



TEST REPORT

Devices: COSMED Quark PFT with X9 PNT (sn 381) for Spirometry & DLco measurements
Testing Dates: April 25, 26, 27, 2012
Location: HRI facility in Shawnee Kansas
Present: COSMED
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Flow Volume Simulator (FVS) Testing Procedure(s)

24 Volume-Time The HRI FVS 1120 series (sn 112-056) was used to generate the standard ATS/ERS 24 Volume-Time waveforms, BTPS delivery conditions for same series waveforms 1-4, and 4 MVV Sinusoidal waveforms as instructed by Cosmed per the validation requirements. The unit under test (UUT) as supplied and setup by Cosmed was the QUARK PFT system (sn 2012010421) with the X9 pneumotach (sn 381). All connectors and filter for the PNT setup with the FVS were provided by Cosmed and are photo documented for this report.

Each of the standard 24 Volume-Time waveforms were injected into the Cosmed X9 Quark system 5 times and the values for the parameters FVC, FEV1, PEF and PEF25-75 were recorded and compared with the FVS values. The Average, Precision (range), Precision % (range %), Accuracy (deviation) and Average % (deviation %) for each of the parameters were listed and computed.

BTPS conditions Each of waveforms 1-4 of the standard 24 Volume-Time series were also injected at BTPS conditions into the Cosmed X9 Quark system 3 times each and the values for parameters FVC and FEV1 were recorded and compared with the FVS values. The Average, Precision (range), Precision % (range %), Accuracy (deviation) and Average % (deviation %) for each of the parameters were listed and computed.

MVV waveforms 4 MVV waveforms as recommended by the ATS/ERS for repeatability of measurement evaluation were simulated using a sinusoidal waveform and were each injected 2 times into the Cosmed X9 Quark system and the values for Breath Rate and MVV were recorded and compared with the FVS values. The Average, Precision (range), Precision % (range %), Accuracy (deviation) and Average % (deviation %) for each of the parameters were listed and computed.

Test Results

24 Standard Volume-Time waveforms

Results: see the attached data sheets

All data collected for the Cosmed X9 Quark system resulted in acceptable performances per the criteria established for Accuracy and Precision when tested with the standard 24 Volume-Time waveforms.

- FVC-FEV1 Accuracy & Precision = +-3.5% or +-0.100 l whichever is greater
- FEF25-75% Accuracy & Precision = +-5.5% or +-0.250 l/s whichever is greater
- PEF Accuracy & Precision = +-12% or +-25 l/min whichever is greater

BTPS conditions testing waveforms 1-4 of the standard 24 Volume-Time series

Results: see the attached data sheets

All data collected for the Cosmed X9 Quark system did not result in acceptable performances per the criteria established for Accuracy and Precision when tested with waveforms 1-4.

FVC-FEV1 Accuracy & Precision = $\pm 4.5\%$ or ± 0.200 l whichever is greater

MVV Sinusoidal waveform testing

Results: see the attached data sheets

All data collected for the Cosmed X9 Quark system resulted in acceptable performances per the criteria established for the MVV testing for Accuracy and Precision = $\pm 10.5\%$ or ± 20 l/min whichever is greater.

DLco Simulator Testing Procedure

The HRI DLco Simulator with EasyLab QC software, 5560 series (sn 556-217) was used to generate known values for the parameters of DL, VA, VI, Exp CO% and Exp CH4% for operation with the Cosmed UUT. The DLco Simulator was connected to the Cosmed Quark PFT system (sn 2012010421) and X9 PNT (sn 381) per Cosmed instructions and supplied filter and connectors. The set up was photo documented as part of this report. Primary Plus® gases ($\pm 1\%$ accuracy) were sourced for these testing purposes for the Patient Test gas (171382) connection to the Cosmed UUT and for the Simulator Low (171371) and Mid (171372) level DL ranges.

HRI was instructed to use two different IVC's of 2 & 4 Liters and two different DL Simulator gases to cover DL ranges of Low through Mid ranges. Each combination of IVC and gas was to be delivered 5 times to the Cosmed UUT and values for the parameters for DLco, VA, VI, Exp CO% and Exp CH4% were to be recorded and compared with the DLco Simulator values for each test.

There are no published acceptance testing criteria when using the DLco Simulator for testing. There have been published papers related to performance criteria with this Simulator that range from ± 2 to ± 3 DL units as an acceptable accuracy for this type of testing.

In our report that is supplied as a summary of the Cosmed device performance we use specific values as limits above which turn the values on the report "yellow" to show out of the range we have selected for each of the measured parameters.

Our selected unit range limits are:

DL ± 3 units or 10% whichever is greater

VA & VI ± 0.100 L or 5% whichever is greater

Exp CO% & Exp CH4% ± 0.05 units or 2% whichever is greater.

Test Results

The performance data collected for DLco units for the Cosmed UUT are well within the ± 3 DL units accuracy. The other parameter values relate to flow and gas measurement accuracy and can be used by Cosmed to evaluate system components.

Results: see the attached Report from EasyLab QC for all data collected and analyzed.

Overall Summary

The COSMED Quark PFT with X9 PNT tested well within acceptable accuracy ranges for Spirometry and DLco performances when tested with the Hans Rudolph FVS and DLco Simulator with the exception of slight deviation outside of accuracy limitations for waveforms 1 & 2 tested at BTPS conditions.

This testing completed at HRI does not imply endorsement or acceptance by the American Thoracic Society or European Respiratory Society.

Best regards,



Kevin Rudolph
CEO Hans Rudolph inc.