Standard Operating Procedure:

Multiple Breath Nitrogen Washout

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

SIGNAL RE-ALIGNMENT

CF Clinical Research Team

The Hospital for Sick Children

Toronto



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1. What is Signal Alignment?

Signal alignment or synchronization refers to the temporal alignment of the flow, oxygen and carbon dioxide trace. The lag time between flow and gas signals may vary between Exhalyzer D units and may differ depending on which DSR is used. This is mainly due to differences in sample flow rate between systems but also results from subtle variances in Nafion tubing length and characteristics of the gas analyzers. Therefore the default delay values in Spiroware will not result in optimal signal alignment.

Recall that:

 $[N_2]$ is calculated from $[O_2]$ and $[CO_2]$

 $[N_2] = 100 - [0_2] - [CO_2]$

During the breathing cycle $[O_2]$ and $[CO_2]$ travel in opposite directions.

Inspiration: $[O_2]$ increases \uparrow and $[CO_2]$ decreases \checkmark Exhalation: $[O_2]$ decreases \checkmark and $[CO_2]$ increases \uparrow



Therefore, if $[O_2]$ and $[CO_2]$ are out of phase with one another characteristic spikes and dips will appear in the $[N_2]$ signal. These deflections can alter FRC calculation and measured CetN₂, which in turn affects determination of end of washout and LCI measurements.



Gas and flow signals must be accurately aligned with one another in time in order to ensure precise estimation and accurate calculation of gas concentration and volume.





Prior to beginning all testing, a trained operator should have performed a number of signal alignment maneuvers to determine the "characteristic" delay of the machine, which is then saved in the system's settings. These values are found in the **Flow-to-Signal Offsets** section at the bottom of **System Settings**.

Signal alignment should then be repeated (values recorded but not saved!) every week to verify that results are within +/-10 ms of previous characteristic delay times. **See section 5.4 of the Multiple Breath Nitrogen Washout SOP.**

Systen	n Settings													
Normative	range normal NO [[dog		V M	n: 200		Мак:	1000					1	
Normathie	range elevated NO	(ppb)		V MI	n: 1000	1	Max:	1200						
Normative	range severe NO []	ppb]		V M	n: 1200	13	Мак:							
Calibra	tion													
I Flow k	ow-pass filtering													
Filt	ter window size (s)			0.25										
Cu	t-off frequency [Hz	1		2										
Latest NO	calification may com	centration (nom)		,										
Labert ND	calibration gas over	in date:		2000-	01-01				(very-m	M-DD)				
Linese no i	canorectori guo expr	, y child.		2005					tree a	(n 00)				
Low/High c	concentration for O	2 calibration gas	[%]	Min:	20.94	Max	100							
Valid flow r	range for large byp	ess [mi/s]		Minc	900	Max:	1300							
Valid flow :	range for small byp	ass (ml/s)		Min:	180	Max	250							
Insert Se	:tungs:		200							10	O2 Response			
Type	Min. Calib. Flow Range	Max. Callb. Flow Range	Callb. Syringe volume	Vol. Detection Sens.	Deadspa	Post Ice Dear	Cap. space	Default	SET Sa	ample Flow prection	Time correction	O2 Response- Time [s]		
Set 1	90	110	100	2	2	3.5		0		1	1	0.03		
Set 2	450	550	1000	15	18.6	9.5		0		1	1	0.03		
Set 3	900	1100	1000	25	33.3	22				~	1	0.03		
Spirette	4000	5000	3000	50	25	25		0		Π.	10	0.03		
Flow-to-	Signal Offsets:	Inspiration Flow to CO2	Flow to MMss											
1185	Offset [s]	Offset [sec]	Offset (sec)											
Set 1	0.73	0.08	0.83										-	
Set 2	0.7	0.065	0.8										1	
Set 3	0.69	0.07	0.8										=	Reset to Defaults
Spirette	0.69	0.07	0.8										1	Save
Number of	washout breaths fr	or synchronization	n	10									-	

The resulting **Flow to O₂ Offset** and **Flow to CO₂ Offset** values (synchronization values/delay times) represent how much the CO₂ and O₂ signals will be shifted in time during recording in order to align with flow.

Examples of poor signal alignment:

Poor signal alignment can be identified by repetitive deflections in the N₂ concentration trace.



The N₂ signal should return to zero between breaths, and provided gas calibration has been performed, should not be a negative value (dip below zero).



2. Why is it necessary to correct signal misalignment?

Signals can occasionally become misaligned during testing. This may occur for a variety of reasons, someone may have unintentionally saved a poor synch calibration to the system settings, or possibly the subject being tested has a breathing pattern that is outside the range of values generated by operator synchronization.

Signals must be aligned in order to generate accurate MBW outcomes, therefore signal realignment must be performed before analysis can occur.

3. Determining correct *Flow to O*₂ *Offset* and *Flow to CO*₂ *Offset* values (synchronization values/ delay times).

Determining correct delay times depends on why the original delay values were incorrect:

- 1. Synchronization Values Known (Section 4)
 - Incorrect synchronization times were accidentally saved to system settings and need to be set back to usual settings. Values can be found in recorded in calibration log.

- Nafion tube was changed and synchronization calibration needs to be performed to determine new characteristic values.
- 2. Synchronization Values Unknown (Section 5)
 - Trials were collected using the usual synchronization settings but the signals were still misaligned.
 - Generate new values by **performing a** *Flow/Channel Signal Synchronization* with existing data.

4. Synchronization Values Known

In order to properly correct signal alignment, system settings must be returned to day of test conditions and correct flow to O₂ Offset and flow to CO₂ offset values (synchronization values/ delay times) must be determined. The following values will be required:

- 1. Environmental settings: ambient temperature (°C) and pressure (hPa) from the time of test
 - Environmental values should have been recorded in a log at the time of test.
 - If values were not recorded or known, they can also be found in the subject's **A-files** (see Section 4.1).
- 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-files** (see Section 4.1).

3. Flow to O₂ and Flow to CO₂ Offset values (synchronization values/ delay times):

- Correct synchronization values can be:
 - 1. Found as recorded in calibration log
 - 2. Determined by performing synchronization calibration with new Nafion tubing.

4.1 Where to find Environmental settings and dead space volume measurements if not recorded.

Environmental conditions and other system settings from time of test are recorded within the raw data or A-file. An A-file is a text document generated for each patient recording (per trial) and contains the raw flow, O₂ and CO₂ offset (synchronization) values.

The location of A-files is specified in the System Settings.

4.1.1 WHERE ARE A-FILES STORED?

- 1. Open Spiroware and navigate to the Administration menu
- 2. Open System Settings, under Sensor heading locate File of unprocessed data

ECO MEDICS - SPIROWARE 3.1.6			
System Settings			0
Sensor			
 CLD 88 sp is present on this machine Device supports auto calibration Exhalvzer D is present on this machine 	M		
Device supports auto calibration Serial port	COM1		Drive and folder location
File of unprocessed data	/		designated for A-files
Target directory	C:\WASHOUT		
File of 61PS and Delay Corrected Data			
Target directory	C:\WASHOUT\b	***	
File of decelerated BTPS and Delay Corrected	Data	ed)	

3. Open the folder that contains raw data and select any A-file from the subject and test occasion you need to correct for signal misalignment. All A-files from the same test will have the same settings.

4.1.2 WHAT INFORMATION DOES THE A-FILE CONTAIN?

1. Environmental Settings: Temperature and Pressure can be found in the header of the A-file.



2. **Pre and post capillary dead space volumes** corresponding to the DSR used during testing can also be found in the A-file.



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4.2 Restore System Settings to day of test conditions and Correct Synchronization Values.

All system settings influence calculation of results; ONLY delay times should be corrected and all environmental and other system settings should be restored to day of test values.

4.2.1 SET GENERAL SYSTEM SETTINGS

- 1. 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

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

2. From the Administration menu, open System Settings

ystem Configuration	Patient Management	Device Management
User Management	Export Data	Device Status
System Settings	Import multiple Patients Import single Patient	Flow / Channel Signal Synchronization
Report Templates	Spiroware 2 Database Import	Device Direct Link Control
Device Calibration		Device Reports
Flow Calibration		Flow Calibration Reports
Channel Calibration		Channel Calibration Reports NO Calibration Reports
		Elow / NO Supphropization Reports
NO Zero Calibration		
NO Zero Calibration NO Span Calibration		Flow / Channel Synchronization Reports

3. Under **Sensor** heading Ensure CLD 88 (exhaled nitric oxide (NO) analyzer) is disabled if not present on device. Ensure Exhalyzer D[®] is enabled (Check in the box). **Note- NO analyzer is specialized hardware that is NOT standard equipment.

Gecomedics - spiroware 3.1.6 System Settings		-@-
Sensor		
CLD 88 sp is present on this machine Device supports auto calibration	N	
Device supports auto calibration Serial port	СОМ1	×

- 4. Raw data files (unprocessed data) should ALWAYS be selected but new A-files will not be created by re-running files. If desired, B, C or Breath Table data re-calculated with new settings can be saved to a folder on your local hard drive <u>provided the following settings are correct:</u>
 - Ensure that the **data type** is selected
 - Ensure that the data is mapped to an existing folder on the C:\ Drive

ECO MEDICS - SPIROWARE 3.1.6		
System Settings		-0-
Sensor		
CLD 88 sp is present on this machine		
Device supports auto calibration	M	
Exhalyzer D is present on this machine		
Device supports auto calibration	J	
Serial port	COM1	×
File of unprocessed data		
Target directory	C:\WASHOUT	
File of BTPS and Delay Corrected Data		
Target directory	C:\WASHOUT\b	
File of decelerated BTPS and Delay Corrected	i Data	
Deceleration factor	2	(frequency: 100Hz)
Target directory	C:\WASHOUT\c	
File of Breath Table Data		
Target directory	C:\WASHOUT	

- 5. Ensure orientation of the flow signal is correct and automatic start and stop are disabled.
 - Scroll down in System Settings confirm Show inspiration flow positive is selected and confirm Automatic start and Automatic stop of the test are NOT selected.

Show inspiration flow positive	
Automatic start of test	
Automatic stop of test	
 Automatic start of washout (AND criteria) 	
when Std. VT Insp. valid	
when Std. VT Exp. valid	
when Std. Cet CO2 valid	\checkmark
when Std. RO valid	×

4.2.2 ENTER DAY OF TEST DEAD SPACE VALUES

- 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

isert Set	tings:											
pe	Min. Calib. Flow Range	Max, Callb. Flow Range	Callb. Syringe volume	Vol. Detection Sens.	Pre-Cap. Deadspace	Post-Cap. Deadspace	Default SET	Sample Flow correction	O2 Response Time correction	O2 Response- Time [s]		
1	90	110	100	2	2	3.5	0	1	1	0.03		
2	450	550	1000	15	18.6	9.5	0	3	V	0.03		
in the second	ann	1100	1000	255	22.2			1991	191	0.00		
t 3	500		1		33.5	22		N		0.03		
rette xw-to-Si	4000	5000	3000	50	25	25	0			0.03		
rs irette ow to Si pe	4000 ignal Offsets:	5000 Inspiration Flow to CO2 Offset [sec]	Bow to MMss Offset [sec]	50	25	25	0			0.03		
rette ow to Si pe t 1	4000 4000 Flow to O2 Offset [s] 0.73	5000 Inspiration Flow to CO2 Offset [sec] 0.08	Flow to MMss Offset [sec] 0.83	50	25	25	0			0.03		
rs inette ow to Si pe t1 t2	4000 ignal Offsets: Flow to O2 Offset [s] 0.73 0.7	Sooo Inspiration Flow to CO2 Offset [sec] 0.08 0.065	Flow to MMss Offset [sec] 0.83 0.8	50	25	25	0			0.03		
nts ow-to-Si pe t1 t2 t3	4000 4000 Flow to O2 Offset [s] 0.73 0.69	Stool 5000 Inspiration Flow to CO2 Offset [sec] 0.06 0.065 0.07	3000 Flow to MMss Offset [sec] 0.83 0.8	50	25	25	0			0.03	ĺ	Reset to Defaults

- 4.2.3 ENTER CORRECT *FLOW TO O₂ OFFSET* AND *FLOW TO CO₂ OFFSET* VALUES (SYNCHRONIZATION VALUES/ DELAY TIMES).
 - Under the **Calibration** header in **System Settings**, Scroll to **Flow**—**to-signal Offsets** enter the correct values in the **Flow to O2** and **Flow to CO2** Offset fields for corresponding DSR.
 - 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

4.2.4 ENTER DAY OF TEST ENVIRONMENTAL CONDITIONS

- System Configuration Patient Management Device Management Export Data User Management Device Status Import multiple Patients System Settings Flow / Channel Signal Synchronizatio Import single Patient Report Templates Device Direct Link Control Spiroware 2 Database Import Device Calibration Device Reports How Calibration Reports Flow Calibration Channel Calibration Reports Channel Calibration NG Calibration Reports ND Zero Calibration Flow / NO Synchronization Reports How / Channel Synchronization Reports Environment Settings (DO/MM/YYYY)
- 1. From the Administration menu, select Environment settings

- 2. Enter the ambient Temperature and Pressure from the time of test, press **SAVE** before returning to the main menu.
 - Note do not need to press Calibrate or Update Measurements

Environment Settings	5	-@-	
Environment Measurements			
		ligibite Resourcements	
Ambient temperature [PC]	26	Calibrate	
Atmospheric pressure [hPa]	1007.9	California	
Manual BTPS Correction Para	meters	_	
F 01PS correction active			
Target Humidity for online values [%]	[o		
Temperature at Flowhead [°C]	30		
Ral, Humidity at Flowhaad [%]	00		
Body Temperature (PC)	37		
Body Humidity [%]	100		
Humsday at Bypass [%]	0		
CO2 Correction Active ATPD Correction Factor	1.006		
Inspiratory flow Correction Active BTPS Correction Factor	1.105		
Expiratory Flow Correction Active BTPS Correction Factor	1.063		
Manual ATPS to BTPS correction factor (br	res. only)		
	13		
			Rapet
			Seve
			Cancel

4.3 How to re-run A-files to correct signal misalignment.

Now that all of the system and environmental settings have been restored to day of test and the new delay values have been saved to system settings the operator may proceed with re-running files to correct signal misalignment.

- 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)
- 4. Press Open.

Select a Fatient			
Pilters	(3)		
Patient List			Register
BABMUS01112008 Baby	Muster	0111.2008	Patie
MUSHAN01012009 Muster	Hans	01.01.1979	Edit
			Ne
			Reload
			Reload
		n 🛛	
		Look in: 😰 Copy 💌 🖝 🖬 🗰	
		A 20140717-140011-1LCL s-Set3	
		V Recent 4 20140717-141114-1LCL = Set3	
		A-20140717-143701-1LCL - Set5	
		Desktop	
		10 million	
		Documents	
		y Computer	
		ly Network File name: "A-20140717-140011-ILCLs-Set3.tsr" "A-20140 • Open	
		Places Files of type All Files (".") Cancel	

3. Select 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+He(s)	
G use current settings	
Confirm	

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

- The rerun will then begin and the A-files will automatically re-play in sequence, once the rerun is complete the software will stop automatically.
- 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.
- In addition to the draft file saved at the time of test, a second draft file, with the date of the re-run, will now be visible in the subject file. **DO NOT DELETE THE ORIGINAL DRAFT FILE!**
- 5. Prior to submitting the corrected file for analysis check that the signals have now been aligned by opening the draft file, and scrolling through each trial inspecting for evidence of signal misalignment.
- If alignment is still not corrected proceed to Section 5

5. Synchronization Values Unknown

In order to properly correct signal alignment, system settings must be returned to day of test conditions and correct flow to O₂ Offset and flow to CO₂ offset values (synchronization values/ delay times) must be determined. The following values will be required:

- 1. Environmental settings: ambient temperature (°C) and pressure (hPa) from the time of test
 - Environmental values should have been recorded in a log at the time of test.
 - If values were not recorded or known, they can also be found in the subject's **A-files** (see Section 5.1).
- 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-files** (see Section 5.1).

3. Flow to O₂ and Flow to CO₂ Offset values (synchronization values/ delay times):

• Synchronization values must be generated using existing raw data files.

5.1 Where to find Environmental settings and dead space volume measurements if not recorded.

Environmental conditions and other system settings from time of test are recorded within the raw data or A-file. An A-file is a text document generated for each patient recording (per trial) and contains the raw flow, O₂ and CO₂ offset (synchronization) values.

The location of A-files is specified in the System Settings.

5.1.1 WHERE ARE A-FILES STORED?

- 1. Open Spiroware and navigate to the Administration menu
- 2. Open System Settings, under Sensor heading locate File of unprocessed data

ECO MEDICS - SPIROWARE 3.1.6			
System Settings			0
Sensor			
 CLD 88 sp is present on this machine Device supports auto calibration Exhalvzer D is present on this machine 	M		
Device supports auto calibration Serial port	COM1		Drive and folder location
File of unprocessed data	/		designated for A-files
Target directory	C:\WASHOUT		
File of 61PS and Delay Corrected Data			
Target directory	C:\WASHOUT\b		
File of decelerated BTPS and Delay Corrected	Data	ed)	

3. Open the folder that contains raw data and select any A-file from the subject and test occasion you need to correct for signal misalignment. All A-files from the same test will have the same settings.

5.1.2 WHAT INFORMATION DOES THE A-FILE CONTAIN?

1. Environmental Settings: Temperature and Pressure can be found in the header of the A-file.



2. **Pre and post capillary dead space volumes** corresponding to the DSR used during testing can also be found in the A-file.



5.2 How to generate new Synchronization Values

When generating new synchronization values, current system settings will influence signal synchronization algorithm, therefore all environmental and other system settings should be restored to day of test values prior to using existing data to generate alternative delay times.

5.2.1 SET GENERAL SYSTEM SETTINGS TO PERFORM FLOW/CHANNEL SIGNAL SYNCHRONIZATION

- 1. 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 •

Administration			
Administration	(Debugging Tools)		
	Simulation	→ 🗸 Ena	ble Patient Simulator
	Window Sizes	 Sim 	ulate in real-time
	Configuration Miscellaneous	Loa	d and feed data file
	Refresh Panel (if applicab	le)	
	Home		

2. From the Administration menu, open System Settings

System Configuration	Patient Management	Device Management
User Management	Export Data Import multiple Patients	Device Status
System Settings	Import single Patient	How / Channel Signal Synchronization
Report Templates	Spiroware 2 Database Import	Device Direct Link Control
Device Calibration		Device Reports
Flow Calibration		Flow Calibration Reports
Channel Calibration		Channel Calibration Reports
		NO Calibration Reports
NO Zero Calibration		Flow / NO Synchronization Reports
NO Span Calibration		Flow / Channel Synchronization Reports
Environment Sattings		

3. Under **Sensor** heading Ensure CLD 88 (exhaled nitric oxide (NO) analyzer) is disabled if not present on device. Ensure Exhalyzer D[®] is enabled (Check in the box). **Note- NO analyzer is specialized hardware that is NOT standard equipment.

© ECO MEDICS - SPIROWARE 3.1.6 System Settings	co medics - spiroware 3.1.6 System Settings	
Sensor		
 CLD 88 sp is present on this machine Device supports auto calibration Fxhalvzer D is present on this machine 	R	
Device supports auto calibration Serial port	COM1	×

- 4. Raw data files (unprocessed data) should ALWAYS be selected but **new A-files will not be created** by re-running files. If desired, B, C or Breath Table data re-calculated with new settings can be saved to a folder on your local hard drive <u>provided the following settings are</u> <u>correct:</u>
 - Ensure that the **data type** is selected
 - Ensure that the data is mapped to an existing folder on the C:\ Drive

ECO MEDICS - SPIROWARE 3.1.6		
System Settings		-@-
Sensor		
□ CLD 88 sp is present on this machine		
Device supports auto calibration		
Exhalyzer D is present on this machine		
Device supports auto calibration	v	
Serial port	COM1	
₩ File of unprocessed data		
Target directory	C:\WASHOUT	
File of BTPS and Delay Corrected Data		
Target directory	C:\WASHOUT\b	
File of decelerated BTPS and Delay Corrected	Data	
Deceleration factor	2	(frequency: 100Hz)
Target directory	C:\WASHOUT\c	
File of Breath Table Data		
Target directory	C:\WASHOUT	
	August and a second and a second a second a second s	

- 5. Ensure orientation of the flow signal is correct and automatic start and stop are disabled.
 - Scroll down in System Settings confirm **Show inspiration flow positive is selected** and confirm **Automatic start** and **Automatic stop** of the test are **NOT selected**.

Calculate integrated re-insp. N2 volume	
Show inspiration flow positive	
Automatic start of test	
Automatic stop of test	
Automatic start of washout (AND criteria)	
when Std. VT Insp. valid	
when Std. VT Exp. valid	
when Std. Cet CO2 valid	\checkmark
when Std. RO valid	V

5.2.2 ENTER DAY OF TEST DEAD SPACE VALUES

- 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

nsert Set	tings:											
ype	Min. Calib. Flow Range	Max. Calib. Flow Range	Callb. Syringe volume	Vol. Detection Sens.	Pre-Cap. Deadspace	Post-Cap. Deadspace	Default SET	Sample Flow correction	O2 Response Time correction	02 Response- Time [s]		
let 1	90	110	100	2	2	3.5	0	1		0.03		
iet 2	450	550	1000	15	18.6	9.5	0			0.03		
iet 3	900	1100	1000	25	33.3	22		1	12	0.03		
								and and	Stand .			
pirette low to S	4000 ignal Offsets:	5000	3000	50	25	25	0		Ē	0.03		
ipirette low to Si	4000 ignal Offsets:	5000 Inspiration	3000	50	25	25	0		Ē	0.03		
ipirette low to Si ype	ignal Offscts: Flow to O2 Offset [s]	5000 Inspiration Flow to CO2 Offset [sec]	Flow to MMss Offset [sec]	50	25	25	0			0.03		
iprette low to S ype et 1	4000 ignal Offsets: Flow to O2 Offset [s] 0.73	5000 Inspiration Flow to CO2 Offset [sec] 0.00	Flow to MMss Offset (sec)	50	25	25	0		E	0.03		
ipirette low to Si ype iet 1 iet 2	4000 fignal Offsets: Flow to O2 Offset [s] 0.73 0.7	5000 Inspiration Flow to CO2 Offset [sec] 0.08 0.065	Flow to MMss Offset [sec] 0.80 0.8	50	25	25	0			0.03		
ipirette F low to Si lype let 1 let 2 let 3	4000 ignal Offsets: Flow to O2 Offset [5] 0.73 0.7 0.69	5000 Inspiration Flow to CO2 Offset [sec] 0.08 0.065 0.07	3000 Flow to MMss Offset [sec] 0.83 0.8	50	25	25	0	E		0.03]c	Reset to Defaults

5.2.3 ENTER DAY OF TEST ENVIRONMENTAL CONDITIONS

6. From the Administration menu, select Environment settings

System Configuration	Patient Management	Device Management
User Management	Export Data	Device Status
System Settings	Import multiple Patients	Row / Channel Signal Synchronization
Report Templates	Spiroware 2 Database Import	Device Direct Link Control
Device Calibration		Device Reports
Flow Celibration		Flow Calibration Reports
Channel Calibration		Channel Calibration Reports NO Calibration Reports
NO Zero Calibration		Flow / NO Synchronization Reports
NO Span Calibration		Flow / Channel Synchronization Reports

7. Enter the ambient Temperature and Pressure from the time of test, press **SAVE** before returning to the main menu.

chivitoninent Settings	6	-@-	
invironment Measurements			
		Ladate Resourcements	
imbient temperature [°C]	26	Calibrate	
trouphen: pressure (HPa)	1007.9	California	
Manual BTPS Correction Parar	neters		
7 BTPS correction active			
Target Humidity for online values [%]	0		
Temperature at Flowhead [90]	30		
Ral, Humidity at Rowhead [%]	60		
Body Temperature [*C]	37		
Body Humidity [%]	100		
Humshity at Bypass [%]	0		
CO2 Correction Active ATPD Correction Factor	1.006		
Inspiratory flow Correction Active BTPS Correction Factor	1.105		
Expiratory Flow Correction Active BTPS Correction Factor	1.063		
Manual ATPS to BTPS correction factor (br)	es. only)		
	1		

• Note – **do not** need to press Calibrate or Update Measurements

- 5.3 Perform Flow/Channel Signal Synchronization using existing data.
- 1. From the Administration menu, select Flow/Channel Signal Synchronization

System Configuration	Patient Management	Device Management
User Management	Export Data	Device Status
System Settings	Import multiple Patients	Flow / Chennel Signal Synchronization
	Import single Patient	
Report Templates	Spiroware 2 Database Import	Device Direct Link Control
Device Calibration		Device Reports
Flow Calibration		How Calibration Reports
		Channel Calibration Reports
Channel Calibration		NO Calibration Reports
NO Zero Calibration		Flow / NO Synchronization Reports
NO Span Calibration		How / Channel Synchronization Reports
Environment Settions		

2. Select Set 2 or Set 3 depending on which DSR Set was used for testing – press Confirm



3. Select "Reload N₂ A-Files"



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4. Select an A-file to be used to generate new delay values.

When selecting an A-file to use for synchronization please ensure the following:

- ✓ The first 10 breaths are tidal breaths; no irregular breaths
- \checkmark The transition from exhalation to inspiration is smooth; no hesitations
- 5. Press Open the file will automatically start running



5.3.1 HOW DO I KNOW IF THE SYNCHRONIZATION IS ACCEPTABLE?

Acceptable:

- ✓ Flow tracing clearly crosses zero during transition between inspiration and expiration for the first ten breaths of the washout.
- ✓ All gas signal marker lines (blue, red) overlap for the first ten breaths of the washout.



Examples of acceptable synchronization





Examples of unacceptable synchronization

8. Only values generated from acceptable synchronization should be saved. If the first A-file is unacceptable select "**Reload N₂ A-file**" again to load the subject's next A-file. You can do this as many times as needed until an acceptable trial is found.



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@ ECO MEDICS - SPIRÓWARE 3.1.6	- @ X
Flow / Channel Signal Synchronization	
1000 / Clining Synchrony Direction 1000 / Clining	Colless Values Piex - [Wild] co - [So] (co - [N] Miles - [Wind] Colles Arquistion Stat Soci Chen Value Rabod N2 A-File
File Time Open Open <th< td=""><td></td></th<>	
Zoom & AI C Modum C Large	
How / Channel Signal Synchronization 00.01.2015 12107 DSA-SETI Set 3 Current values New values Incention Inspiration	
Plow / C2 Japrilar (Block) 0.456 s 0.454 s Plow / C22 spanil affects 0.0459 s	Save
Plan / PMAx symil officet: 0.005 x 0.305 x	Back
Operator: admin (First Last) DSR-SET: Set 3	

9. Once an acceptable trial is found, press <u>save</u>; the newly generated numbers will then be saved in System Settings.



5.4 How to re-run A-files once new delay times have been generated.

Now that all of the system and environmental settings have been restored to day of test and the new delay values have been saved to system settings the operator may proceed with re-running files to correct signal mis-alignment.

- 5. On the Select a Patient page, highlight the subject whose raw data files will be re-run
- 6. Press Reload N₂ A-file(s)
- 7. Find the files for be re-run (can select all at once)
- 8. Press Open.

Select a Patient					
Pilters	(3)				
Patient List					Register
BABMUS01112008 Baby	Muster	91.11.2008			Patier
MUSHAN01012009 Muster	Hans	01.01.2012			Edit
					Ner
					Raload
					2 Reload I
)pen		? 🔀	
		Look in: Dopy	• •	60 df 🔟 -	
		A-201407	17-140011-1LCL s-Set3 17-140643-1LCL s-Set3		
		My Recent A-201407 Documents A-201407	17-141114-1LCL = Set3 3		
		A-201407	17-143701-1LCL s-Set3		
		Desklop			
		2 De la constante de la consta			
		My Documents			
		My Computer			
		My Network File name: Places	"A-20140717-140011-ILCI.s-Set3.tw" "A-	20140 V 0pen	4
		Files of type	All Files (".")	Cancel	

10. Select 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 4-Fie(s) € use current settings	
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 D corrent

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

Please select ar	nd confirm the current DSR-SE	ET:
0.000	(c 15 0 km)	
C Set 2	(> 15.0 kg)	
C Set 3	(> 35.0 kg) (only for EXHALYZER D)	
C Spire	tte (Spirometry)	
	 Confirm 	

- The rerun will then begin and the A-files will automatically re-play in sequence, once the rerun is complete the software will stop automatically.
- 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.
- In addition to the draft file saved at the time of test, a second draft file, with the date of the re-run, will now be visible in the subject file. **DO NOT DELETE THE ORIGINAL DRAFT FILE!**
- 12. Prior to submitting the corrected file for analysis check that the signals have now been aligned by opening the draft file, and scrolling through each trial inspecting for evidence of signal misalignment.
- If alignment is still off, repeat synchronization procedure using a different A-file