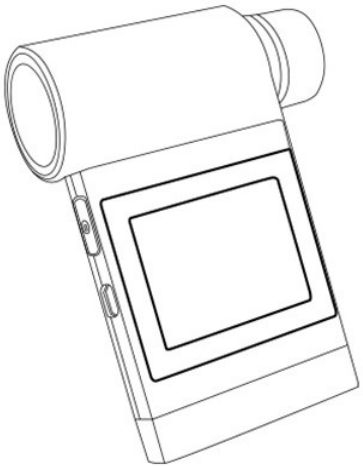
Vitalograph®

micro

MODEL 6300



Instructions for Use

CE
2797

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1. Intended Use/Indications for Use

The device is a spirometer which measures patient respiratory parameters including FVC, FEV_1, FEV6, PEF, MVV and VC. The Vitalograph® micro is a handheld spirometer designed for lung function testing for use on adults and paediatrics, 5 years and older, in a variety of environments such as hospital wards, health centres and private homes under the supervision of a healthcare provider. The indications for use of the Model 6300 Micro is in the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e., spirometry.

2. Contraindications, Warnings, Precautions and Adverse Reactions

2.1. Contraindications and Adverse Reactions

Contraindications

The decision to conduct spirometry testing is determined by the ordering healthcare professional on the basis of their evaluation of the risks i.e., subject fatigue, and the benefits of spirometry testing for the particular patient. Caution should be used for patients prone to fatigue.

Adverse Reactions

Subject fatigue may occur during spirometry testing depending on the subject's characteristics e.g., age, health status. For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between tests.

2.2. Warnings and Precautions

1. No modification of this equipment is allowed. Any unauthorised changes to the device may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.
2. The micro is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. Vitalograph intends that a new Bacterial Viral Filter (BVF™) be used for every subject to prevent cross contamination.

Using a new BVF provides a significant level of protection of the subject, the device, and the user against cross contamination during spirometry manoeuvres. A BVF is for single use only.

4. Spirometry may support or exclude diagnosis, but it cannot make one (ATS/ERS 20191).
5. The device is marked as “Rx Only” and therefore may only be sold in the USA by or on the order of a physician.
6. When using the remote flowhead ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may be affected, or a false reading may be detected.
7. The USB cable supplied with the device has the potential to be a strangulation hazard and therefore should be kept out of the reach of children and pets.
8. The device is rated to IP22 which protects it from solids >12.5mm and dripping water however it is not designed to be waterproof. Do not get the device wet or use in it a wet environment (e.g., in the rain, in a shower). If the device does get wet, it may cease to function however there is no safety risk or potential harm to the user. If the device does get wet, contact the device manufacturer.
9. Take care not to block the flowhead cone with tongue or teeth during testing. A ‘spitting’ action or cough will give false readings.
10. Subject fatigue may occur during spirometry testing depending on the subject’s characteristics e.g., age, health status. For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between tests. The maximum number of efforts for each of the test modules (SVC, FVC and Post) on the micro is 20 manoeuvres.
11. All values displayed are expressed as BTPS values.
12. Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
13. The device should not be used in the presence of flammable liquids or gases, dust, sand, or any other chemical substances.
14. All Spirometry standards recommend completing a

calibration verification of lung function measuring devices daily with a 3-L syringe to validate that the instrument is measuring accurately. The device should never be outside accuracy limits. A calibration verification should also be completed after cleaning or disassembling the spirometer, after adjusting calibration or if the flowhead or device has been dropped.

15. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
16. Maintenance must not be performed while the device is in use by a subject.
17. Do not disconnect the device or USB cable from the computer running the software during data transfer or printing.
18. The device contains a Lithium coin cell battery which is not accessible by the user. Any suspected battery faults should be reported to the manufacturer.
19. The device contains uses 4 x 1.5V non-rechargeable IEC60086 certified AAA alkaline batteries.
20. The AAA batteries should be removed if the micro is intended to be stored, without use, for an extended period.
21. When replacing the batteries all 4 should be replaced together, use batteries from the same manufacturer, never mix new and old batteries, make sure all 4 batteries are inserted in the correct orientation.
22. If the flowhead is removed from the micro (when disassembling for cleaning and/or to attach the remote flowhead adaptor), care should be taken with the exposed edges. During normal use, these edges are covered, are not accessible by the user or subject.
23. Use of accessories and cables other than those specified or provided by Vitalograph for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
24. Non-medical equipment must be kept outside the subject environment i.e., any area in which intentional or

unintentional contact between the subject and parts of the system, or some other persons touching part of the system, can occur.

25. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
26. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
27. Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.
28. This device is 'MR Unsafe', do not use it in an MRI environment.
29. The applied part is the flowhead and device body. These, along with the BVF, are the contact points for the subject during a spirometry session. There are no adverse effects if the subject comes into contact with any other part of the device.

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3. Main Components of the Vitalograph micro

The micro is a standalone spirometer. Device Studio software allows the micro to generate reports to a computer after testing is complete, but it is not required for the device to function. The main components of the micro are:

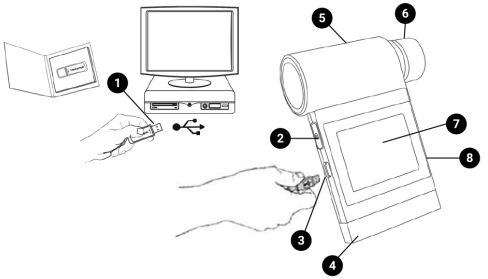


Figure 1

1	USB Flash Drive containing Device Studio Software and manuals
2	Power (On/Off) Button
3	Micro USB Port
4	Plinth
5	Flowhead
6	Flowhead Cone
7	LCD/Touch Panel Display
8	Battery Compartment (4 x 1.5V AAA batteries)

Table 1

Note: *Computer shown for illustration purposes only and not supplied.*

3.1. Features of the Vitalograph micro

The features include:

- Fleisch Pneumotachograph
- Removable flowhead
- Touch screen colour display
- Choice of predicted values
- Report generation through Device Studio software
- Storage of tests and demographic information

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4. Setting Up the Vitalograph micro

Check that the contents of the packaging match those listed on the contents label on the inside of the carton.

Preparing for use:

1. Insert 4 x 1.5V AAA batteries into the battery compartment on rear of device.
2. Alternatively, the device may be powered using the USB cable supplied. Connect one end of the USB cable into a USB port on a computer and the other end into the micro USB connector on the device.
3. Press the On/Off switch to turn the device on.
4. Install Device Studio on the Computer following instructions supplied with the software.
5. To use Device Studio, the micro must be connected to the Computer via USB cable (via ports marked with the symbol).

If the device has just been unpacked or transported, ensure that it is left sitting, fully powered and is at room temperature prior to testing. Ensure a calibration verification is completed on each testing day, prior to using the device (see Section 5.4).

If using with the remote flowhead (not included as standard):

1. Remove the flowhead from the main body of the device by gripping and sliding it firmly in the direction of the flowhead cone (6).
2. Connect the remote flowhead adaptor (4) to the base of the flowhead (5), connect the device cap (2) to the device (1).
3. Unwrap the flowhead connection tubing (3) and connect one

end to device cap (2) and the other end to the remote flowhead adaptor (4). See Figure 2. The tubing is keyed, so it will only connect one way.

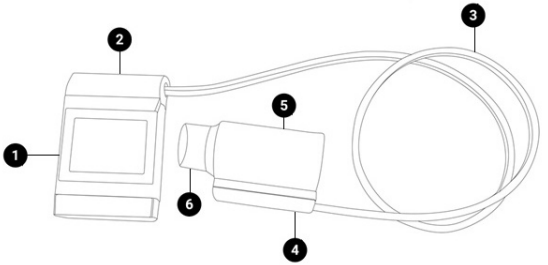


Figure 2

1	Micro Device
2	Device Cap
3	Flowhead Connection Tubing
4	Remote Flowhead Adaptor
5	Flowhead
6	Flowhead Cone

Table 2

5. Operating Instructions

On first time use, the micro opens on the Setup screen for Date and Time . Enter the current date and time.
Press the forward button to save.

Continue to the temperature entry screen . Enter the temperature.
Press the forward button to save.

Continue to the Main Menu screen which includes the following options:

New Subject 

VC Test 

FVC Test 

Post Test 

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The test icons will appear greyed out and can't be selected until a subject is created. The Post Test icon becomes active when an FVC pre-test is performed.
The status bar at the top of the screen shows the following after tests have been completed:

1. V - indicating a VC test has been performed.
2. F - indicating an FVC has been performed.
3. P - indicating a Post test has been performed.

5.1. Entering Subject Data

1. Select New Subject on the Main Menu.
2. The available information fields available are: Date of Birth , Height , Birth Sex ♂ / ♀ , Weight , Population Weight and Population Group are on the second screen and may be enabled in the configuration menu (Subject Options).
3. To enter information for Date of Birth, Height and Weight, touch the blank field on screen to open the touchscreen keyboard. Use the keyboard to enter the information. Units will automatically switch between cm/kg and in/lbs.
4. Select Birth Sex by pressing the male ♂, or female ♀ icon.
5. Select Population Group by pressing the appropriate option on screen. Use the select arrow on the right of the screen to access additional Population Groups.
6. Press the forward button to save the subjects details.
7. If a value is not entered for Birth Sex, Height or Date of Birth

then an Error Icon will appear next to the empty field. If the information is not entered then the predicted values will not appear in test results.

8. To exit the new subject screen, press the forward button.

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5.2. Conducting a Test[1]

Before starting a test session:

a. Ensure that the accuracy of the device was checked recently. (Refer to Section 5.4).
b. Select a subject and ensure the required demographic information is entered.
c. Wash hands (operator and subject).
d. Fit a new Bacterial Viral Filter (BVF) to the flowhead for each test subject. The use of a disposable noseclip is recommended.

5.2.1. Testing

a. Select the test option 'VC' or 'FVC'. Instruct and demonstrate the test as detailed below.
b. Testing may begin when the 'Exhale to Begin' icon appears.
c. The device is now ready to accept a blow.
d. The subject should:
   - Sit upright and maintain this posture throughout the test.
   - Fit the noseclip and relax.
   - Place BVF in mouth and close lips around the mouthpiece.
   - Seal lips around the mouthpiece and keep the tongue down.

1 Derived from terminology and guidance taken from ATS/ERS Standardisation of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e70-e88

5.2.2. VC test session

To perform a VC test (ensure Volume/time (V/t) is selected):

a. Instruct the subject to breathe normally.
b. The subject should inhale completely, with a brief pause when lungs are completely full (≤ 2 secs).
c. Then exhale in a relaxed manner with no hesitation until no more air can be expelled. It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or expiration time reaches 15 seconds).
d. Results may be viewed as either: Volume/time (V/t) or Volume Bar graph by pressing the icon on the side menu. These are not enabled during test.
e. View a full screen graph by using the zoom button at the side of the test screen. Zoom in to return to normal mode. These are not enabled during test.
f. The results summary at the top of the screen shows the VC of the last blow. The number of blows is shown next to the last test VC.
g. The best three tests are shown on the graph in order of rank (best 1, 2, 3 etc.). A legend at the top of the graph explains the order of the tests.
h. Select results from the side menu to view results.
i. Use the left/right arrows to select which test results to view.
j. The tests are shown in order of rank (best is ranked number 1 then 2, 3 etc.).
k. To delete the current blow:
l. Select the Delete option from the side menu. Two delete icons will appear:

Delete (green) : Press to confirm the deletion.

Delete (red) : Press to cancel the deletion.
To clear/delete all the sessions on the device, connect

to Device Studio as outlined in Section 5.3 and move all data to Device Studio to clear it from the device.

m. After performing the VC tests, press the enter button to exit the VC Test screen and return to the Main Menu.

Note: *A single-breath VC technique may also be performed on the device.*

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5.2.3. FVC test session:

To Perform an FVC test :

1. Instruct the subject to breathe normally.
2. The subject should inhale completely and rapidly, with a brief pause when lungs are completely full (≤ 2 secs).
3. Then exhale with maximal effort until no more air can be expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds).
4. It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled. The operator should repeat instructions as necessary, with enthusiasm.
5. Breathe in with maximal effort until completely full. The manoeuvre is now complete, remove the mouthpiece from the mouth.
6. Listen for two beeps. The device is now ready for the next blow.
7. Repeat for a minimum of three manoeuvres, up to a maximum of 20.
8. The results may be viewed as either a Volume/time (V/t) or Flow/Volume (F/V) by pressing the icons on the side menu. These are not enabled during test.
9. The graph may be changed to a full screen graph by using the zoom button on the side menu. Zoom in to return to normal mode. These are not enabled during test.
10. The results summary at the top of the screen shows the FVC and FEV_1 of the last blow.
11. The number of tests (for VC) or the number of usable

tests or bad blow '!' indicator (for FVC) are shown next to the last test results.

12. The best three tests are shown on the graph in order of rank (best 1, 2, 3 etc.). A legend on the top of the graph explains the order of the tests.
13. Select  on the side menu to view results.
    - Use the left/right arrow to select which test to view.
    - Scroll through the results for each test using the up/down arrows. The number of parameters displayed will depend on the configured parameters.
    - The tests are shown in order of rank (best is ranked number 1 then 2, 3 etc.).
    - The results screen has several columns, arranged in a similar manner to the printout. The first column displays the parameter name, the second displays the units, the third the test value and the fourth column shows the %Pred or Z-value, depending on the configuration.
14. To delete the current blow:
    - Select the Delete option from the side menu. Two Delete icons will appear:
    - Delete (green) : Press to confirm the deletion.
    - Delete (red) : Press to cancel the deletion.
    - To clear/delete all the sessions on the device (with the exception of the latest FVC Pre-test), connect to Device Studio as outlined in section 5.3 and move all data to Device Studio to clear it from the device.
15. After performing the FVC tests press the enter button to exit the **FVC Test** screen and return to the **Main Menu**

Note: *A single-breath FVC technique may also be performed on the device.*

Note: *Different tests conducted during the same session i.e. VC and FVC, will be treated as a single session, with a report for that session. A Post test will be treated as a single session, with a report for that session. If more*

than one test is required for the same subject, the device should be switched off and on again between tests so that they are registered as separate sessions and separate reports can be generated.

***Note:** A session ends and is saved when one of the following occur: the device is turned off, a new subject is created, the device is connected to Device Studio.*

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5.2.4. Post Test

A Post test session may be performed on the last FVC pre-test session performed. The device will retain the last pre-test even when it is turned off and on again and/or the data has been transmitted to Device Studio.

To perform a Post test :

1. Select 'Post Mode' from the **Main Menu**.
2. Perform the Post FVC test as outlined in Section 5.2 Performing an FVC Test.

***Note:** A Post Test may only be selected if an FVC pre-test has been completed. When leaving the Post FVC test screen and returning to the main menu the user will not be able to select either the VC or FVC test (they will be greyed out) as the micro is still in Post mode, unless the pre-FVC contains VC data in which case the VC will still be available.*

5.2.5. Saving the Test Session

The micro has the capacity to store a maximum of 325 subject entries with the corresponding session data. Only the best 3 blows will be stored with each session. The session information will also include the subject details entered and the best pre-test if there is a Post-test session.

The micro is intended to be used as a temporary storage device. It may be connected to Device Studio to produce pdf reports of the session data, this will move all subject/ sessions to the Device Studio application and flag them

as deleted on the device except for the last FVC Pre-test.
Note: *If more than the maximum subject/session entries are stored on the device the existing subject/sessions entries will be deleted on a First In First Out (FIFO) basis i.e. the first session entered will be the first to be deleted.*

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5.3. Reporting

The micro prints reports to an external printer through the Device Studio application.
To generate PDF reports:

1. Connect the micro to a computer running Device Studio.
2. The Device Studio application should be open, the micro switched on and in the main screen.
3. When connected, the remote mode icon will display on the micro.
4. Device Studio will search for assessments on the device. The user will be presented with the download screen for each report.
5. Additional information may be added such as name, user interpretation and comments.
6. Device Studio may also be used to print/save calibration verification reports and download/print all assessments.

The settings option on Device Studio allows the user to configure information displayed on the session report.
Additional guidance on using Device Studio can be found in the Instructions for Use supplied on the Device Studio USB flash drive and in the software help menu.
Note: *Do not disconnect the device or USB cable from the computer during data transfer or printing.*
Note: *When the micro is connected to Device Studio it will move, not copy, the stored sessions, with the exception of the latest FVC Pre-session.*
Note: *Different tests conducted during the same session i.e. VC and FVC, will be treated as a single session, with a report for that session. A Post test will be treated as a single session, with a report for that session. If more than one test is required for the same subject the micro should be switched off and on again between tests so that they are registered as separate sessions and separate reports can be generated.*

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5.4. Calibration Verification

The Vitalograph micro should never be outside accuracy limits unless damaged or in a fault condition. In normal use, it is recommended that a daily calibration verification is performed on the device. ISO 26782 recommendations require that the difference between the volume measured by the spirometer and the volume pumped into the spirometer from a syringe is within 3%. To complete a calibration verification:

1. Select the Configuration button on the main menu screen.
2. Select the calibration verification icon .
3. Enter the Syringe volume , serial number SN and ambient temperature using the touchscreen keypad.
4. Connect the flowhead to the syringe and pump air through the flowhead to bring it to ambient temperature. If the flowhead has very recently been used for testing or has come from a cold environment, pump air through it several times to equilibrate its temperature.



Figure 3

5. Press the 'Forward' key to move to the Calibration Verification screen, follow the on-screen instructions.

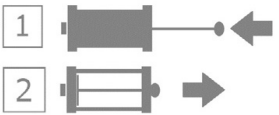
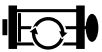
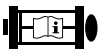


Figure 4

6. The result of each stroke, expiratory (E) and inspiratory (I) displays on the top of the screen with the number of strokes shown in between. If they are reproducible and within 3% this will be displayed on the top of the screen, and a syringe with a green tick pass will display. Pressing the forward key will return to the main Configuration menu and the Calibration Verification pass is recorded.
7. In the unlikely event the result is outside 3% or non-reproducible, an error icon will display.

	Successful verification (green syringe with a tick).
	Non-reproducible syringe strokes (red syringe with 'information' in centre, after the 5th Stroke). Outside 25% (poor technique, repeat verification or an issue with the flowhead/ device, contact technical support)
	Outside 3%, 6% (purple syringe, and shows >3%, >6% on the top of the screen). The higher the %, the more severe the issue. Over 3%, repeat calibration verification. Over 6% may indicate the device requires cleaning or maintenance.

The following icons display after the calibration update:

	Calibration update (purple syringe with purple tick in a circle, % shown on top of screen).
	Non-reproducible syringe strokes (red syringe with 'information' in centre, after the 5th Stroke). Outside 25%.

The following displays on power on if the previous calibration verification has failed:

	Calibration verification failed (orange syringe with triangular warning symbol).

A Calibration Verification report may be printed or saved if required, see Section 5.3.
If the procedure was followed correctly and the error icon is showing, the calibration verification should be repeated. If the error continues to show, contact Vitalograph using the contact information at the start of this document.

Note: *To exit the Calibration Verification screen without performing a check, press the forward key again to return to the Configuration Menu screen. The Calibration Verification will not be logged to the device memory in this case.*
Note: *A calibration verification is recommended daily, if the device has been stored or transported, if the flowhead is dropped or replaced, and if EMI (Electromagnetic Interference) is suspected or possible.*

5.5. Configuration Options

To access the Configuration menu, press the icon  on the main screen.

There are four configuration options:

1. The Subject option  to configure:
   a. Posture: set the posture for the session to sitting or standing .
   b. Weight: turn on  to enter the subject's weight or off  if not required.
   c. Population Group: turn on  to enter the subject's population group or off  if not required.

2. The Device settings options  to configure:

   a. The device  which includes:

- Selecting between % Predicted % or Z-score Z. The parameter selected will then be displayed in the results screen.
- Audio: turn audio off  and put the micro into silent mode.
- User Passcode: use  to lock the device so that any user will be prompted for a passcode on start up.
- Temperature:  enter the temperature, up to 2 decimal places. The default setting is 23°C.

   b. Parameters: Choose  to select which parameters to display on the results screen, use the left/right arrows to navigate between screens. A maximum of 8 parameters can be selected.

The following are all available parameters:

Parameter	Definition
VC	Vital capacity (L)
FVC	Forced vital capacity (L)
FEV_1	Forced expiratory volume after 1 second (L)
FEV_1R	FEV1 divided by the largest VC from the VC or FVC manoeuvre.
PEF L/s	Peak expiratory flow (L/sec)
PEF L/min	Peak expiratory flow (L/min)
FEF_{25-75}	Forced expiratory flow: the mean FEF in the time interval between 25% and 75% of the FVC (L/sec)
FEF_{75-85}	Forced expiratory flow: the mean FEF in the time interval between 75% and 85% of the FVC (L/sec)

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EVC	Expiratory vital capacity (L)
IVC	Inspiratory vital capacity (L)
FIVC	Forced inspiratory vital capacity (L)
FIVC/FVC	Ratio FIVC of FVC
$FEV_{.5}$	Forced expiratory volume after 0.5 seconds (L)
PIF L/s	Peak inspiratory flow (L/sec)
FMFT	Forced mid-expiratory flow time (sec)
FET	Forced expiratory time (sec)
$FEV_{.5}$/FVC	Ratio FEV 0.5 of FVC
$FEV_{.75}$	Forced expiratory volume after 0.75 seconds (L)
$FEV_{.75}$/ FVC	Ratio FEV 0.75 of FVC
FEV_1/VC FEV_1/IVC	Ratio FEV_1 of VC Ratio FEV_1 of IVC
FEV_1/FVC	Ratio FEV_1 of FVC
FEV_1/ FIVC	Ratio FEV_1 of FIVC
FEV_1/ FEV6	Ratio FEV_1 of FEV_6
FEV_1/PEF FEV_3	Ratio FEV_1 of PEF Forced expiratory volume after 3 seconds (L)
FEV_3/FVC	Ratio FEV_3 of FVC
VC FEV_6	Forced expiratory volume after 6 seconds (L)
FEF_{25}	Forced expiratory flow at 25% of the FVC (L/sec)
FEF_{50}	Forced expiratory flow at 50% of the FVC (L/sec)

FEF_{75}	Forced expiratory flow at 75% of the FVC (L/sec)
$FEF_{0.2\text{-}1.2}$	Mean forced expiratory flow in the volume interval between 0.2 and 1.2 L of the test (L/sec)
$FEF_{25\text{-}75}$/FVC	Ratio $FEF_{25\text{-}75}$ of FVC
FIV_1/FVC	Ratio FIV_1 of FIVC
FIV_1	Forced inspiratory volume after 1 second (L)
FIV_1/FIVC	Ratio FIV_1 of FIVC
PIF L/min	Peak inspiratory flow (L/min)
FIF_{25}	Forced inspiratory flow at 25% of the FVC (L/sec)
FIF_{50}	Forced inspiratory flow at 50% of the FVC (L/sec)
FIF_{75}	Forced inspiratory flow at 75% of the FVC (L/sec)
FIF_{50}- FEF_{50}	Ratio FIF 50% of FEF 50%
FEF_{50}- FIF_{50}	Ratio FEF 50% of FIF 50%
MVVind	Maximum voluntary ventilation indirectly calculated from the FEV_1 (L/min)
Rind	Airways Resistance Indirect measurement.
FEV_1/EVC BEV/FVC	Ratio FEV_1 to EVC Ratio BEV to FVC
BEV	Back Extrapolated Volume
EOTV	End of test Volume
tRise	Rise Time
tHes	Hesitation Time

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c. Date/Time: Select to set or change the date and/or time. Use the up/down arrows to edit fields.

d. Service mode/Technician. This option is for servicing and technicians, a passcode is required to activate.

3. Calibration Verification : See section 5.4 for details on performing a Calibration Verification.
4. About : Contains information about the software which should be used if making enquiries to Vitalograph or a service agent. This information includes the Model number (6300), Serial number of the device, the Software reference number, date of the last Calibration Verification and date of Service completion.

6. Power Management

The device may be powered from a computer via the USB cable or from internal batteries. The battery icon shows the power status of the device.
The device uses 4 x 1.5V non-rechargeable IEC60086 certified AAA alkaline batteries.

Note: *When replacing the batteries, all 4 should be replaced together. Use batteries from the same manufacturer, never mix new and old batteries and make sure the batteries are in the correct orientation*

6.1. Battery Power Indications

There are four levels of battery power:

	When the battery is fully charged, a white 'Battery Full' icon displays on the status bar at the top of the screen. Disconnect the device from external power source when it is fully charged.
	When the battery is at less than 20% capacity, an orange 'Battery Low' icon displays on the status bar at the top of the screen. You may continue to use the device, but it is advisable to connect to an external power source.

	When the battery is approaching fully discharged the red 'Battery Discharged' icon displays on the status bar at the top of the screen. If the battery is at less than 5% capacity the device powers down. Connect to an external power source to recharge the battery before attempting to use the device again.
	Battery Discharged - the Battery Discharged icon displays on full screen on power up and a red empty battery icon displays on the status bar. Batteries should be changed immediately, or the device connected to a computer via USB cable to continue testing.

When the USB power is connected, this icon  displays instead of the battery icon.

6.2. Power Save Mode

To improve battery life, when powered by batteries the micro will auto power down if left unused for 5 minutes.
When running off the USB the device screen will go blank if left unused for 5 minutes. The device will not auto power down if powered by USB.
Pressing the screen or on/Off button will bring the device out of power save mode.

7. Cybersecurity Considerations

7.1. Specification

The device does not have an operating system and is inaccessible without the device API or a Vitalograph application. Only Vitalograph PC based applications can access the device over a secure connection. No further controls are required to be applied by users to secure the device.

7.2. Security Recommendation

When connecting to a PC it is recommended that the PC has the following cybersecurity in place:

- Up to date Operating System: the Operating System should be configured for automatic update for security patches and have all of the latest patches applied.
- Antivirus/antimalware: the PC should have a reputable antivirus or antimalware application installed and all updated virus definitions in place.
- Secure Login: the PC should be password protected via industry standard user access controls, via active directory or other methods.
- Firewall: if the PC is connected to the internet ensure a reputable firewall or equivalent protection is in place to protect against unauthorised external access.

8. Cleaning & Hygiene

8.1. Preventing Cross-Contamination of Subjects

A spirometer is not designed or supplied as a 'sterile' device. Vitalograph intends that a new Bacterial Viral Filter (BVF) be used for every subject to prevent cross contamination. Using a new BVF provides a significant level of protection for the subject, the device and the user against cross contamination during spirometry manoeuvres.

The interior of a Vitalograph flowhead does not require decontamination where a new BVF is used for each subject. The outside surfaces of the device and flowhead tube may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection.

Part	Clean/ Low Level Disinfection	Recommended Cleaning/Low Level Disinfection
Case exterior	Clean	Wiping with a 70% isopropyl alcohol impregnated cloth provides a suitable form of cleaning. The exposure time for low level disinfection using 70% IPA wipes is ≥1 minute[2]
Screen	Clean	For the screen, lightly wipe the surface with cotton pad or other soft material. **NOTE: DO NOT use any chemicals. DO NOT wipe in a circular motion. Strokes should be either up/down or over/back.**

Table 3 - Table of Cleaning/Disinfection Methods

Where the user suspects that the flowhead has become contaminated or where local risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per the instructions in 'Cleaning and Hygiene' on the Vitalograph website.

8.2. Inspection of the Vitalograph micro

A visual inspection is recommended on a routine basis.
Examine cone and flow conditioning mesh filter for damage or contamination. If damaged or blocked, it should be replaced with a new part. Examine the Fleisch element and replace if damaged.
If it is suspected that the flowhead has become contaminated or where user risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per the instructions in 'Cleaning and Hygiene' on the Vitalograph website.
It is recommended that a calibration verification is carried out following cleaning and re-assembly as recommended by the ATS/ ERS 2019 guidelines[3].

2 Rutala, W. A. 2017 "Back to the Basics" accessed from disinfection&sterilization.org, June 2020.
3 Derived from terminology and guidance taken from ATS/ERS Standardisation of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e70-e88

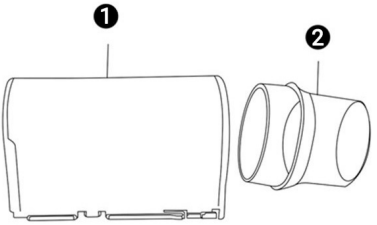


Figure 5 - Flowhead Assembly

1	Flowhead containing Fleisch
2	Flowhead End Cone

9. Fault Finding Guide

Problem Fault Symptoms:	**Calibration verification variations > +/-3%** **False readings suspected**
Possible Cause/Solution: (In probable order)	The % error indicates the severity of the issue. Over 3%, repeat the calibration verification. Over 25%, the user should contact technical support. Was the correct syringe volume selected? Flowhead pressure tapping holes blocked. Contact support. Flowhead Fleisch element assembly sealing 'O' rings damaged. Contact support. Flowhead Fleisch element assembly blocked. Contact support. Cold syringe. Ensure syringe is in its test environment for at least an hour before use. EMI (Electromagnetic Interference) that exceeds EN60601-1-2 EMC standard. Turn off offending device or move the micro to another location and repeat. Internal tubing from pressure ports on device is blocked. Contact support.

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Problem Fault Symptoms:	**Cannot print to external printer**
Possible Cause/ Solution: (In probable order)	Check device is connected to the computer and Device studio is installed on computer. Ensure the device is in the main menu screen. Electronics failure. Contact support.
Problem Fault Symptoms:	**Tests begin automatically.** **Volume accumulates automatically without the subject blowing.** **Very small VC or FVC test displayed.**
Possible Cause/ Solution: (In probable order)	Device (or if using remote flowhead, the flowhead) is not stationary at the start of test. Hold it steady until the 'Ready to Blow' prompt appears. Return to previous menu and re-enter the test.
Problem Fault Symptoms:	**Cannot read screen.**
Possible Cause/ Solution: (In probable order)	Ensure the on/off button was pressed. The batteries may be low, plug in USB cable attached to a computer or replace the batteries. Electronics failure. Contact support.
Problem Fault Symptoms:	**Reversed or no volume measurements.**
Possible Cause/ Solution: (In probable order)	Ensure flowhead is properly connected/ seated on device (if using the remote flowhead also check that the tubing is connected correctly). Electronics failure. Contact support.

9.1. Software Check

Information about the device may be obtained from the About option in the Configuration menu. This information may be used when enquiries are made to Vitalograph or a service agent.

9.2. Product Useful Life Checks

To ascertain whether the device has exceeded its useful life Vitalograph recommends checking the flowhead and the real time clock.
The flowhead may be checked with the daily calibration verification, to be completed by the clinician/healthcare professional, and during the periodic inspection of the device.
Reference Section 5.4 for details on how to check the device flowhead. The clock will reset if the 3V coin cell battery has depleted. This will be evident as the Time/Date option will be displayed every time the device is turned on until the battery is replaced and the time/date is set again.
The coin cell has an expected battery life of 15 years+, which exceeds the devices product life; therefore, a service is recommended at 10 years or when product useful life checks dictate it is required.

10. Customer Service

Service and repairs should be carried out only by the manufacturer, or by Service Agents approved by Vitalograph.
For the names and addresses of approved Service Agents, please refer to the contact information at the start of this manual.
Any serious incident that has occurred in relation to the device should be reported to Vitalograph or its Authorised Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this document.

This IFU is available on the Vitalograph website at the following location:
www.vitalograph.com/ifu/Vitalograph_Micro_Spirometer_IFU.pdf

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11. Accessories/Components

Cat. No	Description
28501	Eco BVF (100)
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip + Disposable Nose Clip (75)
20303	Nose Clip (200)
28350	BVF (50)
36020	3-L Precision Syringe
69131	Flowhead Cone (5)
41653	USB Cable
41660	LCD Spare
41659	Main PCBA Spare
83157	Flowhead Spare
63660	Service Kit
83200	Flowhead adaptor kit

12. Disposal

The device is marked with the WEEE symbol and must be taken to separate collection at the product end-of-life. Do not dispose of these products or the batteries as unsorted municipal waste, they should be disposed of in line with local requirements.



- Used BVFs constitute minimally soiled waste from human healthcare.
- BVFs are made from recyclable material and should be disposed of in line with local requirements.

13. Explanation of Symbols

Symbol	Description
	Type B equipment
	Class II
VA	Power rating
V ⎓	Voltage DC Batt V for battery DC for power supply
	Instructions for Use; operating instructions
	Manufacturer
	Date of Manufacture (include date in format yyyy-mm-dd)
SN	Serial Number
REF	Catalogue Number
MD	Medical Device
	Country of Manufacture
	On/Off
	USB connector

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	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste
	Fragile, handle with care
	Keep Dry
	Do not re-use
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it
Rx Only	Rx Only Restricted to sale by, or on the order of a physician.
	MR Unsafe – Do not use this device in an MRI environment.
IP22	Degree of Protection
UDI	Unique device identifier
#	Model number

14. Description of the Vitalograph micro

The Vitalograph micro is a handheld spirometer which measures subject respiratory parameters. It is designed for portable spirometry but may be connected to the associated Device Studio application to view and print reports. The Fleisch flowhead is used for testing and is integral to the device.

15. Technical Specification

Product	Vitalograph micro, Model 6300
Flow Detection Principal	Fleisch type pneumotachograph
Volume detection	Flow integration sampling @ 100Hz
Maximum test duration	90 seconds
Maximum displayed volume	10 L
Volume Accuracy	±2.5%
Flow Measurement Range	Max. flow rate ±960 L/min (±16 L/s) Min. flow rate ±1.2 L/min (±0.02 L/s)
PEF Accuracy	±10% or ±10L/min of the reading (ISO 23747:2015)
Back pressure	Less than 0.1kPa/L/sec @ 14L/ sec (ATS/ERS 2019)
Operating temperature range	ISO 26782 limits: 17–35ºC Design limits: 10–40ºC
Operating humidity range	30%–75%
Ambient pressure range	850hPa–1060hPa
Performance standards	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
Electrical Safety Standard	EN 60601-1:2006/A13:2024
EMC Standard	EN 60601-1-2:2015 + A1:2021

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Home use Standard	EN 60601-1-11:2015+A1:2021
Coexistence Standard	ANSI C63.27-2017
QA/GMP standards	EN ISO 13485, FDA 21 CFR 820 (QMSR), CMDR SOR/98-282 & Japan's PMD Act
Dimensions	142mm (length) x 81mm (width) x 24mm (height)
Weight	260g (device only, no batteries, packaging or accessories)
Communications	USB 2.0 Bluetooth 2/4
Power Supply	5V DC via USB 4 x 1.5V AAA batteries (6V)
Essential Performance	Flow measurement output
Essential Performance Test Limits	Flow Accuracy ±10% or ±10 L/min with +/- 3% or 3L/min allowed for test apparatus (ISO 23747).
Service life	The recommended service life of the device is 10 years+ or when the product life checks dictate it is required. The battery life of the RTC battery is expected to exceed the device product life. Reference section 8.2 'Product useful life checks'.

Product life	10 years+ when maintenance procedures are adhered to. Reference section 8.2 'Product useful life checks' for information on how to ascertain whether the device or parts on the device have exceeded their useful life and a service is required.
Minimum PC System Requirements	Processor Speed: 2GHz or greater RAM: 2GB (Min), 4GB (Recommended) Disk Space: 1GB or greater Operating System: Windows 10 or above Monitor: 1280 x 800 pixel Other: .Net framework 4.6.1 USB Port Bluetooth Support PDF Viewer

Notes:

- All values displayed are expressed as BTPS values.
- Take care not to block the mouthpiece with tongue or teeth. A 'spitting' action or coughing will give false readings.
- Time zero is determined using the back-extrapolated method, from the steepest part of the curve. The operating conditions specified apply to the device plus accessories.
- The device, flowhead and BVF are classified as type BF applied parts.
- An applied part is a part of the equipment, which in normal use necessarily comes into physical contact with the subject for equipment or system to perform its function.

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16. Electromagnetic Compatibility (EMC) Standards

Marking by the symbol CE 2797 indicates compliance of the Vitalograph Model 6300 micro to the European Medical Device Regulation 2017/745 (EU MDR) as amended.

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The Vitalograph micro is intended for use in a variety of professional healthcare environments, e.g. primary care, hospital wards and occupational health centres, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of the micro should assure that it is not used in such an environment.

The Model 6300 micro has been tested in accordance with:

EN 60601-1:2006 /A13:2024, - Medical electrical equipment. General requirements for basic safety and essential performance EN 60601-1-2:2015 + A1: 2021 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

EN 60601-1-11:2015+A1:2021 - Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – collateral standard: Requirement for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Coexistence: ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence.

EN 60601-1-2:2015 + A1:2021 - Emissions tests During the immunity testing below the device continued to operate within specification		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Model 6300 micro uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 6300 micro is suitable for use in all establishments, including domestic establishments and those connected to the public mains network (e.g. at home and doctor's offices in residential areas).

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EN 60601-1-2:2015 + A1:2021 - Immunity tests		
Immunity test	**Test level**	**Compliance level Reached**
Electrostatic discharge (ESD) EN 61000-4-2	Contact: ± 8 kV Air: ± 2 kV,± 4 kV, ± 8kV,± 15 kV	Contact: ± 8 kV Air: ± 2 kV,± 4 kV, ± 8kV,± 15 kV
Radiated RF EN 61000-4-3	10 V/m 80MHz to 2700MHz 3V 2700 to 6000MHz	10 V/m 80MHz to 2700 MHz 3V 2700 to 6000MHz
Proximity fields from RF devices EN 61000-4-3	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2
Power Frequency Magnetic Field Immunity EN 61000-4-8	30A/m	30A/m
Power Magnetic Field Immunity EN 61000-4-8	8A/m 30kHz 65A/m 134.2 k Hz (2.1 kHz PM) 7.5A/m 13.56 M Hz (50 kHz PM)	8A/m 30kHz 65A/m 134.2 k Hz (2.1 kHz PM) 7.5A/m 13.56 M Hz (50 kHz PM)

Medical Devices may be affected by mobile RF communications equipment including cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Vitalograph

product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible.

Loss or degraded performance due to EMI that exceeds the test levels in immunity test tables above will result in a failed calibration verification. Reference section 5.4 of this document for details on completing a calibration verification on the micro. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

The Model 6300 micro is a Spirometer and so the performance deemed to be essential is the output of the flow transducer

WARNING: No modification of this equipment is allowed.

17. FDA Notice

Caution: Federal Law restricts this device to sale by, or on the order of a physician.

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18. Regulatory Information

Product: Vitalograph Model 6300 micro
Vitalograph hereby ensures and declares that the above product associated with these instructions for use, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Device Regulation {MDR} 2017/745, as amended.
  This device is classified as IIa per Annex IX of the MDR also meets the provisions of the General Safety and Performance Requirements, Annex I, via compliance with Annex IV of the Medical Device Regulation as per Article 52
- Canadian Medical Device Regulation {CMDR SOR/98-282}
- FDA Quality System Regulation {QMSR} 21 CFR 820
- EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body: British Standards Institute (BSI).

BSI Notified Body #: 2797

Certificate Nos. MDR 772430

Signed on behalf of Vitalograph (Ireland) Ltd.



Frank Keane.
CEO, Vitalograph Ltd.

19. Guarantee

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its option replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within two years of the date of purchase of the equipment, unless otherwise agreed in writing by the Company. Registration is not required for this base two year guarantee.
2. An extended five year warranty from date of purchase, is available by registering the products serial number at www.vitalograph.com/warranty within 30 days of purchase.
3. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
4. The Company warrants that the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided that the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.
5. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.
6. If a defect occurs, please contact the supplier from it was purchased for advice. The Company does not authorize any person to create for it any other obligation or liability in connection with Vitalograph® equipment.
7. This Guarantee is not transferable, and no person, firm or company has any authority to vary the terms or conditions of this guarantee.
8. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph equipment.
9. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

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