



Inflammacheck[®]

User manual

Version 3.0





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Inflammacheck® User Manual			
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Intended use

Inflammacheck® is an in-vitro diagnostic device for the definition of a rich Breath Print from a patient being tested. The Breath Print is composed of a quantitative measurement of hydrogen peroxide (H₂O₂) levels in exhaled breath condensate (EBC), combined with values of CO₂ contents in exhaled breath, exhaled breath temperature and relative humidity, as well as breath flow being logged at 10Hz (10 times per second) during the collection of EBC sample for the H₂O₂ measurement. The Breath Print in its entirety as well as individual components thereof are intended to support clinical decisions in the diagnosis and management of patients suspected to have airway inflammation or otherwise impaired airways systems. Inflammacheck® is intended for use by health professionals in a point of care settings and is only for use in adults.

Introduction to Inflammacheck®

Inflammacheck® is a portable hand-held in-vitro diagnostic device that provides a rapid, non-interventional quantification of H₂O₂ in EBC – a biomarker of airway oxidative stress and inflammation. Measurement of EBC H₂O₂ is clinically useful to identify the presence of airway inflammation.¹

In parallel to the EBC H₂O₂ measurement, Inflammacheck® is logging and storing readings from sensors measuring breath CO₂, breath temperature and breath relative humidity, as well as breath flow at a frequency of 10Hz, rendering 10 time-tagged data points per second per sensor.

Jointly, the sensor readings constitute a rich Breath Print which helps gaining further insight into the condition of the airways.

The patient breathes normally into and out of the device for 2–3 minutes during which the above listed parameters are being logged. Thus, at 10Hz, after one minute of sample collection, Inflammacheck® will have logged 600 readings from each.

When the required volume of EBC has been collected, the measurement of H₂O₂ follows automatically and the H₂O₂ concentration is displayed on the screen. The test cycle, including sample collection, assay and presentation of the result, takes about 5 minutes.

Inflammacheck® is for use in adults only, by a trained healthcare professional in a point-of-care setting. Trained status is achieved by completely and thoroughly reading this manual. Please make sure that you are familiar with the device and its assembly, and the test procedure, before conducting tests with patients. A Quick Reference Guide is provided (page 6) as an aide memoire when conducting tests but is not a substitute for reading this short manual.

Inflammacheck® complies with Directive 98/79/EC on in vitro diagnostic medical devices and with the European Respiratory Society technical standards for testing of exhaled biomarkers in lung disease.¹

¹ Horváth, et al. A European Respiratory Society technical standard: exhaled biomarkers in lung disease. Eur Respir J 2017; 49: 1600965, <https://erj.ersjournals.com/content/49/4/1600965>.

QUICK REFERENCE GUIDE

This table is provided as an "aide memoire" when performing test but is not a substitute for reading this short manual. Please read the entire manual and familiarize yourself with the Inflammacheck® and components and test procedure before performing any tests with patients.

Preparation of the Inflammacheck® device	<ul style="list-style-type: none"> • Remove sensor cartridge from cold storage at least 30 minutes before the test, to allow sensor cartridge to reach room temperature • Unpack, assemble and mount the valve housing • Unpack and mount the mouthpiece • Turn on the Inflammacheck® reader
Preparation for the test	<ul style="list-style-type: none"> • Unpack the sensor cartridge and insert into the slot in the reader; the reader will start the shelf-check and cooling • Explain to the patient what you want them to do; put the nose clip into position • When the patient is ready and the cooling process is complete, hand the device to the patient
Sample collection and assay	<ul style="list-style-type: none"> • Sample collection is triggered by the patient breathing through the device • Check that the patient is breathing normally and is not blocking any of the vents • When the device beeps (after 2–3 min), take it from the patient and place it on a flat surface • The assay automatically starts when adequate sample has been collected
Test result	<ul style="list-style-type: none"> • Read and record the H₂O₂ level (μM), average exhaled breath flow (L/min) and test ID • Download test data for further processing and storage
After the test	<ul style="list-style-type: none"> • Remove the mouthpiece, valve housing and sensor cartridge • Dispose of the mouthpiece and sensor cartridge in a clinical waste container • Dismantle and clean the valve housing
<p>Wait 15 minutes before performing the next test. If two consecutive tests are needed for the same patient, a waiting time of 5 minutes is acceptable.</p>	

Components of Inflammacheck®

Inflammacheck® comprises the Inflammacheck® reader, separate valve house and single-use BV-filter (

Figure 1) and is used with a single-use sensor cartridge (Figure 2). It is supplied with a charger and cable, standard USB cable and a USB flash drive for transferring data.

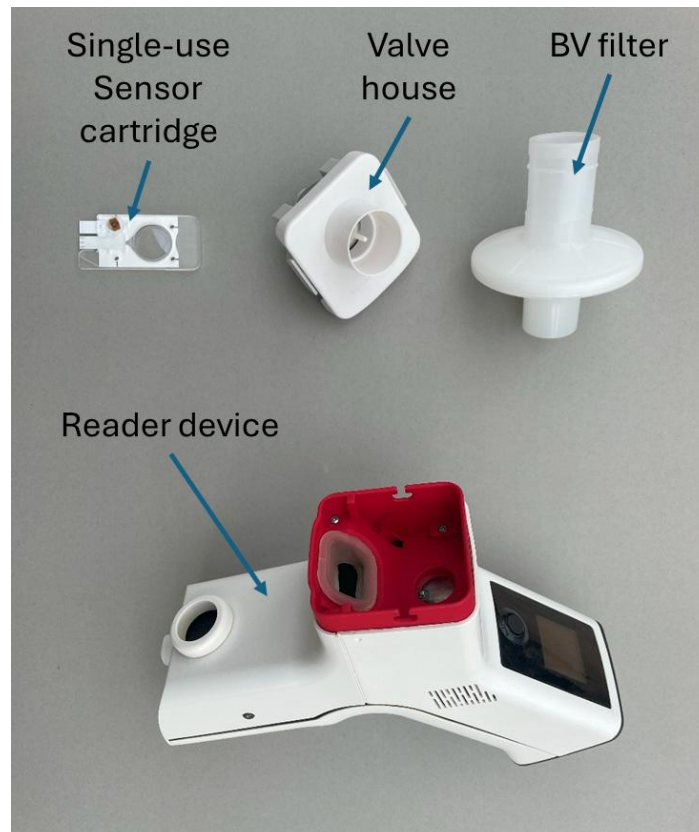


Figure 1: The Inflammacheck® system components

A standard nose clip is also required. An H₂O₂ scrubbing filter can be fitted if desired but is not provided as a standard component.

The Inflammacheck® reader contains cooling for the EBC sample collection, processors for controlling the test procedure, and the algorithm for converting test measurements to the final test result. The system is factory calibrated against standard reference solutions and requires no further calibration.

The valve house and BV filter together control airflow through the Inflammacheck® reader, guiding the exhaled air to the condensing area whilst diverting inhaled air away from the condensing area. The BV filter serves as a saliva trap.

EBC sample collection and H₂O₂ measurement take place in a single-use sensor cartridge (Figure 2). Exhaled breath condenses on a thin hydrophilic film mounted on the underside of the sensor cartridge and collects in a 8 µL chamber just below the condensation area.

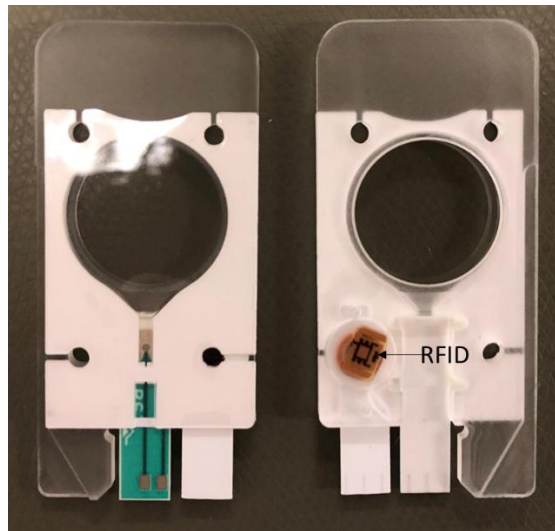


Figure 2: The sensor cartridge

The biosensor contains horseradish peroxidase (E.C. 1.11.1.7) and is dotted with phosphate buffer crystals, which provide optimal conditions for the enzymatic reaction when dissolved in the EBC sample and function as the electrolyte for the subsequent electrochemical reaction. The crystals also contain conditioning chemicals for the reference electrode and a metal ion scavenger. Wetting of the sensor by EBC initiates a nano-current, which is measured and used to calculate the H_2O_2 level from an algorithm.

The sensor cartridge has an RFID tag containing all the relevant information pertaining to the sensor and cartridge, including an identification number. This tag is read automatically when the cartridge is inserted into the Inflammacheck[®] reader.

Starter kit

The Inflammacheck[®] starter kit comprises:

- The Inflammacheck[®] reader
- 10 valve housings
- A charger with cable
- A USB cable
- A USB flash drive containing
 - Inflammacheck[®] PC application set-up file
 - Inflammacheck[®] Instruction for Use – Software
 - Inflammacheck[®] User Manual (this document)
 - Inflammacheck[®] Instructions for Use – Quick Guide
 - Inflammacheck[®] User Manual (this document)

The following consumables are supplied with the starter kit:

- 25 sensor cartridges in a box with cooling elements to keep the temperature below 8°C during transportation

Upon delivery, check the WarmMark® temperature tag (**Error! Reference source not found.**) on the packaging, which changes colour if the package has been above 8°C. If any of the zones are red, the cartridges will not be suitable for use – contact your manufacturer or local distributor for replacement cartridges.

If the cold chain has not been disrupted, transfer the cartridges to a refrigerator for storage ($5 \pm 3^\circ\text{C}$).



Figure 3: The WarmMark® temperature sensor

Unpack on a level surface. Check that all the listed components are provided and undamaged.

Temperatures of -30 to 70°C (-22 to 158°F) are permitted for the Inflammacheck® reader and components during transport for a maximum of 24 hours.

Packaging, storage and disposal

Store the Inflammacheck® reader at normal room temperatures. The packaging, storage and disposal of the consumables are shown in the following table.

Should it be necessary to dispose of the Inflammacheck® reader, it can be returned to the manufacturer (with the battery in place), and with a confirmation of appropriate cleaning included with the shipment. It can also be disposed of locally: the lithium-ion battery in the reader, charger and cable should be disposed of according to local regulations.

Consumable	Description of packaging	Units per carton	Storage	Use
Sensor cartridge	Individual sealed foil bags providing protection from moisture and UV light	25	5 ± 3°C (41 ± 6°F) in original bags	Use by expiry date Single use Dispose of immediately after use in clinical waste container
Valve house	Individual zipped plastic bag	10	Store unused valve houses in their original bags at room temperature	Multi-use A clean house must be used for each patient (see page 16) Dispose of in clinical waste
BV filter	Individual sealed plastic bag	25	Store unused BV filters in their original bags at room temperature	Single use Dispose of immediately after use in a clinical waste container

Operation and training

Inflammacheck® is only to be operated by trained healthcare professionals, as directed in this instruction manual. Trained status is achieved by careful reading of this user manual. Make certain that you fully understand how to assemble the components and conduct a test before using it for the first time with a patient.

The Inflammacheck® system should be operated at 20–28°C (68–82°F) and 15–85% relative humidity.

The Inflammacheck® reader

The user interface on the Inflammacheck® reader has the following features:

- The on–off button – holding the button down for 1 second turns the reader on; holding it down for 2 seconds turns the reader off
- The LCD display – guides the user through the test sequence and displays the test result and any error messages
- An audible notification when particular stages in the test cycle have been reached.



Figure 4: Key features of the user interface on the Inflammacheck reader

Charging the reader

The Inflammacheck® reader has a built-in rechargeable battery and is provided with a charger and cable. It should only be charged using this specific charger. Connect the Inflammacheck® reader to the charger, then the charger to a power outlet. Charge the reader for at least 12 hours before first use. Remove the charger from the reader before use.

A fully charged battery lasts for up to 40 days or 15 tests. It takes about 12 hours to recharge completely and can be put on charge between uses if required.

Performing a test with Inflammacheck®

The sequence for performing a test is shown in the table and summarized on a single-page Quick Reference Guide to use as a prompt while performing a test (page 6). The actual test process is automated, triggered by insertion of the sensor cartridge, making it easy to operate and minimizing the risk of unintended use. The details of each step are provided below.

#	User action	Device action
Prepare for test		
	<ul style="list-style-type: none"> ✓ Remove sensor cartridge from cold storage at least 30 minutes before the test ✓ Leave it in its sealed bag until it is to be used in a test ✓ This will ensure that sensor cartridge acclimatizes to room temperature ✓ The cartridge should not be left at room temperature for longer than four hours ✓ Unpack, assemble and mount the valve housing ✓ Unpack, assemble and mount the BV filter ✓ Prepare and instruct patient for test 	
1	Open sealed bag and take out sensor cartridge	
2	Switch on device and insert sensor cartridge	Performs self-check
3		Cools condensation area down to 4°C
4		Prompts user to start sample collection

#	User action	Device action
5	Start breathing through device	Detects first breath, sample collection period commences
6		Maintains condensation area at 3-4°C
7		Reads and logs breath CO ₂ , breath temperature, breath relative humidity, and breath flow 10 times per second during entire sample collection period
8		Detects when enough EBC has been collected to fill sensor capillary
9		Prompts user to stop sample collection
10	Stop breathing through device, and place it on table	Performs automatic test assay
11		Calculates EBC H ₂ O ₂ contents Stores all test data on built-in memory card
12		Displays Hydrogen Peroxide contents on built-in display
13	Read out result and test ID, and extract sensor cartridge	Shuts down
14		All test data remains stored on and can be extracted from the device for further processing and storage

Preparation

Make sure the Inflammacheck® reader is fully charged. Remove the charging cable.

Take the sensor cartridge out of the refrigerator at least 30 minutes before the test, to allow it to reach room temperature. Keep the cartridge in the original packaging, unopened, until use. Note that the cartridge should not be kept at room temperature for longer than four hours.

Have ready the following:

- a clean assembled valve house for each patient, in its unzipped bag (see next section)
- a new BV filter in an unopened bag
- a nose clip

Allow your patient to be seated for 5–10 minutes before the test while you explain the procedure and assemble Inflammacheck®.

Mount valve house and BV filter



Figure 5: Click the valve house into place in the device and mount the Bacterial Viral (BV) filter onto the valve house.

Remove the single-use mouthpiece from its packaging. Note that the mouthpiece is manufactured in two pieces that you may need to click together. Insert the assembled mouthpiece into the valve housing, aligning the lugs.

Switch on the Inflammachek[®] reader by holding down the on-off button until the logo appears on the screen.

Note that if the reader is idle for more than 5 minutes it will power off automatically.

Press the on-off button again to start the test procedure.

Remove the sensor cartridge from its bag and insert it into the reader when instructed to do so (Figure 6), pushing it in as far as it will go.



Figure 6: Inserting the sensor cartridge into the reader

The device detects the sensor cartridge and automatically starts its self-check procedure, which takes 9 seconds, followed by cooling, which typically takes 60 seconds. The reader beeps when cooling is complete, and the device is ready for use.

Preparing the patient

Check that the patient has not used any teeth whitening/bleaching products or mouthwashes for 12 hours before having the Inflammacheck® test, as several commercial dental products contain large amounts of H₂O₂ and may give an artificially high reading (by as much as a 100-fold increase in signal), although the effects typically dissipate within an hour.



Figure 7: Ask test subject to pick up the device, inhale fully, and start breathing normally through the mouthpiece. The device beeps after 180 seconds timeout or when the sample fill detected.

Make sure your patient is sitting in a relaxed upright position that allows abdominal expansion.

Put the nose clip in place.

Sample collection

Ask the patient to pick up the reader and hold it so that they do not block the air vents on the side and top or the air inlet. He/she should inhale fully, make a tight seal with his/her mouth around the mouthpiece, and then breathe out through the mouthpiece (7), continuing with normal tidal breathing (about 10 breaths per minute). Check that they have created a good seal, are not covering any of the air vents on the device, and that they are breathing normally, with no forced expirations.



Figure 8: Air inlet and vents; these must be unobstructed while performing a test



Figure 9: The Inflammacheck device in use

The reader beeps when sample collection is complete, which takes 2–3 minutes.

Place the device on the table.

If the display shows an error message, refer to the section on this. If you need to repeat the test you will need to wait 15 minutes to allow condensate to evaporate. You can use the same valve housing and mouthpiece but will need to insert a new room-temperature sensor cartridge.

The test result and interpretation

The device will automatically measure the H_2O_2 level and will beep when this is complete (less than 1 minute). The μM concentration of H_2O_2 in the EBC is displayed on the screen, together with the average exhaled breath flow rate (L/min) and test ID

Breath Print

Each test performed with the Inflammacheck[®] is assigned a test ID, and each test performed results in three .CSV files being produced and stored on the Inflammacheck[®], containing all test data.

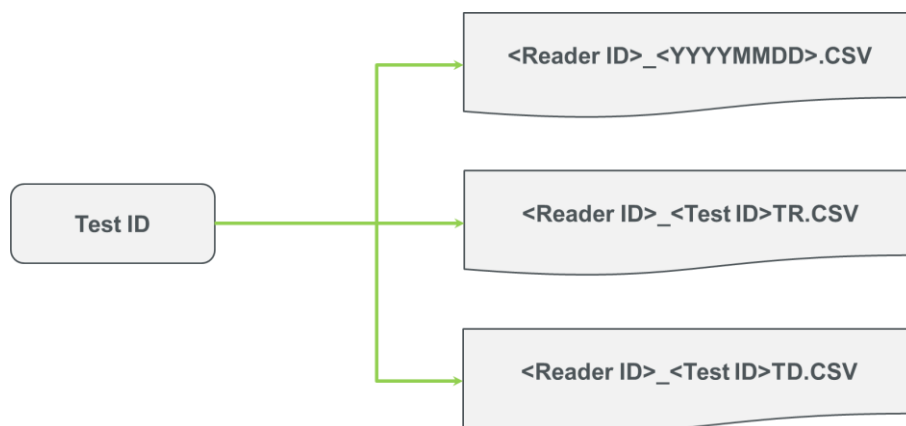


Figure 10: The Inflammacheck[®] test file set

The <Reader ID>_<YYYYMMDD>.CSV file is a log file containing key data on all tests performed on a specific device on a specific date.

	A	B	C	D	E	F	G	H	I	J	K
1	ReaderID	TestID	Test date	Test time	H2O2 [uM]	ERR code	ERR message	Peak CO2 [%]	EXH flow rate [L/min]	Peak breath temperature [oC]	Peak breath humidity [%]
2	IF20042	25	20230725	10:06:15	0.4			4.58	13.38	28.41	75
3	IF20042	26	20230725	11:11:14		R03	Raw signal error	4.68	13.49	29.73	71.87
4	IF20042	27	20230725	11:18:38		D18	Leaking current high				
5	IF20042	28	20230725	11:19:25		D18	Leaking current high				
6	IF20042	29	20230725	11:23:59	1			3.59	16.41	31.44	71.88

Figure 11: Contents of the <Reader ID>_<YYYYMMDD>.CSV file

Each test performed is represented by a single line entry in the file:

- EBC H2O2 test result is presented
- CO2 value is presented as peak value logged
- Exhaled flow rate is presented as average flow logged during exhalation
- Breath temperature is presented as peak value logged
- Breath relative humidity is presented as peak value logged

In addition, the file contains other test specific loggings characterising each individual test.

The <Reader ID>_<Test ID>TD.CSV file pertains to a specific Test ID and contains time tagged readings from the H₂O₂ sensor taken during test assay. Data used by the algorithm determining the EBC H2O2 contents.

Finally, the <Reader ID>_<Test ID>TR.CSV file pertains to a specific Test ID, and contains the time tagged readings from the four other sensors taken during sample collection.

The file contains data defining the breath CO₂ contents, breath flow rate, breath temperature, and breath relative humidity logged every 10th of a second during sample collection.

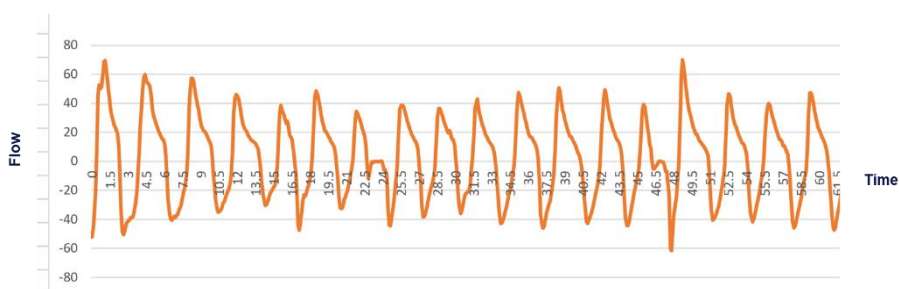


Figure 12: Example of graphical presentation of breath flow loggings from a single test

Jointly with the EBC H₂O₂ value these loggings define a rich 'Breath Print' which lends itself well to analysis across the different parameters e.g., using advanced statistics, Machine Learning, and Artificial Intelligence models.



Result interpretation

The test result prepared by Inflammacheck® should be interpreted by a trained physician, in the context of the patient's other signs and symptoms and clinical examination. It should not be used as the sole basis for a diagnosis.

After the test

When you have finished the test in an individual patient, remove the used sensor cartridge and mouthpiece from the Inflammacheck® reader and dispose of them in a clinical waste container. The reader will turn off automatically when the cartridge is removed.

Remove and dismantle the valve housing for cleaning.

Note that you must wait at least 15 minutes before conducting another test.

Cleaning

Valve house

A clean valve housing should be used for each patient in order to prevent possible cross-contamination.

Dismantle the valve house and wipe each of the three parts with 70% ethyl alcohol solution.

Leave the parts dismantled to air dry for an hour, to ensure all traces of the alcohol solution have evaporated.

Once the pieces are dry, reassemble the valve house and replace it in its resealable bag. Seal the bag and store until required for use.

Inflammacheck® reader

Clean the Inflammacheck® reader once a week.

Wipe the outside of the Inflammacheck® reader with 70% ethyl alcohol solution.

Leave the reader to air dry for an hour to ensure all traces of the alcohol solution have evaporated.

Error and warning messages

Error messages

The Inflammacheck® reader displays an error message if critical parts of the system are not functioning correctly.

The meanings of the error codes are tabulated below.



Error code	User GUI	Error description	User activity
Error messages generated as an output from the device initialization cycle			
ERR: B01	Battery level low	Battery level is too low to ensure a full test cycle can be completed.	Charge device and Restart. If error persists, return to manufacturer.
ERR: B02	Battery level low	Battery capacity is too low to ensure a full test cycle can be completed.	Charge device and Restart. If error persists, return to manufacturer.
ERR: D01	SD card error	Device cannot access built-in SD card.	Restart device. If error persists, return to manufacturer.
ERR: D02	Airflow sensor	Device cannot communicate with sensor measuring Exhaled Breath flow. This can be caused by low battery or device error.	Charge device and Restart. If error persists, return to manufacturer.
ERR: D03	Condensate Temp sensor	Device cannot communicate with sensor measuring the temperature of the condensation area during cooling and EBC collection. This can be caused by low battery or device error.	Charge device and Restart. If error persists, return to manufacturer.
ERR: D10	RTC sensor	Device cannot communicate with Realtime Clock (RTC) sensor. This can be caused by low battery or device error.	Charge device and Restart. If error persists, return to manufacturer.

Error code	User GUI	Error description	User activity
ERR: D11	RTC battery	RTC sensor reports lost power. This can be caused by the RTC battery being flat or a communication error.	Charge device and Restart. If error persists, return to manufacturer.
ERR: D12	Battery charge sensor	Device cannot communicate with sensor controlling the charging of the device battery. This can be caused by low battery or device error.	Charge device and Restart. If error persists, return to manufacturer.
ERR: D13	Battery indicator sensor	Device cannot communicate with sensor measuring battery level. This can be caused by low battery or device error.	Charge device and Restart. If error persists, return to manufacturer.
ERR: D15	Setting file	The device Setting file containing reader information and setting parameters does not have the correct format. Device operation is hindered.	Device needs service. Return to manufacturer.
ERR: D17	SD card is full	The number of tests stored on the built-in SD card is 700. To ensure proper device function, further testing is prohibited until the SD card has been cleared.	Download data from built-in SD card to PC and delete data from SD card afterwards. Please, refer to 'Instructions for Use – Software'.
ERR: D18	High leaking current	High leaking current is detected in the device. This can be caused by sensor being wetted, short circuit or leaking of condensate into the device from previous test.	Remove sensor-cartridge from device and wait for 15 minutes, before recommencing testing with a new sensor-cartridge. If error persists, return to manufacturer.
ERR: D19	High noise level	High noise level is detected from analog frontend board which can introduce noise to the measurement.	Remove sensor-cartridge from device and wait for 15 minutes, before recommencing testing with a new sensor-cartridge. If error persists, return to manufacturer.

Error code	User GUI	Error description	User activity
ERR: D20	RTC reset	RTC does not have correct time.	Device needs service Return to manufacturer
ERR: M01	EMSTAT error	Device cannot communicate with the analog frontend board during the self-testing cycle. Device cannot start self-checking cycle.	Restart device. If error persists, return to manufacturer.
ERR: S01	SD card error	Device cannot communicate with the built-in SD card during the self-testing cycle. Data from self-checking cycle cannot be logged.	Restart device. If error persists, return to manufacturer.
Other error messages			
ERR: D16	Cooling timeout	Prescribed condensation temperature is not reached within 4 minutes. This can be due to low battery, too high ambient temperature or device error. This error generated from cooling cycle.	Charge device and restart, check if ambient temperature is out of operation range. If error persists, return to manufacturer.
ERR: M02	EMSTAT error	Device cannot communicate with analog frontend board and testing cannot be performed. This error is generated from collection cycle.	Restart device. If error persists, return to manufacturer.
ERR: M03	EMSTAT error	Device cannot communicate with analog frontend board and testing cannot be performed. This error is generated from assay cycle.	Restart device. If error persists, return to manufacturer.

Error code	User GUI	Error description	User activity
ERR: R01	Open circuit	<p>H₂O₂ sensor does not detect any sample and device cannot measure H₂O₂ level.</p> <p>This can be due to no EBC flowing to the sensor as a result of too little sample being collected or a physical blockage in the sensor-cartridge, or a bad electrical contact.</p> <p>This error is generated from assay cycle.</p>	Change sensor-cartridge and retest.
ERR: R02	Short circuit	<p>A short circuit is detected in the device and it cannot measure H₂O₂ level correctly.</p> <p>This can be caused by leaking of condensate into device.</p> <p>This error is generated from assay cycle.</p>	<p>Remove sensor-cartridge from device and wait for a couple of hours, before recommencing testing with a new sensor-cartridge.</p> <p>If error persists, return to manufacturer.</p>
ERR: R03	Raw signal error	<p>The signal from the H₂O₂ sensor is not healthy and device cannot measure H₂O₂ level.</p> <p>This can be due to sensor leaking or air bubbles trapped inside the sensor chamber.</p> <p>This error generated from assay cycle.</p>	Change sensor-cartridge and retest.
ERR: R06	False fill positive	<p>A fill signal has been detected, but no EBC has reached the H₂O₂ sensor and thus no measurement is made.</p> <p>This error generated from collection cycle.</p>	Change sensor-cartridge and retest.
ERR: S02	SD card error	<p>Device cannot communicate with built-in SD card and is unable to log test data.</p> <p>This error is generated from collection cycle.</p>	<p>Restart device.</p> <p>If error persists, return to manufacturer.</p>

Error code	User GUI	Error description	User activity
ERR: S03	SD card error	<p>Device cannot communicate with built-in SD card and is unable to log test data.</p> <p>This error is generated from assay cycle.</p>	<p>Restart device.</p> <p>If error persists, return to manufacturer.</p>
ERR: SC01	RFID tag error	<p>The checksum defined on the built-in RFID tag on the sensor-cartridge does not match.</p> <p>Information loaded onto the RFID tag is not correct.</p> <p>This error is generated from scan sensor ID cycle.</p>	Change sensor-cartridge and retest.
ERR: SC02	Sensor expired	<p>The sensor-cartridge has passed its shelf lifetime.</p> <p>This error is generated from scan sensor ID cycle.</p>	Change sensor-cartridge and retest.
ERR: SC04	RFID tag error – RFID tag is broken	<p>The built-in RFID tag on the sensor-cartridge is not readable by the device.</p> <p>The RFID tag is either broken or having an incompatible configuration.</p> <p>This error is generated from scan sensor ID cycle.</p>	Change sensor-cartridge and retest.
ERR: SC05	RFID tag error	<p>Several information fields on the built-in RFID tag on the sensor-cartridge do not have correct format.</p> <p>Information loaded onto the RFID tag is incompatible or not correct.</p> <p>This error is generated from scan sensor ID cycle.</p>	Change sensor-cartridge and retest.

Warning messages

The Inflammacheck® reader displays warning messages if non-critical parts of the system are not functioning perfectly, or if certain ranges have been exceeded.

The meanings of the warning codes are tabulated below.

Error code	User GUI	Error description	User activity
Warning messages generated as an output from the device initialization cycle			
WARN: D07	SHT breath sensor	<p>Device cannot communicate with sensor measuring Exhaled Breath Humidity (EBH).</p> <p>This can be caused by low battery or device error.</p> <p>If user decides to continue the test, EBH will not be logged.</p>	<p>User can decide to continue or stop the test.</p> <p>It is recommended to charge the device and restart.</p> <p>If error persists, return to manufacturer.</p>
WARN: D08	SHT Ambient sensor	<p>Device cannot communicate with sensor measuring Ambient Temperature and Relative Humidity.</p> <p>This can be caused by low battery or device error.</p> <p>If user decides to continue the test, these parameters will not be logged.</p>	<p>User can decide to continue or stop the test.</p> <p>It is recommended to charge the device and restart.</p> <p>If error persists, return to manufacturer.</p>
WARN: D09	BME breath sensor	<p>Device cannot communicate with sensor measuring Exhaled Breath Temperature (EBT).</p> <p>This can be caused by low battery or device error.</p> <p>If user decides to continue the test, EBT will not be logged.</p>	<p>User can decide to continue or stop the test.</p> <p>It is recommended to charge the device and restart.</p> <p>If error persists, return to manufacturer.</p>
WARN: W01	Ambient temperature out of recommended operation range	Ambient Temperature is measured to be outside the recommended range for operation of the device.	<p>User can decide to continue or stop the test.</p> <p>The manufacturer cannot guarantee test reliability under these conditions.</p>

Error code	User GUI	Error description	User activity
WARN: W02	Ambient humidity is out of recommended operation range	Ambient Relative Humidity is measured to be outside the recommended range for operation of the device.	User can decide to continue or stop the test. The manufacturer cannot guarantee test reliability under these conditions.
WARN: W03	High SD card volume	The number of tests stored on the built-in SD card is 500 or more. Large numbers of tests stored on the SD card can cause long processing times when downloading data to a PC.	Recommend downloading data from built-in SD card to PC and delete data from SD card afterwards. Please, refer to 'Instructions for Use – Software'.
Other warning messages			
WARN: R05	No fill detected	No fill signal has been detected, but EBC has reached the H ₂ O ₂ sensor and an H ₂ O ₂ level is measured. However, as the wetting time is unknown, the H ₂ O ₂ level may not be reliable. This warning generated from assay cycle.	Change sensor-cartridge and retest.

Data transfer

The Inflammacheck® system enables download of all test data from the Inflammacheck® reader to a PC for storage and further processing by means of built-in USB port.

Please refer to the 'Instructions for Use – Software' included on the USB stick supplied as part the Inflammacheck® starter kit for guidance and additional information.

Calibration and control

The Inflammacheck® system is factory calibrated and requires no additional calibration before operation.

The Inflammacheck® reader automatically performs a self-check before each test to ensure test performance. If the self-check fails, an error code is displayed, and the reader will cease measuring.

Follow all local, state and federal regulations, and other accreditation requirements.



Care of equipment

Adhere to the guidelines for usage, transportation, and storage for the Inflammacheck® reader and consumables set out in this user guide.

The Inflammacheck® reader

- Avoid strong mechanical shocks.
- Do not expose to liquids. Keep away from wet areas such as sinks and wash basins.
- Keep away from direct sunlight and heat sources.
- Do not insert anything other than the charging cable into the socket.

Consumables

Keep new and cleaned valve houses and sensor cartridges in their original bags until use. Keep the consumables away from direct sunlight and heat sources and from wet areas such as sinks and wash basins. (Sensor cartridges are stored in a refrigerator until 30–60 min before use.)

Charger

Only use the charger provided with the Inflammacheck® reader. Do not use the charger cable if it is damaged or visibly kinked.

Service and maintenance

The Inflammacheck® reader does not require maintenance or servicing. For cleaning, see page 17.

Never open the Inflammacheck® reader or the charger.

If the reader is damaged or malfunctioning, contact the manufacturer. Any repairs must be carried out by the manufacturer or authorized personnel.

Failure to follow the specific operating instructions may result in warranty services offered by the manufacturer being restricted.

For additional service and maintenance information, please contact the manufacturer.

TECHNICAL INFORMATION

Materials

Part	Specification
Surface	
Reader chassis	HMPU5
Valve house	HMPU15HQ
Mouthpiece	Food grade PP-HJ730 – highly isotactic homo polypropylene (HIPP)
Sensor-cartridge	Polymethyl methacrylate (PMMA)
Condensation film	Polyester
Cooling plate	Aluminium
EBC H₂O₂ Sensor	
Base	7 × 25.4 × 65 mm aluminium oxide chip
Working electrode	Screen-printed platinum ink
Reference electrode	Screen-printed silver/silver chloride ink
Conductive tracks	Screen-printed polymeric insulator ink
Enzyme	Horseradish peroxidase (E.C. 1.11.1.7)
Mediator	Contains tetrathiafulvalene (CAS No. 31366-25-3)
Salt dots	Concentrated (33×) phosphate buffer pH 7.4
Gas phase sensors	
CO₂	SprintIR®-6S, GSS Gas Sensing Solutions – data sheet
Breath Temperature and Breath Relative Humidity	SHT31-DIS-B2.5kS, Sensirion AG – data sheet
Breath Flow	SDP800-500PA, Sensirion AG – data sheet

Technical specifications

Operating temperature	20–28°C (68–82°F)
Operating humidity	30–70%, non-condensing
Storage temperature, reader	0–50°C (–30–70°C during transport, 24 h max)
Storage temperature, sensor-cartridge	+5 ± 3°C (41 ± 6°F)
Sample volume	Total collected 20-30 µl, in sensor capillary <10 µl
Measurement range	0.1–4µM
Between-sensor variance (standard deviation)	0.09µM
Typical test cycle time	Less than 5 minutes
Battery	5 V, 4000 mA (charger)
Safety tested in accordance with	0.6 A, 100–240 V AC, 50–60 Hz
Instrument input rating	USB 2.0
Charger input rating	IP 21
Data interface	max 4000 mA from charger
Protection class	Up to 10 tests
Supply current	max 4000 mA from charger
Battery capacity	Up to 10 tests fully charged
Reader dimensions	L 225 mm, W 65 mm, H 150 mm (tbc)
Reader weight	650 g
Dimensions of transport box	L 400 mm, W 250 mm, H 300 mm (tbc)
Weight of reader and transport box	1000 g

The Inflammacheck® system complies with IEC 61326-2-6 for group 1, class B equipment regarding electromagnetic compatibility, emission and interference immunity.

Limitations

Inflammacheck® is only to be used with the standard Inflammacheck® valve house and sensor cartridges, and the charger and cable supplied by the manufacturer.











None of the Inflammacheck® components may be used for any purposes other than those specified.

Inflammacheck® may only be used by trained healthcare professionals. Trained status is achieved by careful reading and following of this manual.

Part numbers

Inflamcheck® reader	ETL1000211
Inflamcheck® valve house	ETL2000281
Inflamcheck® sensor cartridge	ETL2000296
Inflamcheck® charger	ETL6000287
Inflamcheck® charging cable	ETL6000288
Inflamcheck® USB cable	ETL4000377
Inflamcheck® USB flash drive	ETL2000378

Symbols

	Serial number
	CE mark – indicates conformance with the essential requirements of the directive on in-vitro diagnostic medical devices
	In vitro diagnostic medical device
	Catalogue number
	Dispose of the instrument in compliance with local regulations for the disposal of electronic equipment. Do not put in domestic waste.
	Consult Instructions for use
	Attention, see the instructions for use
	Manufacturer
	Direct current
	Humidity limitation



Temperature limitation

IP and patents

Based on the company's intellectual property, Exhalation Technology Ltd develops and commercializes products for the monitoring of H₂O₂ as a marker of airway inflammation, to improve the management and care of patients with airway inflammatory disease.

Inflammacheck® products are protected by patents held by Exhalation Technology Ltd in the US, Europe and a range of other countries.

Information in this document is subject to change. Amendments will be made available by Exhalation Technology Ltd as they occur.

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Document History

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