dead space volume. Technical dead space volume has been divided geometrically into pre and post gas sampling-point volumes (See Figures 1 and 2).

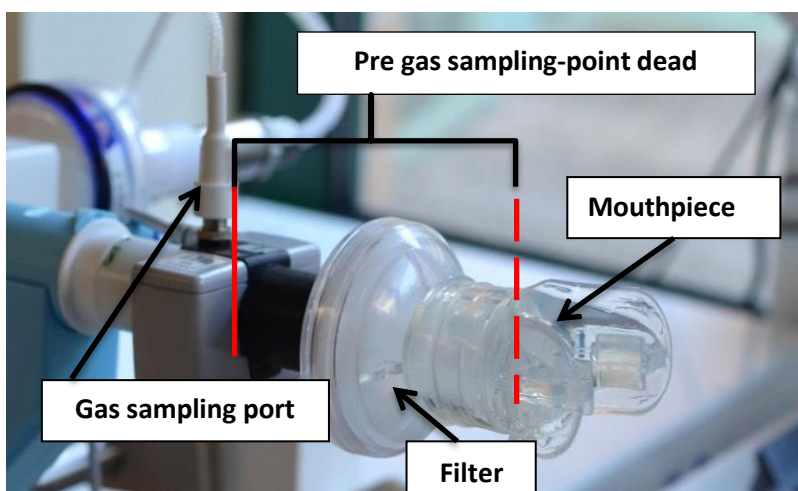


Figure 1. Pre Gas Sampling-point Dead Space

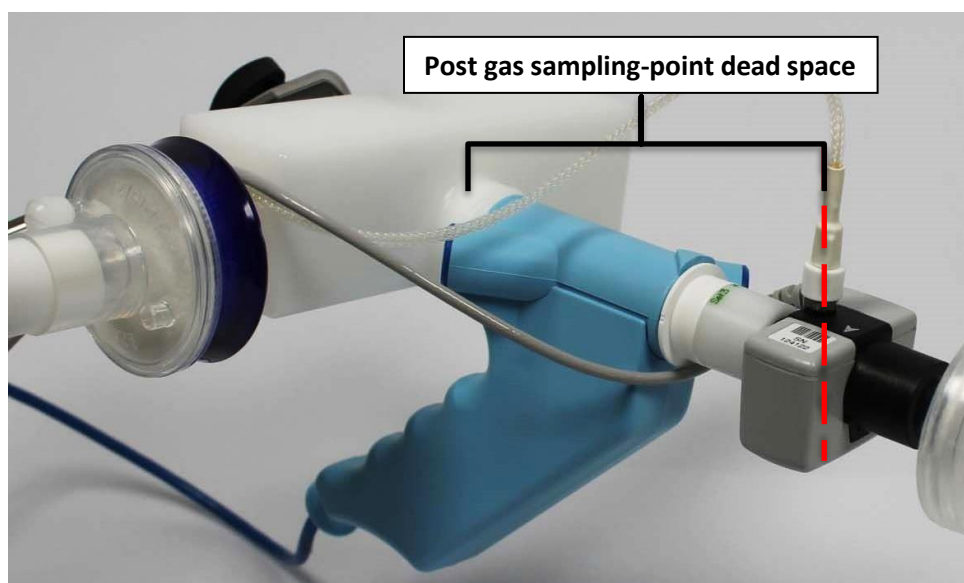


Figure 2. Post Gas Sampling-point Dead Space

- It is VERY important to check that the equipment dead space volumes are entered as specified in the **STUDY PROTOCOL** as these values will influence signal alignment during synchronization and directly affect the results (FRC, LCI, etc.) calculated by the online software.

# Standard Operating Procedure: Multiple Breath Nitrogen Washout 2022

- To verify dead space volume settings, navigate to the **System Settings** page found in the **Administration** menu. Pre and post gas sampling-point dead space volumes for each DSR set can be found under the **Calibration tab** on the system settings page.

**DSR set Settings:**

Type	Min. Calib. Flow Range [ml/s]	Max. Calib. Flow Range [ml/s]	Calib. Syringe volume [ml]	Vol. Detection Sens.	Pre-Cap. Deadspace [ml]	Post-Cap. Deadspace [ml]
Set 1	90	110	100	2	2	3.5
Set 2	450	550	100	15	33.3	9.5
Set 3	900	1100	1000	25	33.3	22
Spirette	4000	5000	3000	50	25	25

Figure 3. Default Dead Space Volumes

## 1.3 Environmental Settings (MBWN2 SOP section 2.4.2.2)

**Gas concentrations are reported as dry. BTPS corrections will take water vapor pressure and relevant temperature into account when reporting respiratory flows, volumes, and gas volumes.**

- Navigate to the **Environmental Settings** page from the main **Administration** menu. Internal instrument readings of temperature and pressure are displayed under the heading **Environment Measurements**.

The screenshot shows the 'Environment Settings' window with the following sections:

- Environment Measurements:**
  - Room temperature [°C]: 24
  - Rel. Humidity [%]: 21.3
  - Atmospheric pressure [hPa]:
    - Input absolute [hPa]: 999.9
    - Input external reference:
      - Reference location: Zürich Airport
      - Reference altitude (above sea-level) [m]: 432
      - Reference atmospheric pressure [hPa]: 985
      - Reference ambient temperature [°C]: 10
      - Laboratory location: Dürnten
      - Laboratory altitude (above sea-level) [m]: 511
      - Calculated atmospheric pressure at laboratory location [hPa]: 975.647
      - Calculated ambient temperature at laboratory location [°C]: 9.487
      - Calculated atmospheric pressure at sea-level [hPa]: 1037.439
- Manual BTPS Correction Parameters:**
  - BTPS correction active
  - Rel. Humidity for online values [%]: 0
  - Temperature at Flowhead [°C]: 30
  - Rel. Humidity at Flowhead [%]: 60
  - Body Temperature [°C]: 37
  - Body Humidity [%]: 100
  - Rel. Humidity at Inlet [%]: 0
  - Other tests:**
    - Rel. Humidity [%]: 0
  - FVC Test:**
    - Temperature [°C]: 36
    - Rel. Humidity [%]: 95
    - Body Temperature [°C]: 37
    - Body Humidity [%]: 100
    - Rel. Humidity [%]: 21.3

Buttons: Calibrate, Update Measurements, Reset, Reset to Defaults, Save, Cancel.

Footer: Operator: admin (First Last) | Sensor: Patient simulator active | DSR set: Unknown

Figure 4. Environment Settings Menu

- Verify that the internal measurements are within acceptable limits. The temperature reading should be within +/- 0.5°C and the pressure within +/- 5 hPa of ambient conditions as measured by high precision reference thermometer and barometer.

- Each lab should have a high precision thermometer, barometer, and hygrometer in the same room as test equipment to be used as reference for internal instrument readings.
- Ambient **Temperature, Pressure** and **Humidity** should be recorded on each day of testing in a calibration log.

\*Note: ambient conditions at time of test are also stored as part of raw data files (A-files).

- If instrument readings are outside limits calibration of system temperature and pressure is required (see section 1.4 Calibration of Ambient Temperature and Pressure).

## 1.4 Calibration of Ambient Temperature and Pressure in Spioware

- Enter temperature (°C) in **room temperature** field; **confirm** by pressing “**calibrate**”, WAIT until system responds.
- Ensure **Input absolute [hPa]** is selected
- Enter pressure (hPa) in **atmospheric pressure** field; **confirm** by pressing “**calibrate**”, WAIT until system responds.
- Select **save** to save new values.
- 

## 1.5 Automatic Start/Stop and Orientation of Flow (MBWN2 SOP section 5.2.1)

- Navigate to the **System Settings** page found in the **Administration** menu. Under the **Multiple Breath Washin/out Tests** tab confirm inspiratory flow is set to positive, leaving this option un-checked reverses the orientation of the flow and volume tracing on the test screen.

**Multiple Breath Washin/out Tests**

Show inspiration flow positive

Start tidal mean limits [% of insp. vol.]	Min: <input type="text" value="70"/>	Max: <input type="text" value="90"/>
End tidal mean limits [% of exp. vol.]	Min: <input type="text" value="90"/>	Max: <input type="text" value="95"/>
SnIII slope limits [% of exp. vol.]		
Set 1	Min: <input type="text" value="70"/>	Max: <input type="text" value="95"/>
Set 2	Min: <input type="text" value="65"/>	Max: <input type="text" value="95"/>
Set 3	Min: <input type="text" value="50"/>	Max: <input type="text" value="95"/>
<input type="checkbox"/> Automatic breath acceptance criteria (SnIII) [± % VT median]		
Set 1	<input type="text" value="25"/>	
Set 2	<input type="text" value="25"/>	
Set 3	<input type="text" value="25"/>	

Figure 5. System Settings; Flow Positive

- Under the **N2 Multiple Breath Washout Test** tab, ensure Automatic start and stop of test are disabled (unchecked).

**N2 Multiple Breath Washout Test**

- Show Patient Feedback Screen
- Min. end expiration O2 concentration [%]: 20.5
- Min. number of pre-phase breaths required: 5
- Number of pre-phase breaths for mean calculation: 3
- Number of test-phase breaths under target: 5
- Valid Flow range [ml/s]: Min: -1000, Max: 1000
- Valid N2 Insp. range [%]: Min: -0.3, Max: 0.3
- Automatic start of test  
Start expiration O2 threshold [%]: 17
- Automatic stop of test
- Automatic start of washout (AND criteria)
  - when Std.Dev. VT Insp. valid:
  - when Std.Dev. VT Exp. valid:
  - when Std.Dev. Cet CO2 valid:
  - when Std.Dev. RQ valid:

Figure 6. System Settings; Auto Start/Stop Settings