VIASONIX

FALCON

PRODUCT FAMILY

Service Manual

FALCON PRO

FALCON QUAD

FALCON ABI+

CE 0344

Doc: VS0152, Rev 1.2

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1 - INTRODUCTION

1.1 About Falcon

The Falcon product family includes the **Falcon/*Pro***, **Falcon/*Quad*** and **Falcon/*ABI*+** systems. The use of the term Falcon in this manual relates to all 3 systems, unless specifically stated otherwise. The **Falcon/*ABI*+** system does not include Doppler options, and therefore all Doppler references in this manual are not related to the **Falcon/*ABI*+** system.

Falcon is an add-on non-invasive peripheral vascular diagnostic system, that plugs into a personal computer via a USB connector for operation, data display and storage. Falcon systems incorporate several technologies for the purpose of non-invasively diagnosing various arterial and venous hemodynamic parameters in the peripheral circulation.

Falcon/*Pro* is the complete peripheral vascular diagnostic system. It includes 10 independent pressure channels for the measurement of blood pressure (BP) or pulse volume recording (PVR). In addition, it includes 5 independent photo-plethysmograph (PPG) channels, 1 skin temperature sensor, and 3 Continuous Wave (CW) Doppler pen-type probes with frequencies of 4 MHz, 8 MHz, and 10 MHz.

Falcon/*Quad* is a focused peripheral vascular diagnostic system. It includes 4 independent pressure channels for the measurement of blood pressure (BP) or pulse volume recording (PVR). In addition, it includes 4 independent photo-plethysmograph (PPG) channels, 1 skin temperature sensor, and 3 CW Doppler pen-type probes with frequencies of 4 MHz, 8 MHz, and 10 MHz.

Falcon/*ABI*+ is a cost-effective peripheral vascular diagnostic system. It includes 4 independent pressure channels for the measurement of blood pressure (BP) or pulse volume recording (PVR). In addition, it includes 4 independent photo-plethysmograph (PPG) channels, and 1 skin temperature sensor.

The Falcon must be operated only by trained personnel. Falcon is intended for use only in adults and children, and should not be used under any conditions for fetal or neonatal examinations.

1.2 About this manual

This manual assumes that the reader is a trained and experienced medical device service professional, which is also familiar with peripheral vascular diagnostics and Doppler blood flow velocity measurements. The manual does not provide any instructions relating to the techniques or methods of acquiring data. The intention of this manual is to provide service instructions to the Falcon products, as well as important warnings and precautions which are related to the safe use of the device. This manual must be read completely by any Falcon service technician before attempting to perform any service operations. If at any time the service procedure is not clear, immediately contact Viasonix Ltd. for further instructions before attempting to proceed with the service.

The symbol  is used in this manual to denote a **warning** that may have a hazardous effect on the patient or user.

The symbol ! is used in this manual to denote a **caution** that may have a hazardous effect on the equipment.

This manual gives instructions for the servicing of the Falcon, including diagnostic sequences to troubleshoot and isolate basic failures, assembly sequences required to remove and replace suspect service parts, and performance verification sequences to ensure that the performance of the repaired unit meets the required specifications. This manual does not include any servicing capability for the ultrasound probes, PPG and temperature sensors, pressure cuffs and tubing, cables or accessories. These items are not serviceable. This manual is not intended to provide detailed repair procedures and technical documentation to isolate failures to the lowest possible level. It is also not intended to support the remanufacture and resale of the Falcon by third parties.

1.3 Service Personnel

This manual is intended for use by biomedical instrumentation technicians and other individuals who are familiar with the routine servicing and maintenance of medical electronic instrumentation. Those individuals should also be thoroughly familiar with the Falcon User Manual.

The servicing personnel should also be proficient with the architecture, components and typical servicing procedures for personal computers running the Microsoft Windows operating system. Customers are not authorized to perform any service to the system during the warranty period of the product.

Viasonix Ltd. understands the importance of feedback to continual quality improvement, and encourages users and servicing personnel to provide any suggestions for improving the products and this manual.

1.4 Warnings and cautions

 Take care to carefully read the following section. Additional warnings and precautions may also appear in the other parts of this manual.

 Only experienced biomedical instrumentation technicians or other individuals who are familiar with the routine servicing and maintenance of medical grade electronic instrumentation should service the system.

 Viasonix Ltd. shall have no liability for any incident resulting from improper servicing, or from the use of any service parts that are not obtained by authorized Viasonix Ltd. sources of supply. Do not use any ultrasound probes, PPG Sensors, temperature sensors, pressure cuffs, air tubes, foot switch, remote control, power supply, or any other accessories that are not supplied by Viasonix Ltd. with the Falcon system.

 Always disconnect the power cord from the power outlet before opening the system. Turn off the power before performing other maintenance activities. Do not clean the system with a wet cloth. Do not immerse the ultrasound probes in water or other liquids.

 Use only the power supply that is supplied with the Falcon. Before turning the power on, make sure that all cables and connectors are properly connected.

 Do not use the system near flammable conditions. Keep away from water or other liquids. Do not operate the system under non-approved environmental conditions.

 Do not operate the system if the power cord or any other cable or connector is damaged.

 Use the system only for valid medical reasons. Keep examination duration to as short as necessary.

 All external devices, including printers, that are used in conjunction with the system, must comply with IEC 60601.

 Place the system only on a flat and hard surface. Never place the system on a cloth, sponge or similar materials.

 The internal electronics of the system are sensitive to damage from electrostatic discharge (ESD). Use appropriate precautions when opening and servicing the unit or handling electronic components and subassemblies. To avoid ESD (Electrostatic Discharge) damage to sensitive components, make sure you are properly grounded before touching any internal materials.

! Turn off the power before connecting or disconnecting any accessories. When re-connecting system components, make sure that you connect them in their proper location.

! Turn off the power before cleaning. Clean the system only with a soft cloth or brush.

! Replace wire ties and reroute wires as they were initially found. Do not leave loose hardware or tools inside the console. Do not attempt to change or modify the Falcon hardware.

! Conduct normal in-house product safety testing for the system after servicing and before returning the unit for use on patients.

! Transferring a copy of the Falcon installation program and/or the installation serial number to people or entities which did not purchase the Falcon system is strictly prohibited.

! Never drop the system or any of its' components. Take special care to prevent the ultrasound probes and the PPG and temperature sensors, from dropping or knocking on a hard surface in order to prevent mechanical damage.

! Do not run any other applications on the computer when operating the Falcon. Make sure all other applications are turned off.

! Never pull on the cables for disconnecting the probes, sensors or other accessories.

! Connect the system only to a personal computer that meets the minimum requirements.

2 – TECHNICAL INFORMATION

2.1 Overview

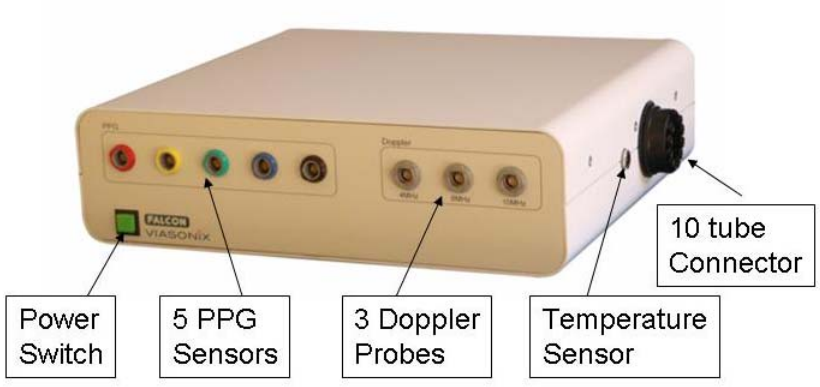
This section outlines the basic technical features of the Falcon system. The Falcon is a peripheral vascular system which is designed to be plugged to a host computer for operation. The Falcon main parts consist of the main control board, an ultrasound unit with PCB mount Doppler connectors which is connected to the main board via a flat cable (not available with the Falcon/ABI+), and pneumatic units which primarily carry the inflating pumps.

The host computer should have the following minimum requirements: Windows XP or 7 operating system, Intel® 3GHz Core™ 2 Duo processor, 2 GB memory, sound card and speakers, and at least 100 GB remaining free disk space on the hard drive.

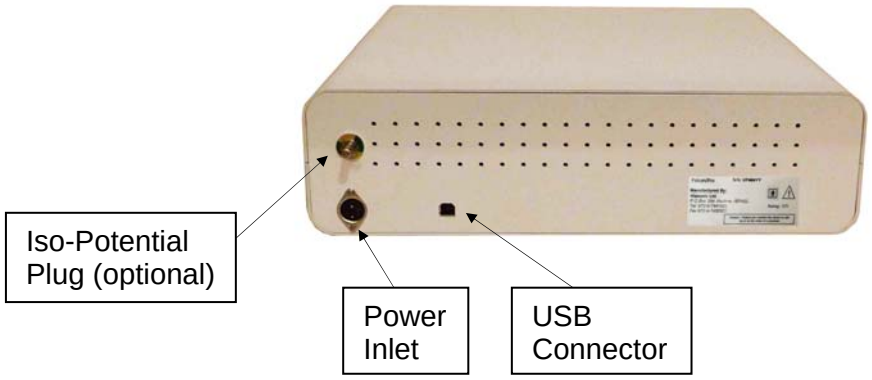
Operator control over the system can be accomplished through the keyboard, mouse, remote control or foot switch which are connected directly to the computer, or through touch screen operation. The system display should be 19'' or higher wide screen with touch screen capabilities. The recommended display resolution is 1280x720 pixels. The display provides the user with direct visual feedback regarding the test performed, examination protocol, active sensors, examined site, signal display region, signal control buttons and settings, and measured parameters.

2.2 Falcon description

A view of the front of the Falcon/Pro main console is given below. Note that the right side of the Falcon is similar for all 3 systems. The front panel, however, shows the system name and logo according to the specific Falcon system. In addition, the black PPG connector (the most right PPG connector in the PPG connector row) is absent in the Falcon/Quad and Falcon/ABI+ systems. Furthermore, the Falcon/ABI+ system also does not have the 3 Doppler connectors as displayed below.



A view of the back panel of the Falcon console is given below. Note that the back panel for all 3 Falcon products is similar (excluding the designated system label).

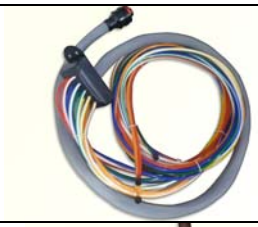


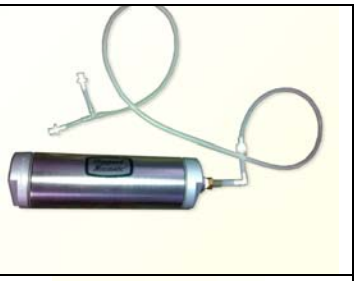
The Falcon housing is designed to comply with applicable global regulatory requirements for safety (EN60601-1) and electromagnetic compatibility (EN60601-1-2). The primary housing is made from metal. The top cover is secured to the unit with 3 screws on each side. Connectors and cables meet applicable regulatory requirements and environmental conditions. The housing basically contains all of the system electronics, pneumatic components, and air tubes. The system receives 12V DC power via a desktop power supply that is approved for Falcon.

3 – FALCON SERVICE AND REPLACEMENT PARTS

3.1 Falcon service kit

The Falcon service kit is required to perform the performance diagnostic tests and to assist in disassembling the system. The basic elements of the kit are detailed in the table below.

Part #	Part Name	Picture Description
PVC0105	Wrench Tool	
PVC0012	PPG-DC Simulator Device	
PVC0013	Temperature Simulator Device	
PVC0064	Falcon external 10-tube Sub-assembly	
PVC0106	Calibrated External Pressure Sensor	

PVC0107	Test Pressure Chamber	
PVC0108	Closed Loop Silicon Tube	

3.2 Falcon replacement parts

The table below lists all of the Falcon sensors and replacement parts, which can be replaced by authorized service personnel.

Part #	Part Name
PVC0072	Falcon 4 MHz CW Doppler Probe
PVC0073	Falcon 8 MHz CW Doppler Probe
PVC0074	Falcon 10 MHz CW Doppler Probe
PVC0075	Falcon PPG Fingerclip Sensor
PVC0076	Falcon PPG Disc Sensor
PVB0070	Adult skin Temperature Sensor
PVB0073	Hokanson Brachial cuff SC10
PVB0074	Hokanson Thigh cuff SC12
PVB0075	Hokanson Digit cuff UPC2.5
PVC0091	Falcon Remote Control
PVB0076	Phillips 3 Pedal Foot Switch
PVC0056	Falcon Adhesive Stickers (Roll of 1000)
PVC0064	Falcon external 10-tube Sub-assembly
PVC0103	Falcon Internal 10-tube Sub-assembly
PVC0057	Falcon Internal PPG Cable

PVC0060	Falcon Internal Temperature Cable
PVC0071	Falcon Doppler Internal Flat Cable
PVC0067	Falcon/Pro Pump Sub-assembly Front
PVC0068	Falcon/Pro Pump Sub-assembly Back
PVC0069	Falcon/Quad Pump Sub-assembly Back
PVC0018+	Housed CW Doppler Board
PVC0080	PPG Holder for cart
PVC0081	Doppler Probe Holder for cart

4 – FALCON PERFORMANCE DIAGNOSTIC TESTING

The initial step when attempting to service the Falcon, is to perform a complete system diagnostic performance testing. The diagnostic performance is performed through the Falcon software, and requires the use of a complete service kit.

The performance testing is conducted when the Falcon is connected to a computer which is loaded with the Falcon software. At the end of the testing a PDF report that summarizes all of the test results can be generated for documentation purposes.

To get started, turn on the Falcon power and start the Falcon software. From the main screen, click on the little *Help* icon on the bottom right of the screen (the little "i"), and select Service/Diagnostics/Performance. A window opens, requesting to enter the technician password.

NOTE – only authorized service personnel are allowed to perform any service activities with the Falcon.

The technician password is: **via123$**

After entering the correct PW, a window opens requiring to enter the system serial number (S/N) and the testers' name. In the S/N section enter in the first field the first 3 digits of the Falcon S/N, and in the second field the last 2 digits (marking the production year). After pressing the *OK* button, the Falcon diagnostics protocol is loaded to the main screen, and a *Help* page opens to explain the next test. A similar help page opens before each step in the test protocol. The tester can reload the respective Help page for each test at any time with the *HELP* button on the right hand side. Once the tester presses the Start button, the first diagnostic test automatically starts. For each test, the text to the right of the protocol list guides the tester on what to do or what to expect.

4.1 Tube Connection Test

Objective: The objective of this test is to check that all of the internal tubing in the Falcon are connected correctly.

Setup: Prior to starting the test, the 10-tube sub-assembly (PVC0064) should be connected to the Falcon, and the external side of all tubes (the cuff side) should be open to air.

Test: Once the *Start* button is selected (or the *Redo* button if the test is repeated), all Falcon pumps become active, and start inflation to open air. The online instructions on the side guide the tester to close the air output of each colored air tube ending with the finger according to a specific color order. Once the tube ending is closed with the finger, pressure should be generated in that specific channel and the instructions guide the tester to the next tube.

Pass/Fail: Pass is considered when all of the tubes generate pressure according to the instructed order. If a a specific channel does not generate pressure when shutting the tube, then the tester should press the Fail button on the right.

Troubleshooting:

a) The external tube sub-assembly may be leaking. Replace PVC0064 and retest.

b) One of the pneumatic elements: valves, pumps or internal tubes, may be responsible for leaking. Follow the instructions in the section for leakage source identification to pinpoint the leakage source.

4.2 Verify Calibration Test

Objective: This test verifies the calibration of the pressure sensors.

Setup: Connect the external pressure sensor (PVC0106) in parallel to one of the 2 free tube ends of the pressure chamber (PVC0107) tubing. Turn PVC0106 on by pressing the power on button (top left button).

Test: Connect the free tube ending of PVC0107 to the tested pressure channel tube of PVC0064, and press Ok to start test. The corresponding pump should inflate to a set target pressure. Wait until a window opens and type in the respective field the pressure shown on the external pressure sensor device PVC0106. Press Ok and to complete the test for the current channel. Press NEXT to continue with the test of the next channel.

Pass/Fail: Pass is defined as a relative error of less then 5% between the tested channel pressure and the external measured pressure.

Troubleshooting:

If the Verify Calibration Test cannot be completed due to failure to build a steady pressure in the pressure chamber, then one of the pneumatic elements: valves, pumps or internal tubes, may be responsible for the failure. Follow the instructions in the section for leakage source identification to pinpoint the leakage source, and repeat the calibration test.

If the Verify Calibration Test fails, then the failed channel name becomes active in the protocol list on the left hand side for the next Calibrate test. The failed channel needs to be calibrated, and then repeat the calibration verification test.

4.3 Calibration

Objective: This procedure is carried out only when the calibration test fails, in order to re-calibrate the pressure sensors of the failed channels.

Setup: Maintain the same setup of the previous Verify Calibration test.

Test: : Connect the free tube ending of PVC0107 to the respective pressure channel tube of PVC0064, and press Ok to start test. The corresponding pump should inflate to a set target pressure. Wait until a window opens and type in the respective field the pressure from the external device. Press Ok and wait for the pump to resume inflation to a second preset target pressure, and the second time that the calibration window pens. Type again the new pressure shown on the external device, and press Ok to complete the calibration for the current pressure channel. Press NEXT to continue with next active pressure channel.

Pass/Fail: Not applicable for this test. The calibration will be verified in the next test.

Troubleshooting:
If the calibration process cannot be completed due to failure to build a steady pressure in the pressure chamber, then one of the pneumatic elements: valves, pumps or internal tubes, may be responsible for the failure. Follow the instructions in the section for leakage source identification to pinpoint the leakage source, and repeat the calibration test.

IMPORTANT – After the calibration process is completed, exit the Falcon software, and then re-enter the program and resume the diagnostic testing. This will ensure proper calibration. Otherwise the calibration data will not be saved for the corresponding pressure channels.

4.4 Repeat Verify Calibration Test

Objective: This test becomes active only when 1 or more pressure channels required calibration. The test verifies the calibration of the pressure sensors.

Setup: Maintain the same setup of the Verify Calibration test.

Test: Connect the free tube ending of PVC0107 to the tested pressure channel tube of PVC0064, and press Ok to start test. The corresponding pump should inflate to a set target pressure. Wait until a window opens and type in the respective field the pressure shown on the external pressure sensor device PVC0106. Press Ok and to complete the test for the current channel. Press NEXT to continue with the test of the next pressure channel tat was previously calibrated.

Pass/Fail: Pass is defined as a relative error of less then 5% between the tested channel pressure and the external measured pressure.

Troubleshooting:
If calibration still fails, contact your authorized Viasonix representative.

4.5 Pumps and Valves Performance Test

Objective: This test is composed of 2 separate tests: Pump performance test, and fast deflation test. The first test is to verify that the pressure chamber inflates adequately, and the second to verify that the chamber deflates quickly when required.

Setup: It is possible to maintain the setup of the calibration tests. The external pressure device can be turned off.

Test: Connect the tube of the tested channel to the pressure chamber. Press Ok to start inflating the chamber and wait while the chamber inflates and deflates automatically and freeze takes place.

Pass/Fail: Pass for the inflation test is considered when the pressure inflates to 240 mmHg in less then 10 seconds. Pass for the fast deflation test is defined as deflation to less then 15 mmHg in less then 10 seconds.

Troubleshooting:
In case of failure of either test, one of the pneumatic elements: valves, pumps or internal tubes, may be responsible for the failure. Follow the instructions in the section for leakage source identification to pinpoint the source of failure.

4.6 Pressure Leakage Test

Objective: This test is designed to verify that the pressure chambers are not leaking.

Setup: Maintain the setup of the previous test.

Test: : Press Ok to inflate the chamber and wait until automatic freeze takes place. The chamber will inflate to a set target pressure, and then hold the pressure for up to a minute, before pressure release and auto freeze.

Pass/Fail: Pass is defined as a pressure drop of less then 3 mmHg over the course of the 20 second test duration.

Troubleshooting:
In case of failure of this test, one of the pneumatic elements: valves, pumps or internal tubes, may be leaking. Follow the instructions in the section for leakage source identification to pinpoint the source of leakage.

4.7 Controlled Deflate RateTest

Objective: This test is designed to verify that the controlled deflate rate is accurate.

Setup: Maintain the setup of the previous test.

Test: : Press Ok to inflate the chamber and wait until automatic freeze takes place. The chamber will inflate to a set target pressure, and then start deflating at a constant rate of 3 mmHg/sec until automatic freeze.

Pass/Fail: Pass is defined as a deflate rate within +/- 1.5 mmHg/sec of the required rate.

Troubleshooting:
In case of failure of this test, one of the pneumatic elements: valves, pumps or internal tubes, may be leaking. Follow the instructions in the section for leakage source identification to pinpoint the source of leakage.

4.8 Automatic Check Valve Test

Objective: This test verifies that the check valves are opened at pressure of 300 mmHg +/- 20%.

Setup: Maintain the setup of the previous test.

Test: : Press Ok to inflate all chambers and wait until automatic freeze takes place. The chamber will inflate to a set target pressure, and then deflate quickly until automatic freeze. In case the tested check valve does not meet the required criteria after the first inflation session, the test is automatically repeated for up to 4 more times.

Pass/Fail: Pass is defined as pressure chamber is between 275 and 315 mmHg. If the pressure is greater than 315 mmHg, proceed with manual measurements with the external pressure sensor, since the limits of the internal pressure sensor are reached.

Troubleshooting:
In case of pressure above 315 mmHg, proceed to perform the manual check valve test.

4.9 Manual Check Valve Test

Objective: This test verifies that the check valves are opened at pressure of 300 mmHg +/- 20%, and is performed only if the automatic test shows pressures higher then 315 mmHg.

Setup: Maintain the setup of the previous test, but turn on the external pressure device.

Test: : Press Ok to inflate the tested pressure channel. Wait until a window opens and type in the respective field the pressure from the external device. Press Ok to complete the test.

Pass/Fail: Pass is defined as pressure chamber is between 275 and 350 mmHg.

Troubleshooting:
In case of pressure above 350 mmHg, the check valve needs to be replaced.

4.10 PPG AC Test

Objective: This test verifies the AC performance of the PPG sensors.

Setup: Connect each PPG sensor to the respective PPG channel and perform a PPG measurement on the same index finger.

Test: : Press Ok to start the PPG measurement and press freeze after several seconds of signal acquisition.

Pass/Fail: Pass is defined when a smooth and oscillatory signal is obtained. If this criteria is not met, press the FAIL button on the right.

Troubleshooting:
a) In case of Failure, try replacing the PPG sensor (PVC0075).
b) If failure persists, try replacing the internal PPG cable (PVC0057).
c) If failure persists, contact your authorized Viasonix service representative.

4.11 PPG DC Test

Objective: This test verifies the DC performance of the PPG sensors.

Setup: Sequentially connect PVC0012 (PPG-DC Simulator Device) to each PPG channel.

Test: : Press Ok to start the measurement and wait for automatic freeze.

Pass/Fail: Pass is defined as DC reading of 21148 +/- 4.00 %..

Troubleshooting:
a) In case of failure try replacing the internal PPG cable (PVC0057).
b) If failure persists, contact your authorized Viasonix service representative.

4.12 PVR Test

Objective: This test verifies the PVR performance of the pressure channels.

Setup: Place a digit cuff (PVB0075) on the index finger ans sequentially connect it to each pressure channel.

Test: Press Ok to start PVR measurement and press freeze after several seconds of signal acquisition.

Pass/Fail: Pass is defined when a smooth and oscillatory signal is obtained. If this criteria is not met, press the FAIL button on the right.

Troubleshooting:
a) In case of Failure, try relocating the digit cuff on the finger.
b) If failure persists, try to fasten stronger the luer connector og the cuff to the respective tube.
c) If failure persists, try replacing the digit cuff (PVB0075).
d) If failure persists, contact your authorized Viasonix service representative.

4.13 Doppler Background Noise Test

Objective: This test checks the Doppler background noise level.

Setup: Connect all Doppler probes to their respective connectors on the front panel.

Test: Press Ok to start the measurement and wait until automatic freeze.

Pass/Fail: Pass is definedcfor low background noise level of less then 2500 and voltage less then 0.85, and current less then 1.75.

Troubleshooting:
a) In case of Failure, try replacing the respective Doppler probe.
b) If failure persists, contact your authorized Viasonix service representative.

4.14 Doppler Spectrum Test

Objective: This test verifies the quality of the Doppler spectrum.

Setup: Connect all Doppler probes to their respective connectors on the front panel.

Test: Press Ok to start the Doppler measurement and acquire a Doppler spectrum from the carotid artery. This test requires knowledge of carotid insonation. Press freeze after several seconds of signal acquisition.

Pass/Fail: Pass is defined when good quality of Doppler spectrum is obtained. If criteria is not met, press the FAIL button on the right.

Troubleshooting:
a) In case of Failure, try replacing the respective Doppler probe.
b) If failure persists, contact your authorized Viasonix service representative.

4.15 Temperature Test

Objective: This test verifies the Temperature accuracy.

Setup: Connect PVC0013 (Temperature Simulator Device) to the temperature port.

Test: Press Ok to start the measurement and wait until automatic freeze.

Pass/Fail: Pass is defined as a temperature reading of 18.7 +/- 2.5%.

Troubleshooting:
a) In case of Failure, try replacing the internal temperature cable (PVC0060).
b) If failure persists, contact your authorized Viasonix service representative.

After completion of the Falcon performance diagnosis testing, the complete test report can be viewed or printed to a hard copy through the *PRINT* button on the right hand side. The test procedure is also saved to the database, and can be loaded for review at any time (file called: *Falcon Dagnostics*).

5 – FALCON DISASSEMBLY

IMPORTANT - After every Falcon service assembly, full system performance testing must be repeated and completed successfully.

The following details the disassembly instructions for the Falcon system. The assembly process is merely a reverse of the disassembly instructions provided here, and therefore is not detailed separately.

Prepare a large, flat and rigid working surface that is free from other items and that will be comfortable for the disassembly process. Carefully place the Falcon on the working surface. Disconnect all of the connectors and cables from the system. Verify that the USB cable and the power supply cable are disconnected from the back panel. Also, verify that the temperature sensor and the counterpart of the 10-tube connector with the colored air tube sleeve are disconnected from the right side of the Falcon. Finally, disconnect all PPG sensors and Doppler probes from the front panel.

5.1 Remove the Top Cover

a) Release slightly the Temperature nut which is located on the right side of the Falcon. Take care not to completely release the nut. In order to avoid scratching of the casing, hold the tool at roughly 90 degrees to the nut, and try to avoid touching the casing as shown below.

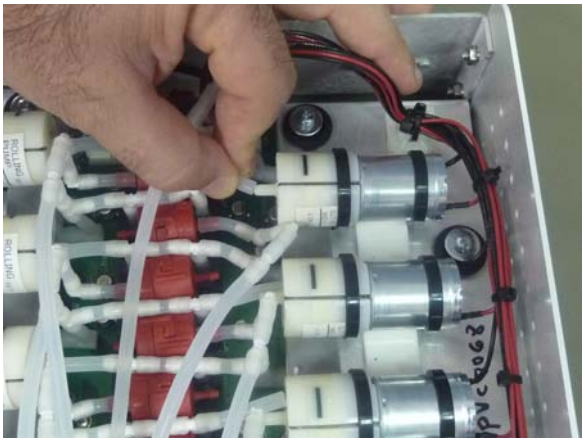
c) There are 3 black screws on each of the right and left sides of the Falcon. Use a standard Philips screw driver to unscrew these screws as shown below, and place the screws aside to be available for the assembly stage.

d)

c) Carefully lift the Top Cover of the Falcon, and place aside on a rigid surface where it is safe from potential scratches.

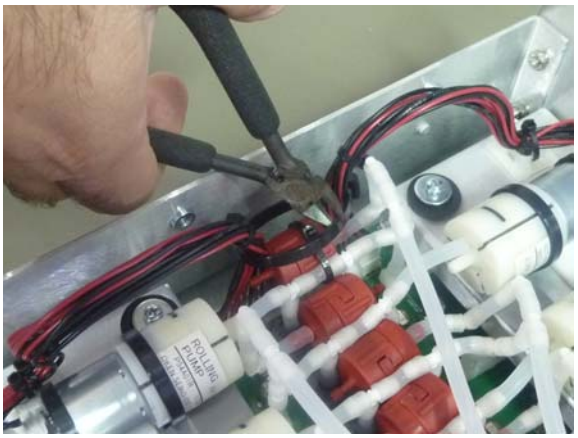
5.2 Release the Tubes from the Pumps

In the Falcon/Pro the pumps are located in 2 rows of 5 or 6 pumps each on PVC0067 Falcon/Pro Pump Sub-assembly Front and PVC0068 Falcon/Pro Pump Sub-assembly Back. In the Falcon/Quad and Falcon/ABI+ there are 4 pumps on PVC0069 Falcon/Quad Pump Sub-assembly Back. Each pump is wired on one end, and connected with a short silicon tube oriented towards the middle of the system. The silicon tube is connected to the air exit of the pumps. Gently pull off the tubes from each of the pump air exits as shown below.

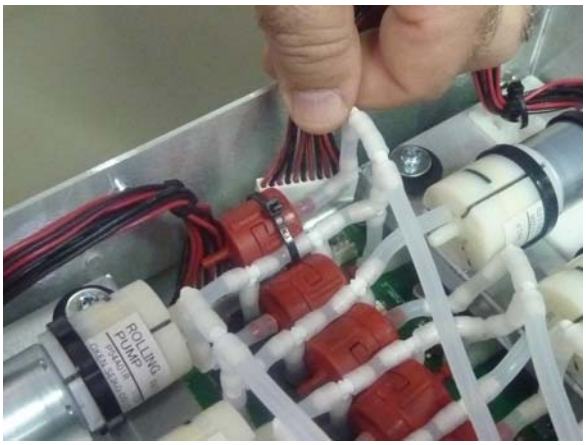


5.3 Remove the Pump Cable Connectors

a) In the Falcon/Pro, the 2 sets of pump wires from each of the pump sub-assemblies are connected together with a wire tie to avoid vibrations on the casing when the pumps are on. Cut the wire tie between the 2 pump sub-assembly cables. As shown below.

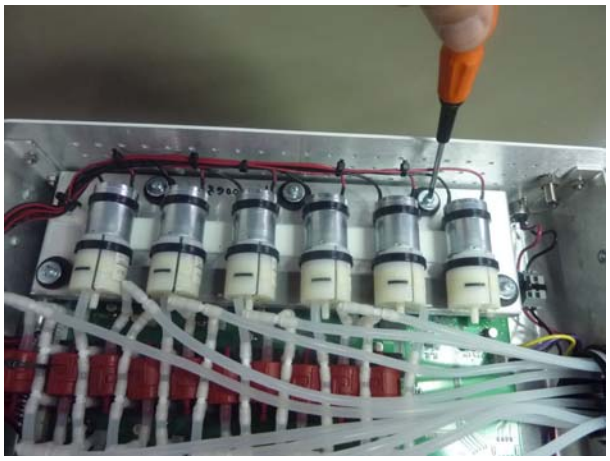


b) Each set of pump wires is connected to the Falcon main board via a connector that is located close to the left side of the Falcon. Release the 2 cable connectors by pulling on the cables as shown below.



5.4 Release the Pump Sub-assemblies

a) Each pump sub-assembly is connected to the Falcon main body through spacers that pass through the Falcon main board. There are 5 special shock absorbers on each sub-assembly that are designed to reduce vibrations when the pumps are active. 3 shock absorbers are located along the external side of the sub-assembly (along the Falcon wall) and 2 shock absorbers are located at each of the corners pointing towards the center of the system. With a standard Philips screw deriver release the 5 screws that are located on each pump sub-assembly. Try not to completely remove the 3 screws that are on the external row.

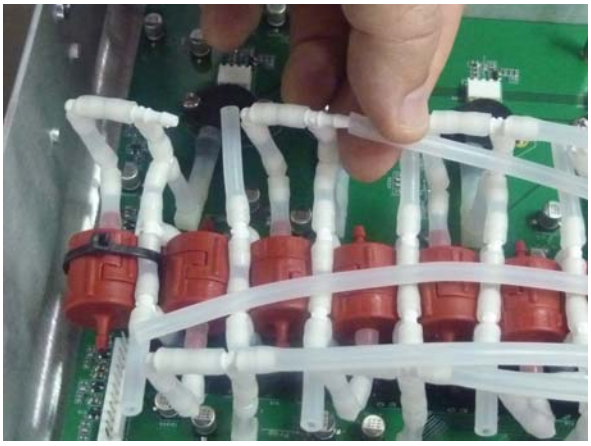


b) The pump sub-assembly is a special metal surface with pumps and cables. Lift out each of the pump sub-assemblies as shown below. Place the sub-assembly aside in a safe location.

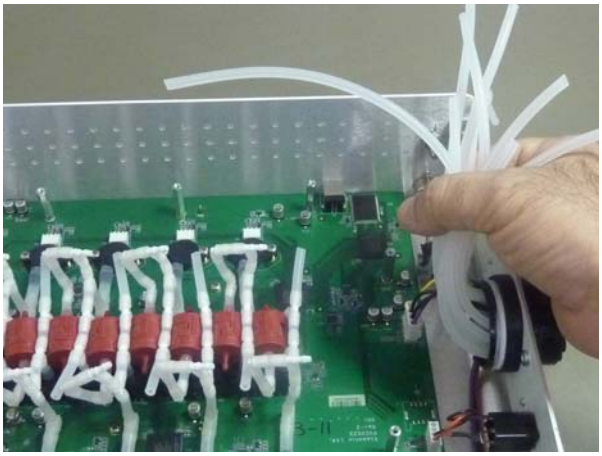
5.5 Disconnect the Tubes

A general view of the Falcon after removing the pump sub-assemblies is shown below.

a) There are silicon tubes of variable lengths leading from the 10-tube connector on the right side of the Falcon to a T connector in front of each pump. Disconnect these long tubes as shown below at the tube module side (the first T connector). You can hold the T connector with 2 fingers and pull the tube carefully to release it.

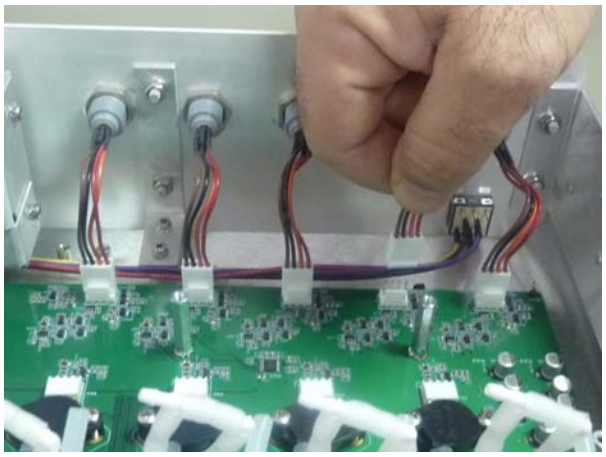


b) Hold together all of the silicon tobes on the 10-tube connector side as shown below, and move aside when continuing with the dissassembly process.

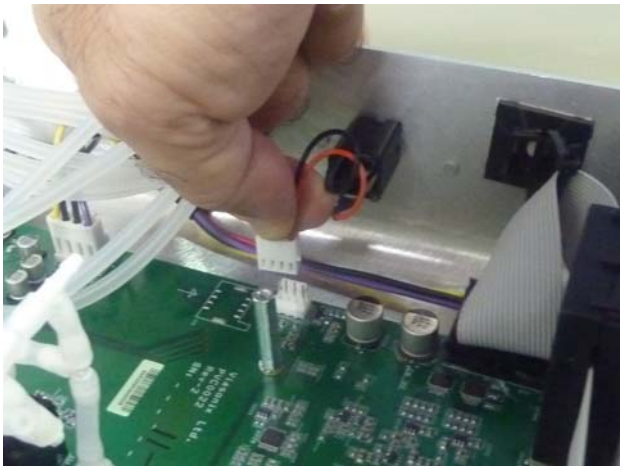


5.6 Disconnect Internal Cable connectors

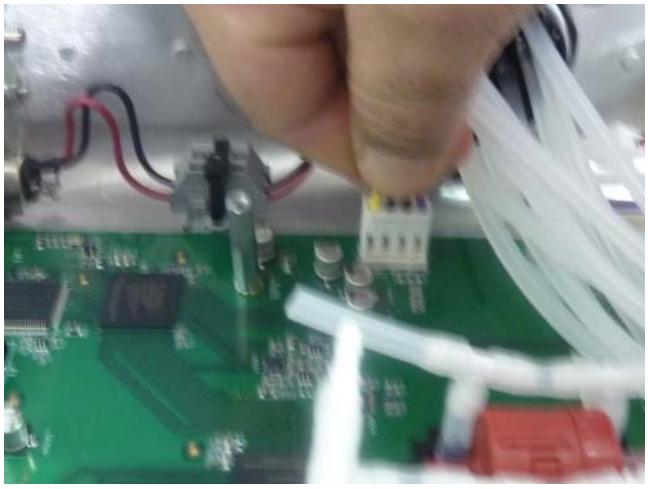
a) There are 5 internal PPG cables (PVC0057) for the Falcon/Pro, and 4 for the Falcon/Quad and Falcon/ABI+. The cables are located on the internal side of the PPG connectors (along the front panel). Disconnect each of these cables by pulling on the internal cable connector as shown below.



b) There is one internal temperature cable (PVC0060) located across the temperature port on the right side of the Falcon board. Disconnect this cable by pulling on the internal cable connector as shown below.



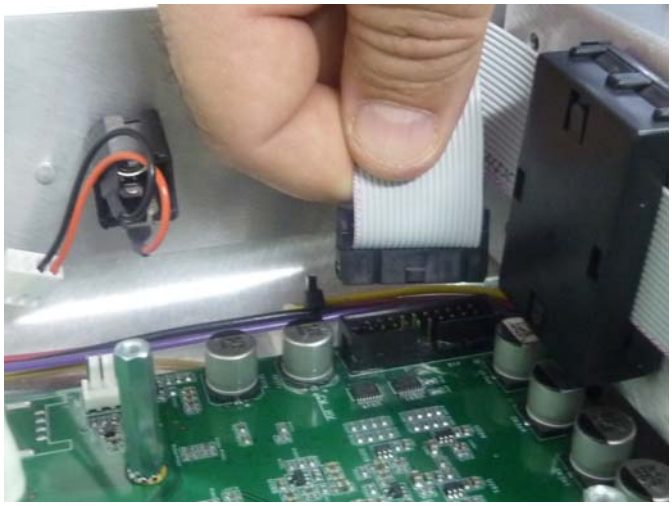
c) The power cable connector is located on the back side of the Falcon board. Disconnect this cable by pulling on the internal cable connector as shown below.



5.7 Release the CW Doppler box

a) The CW Doppler box is located along the internal side of the Falcon front panel across the 3 Doppler connectors (not applicable for Falcon/ABI+). A flat cable coming out of the box connects it to the Falcon main board. The flat cable is connected with a wire tie to internal side of the right panel to avoid potential vibrations. Cut the wire tie on the flat cable as shown below.

b) Pull on the flat wire to disconnect it from the Falcon board as shown below.



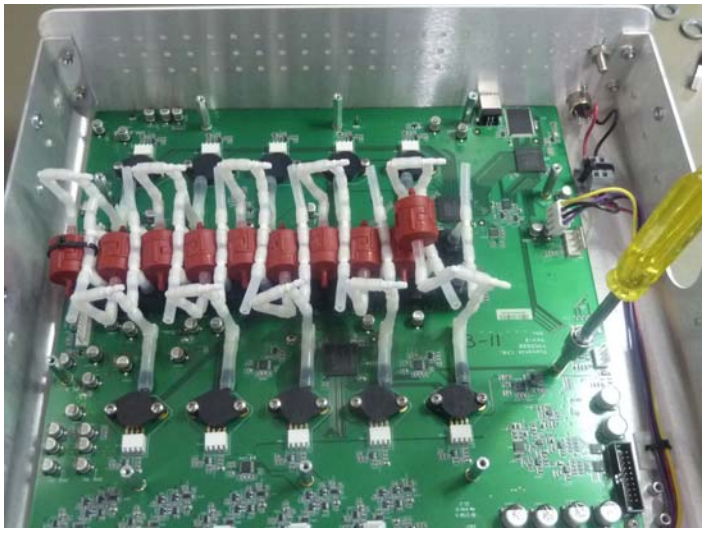
c) The CW Doppler box is connected to the front panel with 2 nuts. With the special tool PVC0105 release from inside the nut that is closer to the panel as shown below.

d) Lift a little the CW Doppler box so it will be parallel next to the front panel, and then release the 3 gray rings that are located on the fron panel for each of the Doppler probes (by unscrewing the rings).

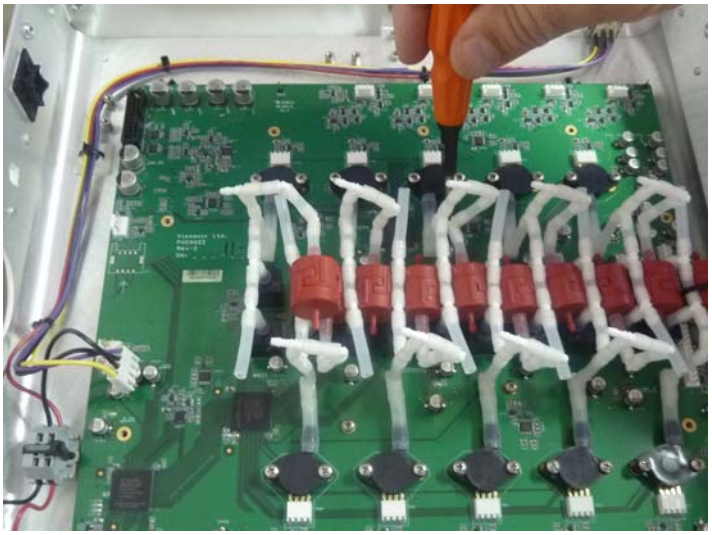
e) Carefully take out the CW box as shown below and place in a safe location.

5.8 Release the Falcon Board

a) There are 10 spacers that hold the Falcon board to the bottom Falcon casing. Release these 10 spacers with a special screw driver as shown below.



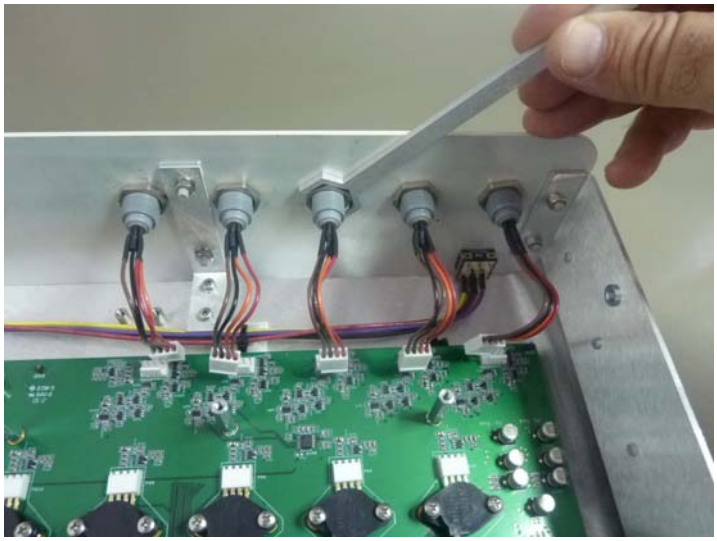
b) There are 4 screws that hold the Falcon board to the bottom Falcon casing. Release these 4 screws with a standard Philips screw driver as shown below. Note that each pressure sensor is connected to the Falcon board with 2 screws. Make sure that you do not mistake the sensor screws with the 4 Falcon board screws.



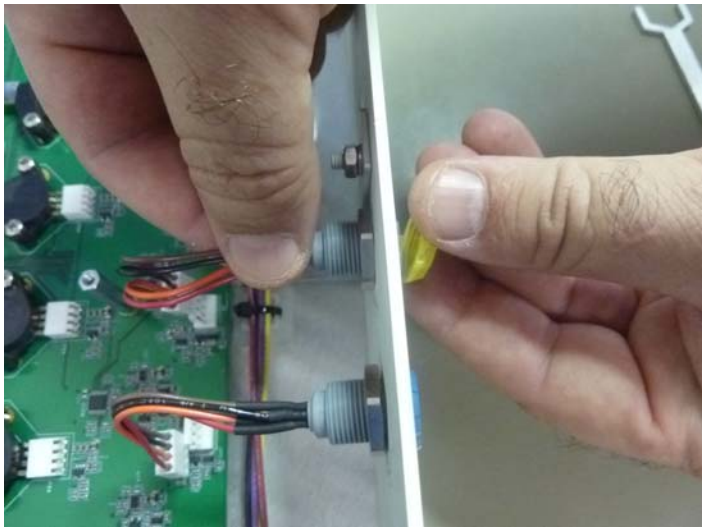
c) Carefully tilt the board up slightly and pull it back a little. Remove the board by tilting it upwards as shown below.

5.9 Release the Internal Cables

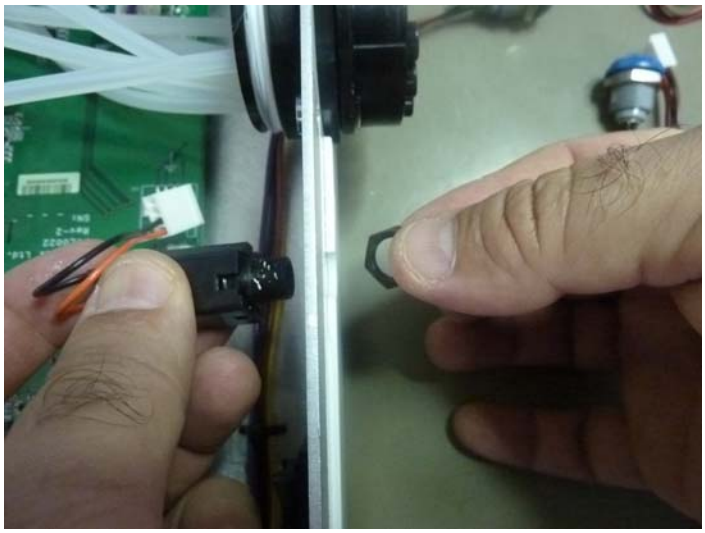
a) Release with the special tool PVC0105 the internal nut holding the PPG cables.



b) Unscrew the external colored PPG nut, and remove it. Note that the “joint” on both the connector and the ring are pointing upward. Remove the internal PPG cable.

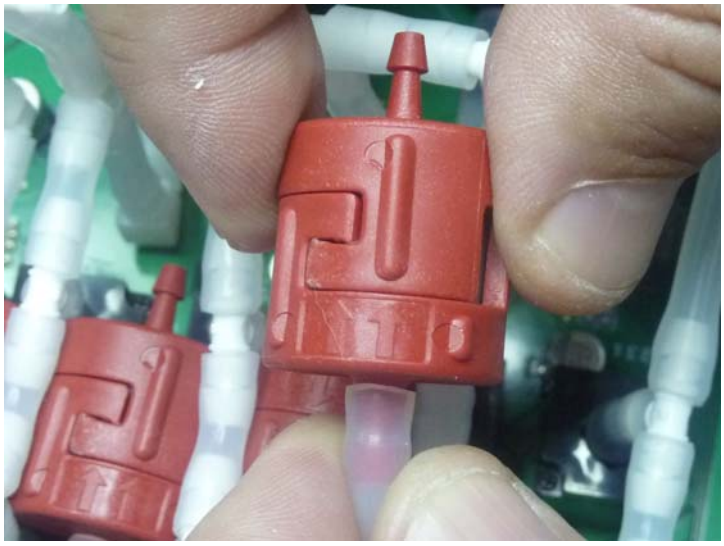


c) Unscrew the external nut holding the internal temperature cable as shown below and remove the internal temperature cable.



5.9 Remove a Check Valve

Each pneumatic channel has one mechanical check valve. The role of the check valve is to ensure that the cuff pressure does not exceed the approved limits. The check valves are directional, and should be connected to the tubing according to the arrow direction which appears on the check valve as shown below. To replace a check valve simply disconnect the valve from the silicon tube by pulling it away as shown below. When replacing the check valve ensure that the arrow on the valve is as shown below.

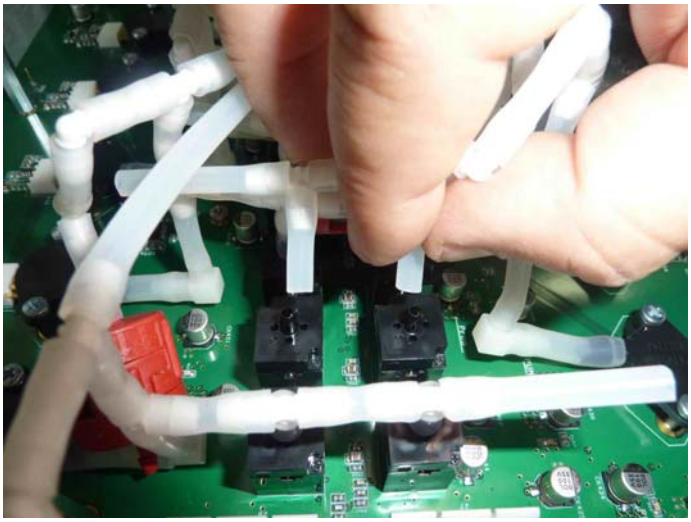


6 – LEAKAGE SOURCE IDENTIFICATION

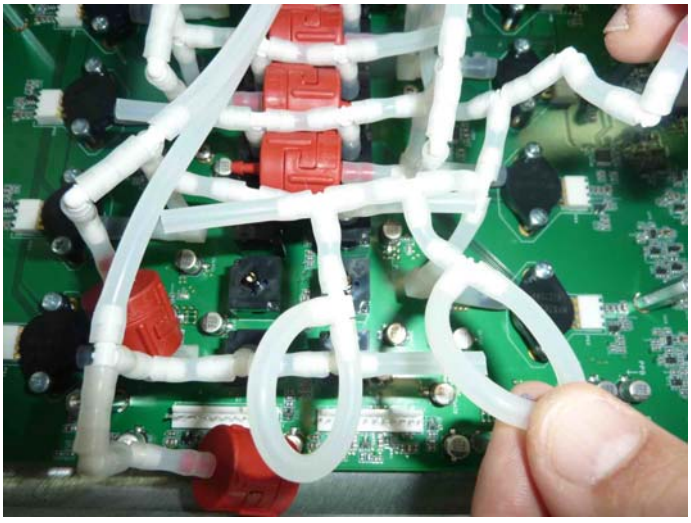
When there is a pneumatic problem identified during the performance diagnostic test, there are 3 potential sources that can cause the problem: the valves, the pumps, or the tubes. This section guides to identify the source of failure is identified.

6.1 Valve Investigation

The valves are a potential source of leakage. There are 2 identical valves connected to each pressure channel. One is the standard operational valve, and the second is a backup for fast pressure release. Each valve is connected to the Falcon board with 2 screws, and to the pressure channel via a slightly wider silicon tube. In order to isolate the pneumatic problem in a specific pressure channel, disconnect the silicon tubes from the valves and instead connect 2 closed loop tubes (PVC0108) to the open pressure channel tube ending that was previously connected to the valves.



Disconnect the silicon tubes from the valves

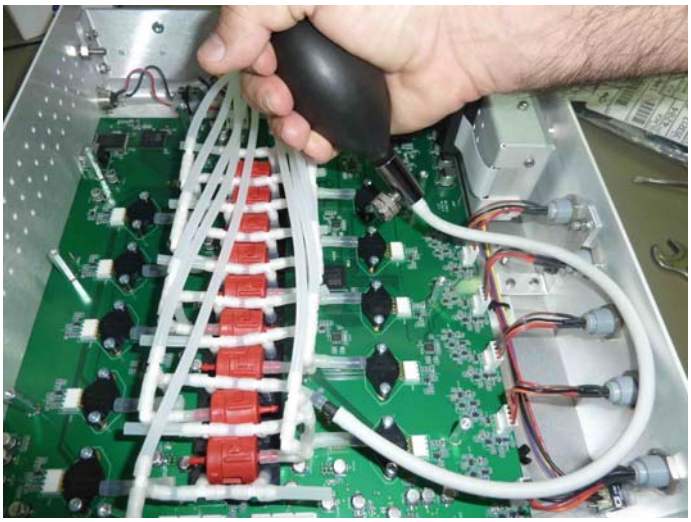


Connect 2 closed loop tubes

Now repeat the pressure leakage test for the failed pressure channel. If the test fails again, then that means that the valves are ok and the source of leakage is in the tubes or pumps. If the test passes ok, that means that there is no leakage, and then the source of leakage has to be one of the 2 valves. Repeat the test with only one valve connected, and then the other valve to isolate which valve is the cause of failure. After identifying the leaking valve mark this valve clearly as the failed valve. This valve needs to be replaced.

6.2 Pump/Tubes Investigation

If the Valve Investigation test shows that the problem lies with the pump or the tubes, then reconnect the silicon tube ending to the 2 valves, and disconnect the silicon tube from the air exit of the pump that is connected to the failed pressure channel. Connect an external manual pressure inflator to the disconnected tube end, and repeat the pressure leakage test for this channel while manually inflating the channel.



If there is still leakage in this pressure channel, that means that the source of problem is the internal tubing of that channel, and the tubes must be replaced. However, if the leakage test passes ok, that means that the pump is the source of leakage, and the pump needs to be replaced.

7 – GENERAL INFORMATION

3.1 Disclaimers

Authorized service representatives of Viasonix Ltd. may perform Service of the Falcon system only to the extent described in this service manual. Any unauthorized servicing operations performed on the Falcon shall automatically void the warranty.

3.2 Replacement parts

Replacement parts used in the repair of the Falcon must be obtained only through Viasonix Ltd. Use of any unauthorized parts in the repair of a Falcon system is not allowed and shall automatically void the warranty. Viasonix Ltd. shall not be liable for any claim for damages resulting from the use of unauthorized parts in the Falcon system, or from unauthorized service.