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

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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, O₂ and CO₂ 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?

- 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.

WECO MEDICS - SPIROWARE 3.1.6		
System Settings		0
Sensor		
CLD 88 sp is present on this machine		
Device supports auto calibration		
 Exhalyzer D is present on this machine 		
Device supports auto calibration	N	
Serial port	COM1	Drive and folder location
✓ File of unprocessed data		designated for A-files
Target directory	C:\WASHOUT	

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)

A-20151015-103730-109_201_001_1-N2MultiBreathWashoutTest-Set2 - Notepad
File Edit Format View Help
Time Flow 02 C02_RAW WMss SampleFlow MMms Serv_3.1.6;DSR=Set2;T=25.36;P=999;BTDS=True;H=0;FT=30;FH=60;BT=37;BH=100;ByH=0;ManBTPS= 0 -0.21 20.01207 4.24 28.33 -0.00325 28.82 -0.21 20.01207 4.24 28.34 -0.00325 28.82 -0.0325 28.82
1. Dead space volume values: Pre and post capillary dead space volumes
False;ManFIC=1;FIC=True;FEC=True;CO2C=True;VS=25;Pre=33.3;Post=22;SFC=True;O2RTC=True;O2RT=0.03;O2=0.6955;CO2=0.073;MMss=0.6005 e;VS=25;Pre=33.3;Post=22;SFC=T
2. Delay times: Flow to O_2 Offset and Flow to CO_2 Offset times (in seconds)
False;ManFIC=1;FIC=True;FEC=True;CO2C=True;VS=25;Pre=33.3;Post=22;SFC=True;O2RTC=True;O2RT=0.03;O2=0.6955;CO2=0.073;MMss=0.6005)

RT=0.03 02=0.6955;C02=0.073;MMss

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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 **<u>correct the erroneous setting</u>** and **restore all** of the <u>other system</u> and <u>environmental settings</u> to day of test conditions.

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

1. <u>Environmental settings</u>: 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. <u>Dead space volumes:</u> 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 O₂ Offset and Flow to CO₂ 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 Afiles.

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**

C ECO MEDICS - SPIROWARE 3.1.6		
Administration	 (Debugging Tools)	
	Simulation •	✓ Enable Patient Simulator
	Window Sizes	Simulate in real-time
	Configuration •	Load and feed data file
	Miscellaneous •	
	Refresh Panel (if applicable)	
	Home	
		-

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).

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

Environment Settings	5	— <u>@</u> —	
Environment Measurements			
		Update Measurements	
Ambient temperature [°C]	26	Calibrate	
Atmospheric pressure [hPa]	1007.9	Calibrate	
Manual BTPS Correction Paran	neters		
BTPS correction active			
Target Humidity for online alues [%]	0		
Temperature at Flowhead [°C]	30		
Rel. Humidity at Flowhead [%]	60		
Body Temperature [°C]	37		
Body Humidity [%]	100		
Humidity at Bypass [%]	0		
CO2 Correction Active ATPD Correction Factor	1.026		
Inspiratory Flow Correction Active BTPS Correction Factor	1.105		
Expiratory Flow Correction Active	1.063		
Manual ATPS to BTPS correction factor (In:	isp. only)		
	1		
			Reset
			Reset to Detaults
			Save
			Cancel

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

Calibration											
Flow low-pass filt	tering										
Filter window	v size [s]	0.25									
Cut-off frequ	ency [Hz]	2									
Latest NO calibration	gas concentration [ppr	n] 2									
Latest NO calibration		· _	-01-01				(YYYY-MM-DD)				
Low/High concentrat	ion for O2 calibration g	es [%] Min:	20.94	Max:	100						
	-										
Valid flow range for l	arge bypass [ml/s]	Min:	900	Max:	1300						
Valid flow range for s	small bypass [ml/s]	Min:	180	Max:	500						
Insert Settings:											
Туре	Min. Calib. Flow Range	Max. Calib. Flow Range	Calib. S	yringe volume	e Vol. Detection Ser	ns. Pre-Cap. Deadspace	Post-Cap. Deadspace	Default SET	Sample Flow correction	O2 Response-Time correction	O2 Response-Time [s]
Set 1	90	110	100		2	2	3.5	0	\checkmark	V	0.03
Set 2	450	550	1000		15	18.6	9.5	0	v	v	0.03
Set 3	900	1100	1000		25	33.3	22	۲	\checkmark	V	0.03
Spirette	4000	5000	3000		50	25	25	0			0.03
Flow-to-Signal O	ffcets										
now to Signal O	iisees.	Inspiration									
Туре	Flow to O2 Offset [s]	Flow to CO2 Offs [sec]	et Flow to [sec]	MMss Offset							

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 O₂ Offset and Flow to CO₂ Offset fields and press **Save**.

Flow-to-Signal Offsets:								
	Inspiration							
Туре	Flow to O2 Offset [s]	Flow to CO2 Offset [sec]	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 N₂ A-file(s)
- 3. Find the files for be re-run (can select all at once)



5. Use current settings and press Confirm.

Please select and confirm the replay settings:					
When selecting 'Settings from A-File(s)', the corresponding system settings inside each A-File will be used. If an A-File does not contain system settings, the current system settings will be used for this A-File.					
When selecting 'Current settings', all system settings inside the A-File(s) are ignored and the current system settings will be used.					
C use settings from A-File(s) C use current settings					
O 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

<u>If the subject ID is incorrect or the file was concluded</u>, 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

nt List nt Number 🔺 Last Name First Name Date of Birth	Select a Patient		— <u>@</u> —	
nt Number Last Name First Name Date of Birth Date of Birth MUS01112008 Baby Muster 01.11.2008 MUS01112002 CF Example 01.01.2012 HAN01012009 Muster Hans 01.01.1979 Restore The	er:	(3)		
nt Number Last Name First Name Date of Birch Patient Multiple Saby Muster 01.11.2008 W050112002 CF Example 01.01.2012 HAN01012009 Muster Hans 01.01.1979 Edit Patient Mistory Edit Patient Mistory Edit Patient New Test Reload FeNO A-File	ient List			Register New Patient
KAD1012012 CF Example 0.10.1.2012 Edit Patient HAND1012009 Muster Hans 01.01.1979 Edit Patient New Test Reload FeVO A-File Reload FeVO A-File	ient Number 🔺 Last Name	First Name	Date of Birth	Register for Future
HAN01012009 Muster Hans 01.01.1979 Edit Patient New Test Reload FeNO A-File	BMUS01112008 Baby			Patient History
New Test Reload FeNO A-File				Edit Dakash
Reload FeNO A-File	SHANOIOI2009 Pidsoer	nans	01.01.1979	Edit Paberit
				New Test
				Reload FeNO A-File
Reload NZ A-Hie(s)				
				Reload N2 A-File(s)

- 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

© ECO MEDIC	S - SPIROWARE 3.1.6		- 7 🛛
Edit Pa	atient — 🕜		
HIS Connectio	n		Save
ID:	Import from HIS		
Patient			
Last name:	999		
First name:	001		
Gender:	Male	Ethnicity: Caucasian	
Date of birth:	2000-01-01 (YYYY-MM-DD)		
ID:	Study_999_001_1 Propose ID		
Height:	150 (cm)	Smoker: No	
Weight:	50 (kg)	Asthma: No	
Notes		(m)	

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
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@ ECO MEDICS - SPIROWARE 3.1.6			
Administration	<u> </u>	(Debugging Tools)	L
			 Enable Patient Simulator
		Window Sizes	 Simulate in real-time
		Configuration I	Load and feed data file
		Miscellaneous 0	
		Refresh Panel (if applicable)	
		Home	

- 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 N₂ 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.