O_2 Conserver Checker

DESCRIPTION

The O_2 Conserver Checker can easily be used to test several key performance functions of supplemental oxygen systems. It can check that pulse type devices deliver a pulse with each breath, while also measuring the amount of oxygen delivered in the pulse. The volume of oxygen delivered can be compared to manufacturer specifications for the device to see if it is providing the proper oxygen dose with each breath. When used with portable concentrators, the model with the oxygen sensor can measure the oxygen concentration. The checker can also be used to test trigger pressure, this is important to check because it gives an indication of how sensitive the device is and if it will detect shallow breathing or a cannula that is not well placed. Many conserver type devices also have a continuous flow mode and the O_2 Conserver Checker can measure the delivered oxygen flow rate in the continuous mode. This can also be used to check the oxygen flow rate of basic continuous flow systems like stationary concentrators or standard flow meters.

This table shows the measurements that can be performed on various supplemental oxygen devices.

Tests	Portable Concentrator	Gas or Liquid Conserver	Stationary Concentrator	Continuous Flow Regulator
Breath Triggering	✓	✓		
Trigger Pressure	✓	✓		
Pulse Volume	✓	✓		
Steady Flow	✓	✓	✓	✓
Oxygen Concentration	✓		✓	

SPECIFICATIONS

Power:	5 volts DC, 600 ma
Breath Rate:	10 to 40 BPM, 1 BPM increments
Trigger Pressure:	-0.025 to -0.80 cmH_2O (-2.45 Pa to -78.4 Pa)
Steady Flow:	0.4 to 17 LPM, ±5% or 0.1 LPM whichever is greater
Volume:	±5% of measured value or 1 ml whichever is greater
Oxygen Concentration:	20% to 96%, ±1.5%, resolution 0.1%, Part Number 100029 only
Operating Temperature:	15 °C to 37 °C (59 °F to 99 °F)
Warmup Time:	20 seconds for startup with O_2 sensor. Full accuracy of O_2 sensor may require 5 minutes warmup.
Dimensions and weight:	7” x 4.5” x 2.5” (117mm x 115mm x 63mm), 1 lb. (454 g)

The system meets the requirements for use in an oxygen rich environment however it is not labeled as such because the intended use does not include oxygen rich environments.

Specifications are subject to change without notice.

Manufactured by Dirks Instruments LLC, Stilwell KS, USA

Recommendation for Disposal

Treat as conventional solid waste in accordance with local and federal regulations.

Federal Communication Commission (FCC) Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. When using the product, maintain a distance of 20cm from the body to ensure compliance with RF exposure requirements.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications or changes to this equipment. Such modifications or changes could void the user’s authority to operate the equipment. NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

WARNINGS

⚠ Do not connect to any power source other than a 5 volt USB power supply.

⚠ Do not connect anything to the oxygen flow port during the startup and zero function.

⚠ Do not put your finger over the small hole next to the power inlet jack.

⚠ To be used only for checking the function of supplemental oxygen systems. Not for calibration purposes or use on human or animal subjects.

⚠ Service on this device should be performed only by an authorized facility. Do not use if the device has been tampered with in any way.

⚠ This device is not designed nor intended for use to monitor life support systems, in anesthesia applications, or for monitoring oxygen concentration from any source other than a conventional oxygen concentrator using molecular sieve beds.

⚠ The oxygen concentration value will not be correct if used with oxygen from sources other than a concentrator. 100% oxygen will read around 90%.

⚠ Do not smoke in an area where oxygen is being used or generated.

⚠ Prior to handling oxygen equipment ensure work area and hands are free of oil, grease and other contaminants.

⚠ Do not submerge or spill fluids on the device. Protect from moisture. Remove humidification devices before connecting to O_2 Conserver Checker.

INTENDED USE

The intended use of the O_2 Conserver Checker is the validation of oxygen regulators up to 15 LPM flow rates, oxygen conserving devices, stationary and portable oxygen concentrators.

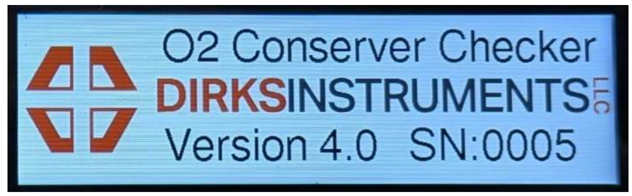
INCLUDED IN THE BOX

- O_2 Conserver Checker
- USB power supply
- USB to DC power jack cable
- 7 ft oxygen tubing
- Operating Instructions
- Calibration certificate

OPERATION

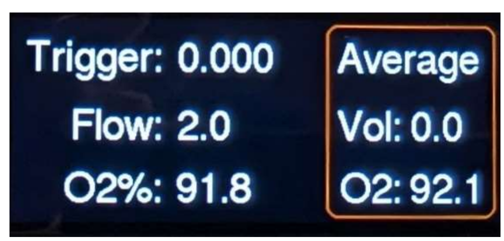
Startup

Do not connect anything to the oxygen inlet port before the unit powers up. Also make sure that your finger is not on the small hole next to the power jack. Connect the provided USB to DC power connector cable to the power jack on the side of the tester and to a USB power source such as a typical USB charger or a USB battery. Once power is applied the display should turn on and show a welcome message and then after a few seconds it will begin to operate. The model with the oxygen sensor will run the fan for 20 seconds to purge the system with air and then set the oxygen concentration. When it starts up the sensors are zeroed and this must be done with nothing attached.



Testing a Device

Connect an oxygen tube to the outlet of the device to be tested and connect the other end to the barb port on the O_2 Conserver Checker. Turn on the device to be tested and put it in the pulse mode or continuous flow mode. The O_2 Conserver Checker fan should begin to run for a short time every 3 seconds. This generates a simulated breath at 20 breaths per minute. If the device is in the pulse mode it should deliver a pulse of oxygen each time the fan starts to run. When a pulse is detected, the fan will shut off and after the pulse is complete the trigger pressure and oxygen volume will be displayed. The model with the oxygen sensor will also display the oxygen concentration reading. In the example above the trigger pressure was recorded as -0.163 cmH_2O and the pulse volume was 29.8 ml of oxygen. The oxygen concentration is shown as 93.0%. The breath rate was set to 20 BPM and the device was delivering pulses at 20 BPM. When the device being tested is put in the continuous flow mode the tester will automatically detect that the flow is continuous and switch to the continuous flow display. The display will then show the measured flow rate in liters per minute (LPM). Readings are updated 2 times per second. The average for the oxygen concentration reading is the average of several of these readings. When the continuous flow ends the tester will automatically switch back to the pulse test mode and begin to deliver simulated breaths.



Average Values

The values below the Average label are an average of several pulses. The average is convenient because these values may change some with each pulse and an average is generally more meaningful. The number of measurements that are in the average is shown to the right. In this case the number of pulse measurements in the average is 5. The number of pulses to average can be changed by clicking on the # Avg: button and entering a new value.

Setting the Test Breath Rate

When the O_2 Conserver Checker is powered up the breath rate will be 20 breaths per minute. This is a typical breath rate for testing on many devices it is important to test at different breath rates. To change the simulated breath rate, touch the BPM: button. A number pad as shown to the right will be displayed. Enter the desired breath rate. If the value is not correct, touch the CL button to clear the display. When the desired breath rate is shown in the box touch the OK button to set this new breath rate. The breath rate can be adjusted from 10 to 40 breaths per minute.

The breath rate setting will be displayed in the button labeled BPM. There are two numbers displayed below the label. The first number is the measured breath rate that the device under test is delivering and the second number is the breath rate that is set to be delivered. When the two values do not match the measured breath rate will be shown in dark red text to indicate that the device is not operating at the selected breath rate. If this is the case there are some reasons why this may occur. If the breath rate has just been changed if may take a few breaths for the device to catch up to the new breath rate. Allow a few pulses to see if the device begins triggering at the set breath rate. Another reason for the breath rate to be less than the set breath rate is if the pulse is long enough or the device is triggering at a high trigger pressure then there may not be enough time to do everything before the next breath should start. This may cause the Checker to not generate breath triggers at the desired breath rate. Part of the breath trigger process is an exhale function that occurs after the pulse is complete. Most devices do not require this simulated exhale so it can be turned off and this should allow the device to trigger breaths at a higher breath rate. To turn off the exhale function use the menu to get to the Settings menu button. See the discussion about that setting later in this manual.

Measured Values

The trigger pressure is always a negative value because this signifies a vacuum which is generated to simulate a breath. The pressure is displayed in cmH_2O. 1 cmH_2O is equivalent to 98 pascals so to convert to pascals you can basically shift the decimal point two positions to the right. The volume is always shown in ml (milliliters) which is the same as cc (cubic centimeters). This is the unit of volume generally used to measure small volumes such as this. The steady flow values are given in liters per minute (LPM).

To properly determine if a unit is performing to specification, it is best to compare the measurements to published values provided by the manufacturer. Manufacturers should be able to provide nominal values for the oxygen delivered at each pulse setting. This may vary depending on the breath rate so it will be important to properly set the test breath rate when comparing measured values to manufacturers specifications. Some manufacturers do not publish the breath trigger pressure so it may be difficult to get specifications from a manufacturer for this value. There is a significant variation in pulse volumes delivered by different units that are on the market so a specific target volume for a particular setting is not given in any standard at this time. The information given below is a normal range for pulse volumes at a given equivalent continuous flow setting. These values are only a general range and are not specific to any device but they can give you an idea what to expect. If you are seeing values that are outside of this range check with the manufacturer of the device to see what the nominal value should be. Most units tend to be around the middle of these ranges. A spreadsheet with specifications for several of the current devices is available on our website. The specifications are taken from user manuals for these devices.

Generalized normal range for pulse volumes at equivalent continuous flow settings at 20 BPM	
Setting	**Pulse Volume Range (ml)**
1	9 to 16
2	18 to 32
3	27 to 48
4	36 to 64
5	45 to 80

When checking a continuous flow setting on a conserver device, concentrator or flow regulator the following tolerance for steady flows based on ISO 10524-1 Standard can be used if the manufacturers specification is not available.

± 20% for flows > 1.5 LPM and ± 30% for flows < or = 1.5 LPM

The trigger pressure is an indication of how sensitive the device is to breathing. Some devices have complex triggering methods that vary the trigger pressure based on several factors so a specific value cannot be given however there are some general ranges that can be helpful in determining if a device is performing well. Shallow breathing or breathing through the mouth will provide a very small pressure signal to the oxygen delivery device. In cases like this a device may not trigger on every breath because the pressure signal is too small. This can also be the case if a cannula is not well positioned on the nose. Devices that have a very sensitive trigger pressure may be able to detect this type of breathing and trigger properly. Breathing like this may generate a trigger pressure of only -0.1 or -0.2 cmH_2O. Normal breathing on a well-placed cannula will generate a pressure of -0.50 to -0.80 cmH_2O or more. Typical trigger pressures will be between -0.10 and -0.40 cmH_2O. The tester will generate a trigger pressure of up to -0.8 cmH_2O or more. If this is not enough to reliably trigger a device then there may be a problem with the sensitivity of the device.

Oxygen Concentration Sensor

The model with the oxygen concentration sensor will run the fan for 20 seconds during the power up function to purge the system with air and then it will set the oxygen concentration using air as a reference. The oxygen sensor will continue to warm up and stabilize for about 5 minutes after powering up. For best accuracy it is best to unplug the power after a few minutes of operation and then reconnect power to start the system with the sensor warm. This should provide the best oxygen reading. For normal operation restarting the device is not needed but if there is some question about the accuracy of the reading then perform this restart. When the device is starting up the input connection must be open to air and disconnected from any tubing or device.

The oxygen sensor will read oxygen concentration from concentrators up to 96% which is higher than a concentrator will normally generate. If you use the O_2 Conserver Checker to test devices that operate from a bottle or other 100% oxygen source the oxygen concentration reading will not be correct. The oxygen sensor will normally read between 90 and 92% when operated on 100% oxygen. This is because the system is assuming the presence of argon and some other gasses that are present in the output of an oxygen concentrator. When checking a concentrator in continuous flow mode it may take 3 or 4 minutes to get the most accurate oxygen concentration reading.

BLUETOOTH COMMUNICATION

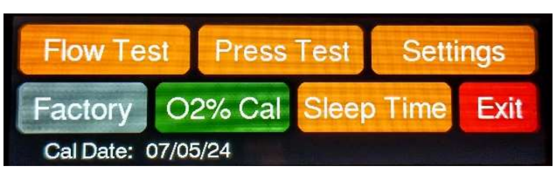
The O_2 Conserver Checker has Bluetooth Low Energy connectivity for streaming measured values to devices configured to receive this information. The connection for the device is named Conserver Checker SN: XXXX with XXXX being the serial number of the Conserver Checker. The device transmits trigger pressure, pulse volume, oxygen concentration, flow rate and breath rate.

Monitor Software

A companion software program that runs on Windows can be used with the O_2 Conserver Checker to capture the measured data and display it on graphs as well as save it to a data file. It also has the ability to use an Excel spreadsheet to guide the user through a set of tests and then a report of the test is created including pass and fail indications for each test.

When the O_2 Conserver Checker is connected to a device over the Bluetooth connection a Bluetooth icon is displayed next to the gear menu icon. The Bluetooth icon is not displayed when there is no connection. The serial number of the O_2 Conserver Checker is displayed next to the Bluetooth icon. This is useful for identifying the particular O_2 Conserver Checker. In the Monitor software the serial number of the devices that are available are shown so you need to know the serial number of the device that you want to connect to.

SETUP MENU

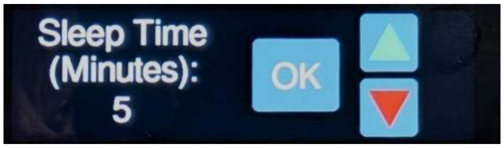


The setup menu provides access to some settings, display modes and calibration checking functions. To enter the setup menu, touch the gear icon in the upper right corner of the display. This will bring up a menu with several buttons that each go to different functions. The Exit button exits the menu and returns to the selected display mode. When the device is measuring pulses it may take several presses, or a long press before the menu button responds. If you have difficulty getting into the menu mode you may need to disconnect the device being tested. When pulses are not being measured the menu is much more responsive.

Note that the last calibration date is shown at the bottom of this display. It is recommended that the calibration be checked at least yearly. The unit can be returned to the factory for a full calibration and certificate. Contact Dirks Instruments LLC for a return authorization and information on the calibration process and cost.

Sleep Time

If the unit does not see oxygen flow for several minutes it will enter a sleep mode and display a message that it is in Sleep Mode. To exit the sleep mode just touch the display to return to normal operation. The time before the unit goes into the sleep mode is 5 minutes by default but this can be changed to 1 to 30 minutes. From the setup menu tap on the Sleep Time button to set the sleep time. Use the up and down buttons to adjust the sleep time to the desired time and then tap the OK button to save this new value and return to operation.



Settings

The Settings button in the menu opens another screen where you can adjust the display brightness and select one of two different display modes that can be used to view the test data when performing pulse tests. It is also where the breath type can be selected. To adjust the screen brightness touch and drag the slide indicator to the left to make the screen darker or to the right to make it brighter. The brightness setting will be saved.

The two buttons labeled Display Mode select the type of data display. The Avg Mode displays the measured values and the average of several readings. The Plot Mode option is used to display the measured values and a graph that shows the flow during the pulse. The button that is orange is the button that is currently selected.

The graph is useful for seeing the shape of the flow waveform and the peak flow rate that is delivered during the pulse. The pulse time is also something that may be of interest. When in the graph display, the measured values for the pulse will be displayed and after each pulse the graph of the pulse will be displayed. The breath rate can be changed from this display by touching the BPM button and selecting a new breath rate. Two breath rate values are shown. The first one is the measured breath rate and the second one is the set breath rate. The graph shows a combination of the trigger pressure and the oxygen flow rate during the pulse. Values that are below zero are the pressure measurement before the pulse is triggered. The scale is 0 to -0.8 cmH2O. Normally you will see a pressure ramp that goes from zero to a little below zero before the pulse begins and the graph indicates the pulse flow. Positive values are the measured flow rate during the pulse. The length of time shown on the graph is one full breath. Each vertical line represents ½ of a second.

The x-axis corresponds to the maximum time for each breath at the set breath rate, so at 20 breaths per minute the graph shows 3 seconds of time. This gives you a way to estimate the pulse time. The pulse amplitude and duration will vary depending on the device and the setting. This may be a useful diagnostic if you know what a properly functioning device normally delivers at a particular setting. If the device is operating in a continuous flow mode the values for flow and oxygen concentration will be displayed. The graph will show the flow for a few seconds until the time is longer than the graph.

Exhale Mode Settings

The O_2 Conserver Checker simulates both the inhale and exhale portions of a breath. The exhale is a small positive pressure that is generated after the pulse is complete. Some portable concentrators look for an exhale signal before detecting the next inhale. The exhale portion of the breath simulation takes some time to execute and since we also use a shallow ramp to simulate the inhale signal there may not be enough time to perform all of these functions at high breath rates. The maximum breath rate that can be simulated depends on the trigger pressure of the device being tested, the length of time that the pulse of oxygen lasts and the time it takes to generate the exhale pressure and return the pressure to zero before the next inhale starts. For most devices breath rates up to 35 breaths per minute can be generated with the exhale portion of the breath active. Some devices with a short pulse duration and a low trigger pressure may have enough time to generate up to 40 BPM. Be sure to check the measured breath rate which is the first of two numbers displayed below the BPM label on the breath rate button. The first number is the measured breath rate and if this value does not match the second number which is the set breath rate, then it may not be possible to generate the desired breath rate or there may be a problem with the device being tested.

If the set breath rate is above 30 BPM and the measured breath rate is not matching then it may help to remove the exhale portion of the simulated breath. To do this press the menu gear to go to the menu and then press the Settings button. This will bring up the settings menu. The Exhale Mode settings of on and off control the exhale signal. Select the On button to turn on the exhale pressure or select the Off to turn off the exhale pressure. With the exhale pressure disabled a higher breath rate is usually possible. The default mode when the device starts up is for the exhale to be enabled.

Factory Settings

The Factory button is used to access special calibration functions that are used at the manufacturer for calibrating the sensors. No user functions are available from this button.

CALIBRATION CHECK MODES

From the menu there are three additional functions that can be used to check the calibration of the O_2 Conserver Checker. There is also a function to adjust the oxygen concentration sensor if it is determined that it needs to be adjusted. This adjustment requires a source of 100% oxygen from a tank of oxygen.

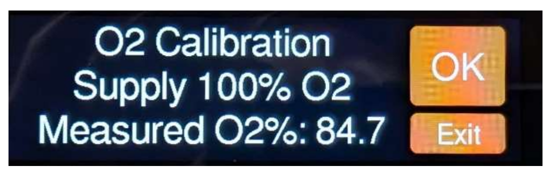
There are two calibration check functions that can be used to check the calibration of the system if the proper equipment is available for the check. One test function can be used to check the flow calibration using a calibration syringe and air. This will verify the flow and volume measurement. Another test function will check the pressure calibration for the sensitivity test.

Oxygen Concentration Check and Adjustment

The oxygen sensor is designed and calibrated to measure oxygen coming from a concentrator. This gas has a mixture of oxygen, argon and some small amounts of other gasses. If you connect the flow port to a source of 100% oxygen and set the flow rate of the oxygen between 1 and 2 LPM the oxygen concentration in the normal mode of operation should read 91.8% ± 1%. Higher flow rates of oxygen may cause the oxygen sensor to read a higher value.

If the oxygen concentration value is off by more than 1% the concentration calibration can be adjusted using the following procedure.

1. Have available a source of 100% oxygen with a flow control that can be set for a flow rate between 1 and 2 LPM.
2. After the Conserver Checker has gone through the normal power up and run for at least 4 minutes to warm up and stabilize put it in the oxygen calibration mode by selecting the O2% Cal button from the menu.
3. A message will be displayed to connect 100% O2. Connect the oxygen supply and set it to flow between 1 and 2 LPM. The display will show an oxygen value that will be around 85-90%. The value is not critical but allow several seconds for this value to stabilize before accepting the new calibration.

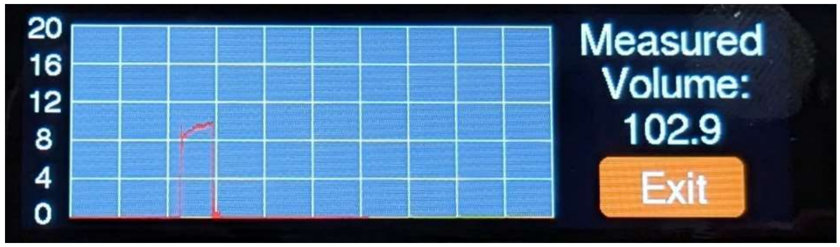


4. Press the OK button to accept this new oxygen concentration calibration. The display will then change and display Calibration Complete then press either the Save or Discard button to end the calibration.
5. Disconnect the oxygen supply.

Flow and Volume Calibration Check

Equipment needed: 100 ml Volume Calibration Syringe Assembly, Hans Rudolph Inc. part number 113636-5510, contact Hans Rudolph Inc. at hri@rudolphkc.com. Other syringes can be used but it is important to be able to provide a steady flow and an accurate volume.

Select the flow test function by pressing on the Flow Test button in the menu. After the initial message is displayed the flow and pressure sensor will be zeroed before performing the test. This test uses room air. Do not use oxygen or other gasses. This test uses a calibration syringe to inject a known volume of air. During the test the flow will be shown on the graph. The flow should be maintained between 0 and 17 LPM. When the flow ends the total accumulated volume will be displayed. If you are using a volume calibration syringe this volume should be close to the volume that was injected using the syringe. In the picture shown, a 100 ml syringe was used to inject air into the device. In this case the volume measured was slightly over the 100 ml expected. Volume measurements should be within 5% of the actual volume. Accurate readings require that the flow be within the measurement range of 0.8 to 17 LPM during the test and the known volume of the syringe being used must be accurate to less than 1%. It is recommended that this test be performed at different flow rates so that the accuracy at different flows can be checked.

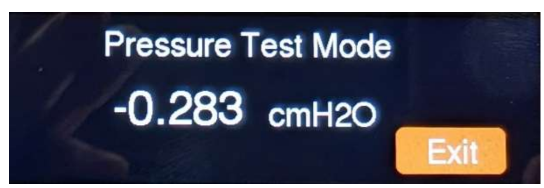


To run the test again or at a different flow rate simply retract the syringe and wait for a second to make sure the flow goes to zero. Press the syringe plunger at a steady speed to perform another test. To end the test, press the exit button.

Pressure Calibration Check

Equipment Required: A very low pressure gauge that can read a negative pressure. The pressure range should be 2 inches of water (500 Pa) or less.

To enter the pressure calibration check function, tap on the Press Test button in the menu. This will cause the unit to go to the pressure check function. In this mode the pressure will be displayed and the fan will run to generate a small vacuum pressure. Connect the flow port to the pressure gauge to measure the pressure. The pressure gauge should measure close to the same pressure as is displayed. Press the exit button to exit this test mode.



WARRANTY

This device is warranted under normal use against any and all manufacturing defects from date of purchase for a period of two years. Any failure resulting from defective parts or faulty workmanship, as determined during evaluation at a manufacturer approved repair facility, will be repaired under warranty. Non-functioning devices are subject to warranty provisions and the manufacturer repair/return policy. Do not attempt to open or repair the device – opening or tampering with the unit voids the warranty. This warranty will be null and void for any unit that has been subjected to abuse, misuse, negligence or repairs other than those performed by an authorized service facility.