

Graphical Tester for Otoplastics
With Bluetooth[®] Low Energy Interface
Hardware Manual

General User Manual

2021

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1 GENERAL

1.1 Terms

A number of **terms** are used in these instructions that are briefly explained here.

- Leak tester:** the device to which the adapter and the otoplastic, by means of a tiny hose, are connected, [also: (leakage) tester, device, unit]
- System:** the physical whole consisting of the leak tester, air hose, adapter, otoplastic and auditory duct
- Platform:** desktop, laptop, smartphone or tablet that will make a connection to the leak tester and on which the control application (app) runs
- Software:** the software running on the platform that controls the leak tester [also: *app*, program, controlling software, user interface]
- Bluetooth®:** the wireless protocol used between the platform and the leakage tester, minimum Bluetooth® Low Energy version on platform: 4.0

The leakage tester, platform, software and Bluetooth® together, form the "graphical tester for otoplastics".

Below, a photo of the tester showing the on/off switch and air hose connection.



Photo 1.1.1: the Bluetooth® Low Energy (LE) leakage tester with standard adapter

1.2 Bringing into operation

1.2.1 Installing batteries

Ensure that the on/off switch is in the off position. The battery compartment can be found at the bottom of the tester, a small (crosshead) screwdriver must be used to release the screw holding the cover after which the cover can be opened. Install the correct batteries [4 pcs. type AA 1.5V] in the battery holder ensuring the correct polarity. For devices purchased since 2017 also NiMH (1.2V) rechargeable batteries can be applied. The photo below shows the compartment with the batteries in the correct position. Click the battery cover back and, for safety's sake, retighten the crosshead screw.



Photo 1.2.1.1: the leak tester, battery compartment

1.2.2 Air hose

Connect an air hose (PVC or silicon) of about 1.2 meters long to the intended connector at the front. Before use, check the air hose for damage, dirt, kinks, discolouration, etc. Only use the prescribed air hose and adapter.

1.2.3 Control

The leak tester is being controlled by a software application (app, OtoBLE) running on a platform that can establish Bluetooth® connections. Bluetooth® facilities are almost standard available on laptops, smartphones and tablets, but on a desktop often not. With respect to maintaining a built-in Bluetooth® system or installing an external (e.g. USB) version (dongle), reference is made to the individual installation instructions. Also you can consult our installation guides on the website.

1.2.4 Platforms

There are three platforms available on which the app can run:

- **Windows 10:** Desktop and Laptop (32-bit en 64-bit), *app* runs on UWP (Universal Windows Platform), as part of the Windows 10 OS (also Microsoft Surface platforms)
- **Android:** Tablet or Smartphone, as of Android 6.0 (Marshmallow, API level 23)
- **Apple iOS:** iPhone, from model 6 (iOS 12.5.1), iPad from model Air (iOS 12.5.1) en MacBook with M1 (ARM) processor

Ideally the maximum distance between the platform and the leak tester is approximately 10m, but can be limited by obstacles in the environment or between tester and platform.

For the description of how to use of the leak tester itself, this document assumes the Windows10 UWP version. In general, usage is identical on all platforms.

1.2.5 Acquisition, installation and use of the app

There is a separate *app* for each of the three platforms. A manual (English and Dutch) is available for each app, describing where to download the app, how to install it and how the *app* should be used. In this General User Manual, the use of the BLE leak tester is discussed on the basis of the Windows UWP app, if necessary read §1.2.5.1.

1.2.5.1 Windows 10: UWP app for desktop, laptop and tablet

To be able to use the OtoBLE *app* under the Universal Windows Platform of Windows10 there is a manual on our website: > Otoplastic Testers > Bluetooth (LE) > Documentation (BLE).

The name of the (pdf) document is BLEmanUWP_EN and the URL to this page is:

<https://www.cursorengineering.nl/en/documentation-bluetooth/>. If you want to read this document at once: https://www.cursorengineering.nl/wp-content/uploads/BLEmanUWP_EN.pdf

1.2.5.2 Android: app for smartphone and tablet

For the application of the OtoBLE *app* on Android platforms there is a manual that can be found on the website:> Otoplastic Testers > Bluetooth (LE) > Documentation (BLE). The document is called BLEmanAndroid_EN, the URL: <https://www.cursorengineering.nl/en/documentation-bluetooth/>. Read it right away: https://www.cursorengineering.nl/wp-content/uploads/BLEmanUWP_EN.pdf.

1.2.5.3 Apple iOS: app for iPhone en iPad and MacBook

For the application of the OtoBLE *app* on iOS platforms there is a manual that can also be found on the website: > Otoplastic Testers > Bluetooth (LE) > Documentation (BLE). This document is called BLEmaniOS_EN. The URL of the page is: <https://www.cursorengineering.nl/en/documentatie-ble/>. If you want to read this document at once: https://www.cursorengineering.nl/wp-content/uploads/BLEmanUWP_EN.pdf

1.3 Environment

The leak tester is made of precision components and therefore must be handled with care and not exposed to extreme or sudden changes in temperature, moisture and/or air pressure. The space in which the tester will be used must meet the following requirements:

- Normal air humidity (30...70%RH)
- Constant temperature (+10°C...+30°C)
- Stable environmental pressure (e.g. do not open/close doors during session)
- No direct sunlight (on the tester)
- Relatively dust free and of course smoke free

Ensure that if the conditions in the room change that the tester is given some time to acclimatise. In case of major changes, switch tester off and switch it on again (zero point recalibration). The work surface should be flat and solid and non-metallic. Maintain space around the tester, so that the air hose does not become kinked or trapped. If the air does not have free access, measurement errors can occur. During the measurements, do not touch or deform the housing or hose.

1.4 Batteries

The tester operates on four batteries, type AA [IEC: LR6], preferably Alkaline. Rechargeable batteries, e.g. NiMH (1.2V), can be applied and NiZn batteries (1.6V) are also applicable. Discharged or almost discharged batteries can leak and damage the tester, therefore, remove the batteries if the tester will not be used for a long time (e.g. a few months). When storing the tester, turn the on/off switch to the off position.

1.5 Standby mode

With each measurement, the 'time out' counter is reset to 20 minutes. If the tester has not been operated by the control software for 15 minutes, the tester will go into 'standby' mode: the user then has 5 minutes to reset the counter before the *app* shuts down and thus puts the tester into 'sleep' mode. Unit and *app* then be rebooted. Even if the tester was turned on, but for some reason was never connected to the app the tester also will go into 'sleep' mode after 21 (20 + 1) minutes.

1.6 Maintenance

The tester requires no specific maintenance. The housing can be cleaned with a soft, if required, slightly moistened cloth. The housing is made of PMMA (acrylic) therefore do not use solvents to clean it. **No regular calibration is required**, because the pressure sensor is LASER calibrated and has an extremely short drift over time. The zero point setting for the instantaneous air pressure takes place automatically during start-up and at regular times during use.

Prior to every measurement, check that end of the air hose is free from obstruction and that the hose is free of kinks or constrictions. Regularly check the air hose for permanent kinks and damage. If considered necessary, replace the air hose with one of the prescribed type.

Occasionally take a measurement with the end of the air hose closed to check that the tester itself is still airtight. Do not lose the rubber feet and store the leak tester whenever possible, and certainly when it is being transported, in a suitable storage system.

Please read the *note* on the next page.

NOTE: The unit contains a special air chamber for stabilizing the system pressure and makes the tester a very delicate instrument: handle the tester with care as a sensitive measuring instrument and avoid applying mechanical forces to the enclosure. The tester may be used in several positions, but do not use metals or magnets to maintain that position.

1.7 Closedown

The batteries should always be removed before the tester is sent by post, for instance for service.

Discharged batteries should not be discarded as normal waste, but as chemical waste.

When the unit will no longer be used, you are free to return the unit to the supplier or manufacturer for proper disposal and recycling.

2 MEASUREMENTS

2.1 Getting started

Switch on the tester. The **blue** LED indicator in the switch (see §3.2 for more information) will pulse over time with a frequency of 1.50s (the so-called 'wait' mode) and a short beep will be heard. Now is the time to start the *OtoBLE app*. **The further description is based on the Windows UWP app.**

After starting the *app*, it will try to establish a Bluetooth® connection with the leakage tester.

When the image below (here for the BLE2002) appears, the LED will light up continuously and the tester is ready for use.



Figure 2.1.1: the measurement window

2.2 Standard measurement

Measurements can start when the measurement window is visible and when both adapter and otoplastic are correctly connected. Use the mouse to click **START**, the air pump in the tester will raise the pressure within seconds to 5mB. The actual leakage measurement will take five seconds. In this period, ideally the pressure must remain at 5mB, but a slightly lower value is often allowed. The 4mB lower limit is depicted as an orange line. The figure below shows a possible result of a measurement.



Figure 2.2.1: an ideal measurement result

2.3 Screen legend

2.3.1 general

This document only provides a rough overview of the functionality of the app. The functionality and operation of the *app* is roughly the same for all platforms. As mentioned, there is a manual for each platform for the corresponding *app*, see section 1.2.5.

2.3.2 buttons

- **Exit:** the *app* will be terminated and, if there was a connection present, the leakage tester on his turn will enter the '*sleep*' mode, this mode is discussed in §3.45
- **Save Graph:** the graph can be saved with a name of your choice plus date/time stamp, the procedure to save the graph is being treated in §4.2
- **Start Test:** a new session starts: the caption on the **Exit** button will change to **Stop Test**
- **Stop Test:** the running session will terminate, after a short time the *app* returns to *READY*

2.3.3 graph

- **mB:** the y-axis indicates the relative pressure in millibar [mB] with respect to existing air pressure; measurements are always taken with a pressure of 5mB. The dotted lines above and below the 5mB value form the extreme limits within which a perfect measurement result has been or will be achieved ($5\text{mB} \pm 0.1\text{mB}$). The orange line indicates the value (4mB) at which the measurement is still considered sufficient (the hearing care professional decides). SI unit for pressure: the Pascal [Pa] ($5\text{mB} \equiv 500\text{Pa}$).
- **sec.:** the x-axis represents the total measurement time in seconds. The measurement time can only start when an initial pressure of 5mB has been achieved.

2.3.4 status

The status line, displayed just above the graph, shows to the right of [STATUS:] the condition the leakage tester is in. At the end, the *progress bar*, indicating the duration of a changing status. The leakage tester has a number of conditions, the most important of which will be discussed in section 5.

If only the user's attention is required, the background will turn **orange**, however, in the event of an error message, the background will turn **red**.

If, at the end of the status message, the addition (**RESUMED**) is visible, this indicates that the *app* has been restarted after the screen has been in *sleep* mode or after the *app* has been minimized [_].

The leak tester has a number of conditions, the most important of which are:

- **Your BLExxxx is ready to go!**: the tester is ready for the first session
- **AIR IN**: the air pump starts and brings the pressure to just above 5mB
- **MEASURING PRESSURE**: sampling begins at a pressure of 5mB; the graph will be plot
- **READY**: the system is ready for the next session

2.3.5 info panel

To the right of the graph, the data is visible with information about the course of a measurement:

- **test** : [number] : the number of measurements since the *app* was launched
 [LED colour] : *example*
 [light green] : the last measurement completed within specifications
 [dark green] : measurement is running, not finished yet
 [red] : something went wrong: see status line for more information
 [orange] : last measurement completed, but outside the specifications
- **sample** : the current number of measurements (samples) during the total session time
- **pressure** : the current measured pressure, or the last measured pressure (**mB**)
- **time out** : the time [mm:ss] remaining before automatic *app* termination **and** putting the tester into '*sleep*' mode (max. 20 minutes)

3.2.6 battery icon

The battery icon shows the charge status of the batteries *in* the leakage tester. The value is only an indication, remember that a transitional situation can occur in which the tester will start normally, but may not have sufficient power to operate the pump and valve, or build up sufficient pressure. The battery *voltage* (V) has been chosen as a reference; the unit operates reliably at battery voltages greater than approx. 3.3V.

3.2.7 company logo

Tapping the logo (bottom right) offers two functions:

- it opens a pop-up window with some information about the tester, software etc. for five seconds
- it can reset the 'time out' counter in both *app* and tester without the need to run a *dummy* test or restart unit and *app*; there is a warning when entering the '*standby*' mode; read §4.1.4 on how use this function

2.4 After use

It is good practice, once all of the measurements have been taken, to immediately remove the otoplastic and to lay out the air hose.

When all work is done, the *app* can be closed and the unit will go into the so-called '*sleep*' mode and consume very little energy, switch off the unit now. This '*sleep*' state also occurs if the tester has not been operated by the *app* for 20 minutes. Even if the tester was turned on, but for some reason was never paired with the control app, the tester will go into '*sleep*' mode by itself after twenty-one minutes (20+1).

In this '*sleep*' mode the on/off switch of the unit, of course, will remain pressed; although the power consumption in this mode is extremely low, make a habit of switching off the unit, this will reduce the power consumed to zero.

The tester can only be resumed from sleep mode by turning the power switch (off and then) back on. It is allowed to switch off the tester without further ado: the *app* will come up with an error shortly afterwards and shuts down itself two minutes later.

Store the leak tester in a safe place.

3 STATUS MESSAGES

3.1 General

The condition of the leak tester and *app* is constantly monitored.

The status of the tester is partly indicated by the **blue** LED in the switch and, if the communication between tester and *app* works correctly, also through the status information in that *app*.

The status information in the app is only discussed briefly here; for a comprehensive overview, please refer to the app manuals for the various platforms.

3.2 Leakage tester

3.2.1 switch on

After pressing the on / off switch, the tester becomes active.

By '*switching on again*' is meant turning the tester *off* and then *on* again.

The **blue** LED in the switch indicates, by means of flashing at different frequencies, the internal state.

Example: an interval of 0.50s means that the LED is lit ½s and is extinguished ½s.

In the following sections, the different frequencies with the corresponding condition are discussed.

3.2.2 LED indicator

The blue LED in the switch can flash at different intervals, but also light up continuously or even go out. The possible intervals are listed below.

3.2.2.1 no interval (LED off)

The tester is inactive, which can be for several reasons:

- the tester is not switched on: *switch on*
- the batteries are exhausted: *replace*
- the tester is in 'sleep' mode: *switch on again*

3.2.2.2 interval 0,10s

The tester is running, but an error has occurred. If the error occurs:

- after initialization (§ 3.2.2.6), the zero setting has not proved stable; the tester may not be sufficiently acclimatized yet: *wait a while and switch on again*
- when setting up the Bluetooth® LE connection between tester and *app*, the data between the two was not correctly exchanged: *switch on again*
- during normal use of the leakage tester, an error - usually temporary - has occurred during the session: *check the status line!*

3.2.2.3 interval 0,25s

The tester is in the initialization phase, so immediately after switching on the leak tester. During this phase, batteries, air pump (audible) and the zero setting for ambient pressure are tested and determined (offset). The Bluetooth® antenna becomes active.

3.2.2.4 interval 0,50s

This frequency can be observed during a measurement during the complete measurement cycle (approx. 10s). This phase can be interrupted by error messages (§3.2.2.2).

3.2.2.5 interval 1,50s

This occurs:

- after initialization, if completed correctly; the tester is quietly waiting in this so-called 'wait' mode for a request from the app to establish a connection (via Bluetooth®), or the connection is just established
- during normal use in 'standby' mode (as a pre-indication of the 'sleep' mode): see §1.5, §2.3.7 and the manuals of the resp. apps

3.2.2.6 no interval (LED on)

The tester is ready for the next session.

3.3 Control *app*

3.3.1 start off

It is good practice *not* to start the app until the tester is in 'wait' mode ($t = 1.50s$), the *app* will then immediately try to connect to the detected tester.

If the app detects multiple Bluetooth® LE testers, a selection menu will be displayed (UWP, Android), or the tester connects directly to the unit that has the strongest (RSSI) Bluetooth® transmitter (iOS).

3.3.2 error messages

The status messages in the various apps are largely identical, but for details, please refer to the various app manuals. For example, depending on the Operating System, an app can indicate in various ways that Bluetooth® is not switched on or not even present.

Permissions to actually use Bluetooth® or to store files are also handled in different ways.

Some examples of error messages during a measurement:

- TARGET PRESSURE (5mB) NOT REACHED OR UNSTABLE

The system loses so much air that the system pressure cannot be reached. The otoplastic may have a very poor fit, incorrectly positioned, or there may be line or air-chamber leaks. Before drawing any conclusions, the system should be checked for leaks without an otoplastic and with the air hose sealed at the very end; check that the air pump operates well.

- READY (BELOW REJECTION LEVEL)

The session has finished, but during the inquiry the system pressure has been at or below 4mB at some point. The graph shows an orange line at the 4mB level, this is an arbitrary value above which the result of a measurement can still be considered sufficient.

The final assessment is of course with the hearing care professional.