Training Guide: Multiple Breath Nitrogen Washout

For the Exhalyzer® D, ECO MEDICS AG

Spiroware Software Version 3.1.6

This is an abbreviated summary of the Multiple Breath Washout Standard Operating Procedure, intended to facilitate virtual training. Disclaimer: please refer to the complete document titled “Standard Operating Procedure: Multiple Breath Nitrogen Washout” for details.

2020-06-26

Version 1.0
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1. **DAILY SYSTEM SETUP CHECK LIST:**

   Please refer to Section 2 of the MBWN₂ SOP for additional details

1. **Turn ON Exhalyzer® D**
   - ✓ Wait at least 5 minutes before beginning calibration

2. **Check System Settings** *(MBWN₂ SOP 2.4.2)*
   - ✓ Check A-Files are being saved to an existing folder
   - ✓ Automatic start of test/washout and stop of test is unchecked
   - ✓ Pre and post cap dead space settings are entered correctly

3. **Environmental Calibration**
   - ✓ Accurate room temperature and pressure is entered
   - ✓ Manual ATPS to BTPS correction factor is unchecked

4. **Perform Flow Calibration – DSR Set 3** *(MBWN₂ SOP 2.4.3.1)*

5. **Perform Gas/Channel Calibration** *(MBWN₂ SOP 2.4.3.2)*

6. **Setup for testing** *(MBWN₂ SOP 3.3)*
   - ✓ DSR to be used for testing is dependent on the subject's weight:
     - ✓ If child is > 35 kg ⇒ System is calibrated, begin testing on DSR Set 3
     - ✓ If child is ≤ 35 kg ⇒ Go to Step 7

7. **Perform Flow Calibration – DSR Set 2** *(MBWN₂ SOP 2.4.3.1.2)*
   - ✓ Must perform flow calibration for DSR Set 2, after completing steps 1-5

8. **Begin Testing** on DSR Set 2 for subjects ≤35kg.
2. **STANDARD SYSTEM SETTINGS**

“System Settings” are accessed through the Administration menu of Spiroware. **Please check the following system settings are correctly entered** at the initial setup of your MBW device. **Note:** These settings may change between user accounts. Always double check these settings before testing.

1) Ensure “File of unprocessed data” is **checked** and mapped to an **existing folder.** This is where RAW DATA will be saved in the form of A-files. If A-files are not saved, errors in settings cannot be corrected and lost data cannot be recovered.

2) Under the heading “N2 Multiple Breath Washout Test”
   - The automatic start of test/washout and stop of test should be **unchecked**
   - Ensure “show inspiration flow positive” is **checked**

3) Under the heading “Calibration”, ensure the post-cap dead space values corresponding to the dead space reducer Set # (set 2 or set 3) are correctly entered PRIOR to calibration. **Pre-cap dead space values are study specific and will correspond with the study specific equipment being used.**

![Sensor Settings](image)
3. **ENVIRONMENTAL CALIBRATION**

“Environmental Settings” are accessed through the Administration menu of Spiroware. Environmental calibrations should be performed daily prior to any testing performed, this involves checking:

- Accurate room temperature and pressure are entered – **Double check your units**
- Manual ATPS to BTPS correction factor is unchecked

**Note:** Ensure the system has warmed up prior to calibrating temperature & pressure values (at least 5 min).

These values should be entered daily.

These values are default and should not be adjusted.

Correction factors will be determined based on BTPS calculations which consider default system settings and daily conditions.

This should remain **unselected**. This would only be selected if the operator is manually deriving BTPS correction factors and over-riding the systems calculated factors.

*Please refer to section 2.4.2 of the MBWN₂ SOP for more details*
4. Flow Calibration: Setup DSR Set 2 and 3

Set 2 or 3 DSR with Spirette

Capnostat Cuvette

Study Specific Filter

Set 3 DSR: > 35 kg (green)
Set 2 DSR: 15 to 35 kg (blue)

DSR to be used for testing is dependent on the subject’s weight:

- Is your capnostat cuvette cold?
- Are all fans or sources of air flow turned off?
- Is your equipment correctly aligned?
- Are you starting with your syringe fully compressed?
An Acceptable Calibration should have:

1) Peak flows in the shaded target areas for all strokes
2) Minimal volume drift
3) Inspiratory and expiratory deviation both less than +/- 2%
4) If the Calibration is acceptable press Save to store the new calibration parameters

CALIBRATION TIP
If your calibration is unsuccessful perform the following troubleshooting steps:

- Check your equipment setup: Re-assemble all equipment, ensure alignment is correct, no leaks
- Check your environmental settings: Temperature drift may result in volume drift
- Check your technique: Confirm that flow calibration was well done (Smooth transition across zero flow, within green zone)
- Check your equipment: Consider replacing your calibration filter or spirette
- Check your numbers, Save: Repeat flow calibration to confirm that new flow calibration values are repeatable (+/- 2% Insp/Exp Deviation)

*Refer to section 2.6.1 Flow Calibration Troubleshooting in the MBWN2 SOP*
5. **Gas/Channel Calibration: Setup DSR Set 3**

- **Plug is IN to divert bias flow past gas analysers.**
- **Nafion tube connected tightly.**
- **NO filter or mouthpiece.**
- **Capnostat warmer and analyser attached to capnostat cuvette.**
- **Bias flow connected to bias flow block.**
- **Ultrasonic flowmeter, Spirette and DSR Set 3.**

---

**Gas Channel Calibration – DSR Set 3**

*View from above.*
5.1 Gas/Channel Calibration: When to Save

Confirm the following prior to saving calibration:

- Flow Calibration with DSR Set 3 has been performed
- Ensure that DSR Set 3 is inserted correctly into the flowhead
- Ensure that the capnostat warmer/sensor (grey) is attached
- Ensure capnostat cuvette (black) is warm to touch
- Ensure Nafion tubing is tightly attached to capnostat cuvette

Two Point Oxygen Calibration

High: 100% O₂
Low: 20.94% O₂

Ensure that the flow reading is at least 950 mL/s

O₂ (low) calibration should be less than +/- 0.5%
O₂ (high) calibration should be less than +/- 0.5%

Once the Gas/Channel calibration is successful, press Save to retain the new calibration factors

*If the channel/gas calibration is unsuccessful please refer to section 2.6.2 Gas Calibration Troubleshooting in the MBWN₂ SOP.
+6 years Testing – DSR Set 2 or 3
Air Safety Slimline Paediatric Filter

| Gas Delivery Line & Large Particle Filter |
| Set 2 or 3 DSR with Spirette |
| Nafion Tube connected |
| Noseclips |
| Bias Flow Block |
| Ultrasonic Flow Meter |
| Capnostat Cuvette and warmer/analyzer |
| Study Specific Filter |
| Silicone Mouthpiece |

Dead Space Settings for this Setup
- Pre-cap dead space volume: 33.3 mL
- Post-cap dead space volume:
  - Set 2: 9.5 mL
  - Set 3: 22 mL
<table>
<thead>
<tr>
<th>Trial#</th>
<th>Baseline O2</th>
<th>Baseline N2</th>
<th>Last Breath #</th>
<th>FRC</th>
<th>Rejected If:</th>
<th>Questionable If:</th>
<th>Accepted If:</th>
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<td>Leaked Detected</td>
<td>Sigh Detected</td>
<td>Stable VT and EELV?</td>
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<td>Less than 3 breaths under target?</td>
<td>Trapped Gas</td>
<td>Stable/Relaxed Flow?</td>
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<td>Breathing pattern unstable</td>
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<td>[O2] and [N2] Return to Baseline</td>
<td>Stopped</td>
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<td>Trial#</td>
<td>Baseline O2________ Baseline N2________</td>
<td>Stopped ○</td>
<td>Rejected If: Leak Detected Less than 3 breaths under target? ○</td>
<td>Sigh Detected ○ Trapped Gas ○ Cough? ○ Questionable first breath ○ Breathing pattern unstable</td>
<td>Questionable If:</td>
<td>Accepted If: Stable VT and EELV? ○ Stable/Relaxed Flow? ○ Report ○</td>
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Remember:
- [CO2] should be stable (4-8%)
- Pre-phase VT should be stable for 3 breaths before the washout begins. VT should remain appropriate for patient throughout the test
- A normal respiratory rate, stable flow and a stable end expiratory lung volume should be maintained

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MBW TESTING CHECKLIST

✔ Are your ‘A’ files being saved?
✔ Are the equipment dead space volume settings correct?
✔ Is the file correctly named according to specific study protocol?
✔ Are you using the correct interface and DSR?
✔ Is the starting N₂ concentration >77% in the first trial, and has it returned to baseline in subsequent trials?
✔ Are there at least 5 stable, relaxed and appropriately-sized breaths prior to the start of the washout?
✔ Is the breathing pattern stable and relaxed throughout washout?
✔ Is CO₂ stable? 4-6% and not steadily changing.
✔ Is there any evidence of leaks?
✔ Are there at least 5 stable, relaxed and appropriately-sized breaths below the end test target N₂ concentration?
✔ Are there any error messages?
✔ Are you confident you have at least 3 acceptable trials?

IF IN DOUBT, COLLECT ANOTHER

Questions? Email us at mbw.centre@sickkids.ca
7. FILE MANAGEMENT

7.1 CREATING A SUBJECT FILE

1. Navigate to “Select a Patient” menu. This screen appears automatically once operator logs onto Spiroware software and can be accessed from the Administration menu by selecting the Back button.

2. Create a file for a new patient by selecting “Register New Patient”.

3. Enter subject demographics as appropriate. **Note:** Ensure height and weight entered are measured on day of testing.

4. Enter the “Patient ID”, “Last name” and “First name” EXACTLY as specified in the study specific protocol. **It is essential that no additional punctuation or spaces are entered into these fields.**

7.2 FILE NAMING FORMATS

Patient ID file naming format is study specific. Correctly adhering to the study specific file format is essential.

Typical File Naming format:

```
VVV_WWW XXX Y
Study_Institution_Subject_TestOccasion
```

It is essential that no extra characters are added to a Patient ID, as the format will no longer correspond to the intended **position** within the full ID.
7.3 Saving and Submitting MBW Data

Once a MBW trial is complete, it is important to correctly save and submit your .spx file.

1. Select “Save as Draft”.

![Image of Save as Draft button]

2. Export the newly created draft file by selecting “Export Patient” and select your file destination.

![Image of Export Patient button]

3. After the .spx file has been saved to your desired location, proceed with the appropriate study specific file submission process.
8. TROUBLESHOOTING TIPS

8.1 SIGNAL MISALIGNMENT AND CORRECTION

8.1.1 Identifying Signal Misalignment

Signal misalignment can occur for a number of reasons:

- Signal delay values are incorrect, new signal delay values must be established
- Bent, kinked or manipulated Nafion tubes at the time of test
- Individual breathing pattern can vary slightly between patients, resulting in slight misalignment

Signal Misaligned

At the time of test, it is important to identify signal misalignment when it occurs. Ensure that the Nafion tube is not being physically manipulated in a way that might cause signal misalignment.

If you observe severe signal misalignment:
- Pause your study visit
- Establish appropriate synchronization values for your subject
  - Resume testing - Collect 3 technically acceptable trials

If you observe minor signal misalignment:
- Complete your study visit
- Collect extra breaths under the target value (at least 5 breaths)
- Re-run data after establishing appropriate synchronization values

Signal misalignment is possible when the Nitrogen tracing has signal peaks despite the lack of corresponding peaks in the Oxygen tracing, or Carbon Dioxide tracing.
8.1.2 Flow/Gas Signal Synchronization

To ensure accurate calculation of results, gas and flow signals must be aligned in time.

Important Notes:

- Initial flow to gas offset values (delay times) should be saved at system installation
- Flow/gas signal synchronization should be subsequently checked weekly
- It is recommended that synchronizations be done on a day where no testing is scheduled
- Flow and Channel Calibrations MUST be performed prior to signal synchronizations
- Synchronizations are DSR Set # specific

SIGNAL SYNCHRONIZATION: WEEKLY SYNCRONIZATION CHECK

1. Navigate to the Administration menu and select System Settings.
2. Confirm the correct Post-Cap dead space volumes are listed under Insert Settings, for each DSR Set.
3. Confirm the number of washout breaths for synchronization is set to 10.

4. Navigate to the Administration menu and select Flow/Channel Synchronization.
5. Wearing nose clips, place mouthpiece and begin tidal breathing through the system, press **Start**.
6. Once your breathing pattern has stabilized with peaks in the green band, press **Open Valve**.
7. **Routine Synchronization Check**
   - With the appropriate equipment, dead space settings, and breathing pattern, new synchronization values should be within +/- 0.010 s of current values.
   - If values are outside +/- 0.010 s limit check equipment setup, confirm correct settings and breathing pattern before saving any flow to gas offset values (delay times).

**Note:** Signal delay values that work for a majority of subjects may not be correct for subjects with varying flow patterns. It is important to establish delay values that work for the majority, and re-run outliers as needed.

Instructions on Signal Misalignment and General Re-running instructions can be found here: [http://lab.research.sickkids.ca/ratjen/mbw-centre/#1476992209687-c1cb9a30-1722](http://lab.research.sickkids.ca/ratjen/mbw-centre/#1476992209687-c1cb9a30-1722)
9. MBW Testing Setup for Subjects <6 Years (DSR Set 2)

Preschool Testing – DSR Set 2

Air Safety Slimline Paediatric Filter

Dead Space Settings for this Setup
- Pre-cap dead space volume: 33.3 mL
- Post-cap dead space volume (Set 2): 9.5 mL

T-Piece
Set 2 DSR with Spirotrac

Delivery Line & Large Particle Filter

Ultrasonic Flow Meter

Capnostat Cuvette and warmer/analyser

Study Specific Filter

Nafion Tube Connected

Paediatric Mask

Putty

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