Standard Operating Procedure:

Multiple Breath Nitrogen Washout

Exhalyzer D ® (Eco Medics AG, Duernten, Switzerland)

Instructions for Re-running Data for incorrect settings or file management

Australian CORC

The University of Queensland

CF Clinical Research Team

The Hospital for Sick Children

Toronto

May 31, 2016

Contents

1. Why does my data need to be re-run?

Many corrections (i.e. BTPS correction factors, dead space volume, signal alignment) are applied to raw MBW data which influence the calculation, and hence, the final value of MBW outcomes (LCI, FRC etc). Re-running A-files allows the operator the opportunity to correct any system settings that were incorrect when the data was acquired. Re-calculated results can then be included in the final data set. Additionally, poorly managed files will create irreconcilable results in the final data set and must be corrected before final values can be generated.

Common reasons to re-run data:

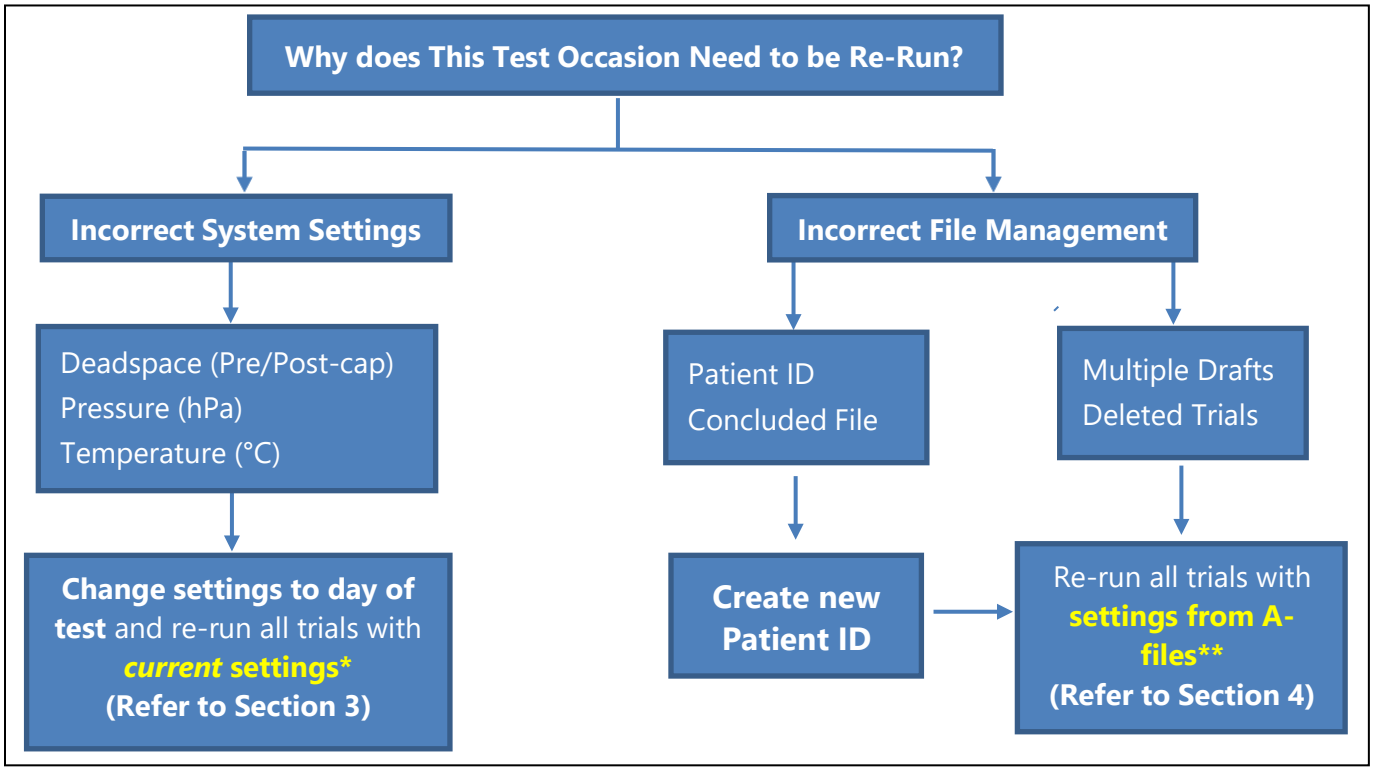
Incorrect System Settings

- Incorrect temperature or pressure
- Incorrect dead space values
- Incorrect signal delay values
  **For more detailed instructions refer to signal re-alignment SOP*

Incorrect File Management

- Incorrect file naming
- Trials from the same test occasion saved as multiple draft files
- File has been concluded and not saved as 'Draft'
- Trials have been deleted in the .spx file by the site

1.1 Summary Guide of Common Solutions to Re-running Data



***Current settings** - All system settings inside the A-file are ignored and the current system settings will be used.

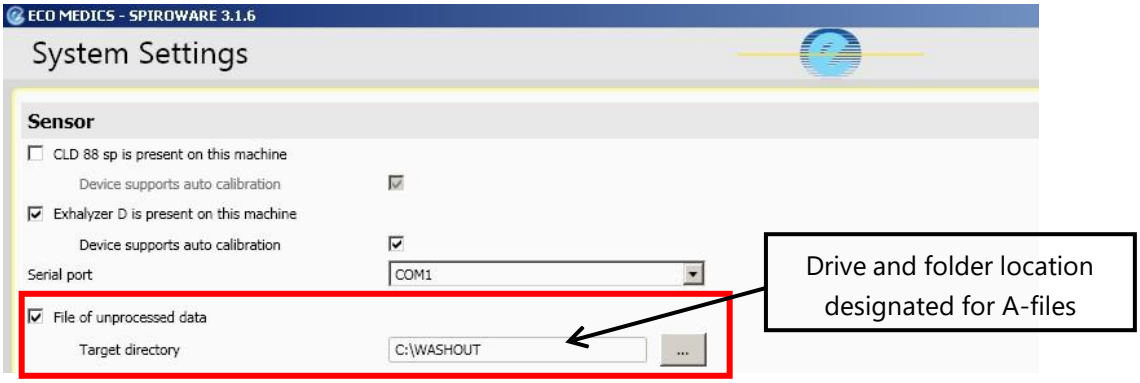
****Setting from A-files** - The corresponding system settings inside each A-file will be used.

2. A-Files are Necessary to Re-run Data

An A-file is a text document generated for each patient recording (per trial) and contains the raw flow, O_2 and CO_2 values. Environmental conditions and other system settings from time of test are recorded within the raw data or A-file. **A-files are required to re-run data to correct an error in the system settings or file management.**

2.1 How to find A-files?

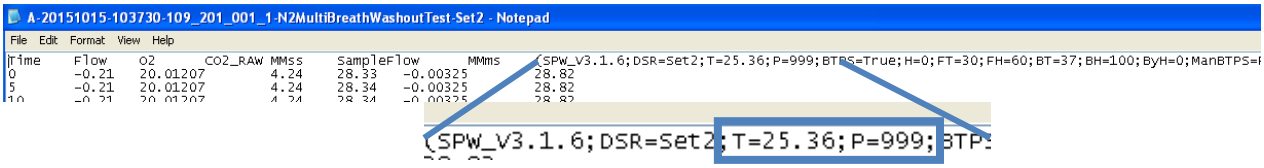
1. Open **System Settings** from the **Administration** menu; under **Sensor** heading locate **File of unprocessed data.** **To generate A-files this box must be checked and the data must be mapped to an existing folder on the C:\ Drive
2. Open the folder that contains raw data and select any A-file from the subject and test occasion you need to correct. All A-files from the same test will have the same settings.



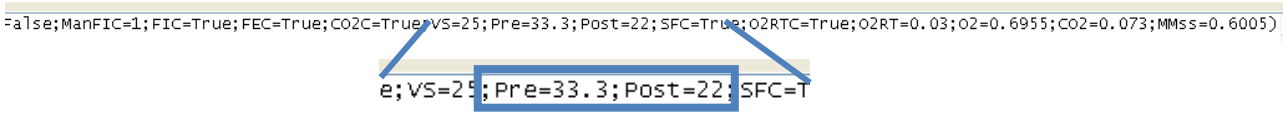
2.2 What information does the A-file contain?

The header of the A-file contains the following system settings that were used on the day of test

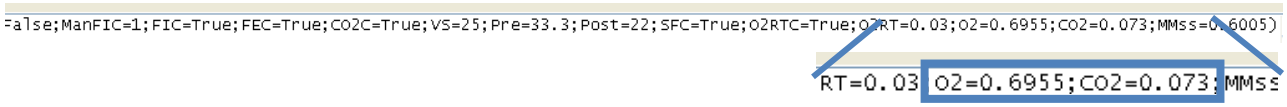
1. **Environmental Settings:** Temperature (°C) and Pressure (hPa)



1. **Dead space volume values:** Pre and post capillary dead space volumes



2. **Delay times:** Flow to O_2 Offset and Flow to CO_2 Offset times (in seconds)



3. Steps to Fix Incorrect System Settings

3.1 Information required to re-run data collected with incorrect settings

Prior to re-running data, operators will need to **correct the erroneous setting** and **restore all of the other system and environmental settings to day of test conditions**.

The following values must either be corrected or returned to day of test conditions:

1. **Environmental settings**: ambient **temperature** (°C) and **pressure** (hPa) **from the time of test**
    - Environmental values should have been recorded at the time of test.
    - If values were not recorded, they can also be found in the subject's **A-files**.
      NOTE: IF ENVIRONMENTAL SETTINGS WERE ENTERED INCORRECTLY AT THE TIME OF TEST THE VALUES FROM THE A-FILES CANNOT BE USED.

2. **Dead space volumes:** corresponding to the equipment used at **time of test.**
    - **Study specific** dead space settings used should be based on the study the subject is enrolled in.
    - If values were not recorded or known, they can also be found in the subject's **A-file**.
      NOTE: IF DEAD SPACE VALUES WERE ENTERED INCORRECTLY AT THE TIME OF TEST THE VALUES FROM THE A-FILES CANNOT BE USED.

3. **Flow to O_2 Offset and Flow to CO_2 Offset values (synchronization values/ delay times):**
    - Signal synchronization values should be recorded in calibration log
    - If values were not recorded or known, they can also be found in the subject's **A-files**.
      NOTE: IF SYNCHRONIZATION VALUES WERE ENTERED INCORRECTLY AT THE TIME OF TEST (I.E. SIGNALS ARE MISALIGNED) THE VALUES FROM THE A-FILES CANNOT BE USED.

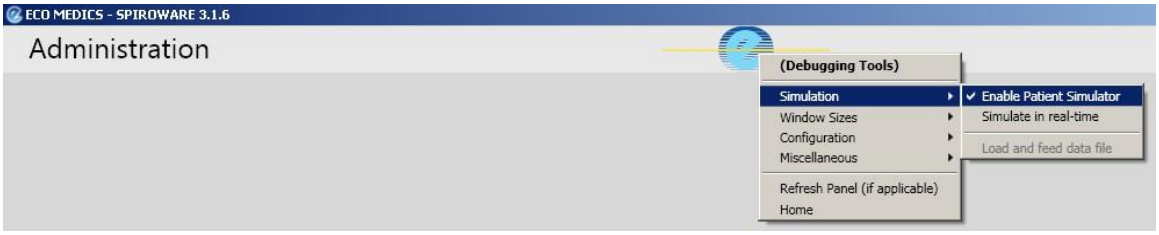
If correct synchronization values are not known or usual settings are not working refer to Signal Re-alignment SOP

3.2 What software and system settings must be set before re-running data?

1. Patient Simulator

If Exhalyzer D® system is **not actively running** (i.e. turned off) Spiroware must be set to simulator mode.

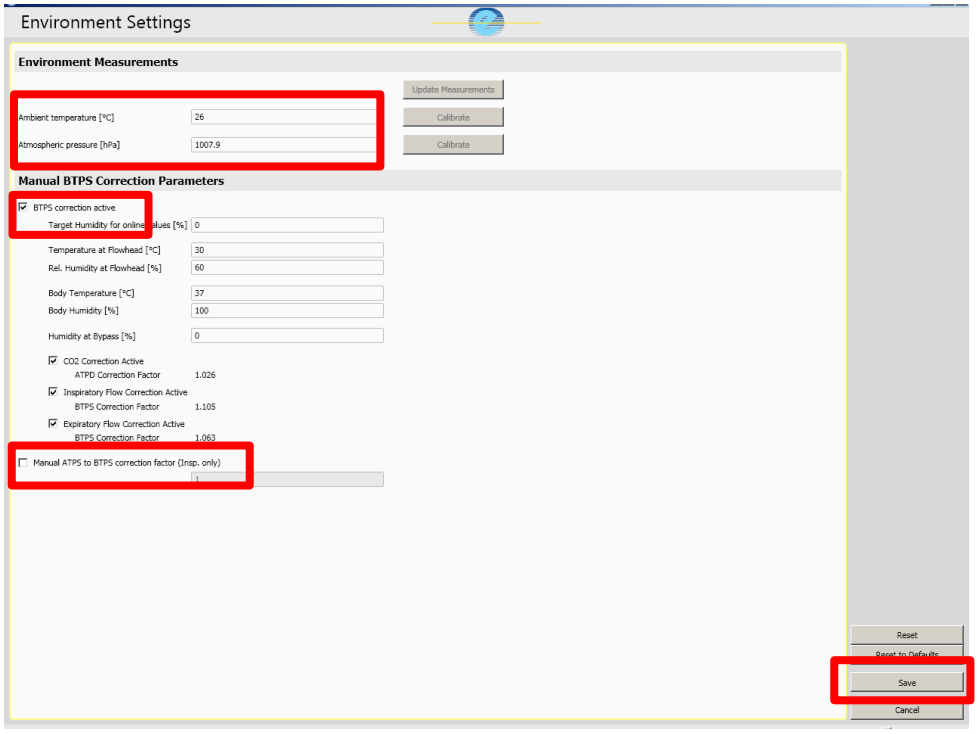
- Right click on Ecomedics symbol in the header of the Administration page
- Select **Simulation**
- Select **Enable Patient Simulator**
- Deselect **Simulate in real-time**



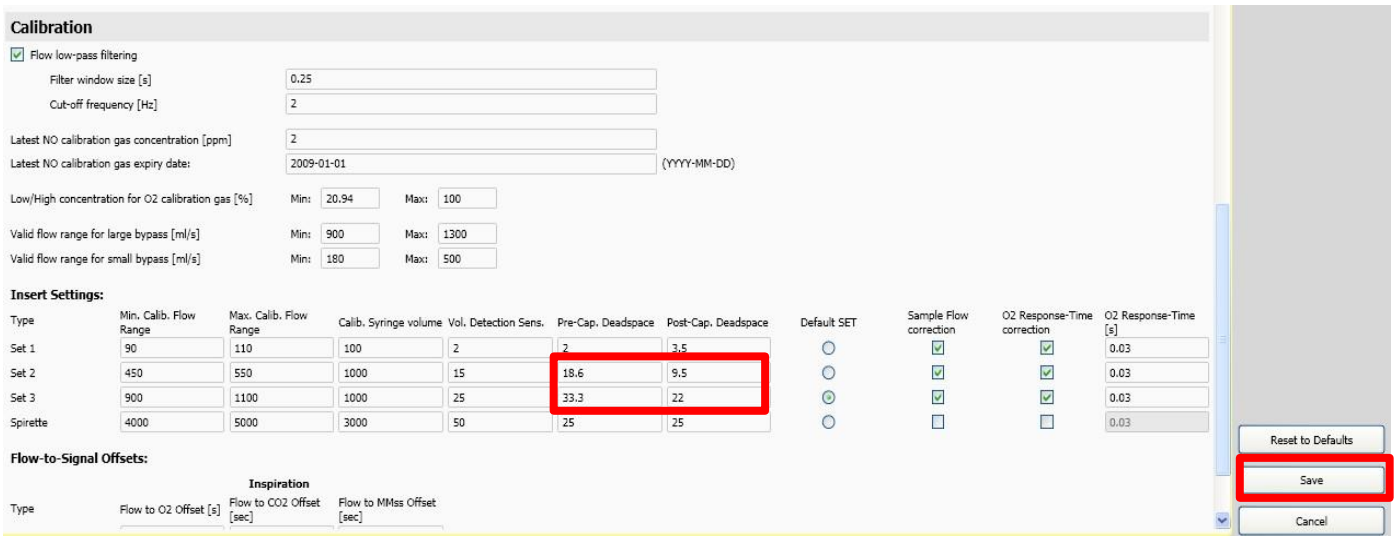
2. Environmental Settings

From the **Administration** menu, select **Environment settings.** Enter the ambient Temperature and Pressure from the time of test, press **SAVE** before returning to the main menu (**do not** need to press Calibrate or Update Measurements).

- Ensure that BTPS correction active is **checked**
- Ensure that Manual ATPS to BTPS is **unchecked**



3. **Dead space settings**
   - Scroll to the ***Calibration*** header in System Settings
   - Enter the **Pre-Cap Deadspace and Post-Cap Deadspace** values that correspond to equipment used at time of test for appropriate DSR Set # (Set 2 or Set 3, depending on which set was used for the test).
     - ➢ Different studies have specific values
   - Press **SAVE** before returning to the main menu



4. **Synchronization values**
   - From the **Administration** menu navigate to **System Settings**, enter the correct values (not necessarily the values shown here!) corresponding to DSR (Set 2 or 3) in the Flow to O_2 Offset and Flow to CO_2 Offset fields and press **Save.**

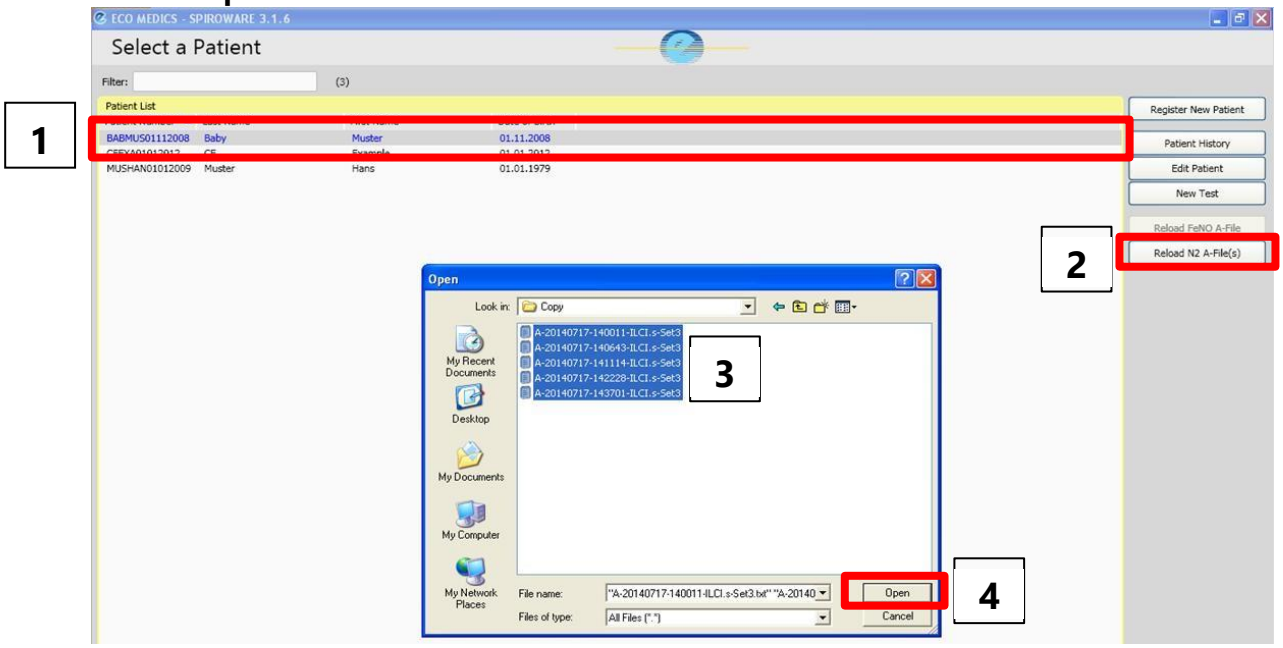
Flow-to-Signal Offsets:

Type	Inspiration: Flow to O2 Offset [s]	Inspiration: Flow to CO2 Offset [sec]	Inspiration: Flow to MMss Offset [sec]
Set 1	0.73	0.08	0.83
Set 2	0.68	0.065	0.68
Set 3	0.553	0.0715	0.553
Spirette	0.69	0.07	0.8

3.3 How to re-run A-files once all settings have been entered correctly?

Now that all of the system and environmental settings have been restored to day of test, the operator may proceed with re-running files.

1. On the Select a Patient page, **highlight** the subject whose raw data files will be re-run
2. Press **Reload N_2 A-file(s)**
3. Find the files for be re-run **(can select all at once)**
4. Press **Open**.



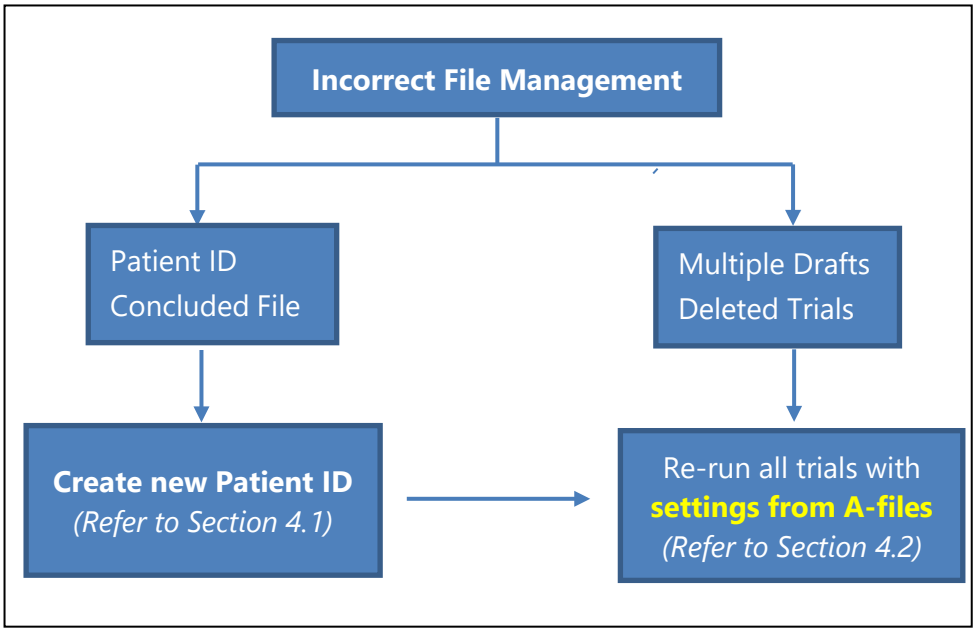
5. **Use current settings** and press **Confirm.**

6. Select the **DSR set** to be used and press **Confirm**. Use the same set as the time of test.

7. The re-run will then begin and the A-files will automatically re-play in sequence, once the re-run is complete the software will stop automatically. When the re-run is complete, **navigate to the Analysis Page (exactly the same as during a live test) and be sure to SAVE AS DRAFT before leaving the test occasion.**

8. In addition to the draft file saved at the time of test, a 2nd draft file, with the date of the re-run, will now be visible in the subject file. **DO NOT DELETE THE ORIGINAL DRAFT!**

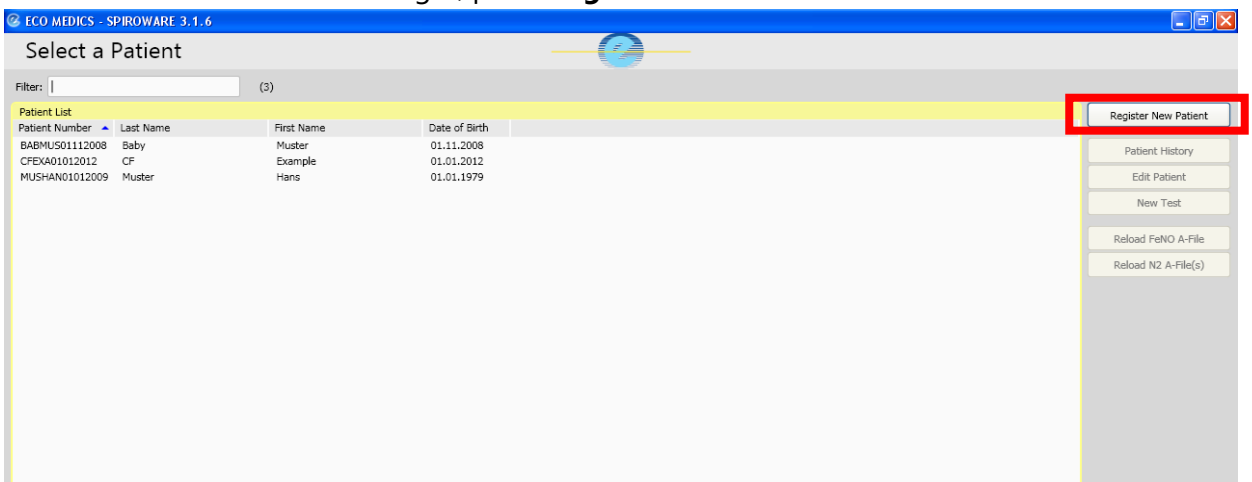
4. Steps to Fix Incorrect File Management



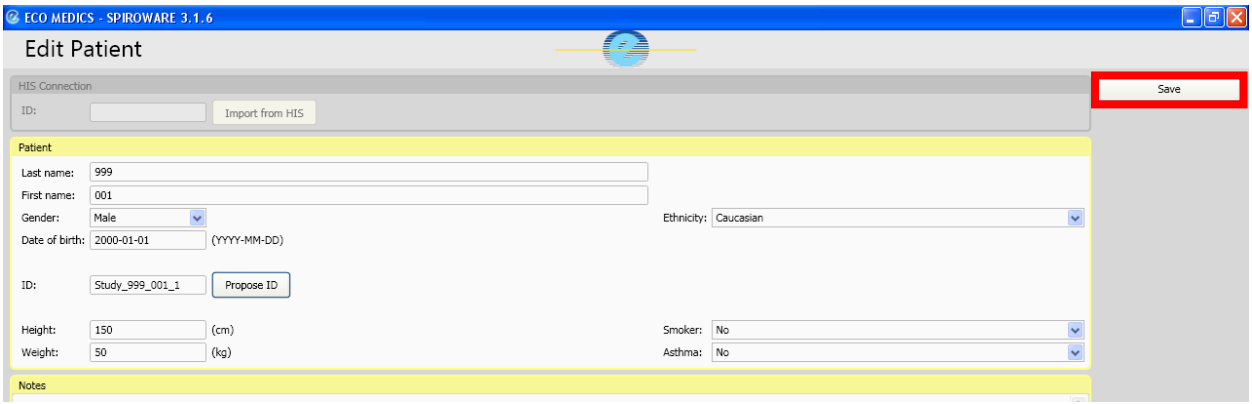
4.1 Creating a new Patient ID

If the subject ID is incorrect or the file was concluded, a new patient entry must be created with the correct subject ID and patient information, prior to reloading the A-files. Please note, if the new subject ID is identical to an existing subject ID, Spiroware will not allow two subjects to have identical subject IDs, thus the incorrect file must be deleted before a new one can be created. ***Prior to deleting the incorrect file, export the incorrect .spx file to have a copy of the original test occasion.**

1. Make note of the correct subject ID, first and last name, and patient information (i.e. DOB, weight, height, gender, and demographic)
2. On the "Select Patient Page", press **Register a New Patient**



3. Enter the Subject ID and patient name using the following naming scheme:
    a. **Last Name**: Study Site Number
    b. **First Name**: Patient Number
    c. **Subject ID**: Study number_ study site number_patient number_visit
    Please enter accurate patient information (weight, height, DOB, gender and demographic)
4. Press Save

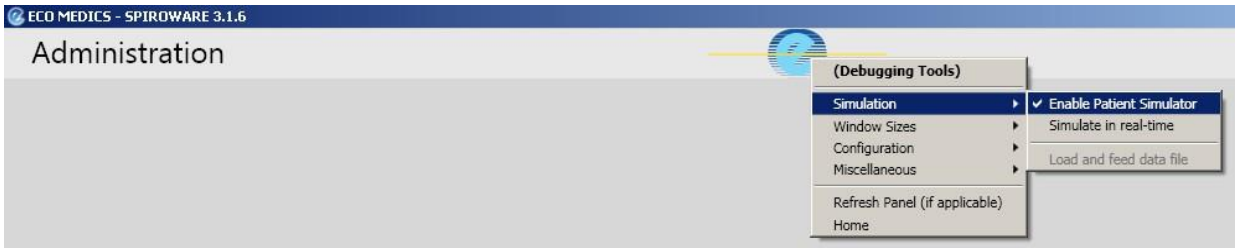


4.2 How to re-run A-files to correct file management?

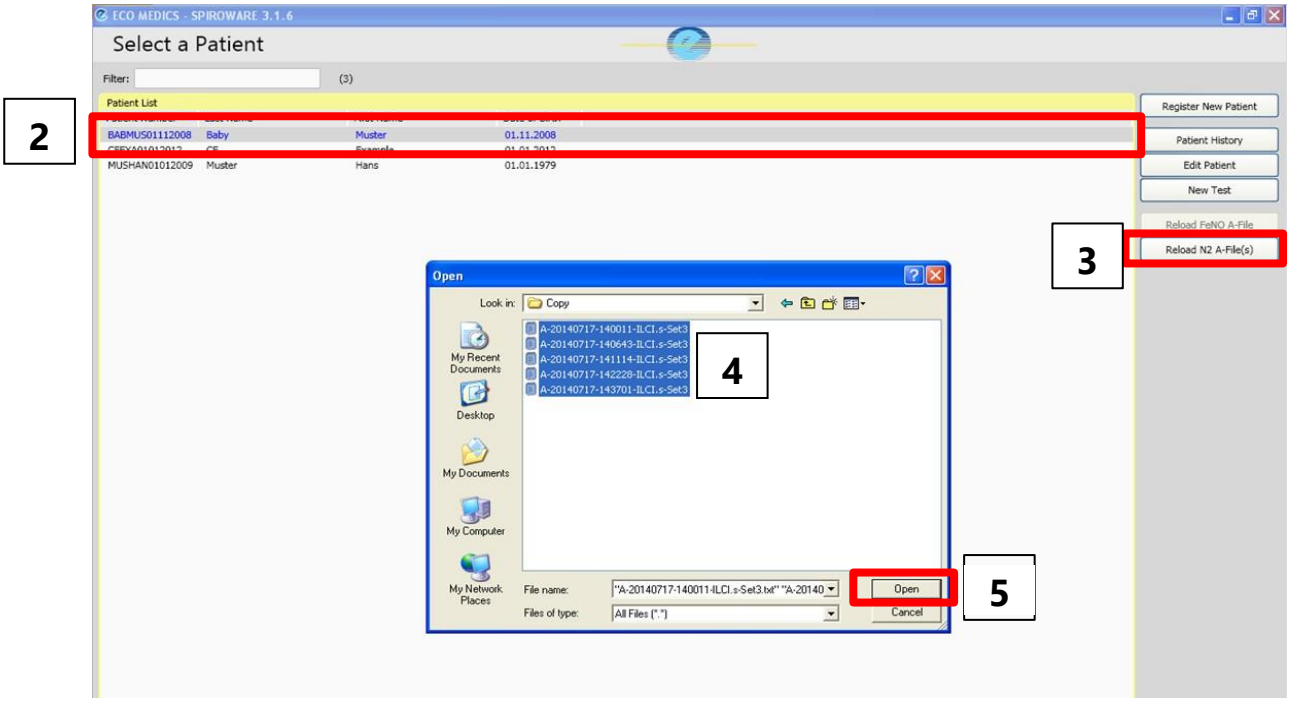
1. Patient Simulator

If Exhalyzer D® system is **not actively running** (i.e. turned off) Spiroware must be set to simulator mode.

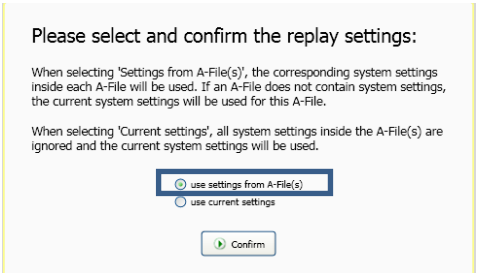
- Right click on Ecomedics symbol in the header of the Administration page
- Select **Simulation**
- Select **Enable Patient Simulator**
- Deselect **Simulate in real-time**



2. On the Select a Patient page, **highlight** the subject whose raw data files will be re-run
   *If a new patient entry was created then highlight the newly created patient
3. Press **Reload N_2 A-file(s)**
4. Find the files for be re-run **(can select all at once)**
5. Press **Open**.



6. Select **Use settings from A-files**



7. Select the **DSR set** to be used and press **Confirm**. Use the same set as the time of test.

8. The rerun will then begin and the A-files will automatically re-play in sequence, once the re-run is complete the software will stop automatically.

9. **Once the re-un is complete, navigate to the Analysis Page (exactly the same as during a live test) and be sure to SAVE AS DRAFT before leaving the test occasion or the results will not be saved.**