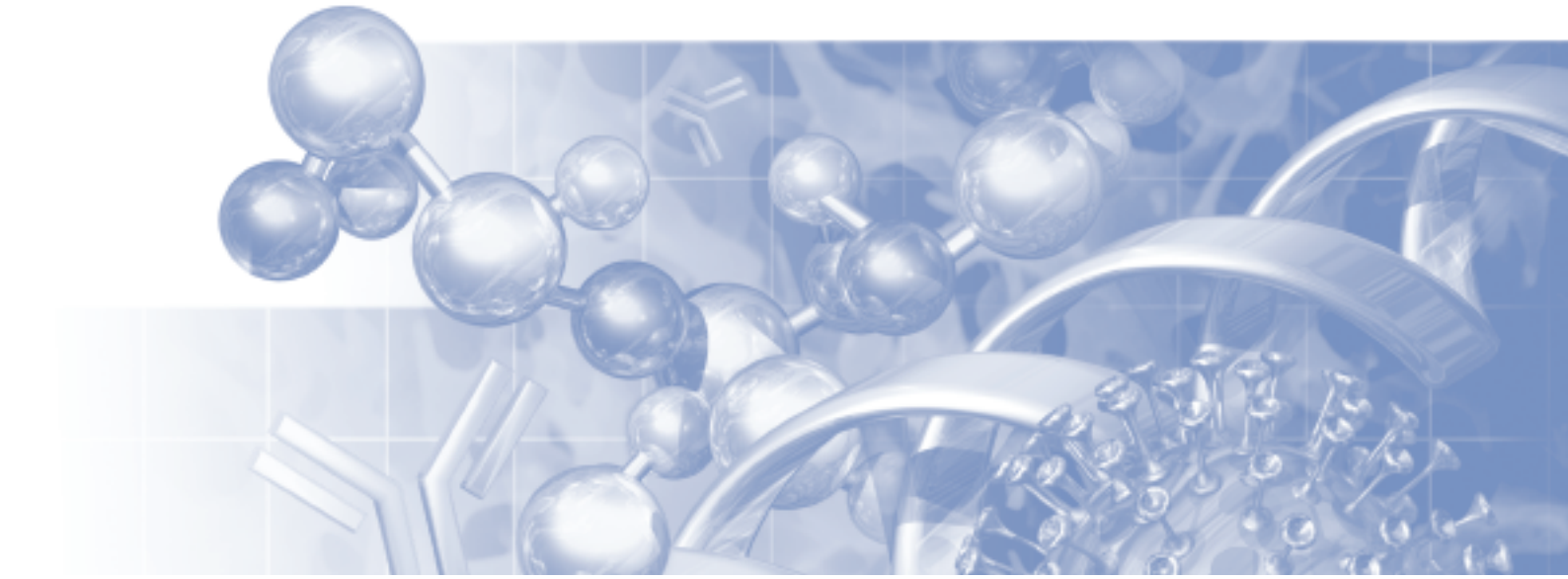
Life Sciences

Instructions For Use

USD 2642

Palltronic® Flow Check II Unit

Part numbers: FC02, FC02M and FC02H



Filtration. Separation. Solution.SM

Contents

Safety and Information Symbols

Safety and information is identified in this instruction manual with the following symbols:

Warning! Identifies a dangerous situation where there is a safety risk and personal injury may follow.

Important: Identifies a potentially dangerous situation, a risk to the equipment or other important information.

Note: Identifies user tips and other useful information.

1. Safety Instructions

Warning! Please read the following instructions carefully and completely before using the Palltronic Flow Check II unit.

Please also read the Operating Instructions for the applicable integrity test instrument which will be used with the Palltronic Flow Check II unit to ensure safe use. The list of literature is as follows:

Table 1
Literature

Document Title	Number
Palltronic Flowstar IV Integrity Test Instrument: Instructions for Use	USD2594
Palltronic Flowstar XC Integrity Test Instrument: Operating Instructions	USD2005
Palltronic Flowmod Filter Integrity Test Instrument: Operating Instructions	USD2223
Palltronic Flowstar MUX Integrity Test System: Operating Instructions	USD2292
Palltronic AquaWIT XC Automatic Integrity Test System: Operating Instructions	USD2363

Please contact your local Pall office or distributor if you require a copy of the latest revision of any of these documents.

1.1 Personal Safety

- Appropriate protective clothing should be worn by operators (e.g., gloves and safety goggles) when working with chemicals and compressed gas supplies during filter integrity testing.
- All pneumatic tubing used for integrity testing and with the Palltronic Flow Check II unit should be rated to withstand the gas pressure used (up to 8 bar or 116 psi).
- The operator should check the tubing and connectors for damage before each use.

1.2 Safe Use of the Palltronic Flow Check II Unit

- The Palltronic integrity test instrument uses compressed air when in use and, therefore, caution is necessary when disconnecting pneumatic connections from the Palltronic Flow Check II unit. It is the user's responsibility to ensure that an oil-free regulated gas supply is used during operation of the Palltronic integrity test instrument and Palltronic Flow Check II unit.
- The maximum operating pressure of the Palltronic Flow Check II unit is 3.0 bar (43.5 psi) at a maximum operating temperature of 40 °C.
- ***Do not exceed the maximum operating pressure.***
- Compressed gas exits the Palltronic Flow Check II unit at low velocity through the 'VENT' port. To ensure correct and safe operation, the 'VENT' port must be open to atmosphere.

2. Introduction

The Palltronic Flow Check II unit contains a capillary with a certified flow rate, protected against oil and fluid contamination by an integral Gaskleen® filter on the 'IN' port.

The Palltronic Flow Check II unit can be used to perform a fast and simple check to verify the operation and the calibration status of a Palltronic integrity test instrument. The Palltronic integrity test instruments feature a 'Flow Check' test that will measure the flow rate through the Palltronic Flow Check II unit and compare the measured value with the calibrated value supplied for the Palltronic Flow Check II unit. If the deviation in flow measurement is less than 5% then the Palltronic integrity test instrument is functioning and measuring correctly. This 'Flow Check' test should be performed regularly to show that the flow measurement function of the Palltronic integrity test instrument is working correctly.

The Palltronic Flow Check II unit is used in place of a filter for the purposes of the 'Flow Check' test and is available in three flow ranges:

Table 2
Flow Ranges

Part Number	Flow Rate Range	Upstream Volume Requirements
FC02	8 ± 1 mL/min	0.5 to 2 meter hose
FC02M	90 ± 10 mL/min	0.5 to 2 liter vessel
FC02H	900 ± 50 mL/min	2.5 to 6 liter vessel

2.1 Key Features and Benefits

Within the pharmaceutical industry there is a regulatory requirement to integrity test filters both before and after use in a production environment. Therefore, a fully functional integrity test instrument is required to provide documentary evidence of filter integrity. The main benefit of the Palltronic Flow Check II unit is to provide the operator with the ability to verify that a Palltronic integrity test instrument is functioning and measuring correctly before using it to verify the integrity of a critical filter.

2.2 Standard Functions

The Palltronic Flow Check II unit can be used to verify the operation and the calibration status of a Palltronic integrity test instrument.

Important: The Palltronic Flow Check II unit can be used to verify the operation of a Palltronic integrity test instrument that displays a 'SERVICE!!!' message on screen, but it cannot be used to replace a regular calibration.

We recommend that integrity test instruments undergo a full service every 3 years by Pall, during which all components are cleaned and checked and a recalibration is carried out. A calibration is recommended at least every 12 months. This can be performed locally on site or at an approved Pall service centre. For more information regarding this, please contact your local Pall office or distributor.

If the Palltronic integrity test instrument is displaying 'SERVICE!!!', please consult the Operating Instructions for that instrument for further information and troubleshooting steps.

3. Using the Palltronic Flow Check II Unit

3.1 Features

The Palltronic Flow Check II unit provides two pneumatic ports, as follows:

Figure 1

1 = Specification label
2 = 'IN' port
3 = 'Vent' port

The specification label attached to the enclosure displays the certified flow rate using air at an atmospheric pressure of 1000 mbar (14.5 psi), the associated test pressure and the unit serial number.

The display is switched on by pressing the button on the right hand side:

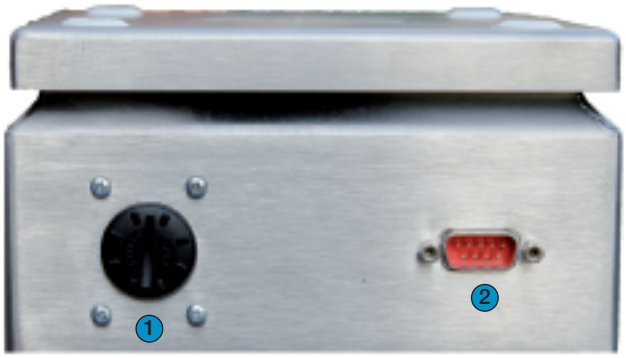
Figure 2

1 = 'Start' Button
2 = Display

On the rear side there is a serial port and the compartment for the battery:

Figure 3

1 = Battery compartment
2 = Serial port (Service use only)



3.3 Display Function

Pressing the 'Start' button activates the following display sequence

Table 3

Typical Display Functions

Step	Display	Meaning
1	FLOWCHECK FC02 14028417 / V1.04	Device type Serial number/Version number
2	Ref: 1000.0 mbar => 7.82 ml/min	Atmospheric pressure (Reference value) Flow in mL/min (Reference value using air)
3	T: 25.5 C 7.84 ml/min	Actual temperature Expected flow in mL/min (Corrected for ambient pressure)
4	P-Atm: 1004mbar 7.84 ml/min	Actual atmospheric pressure Expected flow in mL/min (Corrected for ambient pressure)
5	P-Test: 2000mbar 7.84 ml/min	Test pressure Expected flow in mL/min (Corrected for ambient pressure)

The display changes from 3 – 5 until a timeout switches the display off after 10 minutes to conserve battery power.

The display can be switched off manually by pressing the start button for more than 5 seconds. This is recommended to extend the battery life.

The unit displays the pressure in mbar only.

The test pressure is normally 2000 mbar (29 psi, 200 kPa, 2.039 kp/cm^2).

3.3 Test Preparation

The integrity test assembly (comprising the Palltronic Flow Check II unit and the integrity test instrument) should be brought to room temperature (between 18 °C and 25 °C) before conducting a 'Flow Check' test.

Important: Operating the Palltronic Flow Check II unit brought from a cold environment to a warm environment can cause condensation to form within the capillary. The capillary is extremely sensitive to water and will cease to function if water is allowed to form within or enter the Palltronic Flow Check II unit.

- Connect the 'OUT' port of the integrity test instrument to the male Stäubli◆ 'IN' connection on the Palltronic Flow Check II unit. If an upstream volume is required (see Section 2) then this should be connected between the integrity test instrument and the Palltronic Flow Check II unit.

Note: The remote vent valve may be additionally installed between the integrity test instrument and the Palltronic Flow Check II unit (or between the integrity test instrument and the upstream volume, if required) so that leaks within the remote valve may be detected. Therefore, should the Flow Check test fail, please repeat the Flow Check test without the remote vent valve attached to determine whether the remote vent valve is the cause of the failure or not.

- Ensure that the 'VENT' connection on the Palltronic Flow Check II unit is open to atmosphere.
- It is recommended that the red pneumatic tubing supplied with the Palltronic Flow Check II unit be used exclusively for this purpose. It is also highly recommended that this tubing is kept clean and dry. In this way accidental contamination of the internal capillary within the unit can be mitigated.

Important: Although the Palltronic Flow Check II unit has an integral Gaskleen filter in order to limit the possibility of contaminating the internal capillary, the operator should still take great care to avoid contamination. Should either the integral filter or the capillary become contaminated, damaged or blocked, the operation of the Palltronic Flow Check II unit will be severely compromised.

3.4 Performing a 'Flow Check' Test

Note: The following test procedure assumes that the integrity test instrument provides a dedicated 'Flow Check' test (see your integrity test instrument Operating Instructions for the instrument capabilities). If the dedicated 'Flow Check' test is not available, a 'Forward Flow' test may be used instead. In this situation, the 'Expected Flow' becomes the 'Maximum Flow' test parameter and the pass/fail result at the end of the test should be ignored: refer instead to Section 3.5 for the interpretation of the result.

- Select a 'Flow Check' test on the Palltronic integrity test instrument (for more information, see the relevant Operating Instructions for your integrity test instrument).
- Enter the following test parameters (and where indicated by [1] below, using the relevant values displayed by the Palltronic Flow Check II unit in use, see also Section 3.2.

Test Pressure[1]: 2000 mbar (29 psi)

Test Time: 600 seconds

Ref. Unit Serial No.[1]: 1234567

Expected Flow:[1] X.XX mL/min

- Press the 'Start' button on the Palltronic integrity test instrument to activate the 'Flow Check' test.
- On completion of the test (i.e. after the test time has elapsed), the measured value will be given with a percent deviation value between the measured and the expected values (if the dedicated 'Flow Check' test has been used).

Note: After use, the Palltronic Flow Check II unit should be carefully disconnected from the Palltronic integrity test instrument, the protective caps should be replaced on the inlet and vent ports and the unit stored in a dry place at room temperature.

3.5 Understanding the Test Results

The test result will be reported as a flow rate value. Under stable test conditions, the Palltronic integrity test instrument should be within ± 5% of the expected flow value displayed by the Flow Check II unit.

The expected flow value is calculated from the reference value (as shown on the side of the Palltronic Flow Check II unit and on the calibration certificate provided with the Palltronic Flow Check II unit) by compensating for any variation in atmospheric pressure.

If the dedicated 'Flow Check' test has been used, the percent deviation value will be calculated and presented by the integrity test instrument. If, however, the integrity test instrument does not

provide a dedicated 'Flow Check' test, the following calculation may be used to determine the deviation value from the 'Forward Flow' test result:

Equation 1

Deviation Value from Forward Flow Test Result

$$\text{Deviation (\%)} = \frac{\text{Measured flow} - \text{Expected flow}}{\text{Expected flow}} \times 100$$

Note: A low measured flow value may indicate the presence of moisture in the internal capillary. In this case, it is recommended to blow clean, dry air at 2 bar (29 psi) pressure for 2 hours through the Palltronic Flow Check II unit.

If test results are consistently outside the 5% limit, please contact your local Pall office or distributor as either the Palltronic Flow Check II unit or Palltronic integrity test instrument may require service and/or calibration.

4. Maintenance

The Palltronic Flow Check II unit requires no maintenance except that the battery should be changed when required.

4.1 Changing the Battery

Open the black cover of the battery compartment by using a coin or a screwdriver.

Remove the old battery and replace it by a new 1.5 V battery type AA (LR06/AM-3)

The negative (–) terminal of the battery should be inserted into the unit.

Close the battery compartment.

After changing the battery the 'Battery failed' message can be erased by pressing the 'Start' button for more than 5 seconds to switch the unit off.

Used batteries should be discarded in accordance with relevant local and national regulations.

The battery will be replaced as part of a standard service and calibration at a Pall facility.

5. Troubleshooting

5.1 Preliminary Troubleshooting

If any difficulties are experienced with the value measured through the Palltronic Flow Check II unit, please try the following:

- If the display cannot be activated by pressing the button on the right side, then replace the battery
    - It is possible to operate the Flow Check II unit without the display switched on or with no battery installed. In this case the atmospheric pressure should be measured using an independent method of measurement. The reference value of flow shown on the label should then be corrected by multiplying by the correction factor given in Appendix A.
- Check that the Palltronic Flow Check II unit is correctly connected to the integrity test instrument
- Check if the environmental temperature is out of the recommended range between 18 °C and 25 °C.
- Check that the integrity test instrument is correctly supplied with the appropriate air supply and that the air supply is oil and water free

Note: The Flow Check II instrument is calibrated with air. If it is intended to use Nitrogen or other gases the expected flow value will not be correct. Please contact your local Pall office or distributor if it is intended to use a gas other than air.

- Ensure that the Palltronic Flow Check II unit is dry – if you suspect that the moisture is present in the internal capillary, it is recommended to blow clean, dry air at 2 bar (29 psi) pressure for 2 hours through the Palltronic Flow Check II unit

Note: If the internal capillary has moisture present or is contaminated, the flow measured by the integrity test instrument will be low compared to the expected value. The display on the Flow Check II unit will still show the expected value, corrected for the ambient pressure.

- Check that the test parameters (especially test pressure) are set correctly – these details are available with the Palltronic Flow Check II unit, see Section 3.4 for more information.
- If the remote vent valve is installed, repeat the Flow Check test without the remote vent valve to determine whether the remote vent valve is the cause of the failure or not.

If test results are consistently outside the 5% limit, please contact your local Pall office or distributor as either the Palltronic Flow Check II unit or Palltronic integrity test instrument may require service and/or calibration.

5.2 Continued Difficulties

If following the steps in Section 5.1 has not solved the problem or additional technical support is required (available as a charged service), please contact your local Pall office or distributor. Supplying a detailed written description of the problem will facilitate a quick response.

Appendix A – Atmospheric Pressure Correction Table

The flow value measured with the Palltronic Flow Check II unit is dependent on atmospheric pressure and is given as a reference value normalized for an atmospheric pressure of 1000 mbar (absolute), using air. The unit measures the actual atmospheric pressure which is influenced by the altitude and the actual atmospheric conditions and displays a corrected "expected" value. Table 4 shows the influence of the atmospheric pressure on the capillary flow value.

Table 4

Atmospheric Pressure Correction Values

Atmospheric Pressure (mbar)	(kPa)	(psi)	Approx. Altitude Above Sea Level		'Expected Flow' Deviation (%)	Correction Factor
1070	107.0	15.52			+3.5	1.035
1060	106.0	15.37			+3.0	1.030
1050	105.0	15.23			+2.5	1.025
1040	104.0	15.08			+2.0	1.020
1030	103.0	14.94			+1.5	1.015
1020	102.0	14.79			+1.0	1.010
1010	101.0	14.65	0 m	0 ft	+0.5	1.005
1000	**100.0**	**14.50**			**0.0**	**1.000**
990	99.0	14.36		750 ft	-0.5	0.995
980	98.0	14.21	250 m		-1.0	0.990
970	97.0	14.07		1500 ft	-1.5	0.985
960	96.0	13.92	500 m		-2.0	0.980
950	95.0	13.78			-2.5	0.975
940	94.0	13.63		2250 ft	-3.0	0.970
930	93.0	13.49	750 m		-3.5	0.965
920	92.0	13.34		3000 ft	-4.0	0.960
910	91.0	13.20	1000 m		-4.5	0.955
900	90.0	13.05			-5.0	0.950
890	89.0	12.91		3750 ft	-5.5	0.945
880	88.0	12.76	1250 m		-6.0	0.940
870	87.0	12.62		4500 ft	-6.5	0.935
860	86.0	12.47	1500 m		-7.0	0.930
850	85.0	12.33		5250 ft	-7.5	0.925
840	84.0	12.18			-8.0	0.920
830	83.0	12.04	1750 m		-8.5	0.915
820	82.0	11.89		6000 ft	-9.0	0.910
810	81.0	11.75			-9.5	0.905
800	80.0	11.60	2000 m	6750 ft	-10.0	0.900
790	79.0	11.46			-10.5	0.895
780	78.0	11.31	2250 m		-11.0	0.890
770	77.0	11.17		7500 ft	-11.5	0.885
760	76.0	11.02			-12.0	0.880
750	75.0	10.88	2500 m	8250 ft	-12.5	0.875
740	74.0	10.73			-13.0	0.870
730	73.0	10.59	2750 m	9000 ft	-13.5	0.865
720	72.0	10.44			-14.0	0.860
710	71.0	10.30			-14.5	0.855
700	70.0	10.15	3000 m	9750 ft	-15.0	0.850

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

10/09, PDF, UK GN09.3875 USD 2642