How to Identify a Leak

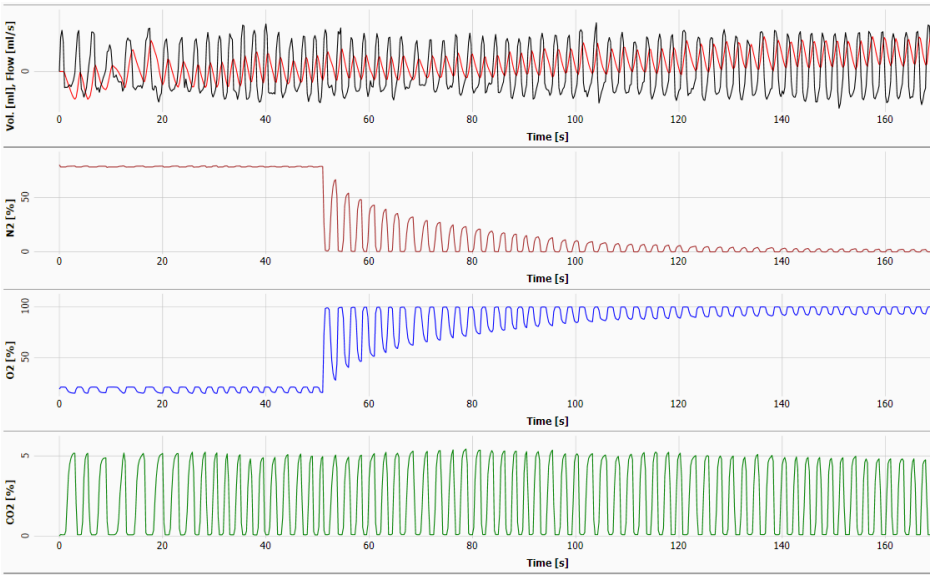
This document is intended to help operators identify leaks during the multiple breath nitrogen washout test ($MBWN_2$). According to the ETS/ARS consensus statement, a resident inert gas (e.g N_2) leak during the washout phase of $MBWN_2$ is defined as:

- *A sudden spike in N_2 concentration during inspiration*
- *Premature rise in N_2 signal early in expirogram of following breath, where N_2 should be zero in the initial absolute dead space portion, or a decrease in airway dead space volume.*
- *A sudden step change in volume time trace or a step-up in N_2 concentration plotted versus turn over (TO).*

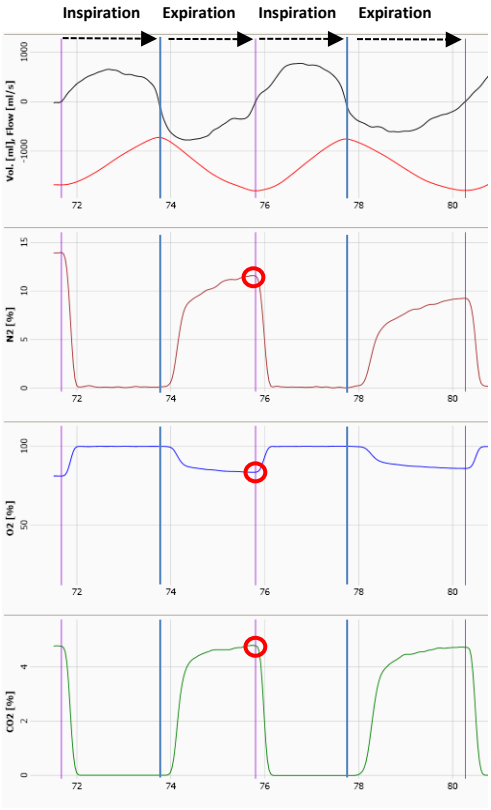
A **leak** can occur during the washout when room air enters the breathing circuit OR when exhaled gas escapes from the breathing circuit and does not get measured, ultimately affecting the gas tracings and all outcomes. If a leak is observed and **confirmed** during testing, stop the test and begin a new test. If a leak is **suspected** during testing, complete the test and closely inspect for leak before beginning the next trial. If a leak is subsequently confirmed or suspected it should be marked as excluded, the equipment setup should be inspected, and a further trial collected. Always write in the comments box if a leak was confirmed or suspected and the action taken.

An ideal test will have…

- ✓ **Stable flow and EELV**
- ✓ **An overall continuous decay in end-tidal N_2 (etN_2)**
- ✓ **An overall continuous rise in end-tidal O_2 (etO_2)**
- ✓ **Stable end- tidal CO_2 ($etCO_2$)**



The expected gas tracings during the washout with 100% O_2



The gas tracings should follow the subjects breathing pattern

- If flow is positive, the patient is inhaling.
- If flow is negative, the patient is exhaling.

Note: This document refers to inspiratory flow as positive, which can be changed under system settings.

During Inspiration:

- $[N_2]$ and $[CO_2]$ should return to zero
- $[O_2]$ should read 100%

During Expiration:

Note: End-tidal gas concentrations (Cet) measured at the end of each exhalation (shown with red circles)

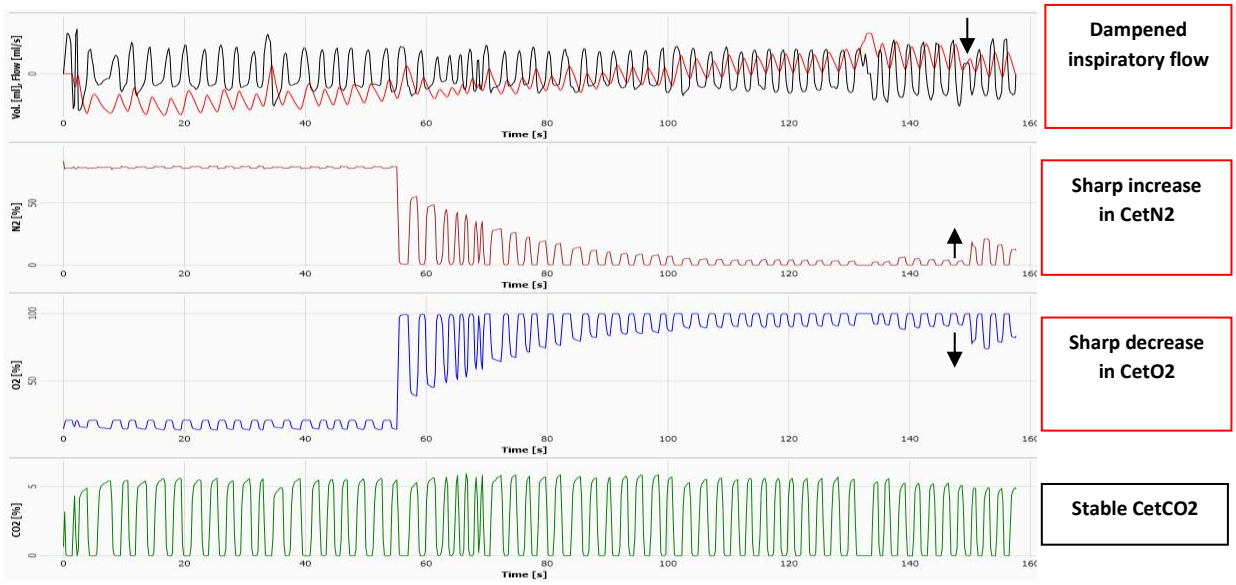
- Overall, there should be a continuous decay in $CetN_2$ and a corresponding rise in $CetO_2$ with every exhalation. Small fluctuations in $CetN_2$ may be observed near the end of test in subjects with more severe disease.
- $CetCO_2$ should be stable and between 4-6%

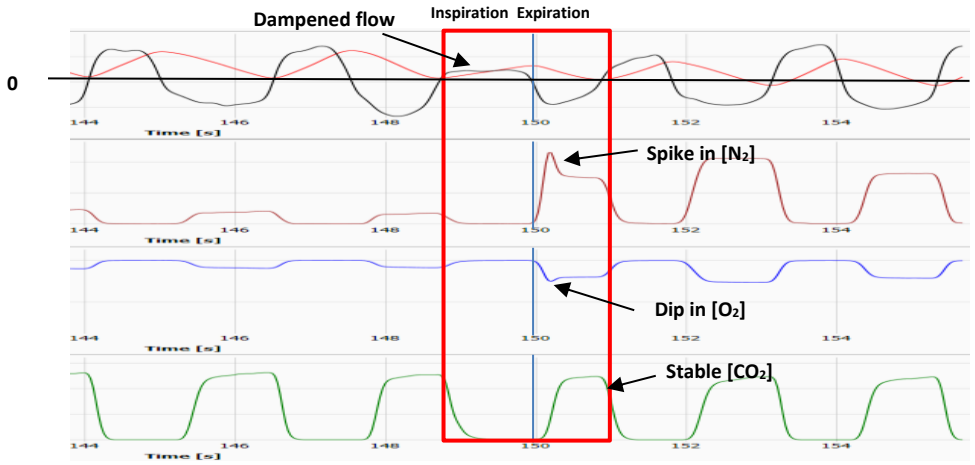
*The following are examples of leaks or signs that a leak may have occurred and should prompt a response from the operator. If you observe a **confirmed** leak during the washout, **abort** the trial and collect a new one. If you are unsure, complete the trial and inspect for a leak before beginning the next trial.*

If a leak is confirmed or suspected, collect an additional trial!

1) Inspiratory Leak

Description	• Sudden spike in [N_2] and corresponding dip in [O_2] at the beginning of exhalation, with a stable [CO_2] tracing. The leak has occurred during the end part of the inspiration but is measured by the device and shown during exhalation. • The subsequent breaths may have a drastic or minor increase in $CetN_2$, depending on the severity of the leak.
Source	• Most often occurs due to loose lips at the mouthpiece or slipping nose clips. NB keep a constant check on the seal at the mouthpiece • During inspiration, the gas tracings look normal, BUT the flow is dampened. This suggests a leak at the interface resulting in the subject inhaling room air.
Action	• If a leak is **confirmed or suspected,** collect an additional trial. • Operators should always remind the subject before and throughout the washout to keep a tight seal at the mouthpiece, and check nose clips are on tight. If testing preschoolers, coach them during the trial to avoid drastically moving their head/neck and making big facial expressions.

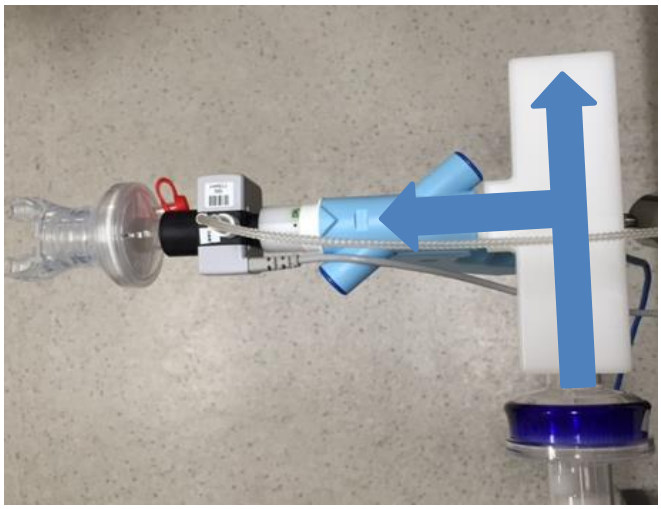




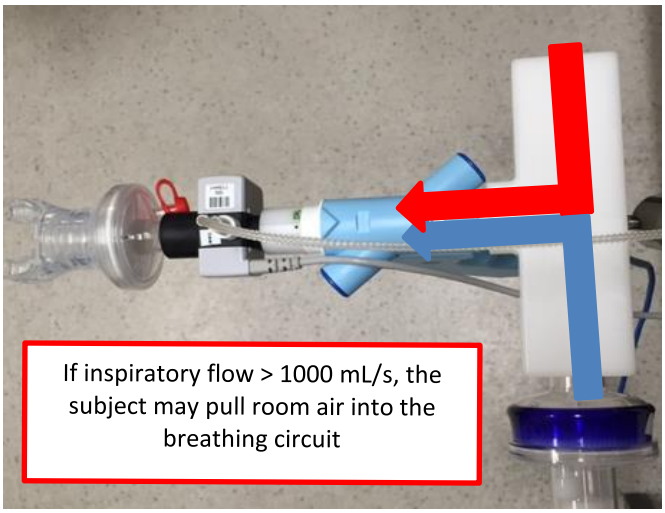
2) Inspiratory Leak when inspiratory flow > 1000 mL/s

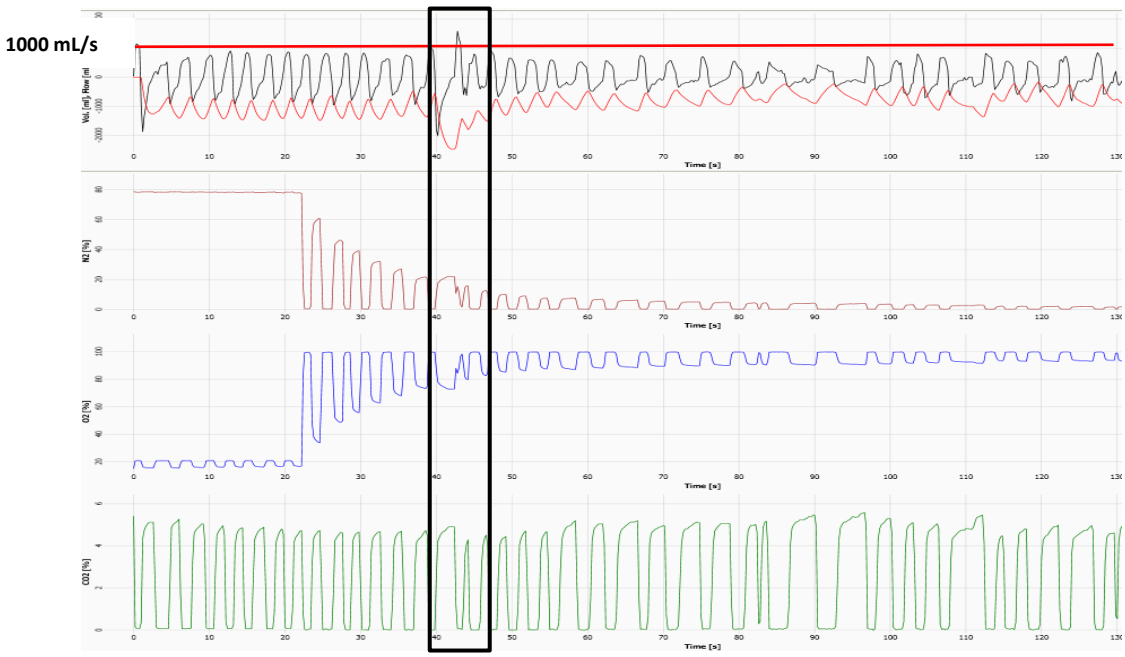
Description	• $[O_2]$ should be 100% while the flow trace is positive (i.e. inspiration). Notice the $[N_2]$ spike during inspiration (should be 0%) and $[O_2]$ dips from 100% during inspiration. $[CO_2]$ is normal and returns to zero during inspiration.
Source	• The Exhalyzer D delivers medical air and 100% $[O_2]$ in the bias flow at approximately 1000 mL/s. If the subject inhales faster than the delivery speed (inspiratory flow > 1000 mL/s), they may pull room air into the breathing circuit causing an inspiratory $[N_2]$ leak.
Action	• Inspect closely for a leak if prompted with the error message that reads: **Flow during inspiration is too high (>1000 mL/s)** • If a leak is confirmed, abort the trial. Before collecting another trial, coach the subject to avoid taking sharp inhalations.

Inspiratory flow < 1000 mL/s

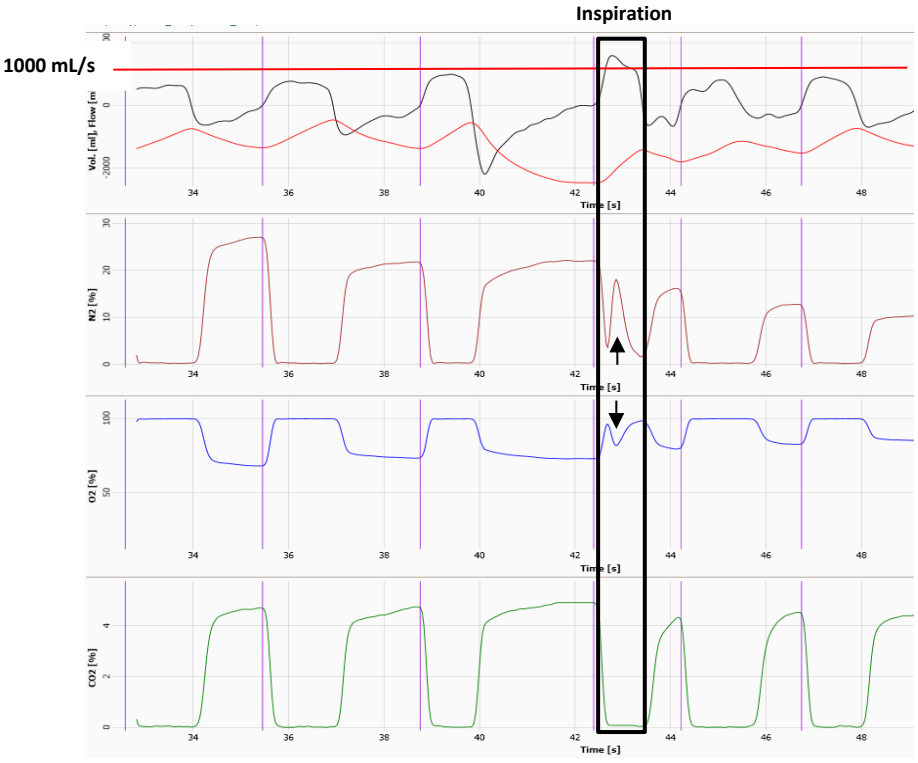


Inspiratory flow > 1000 mL/s





Flow during inhalation exceeds 1000 mL/s.



Insp flow >1000 mL/s

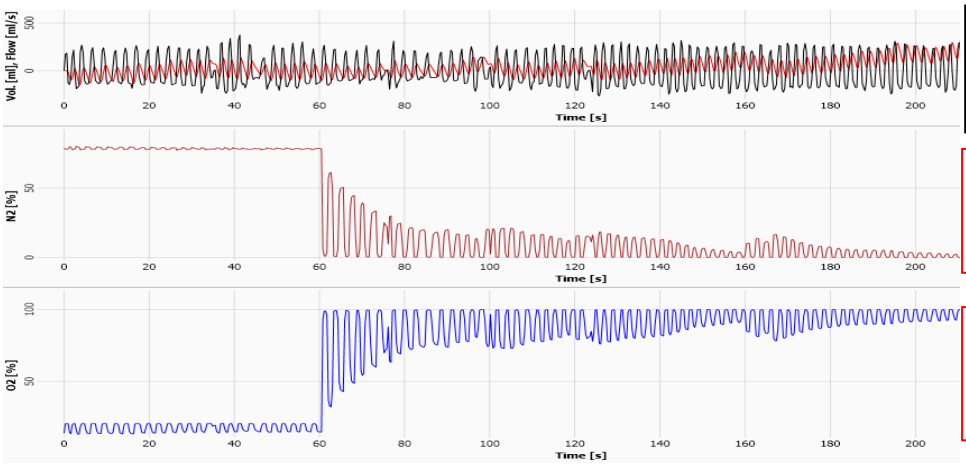
[N_2] peaks during inspiration

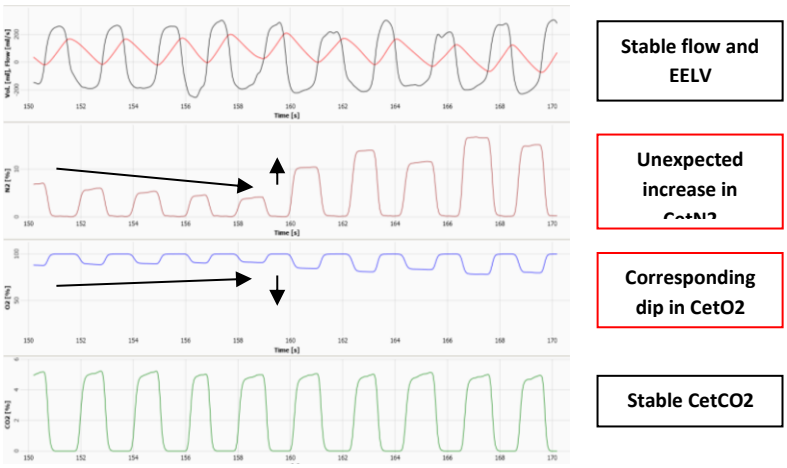
[O_2] dips below 100% during inspiration

[CO_2] normal, 0% during inspiration

3) Transient Inspiratory Leak

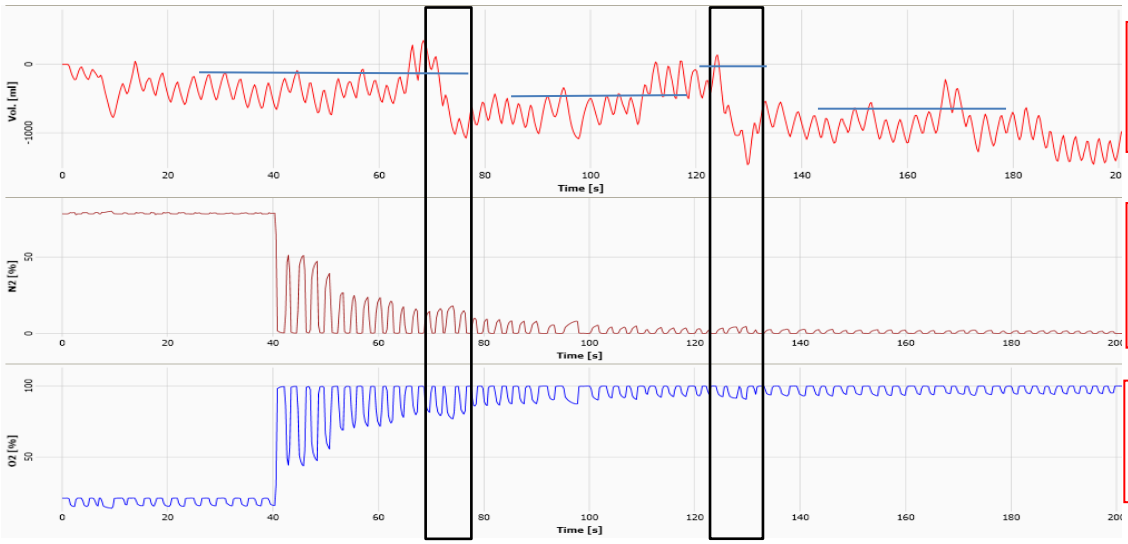
Description	• The Roller Coaster; CetN_2 does not display an overall continuous decay, the [N_2] tracing may start to resemble the shape of a roller coaster where the CetN_2 goes up and down. This is more apparent in the zoomed out "All" view.
Source	• A result of multiple transient leaks at the mask or mouthpiece where gas from the subject is temporarily leaked to the atmosphere and room air enters the circuit; happens most often with mask. • Note the corresponding changes in [O_2], while the flow and tidal volumes are stable. • Please note that some CF subjects may display more unstable CetN2 decay near the end of test. However this will likely not be apparent in the "All" view. This may be due to the severity of the underlying disease and does not represent a true leak. If you notice this, it is vital to inspect the subject and the seal around the mouthpiece
Action	• Abort the trial and include comments about the integrity of the interface seal. Ensure a tight seal at interface and nose clips are on correctly. If necessary, practice maintaining the tight interface seal in between trials.





4) An abrupt shift or step change in the volume/time trace

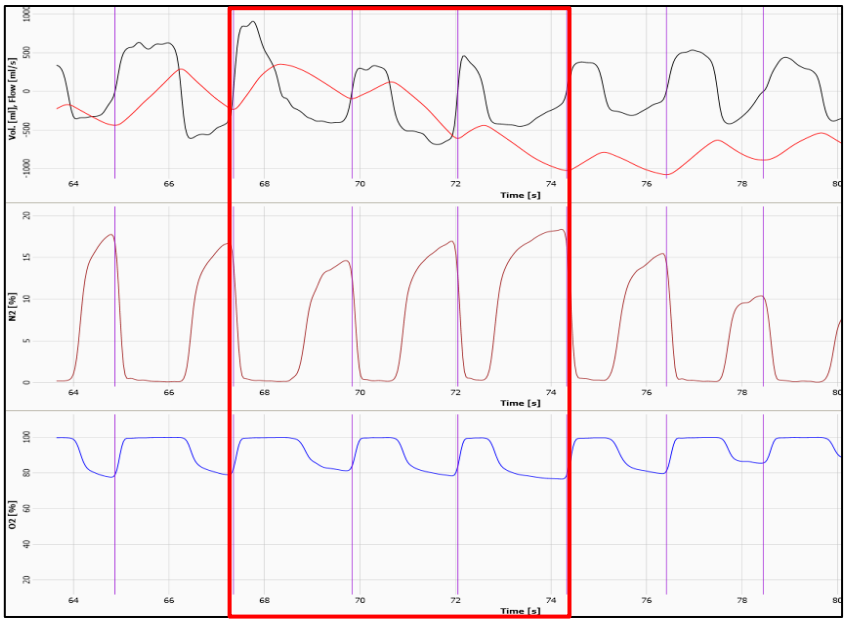
Source	• Most often caused by an expiratory leak at the mouth where all or some of the expiratory breath is lost to the atmosphere (before it reaches and is measured by the flowmeter). This causes the measured Inspiratory and Expiratory tidal volumes to be unbalanced (i.e. inspiration measured correctly but expiration underestimated) resulting in the abrupt shift in the volume/time trace. • May also be caused by irregular breathing pattern where inspiratory and expiratory tidal volumes are unequal. Important to inspect closely for cause.
Action	• Step change in the volume time trace does not necessarily mean there is a leak, if $CetN_2$ continues to decay then continue testing. • Prudent to inspect the trial for a leak; if unsure, collect another trial. If observe a steady increase in $CetN_2$ with a corresponding dip in $CetO_2$, this is evidence of a leak and the trial should be aborted.



Sudden step change in volume trace

$CetN_2$ increases due to the step change

$CetO_2$ decreases due to the step change



Sudden step change in volume trace (in red)

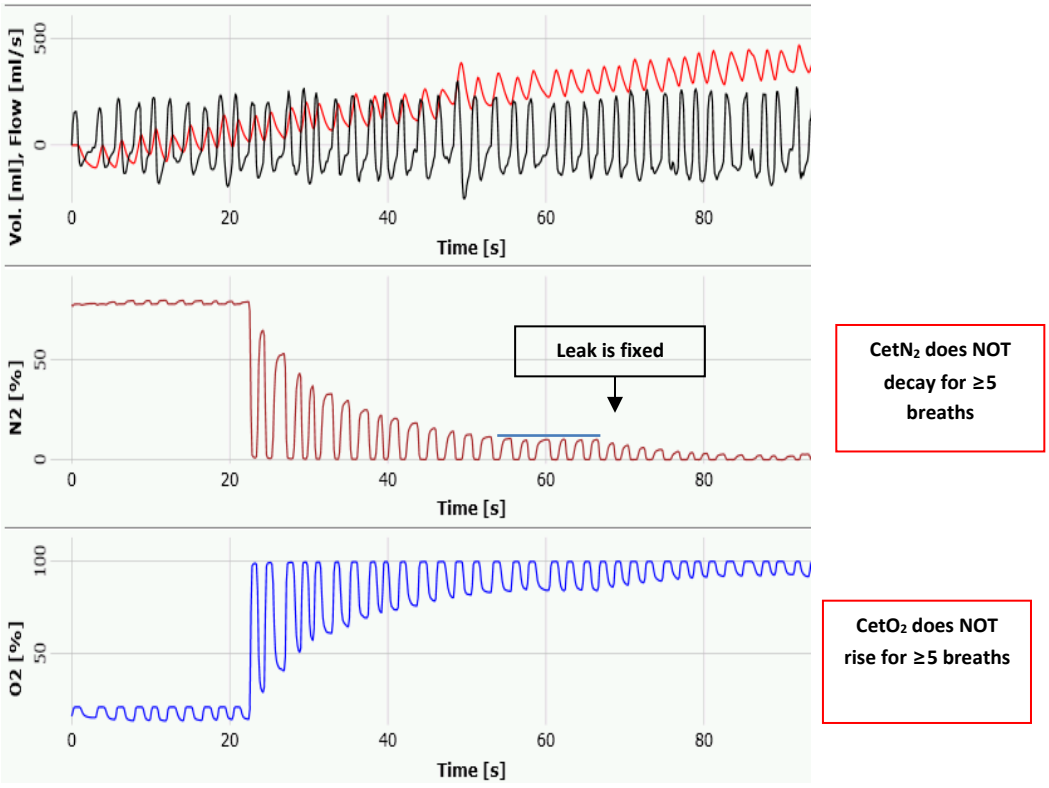
$CetN_2$ increases due to the step change

$CetO_2$ decreases due to the step change

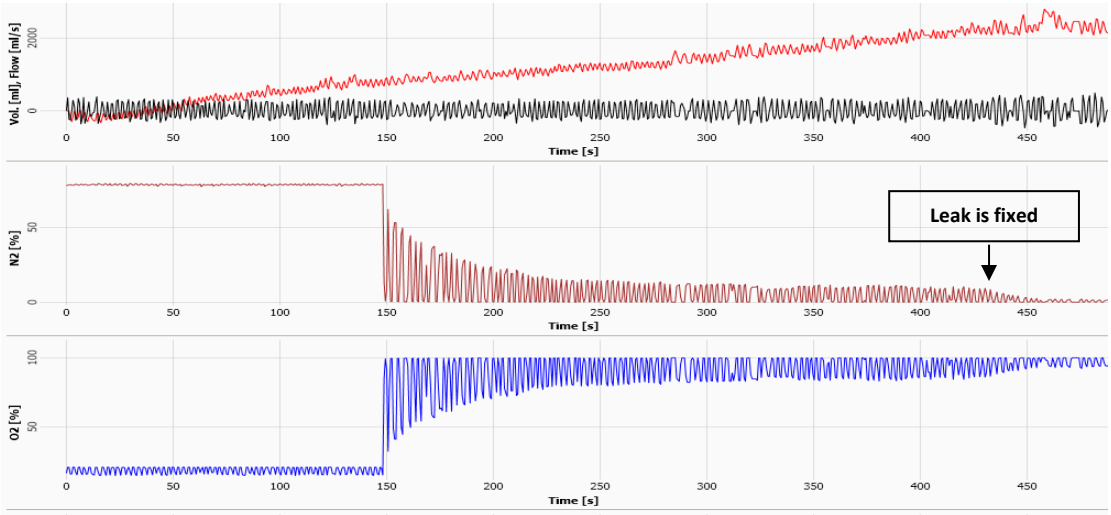
5. Constant Leak: $CetN_2$ plateaus or no longer decays for 5 or more consecutive breaths

Description	• If there are 5 or more consecutive breaths with no apparent decay in $CetN_2$, there is a high likelihood that there is a leak. This type of leak varies in severity, please see examples below. • The leak can be confirmed by noting the discrepancy in the number of washout breaths required to meet end of test between the trial with a suspected leak and subsequent trials where the leak has been corrected. Ensure you take the number of washout breaths from the correct place, as if you take this value from the trials box it will include all breaths after the end target giving a false number of breaths!
Source	• Most often caused by a small leak at the lips (loose lips around the mouthpiece) or loose nose clips. • May also be caused by a small leak at the Nafion Tubing **however in this situation there will be other signs pointing to a leak at the tubing connection (See Leak #6).
Action	• Before collecting another trial: ensure a tight seal around the interface, nose clips and nafion tube. If you are testing with a t-piece, ensure it is tightly secured to the dead space reducer. • <u>Note</u>: In subjects with more severe disease, the decline in $CetN_2$ may be more subtle; $CetN_2$ may also increase and decrease with breath size but is unlikely to plateau.

<u>Example A</u>: Small leak mid-washout; $CetN_2$ and $CetO_2$ plateau for ≥5 breaths. Note when the leak is fixed and N_2 continues to decay.



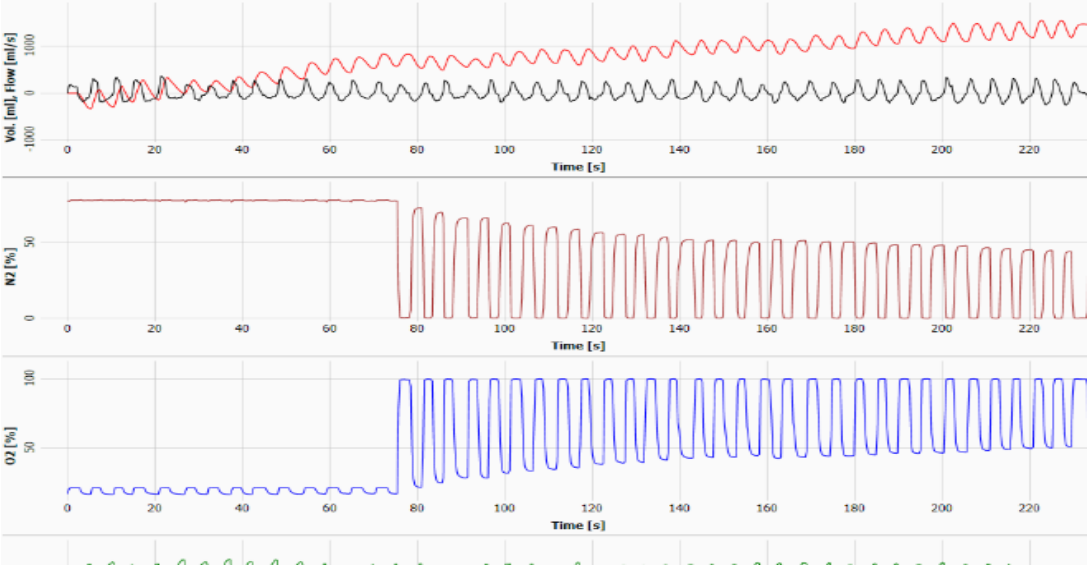
Example B: Small constant leak; $CetN_2$ and $CetO_2$ plateau for ≥5 breaths. Note when the leak is fixed and N_2 continues to decay.



$CetN_2$ does NOT decay for ≥5 breaths

$CetO_2$ does NOT rise for ≥5 breaths

Example C: Large constant leak; $CetN_2$ and $CetO_2$ plateau early in the washout.

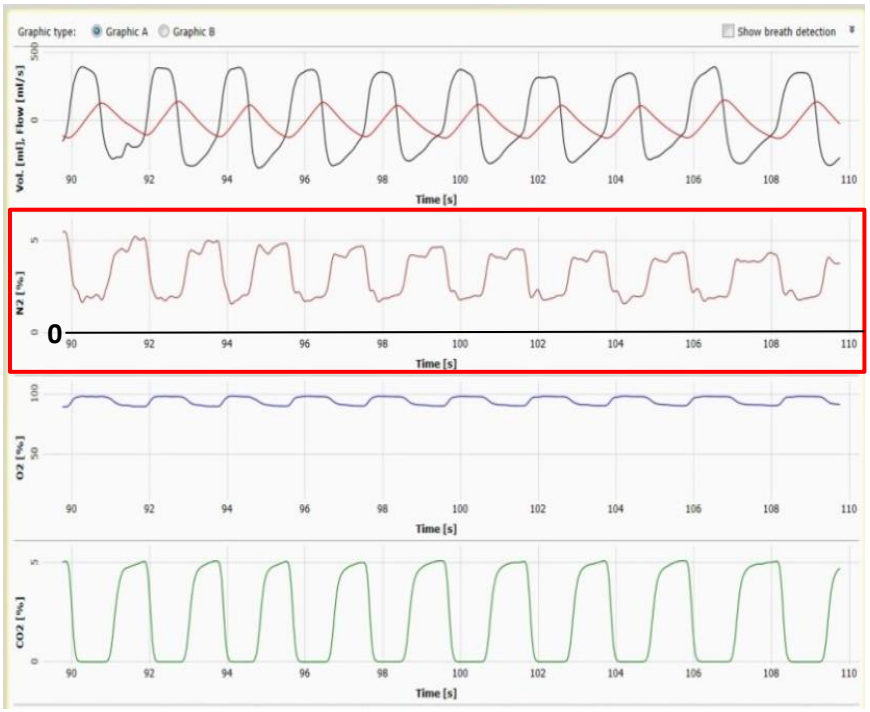


$CetN_2$ does NOT decay for ≥5 breaths

$CetO_2$ does NOT rise for ≥5 breaths

6. Leak at the Nafion Tube

Description	• [N_2] tracing has an elevated baseline and does NOT return to zero during inspiration when the subject should be breathing 100% [O_2]. This leak may also cause a plateau in CetN_2 as described in **Leak #5** and will likely result in the subject taking longer to washout (higher number of breaths to reach end of test). • If the mean inspiratory [N_2] is elevated over the course of the washout, this will trigger an error message that reads: **Mean N2 Insp. is out of valid range**
Action	• <u>Action</u>: Check the connection and integrity of the nafion tube (cracks, kinks or loose luer connection) before starting another trial. Replace nafion tube if a micro crack is suspected or the tube appears old and worn.



Stable flow and EELV

[N_2] does NOT return to zero during inspiration

[O_2] is diluted and does NOT reach 100% during inspiration

Stable [CO_2]