Operating Manual

PT-LT100
Leak Testing Instrument

Version 1.2

Pharma Test Apparatebau AG
Siemensstr. 5
63512 HAINBURG
GERMANY
T: +49 6182 9532-600
F: +49 6182 9532-650
info@pharma-test.de
www.pharma-test.com

bsi. ISO 9001 Quality-management ISO 14001 Environmental-managment
Certificate No FS 529019/0388D

The Documentation

This document describes the set-up, operation and general maintenance of the Pharma Test instrument. It should be used by the operators and the technical support staff responsible for the installation and set-up of equipment.
All attached equipment and parts must be used in compliance with the manufacturer's manuals and papers supplied.

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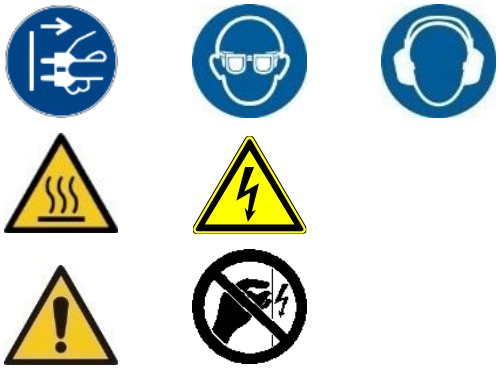
How to Use the Manual

To understand the different information, we use different formatting:

- **< >press any key (i.e. <Esc> OR <ENTER>)**
- " " display information
- *Information entries*
- **[ ] Select item from a menu**
- **Note:** information about special use case OR points to consider



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Document History

Version	Valid from	Author	Change	Remark
1.0	30.06.2025	Pharma Test	N	First release
1.1	04.07.2025	Pharma Test	R	Minor text revision
1.2	13.02.2026	Pharma Test	R	Inserting text and table for air pressure correction. Insert references.

Table 1 Document History

Index Information - Change:

N = New Document

C = Correction

R = Revision

1. About PT-LT100

Thank you for choosing a Pharma Test PT-LT100 leak testing instrument. PT-LT100 is used to test for the integrity of packed strips, blisters, bottles and small sachets containing tablets, granulates, liquids and similar in pharmaceutical environments. It can also be used to check the air tightness of packets for candies, ready-to-eat foods, chewing gums, confectionery items, noodles and any item which is packed and sealed for better shelf-life. The instrument is used to test the quality of the packaging process and to check that the seals enclosing the product are perfectly intact.

Figure 1: PT-LT100 Leak Testing Instrument

PT-LT100 is designed to find the smallest holes and imperfections in blister packs and other semi-rigid product packaging. Samples are placed into the desiccator's housing and the lid is placed in position. The pump starts to produce a vacuum inside the desiccators, and the vacuum is held for a pre-set time. The first thing to observe is that the tested package should keep its shape during this test; otherwise, the sealing is not correct. Secondly, as the package is immersed in a colored dye solution (normally Methylene Blue), the venting of the desiccators will allow any holes to be penetrated by the dye and the contents of the flexible packaging will also be stained with the same coloring material. Similarly small bottles can also be tested. A sheet of paper will absorb any leaking fluid.

PT-LT100 is fully compliant with the current USP <1146> monograph.

If the instrument is used in any other way as described in the manual, the integrated safety features may be affected and there could be the possibility of injuries to the operator.

Standard Supply Scope

Main Instrument

PT-LT100 comes ready to use with its standard scope of supply:

Part No.	No.	Description
283-0420	5	Paper rolls for internal printer
101-2119	1	Silicon tube
34-08400	1	Power supply, external
34-08500	1	Mains cable, EUR or
34-08510	1	Mains cable, CH or
34-08511	1	Mains cable, US or
34-08512	1	Mains cable, GB or
34-08513	1	Mains cable, AR/AUS/NZ or
34-08514	1	Mains cable, IN/ZA or

Table 2: Standard supply scope main instrument

Desiccators

A desiccator is required to use the instrument. Usually, a desiccator is supplied together with the instrument, but a suitable desiccator may also be supplied locally. Pharma Test offers the following types of desiccators:

Part No.	Description	Specification
26-02010	Desiccator, plastic, 150mm Ø	Inner height 135mm, volume: 2.15l
26-02030	Desiccator, plastic, 200mm Ø	Inner height 175mm, volume: 4.45l
26-02020	Desiccator, plastic, 250mm Ø	Inner height 225mm, volume: 9.2l
26-02040	Desiccator, glass, 380mm Ø	Inner height 283mm, volume: 18.5l

Table 3: Desiccators

Optional Items

In addition to the standard scope of supply, the following optional items are available for PT-LT100:

PT-Node Network Adapter

PT-Node is an adapter that connects up to two Pharma Test instruments simultaneously to a network using a wired LAN connection. This way you can print test results from the instrument via your web browser on any local or network printer. Furthermore, it is possible to transfer the test results from the instruments to external systems in the same network.

Part No.	Type
24-00100	PT-Node network adapter
34-01205	Serial cable to connect PT-LT100

Table 4: PT-Node network adapter

Ticket Printer

The Epson ticket printer is a robust, high-performance receipt dot matrix printer that is particularly easy to use. It prints on plain paper. This printer can be used as an alternative to the integrated thermal printer of PT-LT100.

Part No.	Type
29-02200	Epson TM-U220D ticket printer
34-01224	Cable to connect PT-LT100
007-0230	Ink ribbon for Epson ticket printer

Table 5: Ticket printer

Consumables

Part No.	No.	Description
126-2050	1	Desiccator grease, 1kg
126-0305-10	10	Filter elements for vacuum filter
283-0420-10	10	Spare paper rolls for thermal printer, 10 rolls
283-0420-50	50	Spare paper rolls for thermal printer, 50 rolls
283-0420-100	100	Spare paper rolls for thermal printer, 100 rolls

Table 6: Consumables

Technical Specifications

Parameter	Specification
Final vacuum level	100 to at least 920mbar, depending on ambient atmospheric pressure. (See item 2, Technical background: air pressure)
Maintain vacuum level	Yes, adjustable in method
Maximum vacuum hold time	99 hrs. 59 min. 59 sec.
Number of vacuum levels	Up to 4 vacuum levels per test
Number of vacuum hold times	Up to 4 vacuum hold times per test
Number of test runs	Up to 9 runs per test run adjustable in method
Method management	Up to 256 test descriptions (methods) can be stored on the instrument
User management	Up to 32 users with selectable user right levels can be stored on the instrument
Result data storage	Store copies of result reports by connecting a USB flash drive
Display	LCD with color-changing backlight
Data entry	Keypad with function keys and click wheel
Interfaces	USB type A host port to USB type B device port to connect flash drives, for serial data export and firmware updates RS-232 printer port for optional balance or external printer

Table 7: Technical specifications

2. Technical background for selecting the differential pressure

The target vacuum value set on the PT-LT100 device refers to a relative (low) pressure in relation to the actual ambient air pressure. Please note that a pressure difference can only be achieved if the absolute air pressure is higher than the value set on the device.

The Pharma-Test factory premises are located at an altitude of approximately 100 meters above sea level, enabling tests to be carried out on the PT-LT100 at 920 mbar (690 mmHg). This high value allows us to document the optimal functionality and high tightness of the device.

If the PT-LT100 is installed at an altitude of 300 meters above sea level or higher, vacuum higher than ~900mbar will no longer be achievable. The maximum atmospheric pressures can be found in the following table. Since the pump operates at a differential pressure of 50 mbar (37.5 mmHg), this value must be subtracted from the table values to determine the maximum achievable vacuum setting at the location.

Since we do not know at the factory the sea level of the installation location, it is possible that unattainable values may be entered into the device. If the PT-LT100 is started with improper target values, it may can´t fulfill it.

Elevation above sea level	Atmospheric pressure	
(meter)	(mbar)	(mmHg)
0	1013.25	760
100	1000	750
200	988	741
300	975	731
400	962	722
500	950	713
600	938	704
700	926	695
800	914	686
900	903	677
1000	891	668
1500	836	627
2000	784	588
2500	735	551

3. Setting Up the PT-LT100 Instrument

Check the indicated mains voltage on the external power supply included with the instrument. It must match the mains available locally on your end. If this is not the case, the external power supply must not be connected to this mains supply.

Main Components

This section describes the main components of the PT-LT100 instrument.

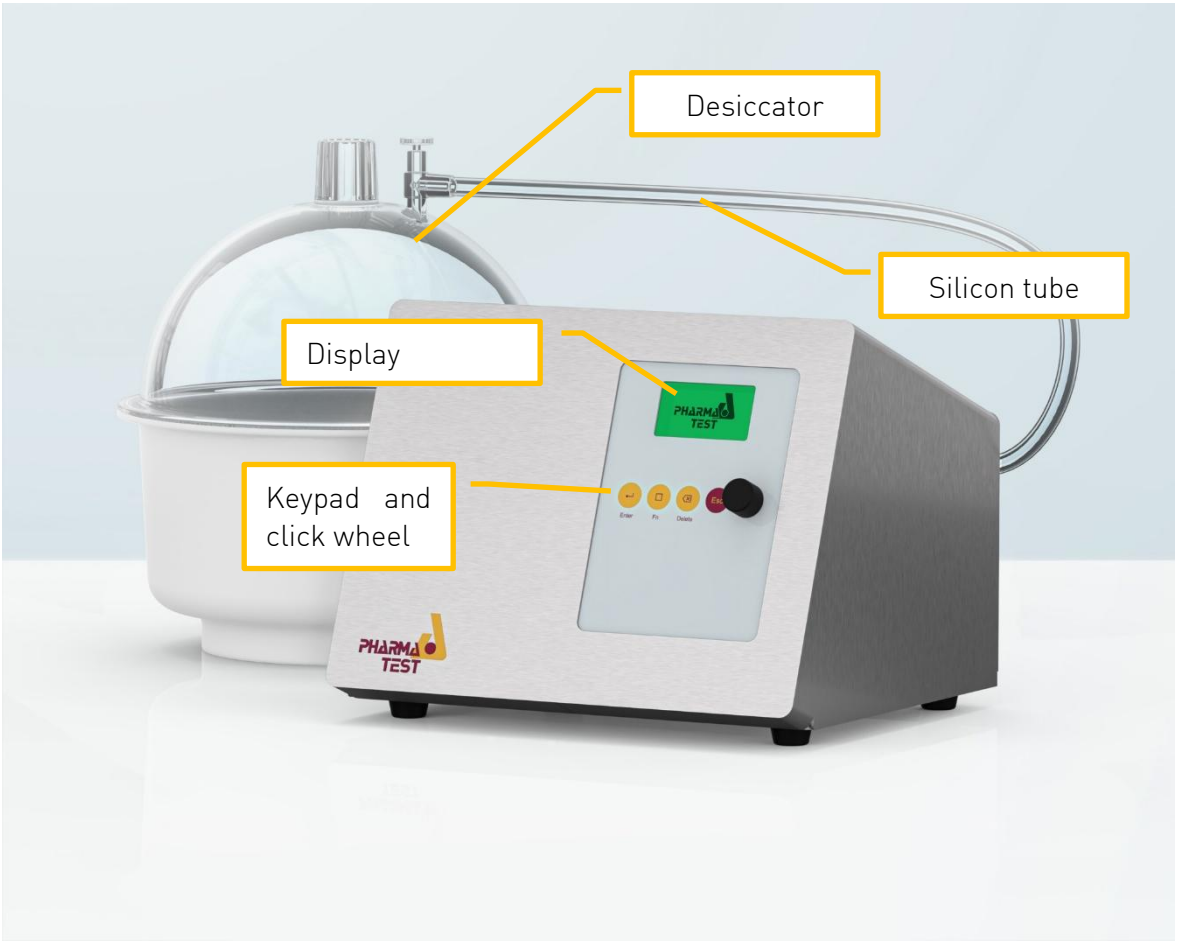


Figure 2: PT-LT100 front

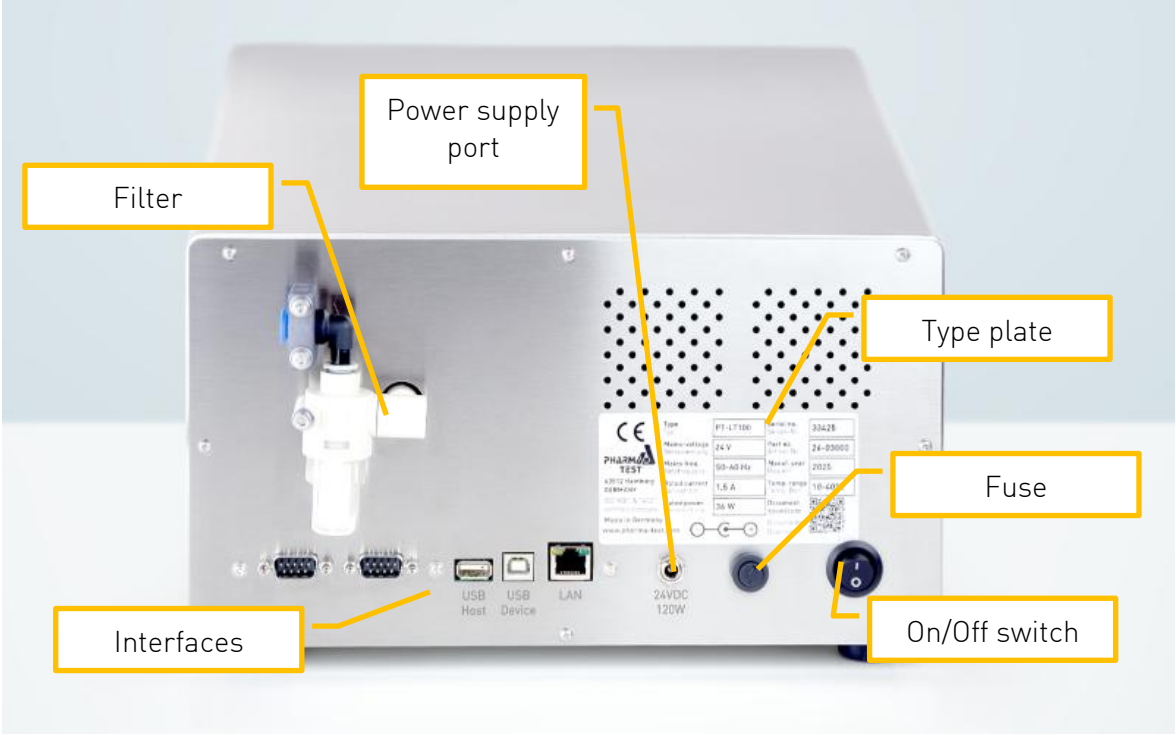


Figure 3: PT-LT100 back side

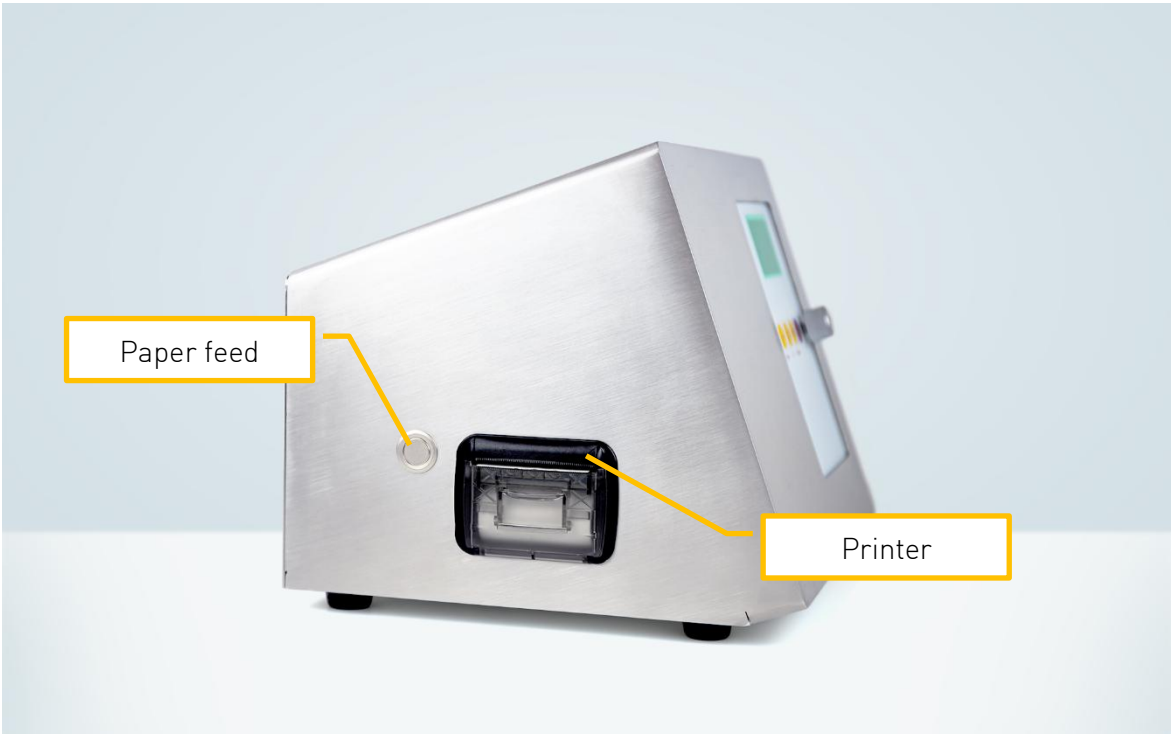


Figure 4: PT-LT100 side

Desiccator

Desiccators have a removable clear top lid fitted with a connection valve/fit through which the tubing is connected to the vacuum inlet of the instrument. Packed strips/packets to be tested are put inside the desiccators after filling it with enough water or usually Methylene Blue dye into the base part of desiccator [in some cases such as candy, the testing can be done without any liquid]. A perforated polypropylene disc is included with the desiccator so

that the light-weight strips or blisters do not float in water. The disc is used to cover the samples with the liquid.

Assembling a Desiccator

Before use, the desiccator needs to be assembled. A desiccator consists of these main components:

No.	Description
1	Bottom bowl
2	Dish
3	Perforated disc
4	Sealing ring
5	Top bowl
6	Stopper
7	Tube connector
8	Silicon tube (part of PT-LT100 supply scope)

Table 8: Desiccator components

The base part of the desiccator is composed of four parts:

Figure 5: Base part components

Figure 6: Base part assembled

Insert the dish (**2**) into the bowl (**1**) and place the perforated disc (**3**) on top of the dish (**2**). Insert the sealing ring (**4**) into the notch of the bowl (**1**). Make sure the sealing is fitting correctly:

Figure 7: Sealing ring inserted properly

Figure 8: Sealing ring not OK

The top bowl includes a tube connector and a stopper:

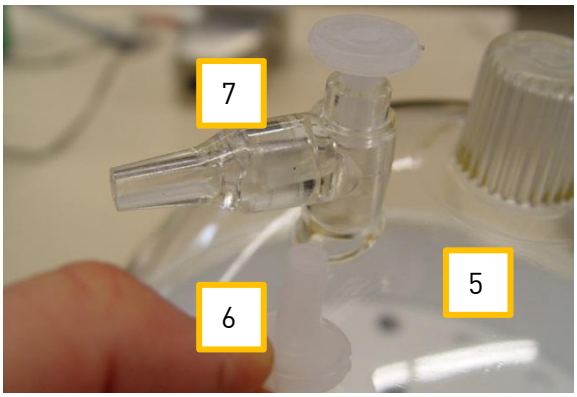


Figure 9: Top bowl and tube connector

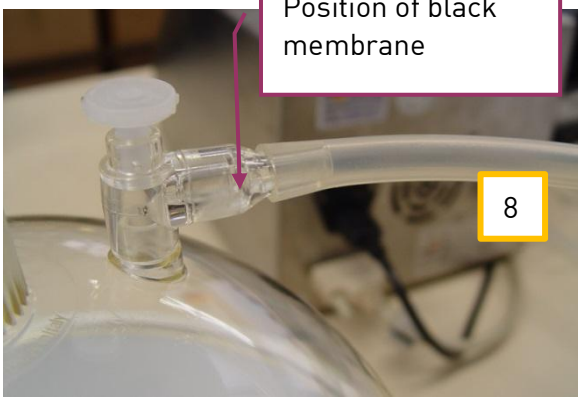


Figure 10: Tube connector with silicon tube

Remove the black membrane inside the tube connector, unless it has already been removed. To remove the membrane, it might be necessary to push the membrane carefully with a 2mm Allen key or a similar tool from the right side to the left side and into the vertical shaft to be able to remove it. Then remove the stopper (**6**) from the top bowl and place the tube connector (**7**) onto the bushing. Put the silicon tube (**8**) onto the horizontal vacuum outlet fitting of the tube connector as shown above.

Connect the other end of the silicon tube (8) to the vacuum inlet of the PT-LT100:

Figure 11: Connecting tube to vacuum inlet

Using a Desiccator Dry or with Liquid

Depending in your application, a desiccator may be used with ur without liquid (dry):

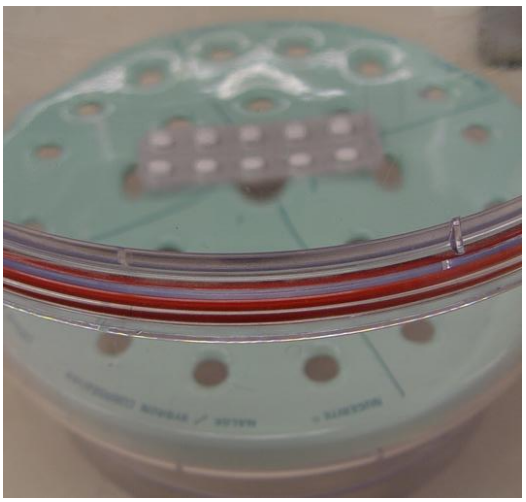


Figure 12: Desiccator without liquid

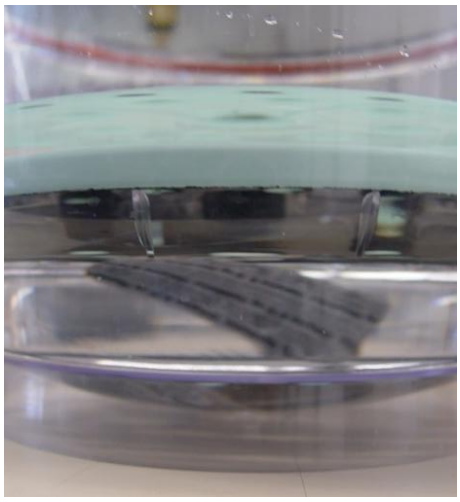


Figure 13: Desiccator with liquid

Use Without Liquid (Dry)

Insert the blister or other sample into the desiccator. Place it onto the plate, close the top bowl (lid) and start a test run. During the rise of the vacuum, if there is no leak, the blister will be visibly stretched. If this does not happen, there is a leak on the blister itself. It is possible that the blister bursts while the vacuum rises. In this case reduce the maximum vacuum set in your method.

Use With Liquid

Fill the desiccator with enough liquid so that the perforated plate is immersed. Place the blister or other sample under the perforated plate. The plate ensures that the blister is completely immersed in the liquid. During a test run, air will leave the blister in case of any leaks. After releasing the vacuum, the liquid will have been sucked inside the blister and the sample will have gotten wet. If you use Methylene Blue dye for the test, the sample will be tinted blue, and the operator can visually detect the amount of the leakage.

To prevent the plastic plate from floating, weigh it down with some additional weight while using the desiccator with fluid:

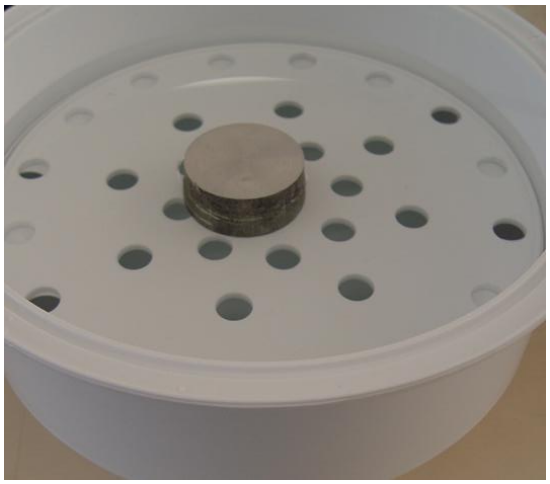


Figure 14: Desiccator plate with additional weight

PT-LT100 User Interface

This section describes the main components of the user interface and the instrument interface connections.

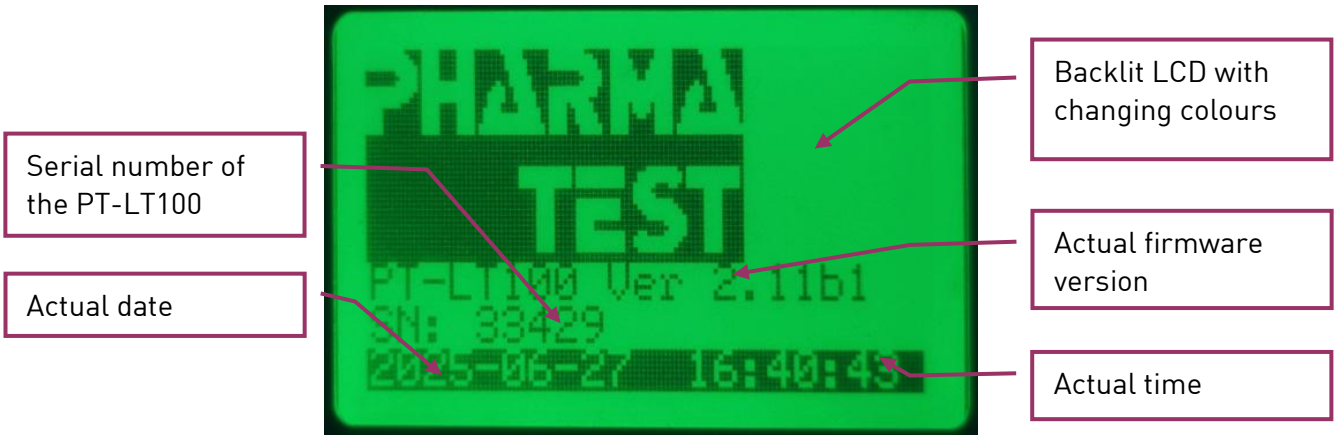


Figure 15: Start screen of the instrument

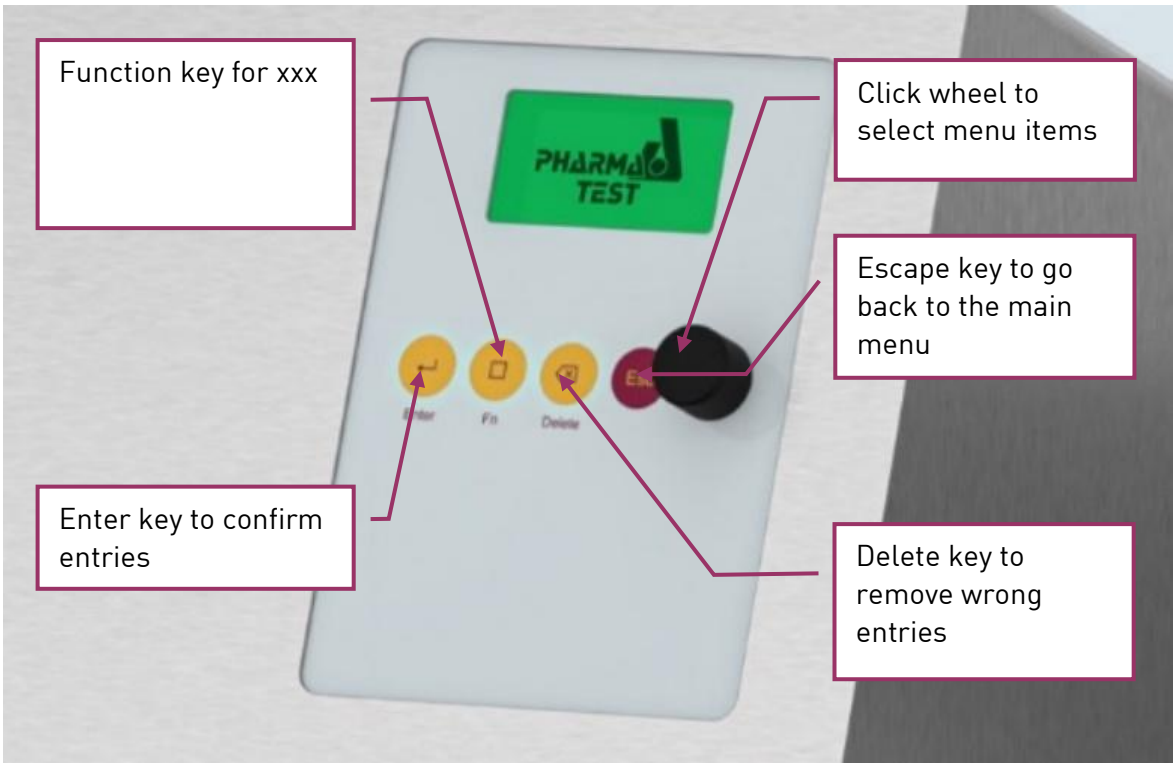


Figure 16 Control panel of the instrument

Generally, the click wheel is used to navigate the menus. Turn the click wheel to select items on screen. To make numeric entries, rotate the click wheel clockwise to increase the number and counterclockwise to decrease the number. Pressing the click wheel confirms the selection.

To start a test run, a desiccator must be connected to the instrument. The test is defined by the operator entries within the test method data file. A test method must be created and selected for each test run. In total up to 256 different test methods can be stored on the instrument. During a run the display will show the actual operating parameters like time or

vacuum. Once a test is finished the test results as well as the test information can be printed. To transfer data the serial interface or a USB flash drive may be used. The USB port is also used to install firmware updates.

Figure 17: Instrument overview – interfaces

No.	Label	Description
1	USB device	USB port for PC connection
2	LAN	For future use
3	Power supply	Port to connect the external power supply; to the right of the port are the fuse box and the mains switch
4	USB host	USB port for loading and saving files on an USB drive
5	Balance	RS-232 port to connect an external analytical balance (not applicable with PTZ x00)
6	Printer	RS-232 port to connect an external printer

Table 9: Instrument interfaces

First Steps

Make sure you follow these steps before turning on the instrument for the first time:

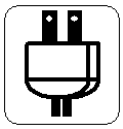
NOTE: This instrument requires an electrical installation with a good quality, grounded, interference-free earth ground. In the case of all electrical installations where liquid handling is an integral part of the instrument function, then all mains (line) supplies should be protected with an GFCI (Ground Fault Circuit Interrupter) which typically trips out when current leakage to ground (earth) of ca. 30mA is detected.

As you unpack your new instrument, please make sure that the package contains all items listed on the packing list and that there has been no damage during transport. Please also

check that the details on the serial plate are correct, especially the mains (line) supply voltage. If this is not the case, the instrument should not be released for use.

Place the PT-LT100 onto a common laboratory bench. The distance between the instrument and the lab wall should be at least 10cm.

Before Power On



Check that your mains voltage corresponds to the voltage written on the external power supply. Connect the supplied external power supply to your local mains socket. Connect the external power supply to the power port on the instrument. All cable connections must be made while all instruments are switched off. Switch the instrument on. The LCD lights up and shows the start screen.

Installation Qualification (IQ)

It is recommended to follow the IQ protocol for the PT-LT100. This document is available free of charge from Pharma Test as a PDF download.

Operation Qualification (OQ)

After completing the IQ, it is recommended to follow the OQ protocol for the PT-LT100. This document is available free of charge from Pharma Test as a PDF download.

Warranty Certificate

A warranty certificate (yellow sheet) is supplied in duplicate in the instrument folder. Fill both certificates and return the "COPY" to Pharma Test. Pharma Test grants 24 months warranty for material and quality issues from the date of the first performed IQ and OQ (or 30 months after date of delivery).

Connecting a USB Flash Drive to the PT-LT100 (optional)

Connect a USB flash drive to the USB Host port on the instrument's back. All data and results will be saved automatically on the USB drive. Files which were saved to the USB drive beforehand can be loaded from the settings menu, for example additional language files for the user interface can be installed this way.

Figure 18: Port for USB flash drive

4. Using the PT-LT100 Instrument

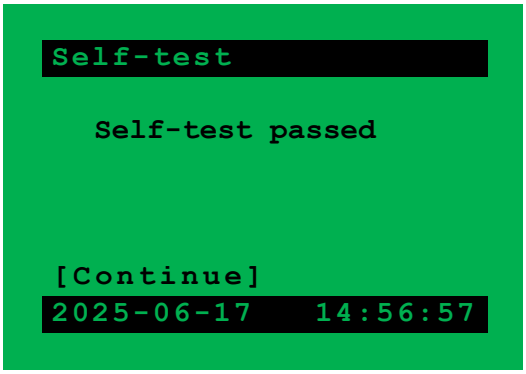
This section describes how to navigate the menus of PT-LT100 and explains the functions of the various menu items.

Start-Up and Login

As soon as the PT-LT100 is switched on, the display lights up and shows the start screen.

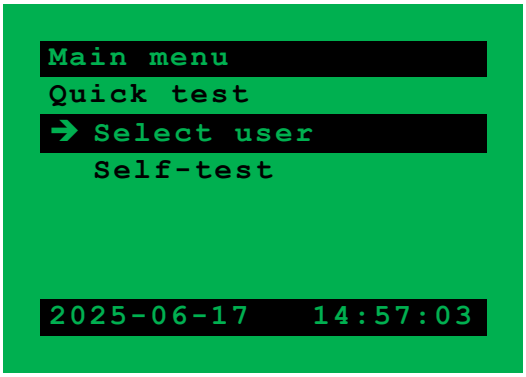
Self-Test

PT-LT100 performs a self-test after start-up. In case you do not want this self-test procedure to be performed, you can skip it by pressing the <Esc>-key on the start-up screen to go directly to the pre-login main menu. As soon as you press <Enter> or press the click wheel on the start-up screen, the self-test procedure starts automatically. A desiccator must be connected to the instrument to be able to successfully pass the self-test.



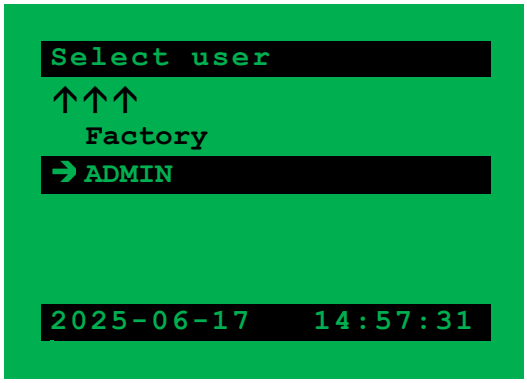
In case the self-test is started, the display will turn red during execution, wait for it to complete and select [Continue] by turning the click wheel and pressing it to confirm the selection.

Login



After either a skipped or a passed self-test the pre-login main menu is displayed. Here you can repeat the self-test or proceed to the login screen.

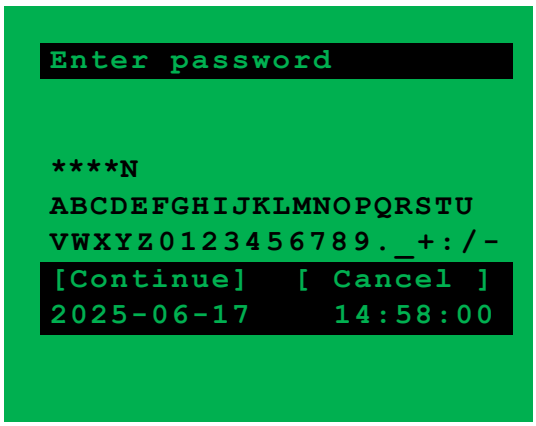
To login, select [Select user].



The login screen shows a list of all users available on the instrument. For now, only the administrator and factory users exist. The administrator "ADMIN" has the rights to create new users, product information, testing methods, and to change settings, like language, time and date and qualification interval timing (PQ).

Now select the user "ADMIN".

Note: The user "Factory" is used for extended service by authorized Pharma Test personnel and protected by a secret password.



To login as a user, the password for this user must be entered. To enter the password, select the individual characters from the text entry line using the click wheel.

The default password for the user "ADMIN" is

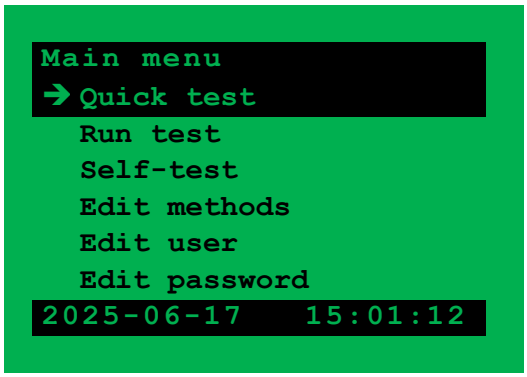
"**ADMIN**"

Confirm your entry by selecting [Continue].

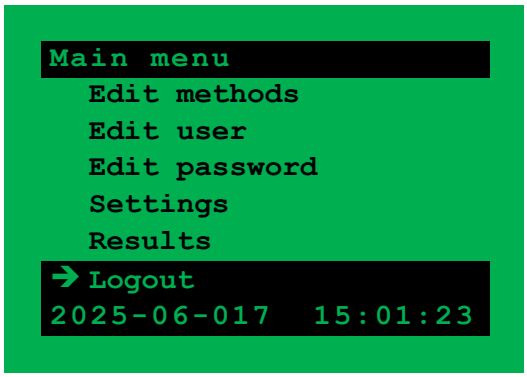
The main menu appears. You are now logged in as the user "ADMIN". See the following sections of this manual for explanations of each of the menu items.

Main Menu

This section provides a short overview of each item on the main menu of PT-LT100. More details are found in later sections of this manual:



This is the main menu of PT-LT100, which appears after logging in to the instrument. Some menus have more list items than can be displayed at once. Use the click wheel to scroll through the list.



By selecting "Logout" at the bottom of the main menu, the current user is logged out and you are returned to the login screen.

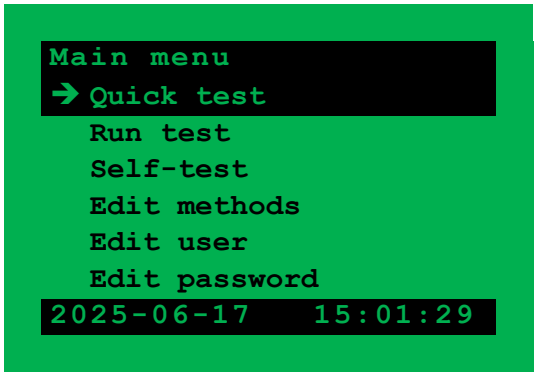
Refer to this table below for an overview of each item on the main menu:

Main menu item	Description	Further details on
Quick test	Perform a test without using a pre-defined method.	Page 23
Run test	Perform a test using a pre-defined method.	Page 27
Self-test	Perform a self-test of the vacuum function.	Page 20
Edit methods	Add, edit or delete methods. A method describes the test procedure and parameters. Methods are required for "Run test" (and not for "Quick test").	Page 32
Edit user	Create or delete a user, change user password or user rights.	Page 38
Edit password	Change the password of the currently logged in user.	Page 40
Settings	Edit instrument settings and save or load files.	Page 44
Results	Repeat a print-out of latest test report.	Page 31
Logout	Log out the current user and return to the login screen.	NA

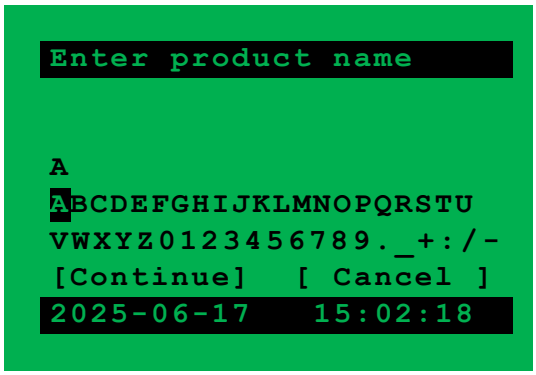
Table 10: Main menu items overview

Quick Test

The “Quick test” function is designed to quickly start a test by entering only minimal data. The quick test always performs one run only.

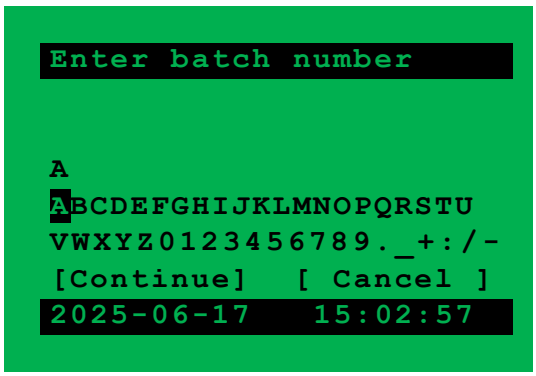


Select “Quick test” from the main menu.



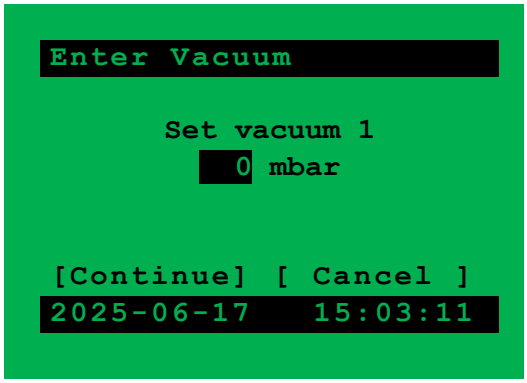
Next the name of the product being tested can be entered or be left blank. The product name is printed on the result report.

Select [Continue] to confirm.



Next the batch number of the product being tested can be entered or be left blank. The batch number too is printed on the result report.

Select [Continue] to confirm.



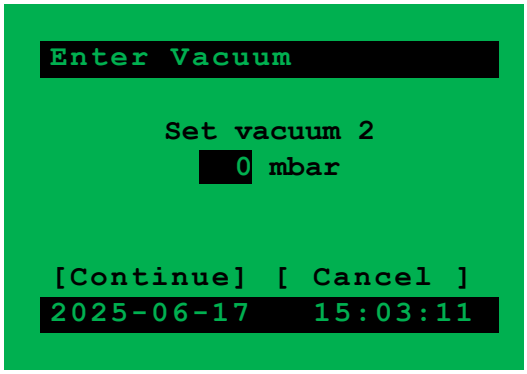
Now enter the vacuum for this test. You can set a vacuum of up to 950mbar. (See item 2, Technical background: air pressure)
Rotate the click wheel clockwise to increase the number and counterclockwise to decrease the number. Press the click wheel to confirm the entry.

Select [Continue] to proceed.

Enter a holding time (hh:mm:ss) for the vacuum. During the test, the instrument will actively maintain the target vacuum during the holding time.

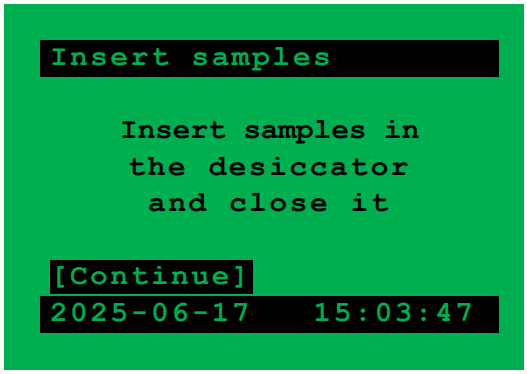
Here the time is set to one minute.

Select [Continue] to proceed.



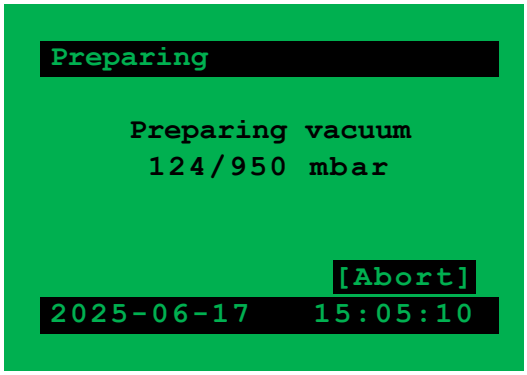
You can set up to four vacuum targets. If you do not want to set additional vacuum targets, enter 0 mbar. This will skip this vacuum target and all subsequent vacuum target and time entries.

Select [Continue] to proceed.



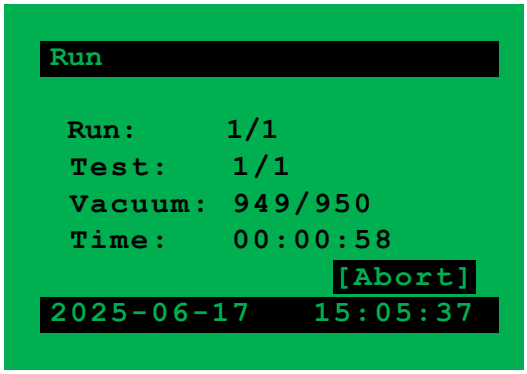
The instrument now prompts you to insert your sample into the desiccator and to close the lid. See above from more details on how to use the desiccator.

Select [Continue] to proceed.



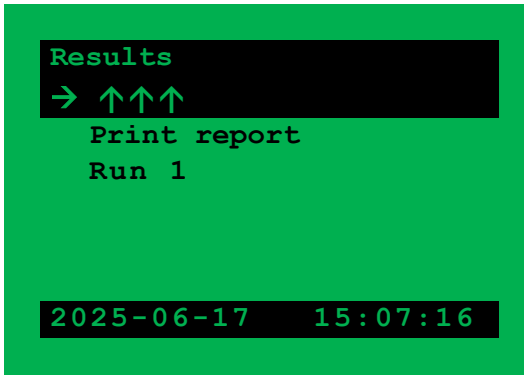
The instrument now builds up the vacuum inside the desiccator. Wait until the target vacuum is reached.

Select [Continue] to proceed.



The instrument will maintain the vacuum until the holding time is elapsed. Wait until then for the test to be completed.

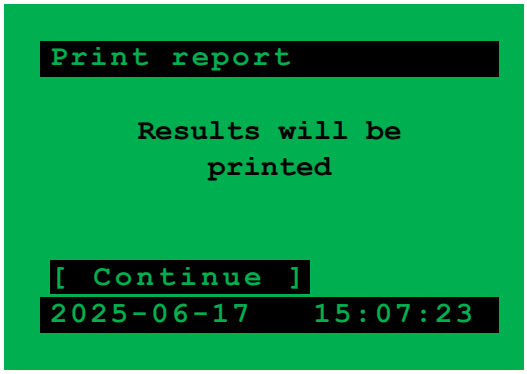
Select [Continue] to proceed to the results.



Here you can print the test report or view the details by selecting "Run 1".

Select "↑↑↑" to return to the main menu.

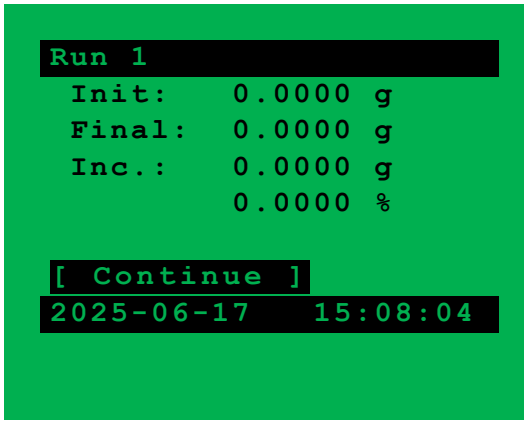
Printing the Test Report



Select [Continue] to print the test report. Afterwards the instrument automatically returns to the main menu.

See below for an example of the test report.

Viewing Test Run Details



This screen shows the initial weight of the sample before the test, the weight of the sample after the test and weight increase in absolute and percentages.

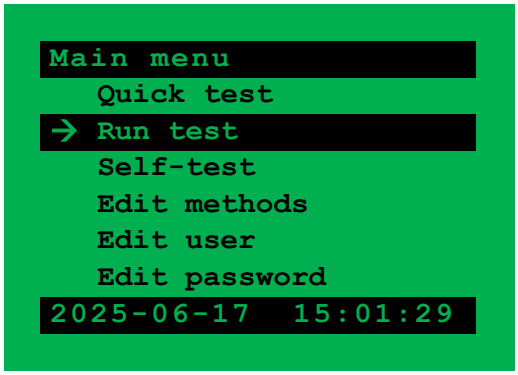
Note, that these results only apply in case a balance is connected. Otherwise, the test result is obtained visually by the user.

Select [Continue] to return to the results menu.

Run Test

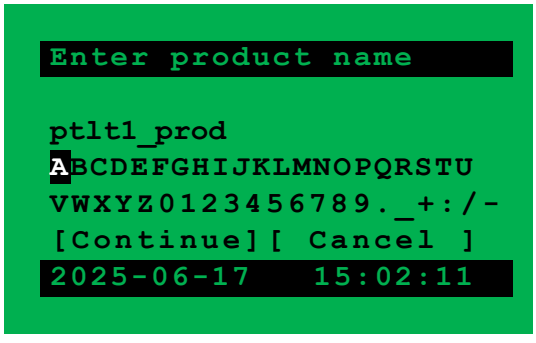
Run test is used to perform a test with pre-defined parameters, based on a method. A method contains the name of the method and product, if an evaluation of the test result should be included, the log interval time, the type of desiccator to be used, if the instrument should readjust the vacuum during the test or not, the vacuum targets and holding times and the number of runs to be performed.

This means to use the run test menu, you must create at least one method first. One example method is available on the instrument by default. Otherwise, if you do not want to work with methods you can use the quick test instead. This section describes how to run a test from a method. For more details on how to create and edit methods see further down below in this document.



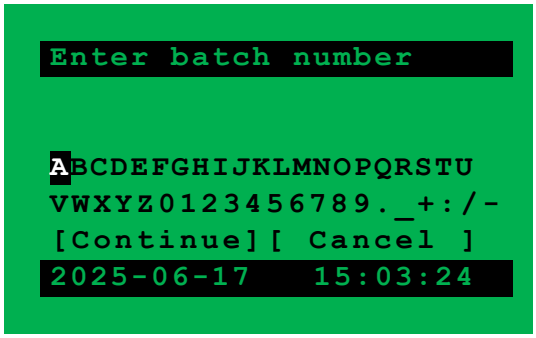
Select “Run test” from the main menu.

All available methods are listed here. By default only one example method will be available on the instrument. Select one of these methods to perform a test based on it.



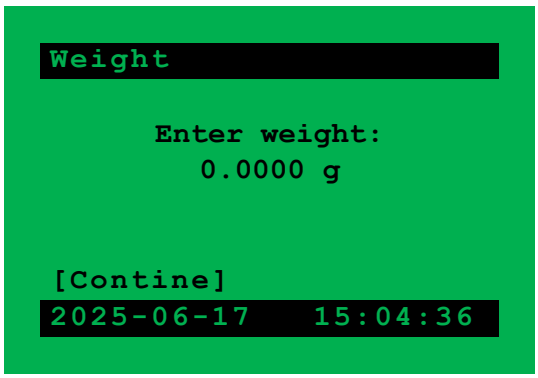
The product name, as defined in the method, is displayed. If needed, it can be edited right now for this test. This input may also be left blank. The product name is printed on the result report.

Select [Continue] to confirm.



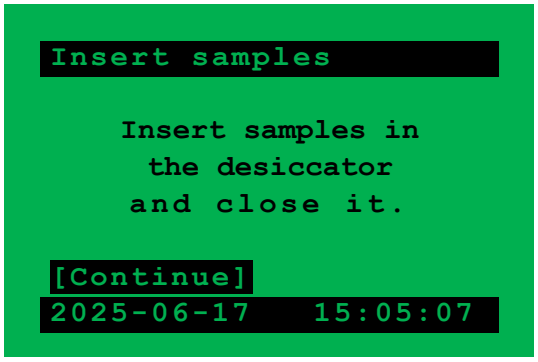
Next the batch number of the product being tested can be entered or be left blank. The batch number too is printed on the result report.

Select [Continue] to confirm.



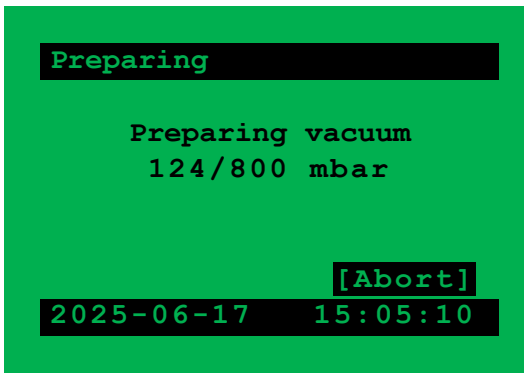
Enter the initial weight of the sample.

Select [Continue] to confirm.

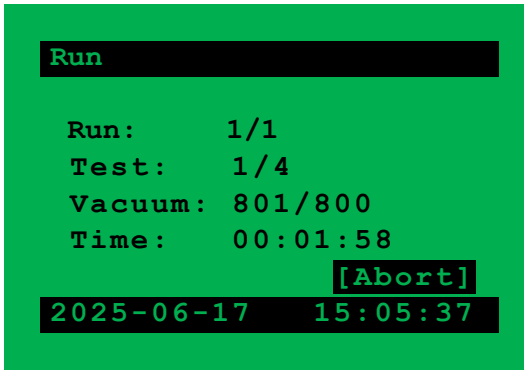


The instrument now prompts you to insert your sample into the desiccator and to close the lid. See above from more details on how to use the desiccator.

Select [Continue] to proceed.

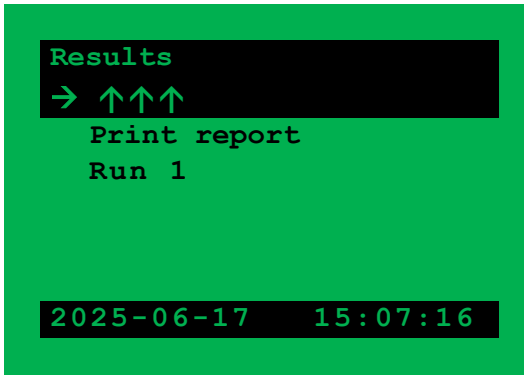


The instrument now builds up the vacuum inside the desiccator. Wait until the target vacuum is reached.
(See item 2, Technical background: air pressure)
Select [Continue] to proceed.



The instrument will maintain the vacuum until the holding time is elapsed. Wait until then for the test to be completed.

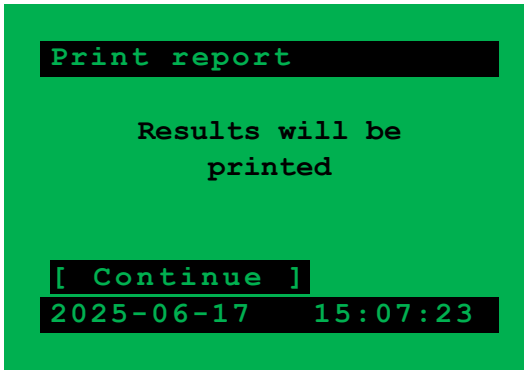
Select [Continue] to proceed to the results.



Here you can print the test report or view the details by selecting "Run 1".

Select "↑↑↑" to return to the main menu.

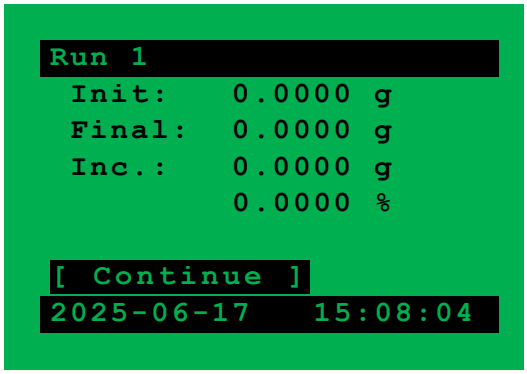
Printing the Test Report



Select [Continue] to print the test report. Afterwards the instrument automatically returns to the main menu.

See below for an example of the test report.

Viewing Test Run Details



This screen shows the initial weight of the sample before the test, the weight of the sample after the test and weight increase in absolute and percentages. Note that these results only apply in case a balance is connected. Otherwise, the test result is obtained visually by the user.

Select [Continue] to return to the results menu.

Example Test Report

```
TEST REPORT - RUN TEST

Department:         Department
Device-ID:          ABC123
Device:             PT-LT100
SN:                 27777
Version:            2.10 b6
Date:               2025-02-25
Time:               11:36:20
User:               Admin

Method:             SENOGENO-100
Product:            SENO-1
Batch:              ABC123
Analysis-ID:        22
EP/USP:             yes
Diameter:           250 mm
Time   1:           00:02:00
Vacuum 1:           400 mbar
Readjustment:       yes
Max. Runs:          1

Results in 1 Run:

.....Run: 1.............
Trip vacuum 1:      399 mbar

Start weight:       313.0000 g
End weight:         313.1287 g
Weight Incr.:       0.1287 g
Weight Incr.:       0.0411 %
.....................................

Test Result:
Test passed

Printed: 2025-02-25  11:39:06


Operator name


Signature
```

Customer department
Customer device-ID
Instrument model name
Instrument serial number
Instrument firmware version
Date of test start
Time of test start
User performing test
Method name
Product name
Batch number for each test
Analysis ID (automatically ascending)
Text according to EP/USP or not
Diameter of desiccator
Vacuum hold time 1
Vacuum level 1
Maintain vacuum or not
Total number of test runs

Vacuum level at end of test
Start weight (measuring weight is optional)
End weight
Absolute weight increase
Relative weight increase

Test has passed

Date and time when the report was printed

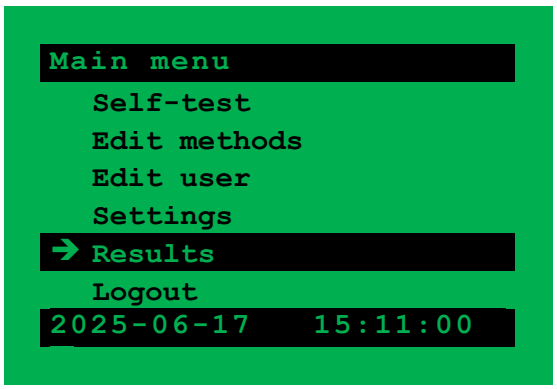
Space to write operator name

Space to sign the report

Figure 19: Example Test Report

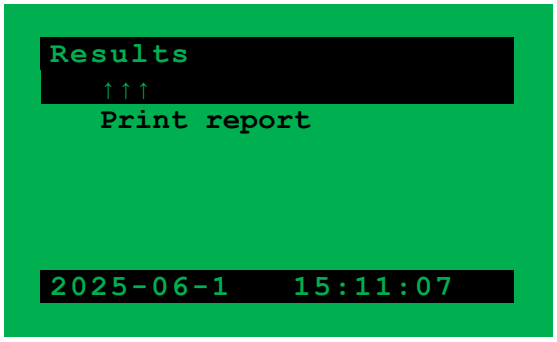
Repeat Print of the Last Result

Note: PT-LT100 stores the result of the latest run only! Only this can be re-printed. As soon as a new test is started (even in case this run is aborted), the previous results are irretrievably discarded. The same for a cold restart of the instrument. After switching on the PT-LT100, the result memory is empty again. So always make sure to print your results immediately or use the repeat print function in case you need to print the last result again (for example in case you reached the end of a paper roll).



It is possible to see and print the last method test results which were obtained by the instrument.

Select [Results] from the main menu to check and print out the last results.



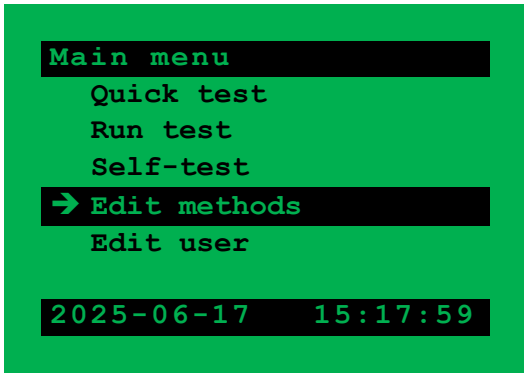
Select “Print report” to print out the test report of the latest test performed via the run test function.

To exit the screen, select the up arrows.

Edit Methods

This section describes how to create, edit (update) and delete methods.

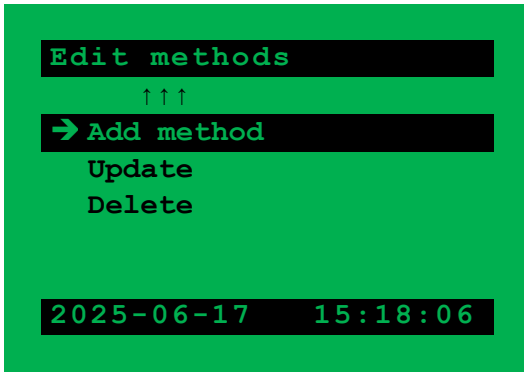
A method determines the name of the method and product, if the test should be performed according to EP/USP, if an evaluation of the test result should be done by the instrument, the log interval time, what desiccator should be used, whether or not the vacuum level should be actively maintained by the instrument, vacuum levels and holding times and number of subsequent runs to be performed:



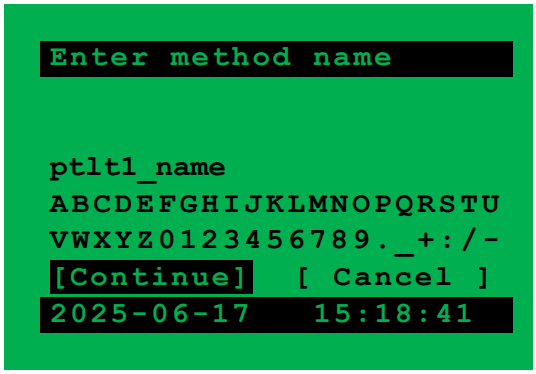
From the main menu select [Edit methods].

Adding a Method

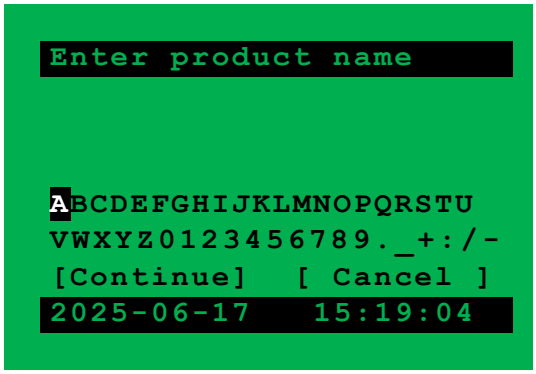
This section describes how to create a new method.



From the "Edit Methods" menu select [Add method].

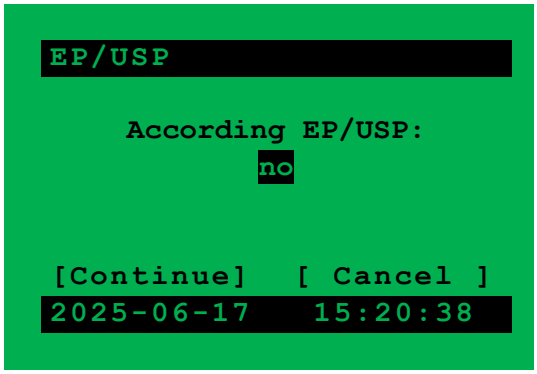


First enter a name for the new method and confirm with [Continue].

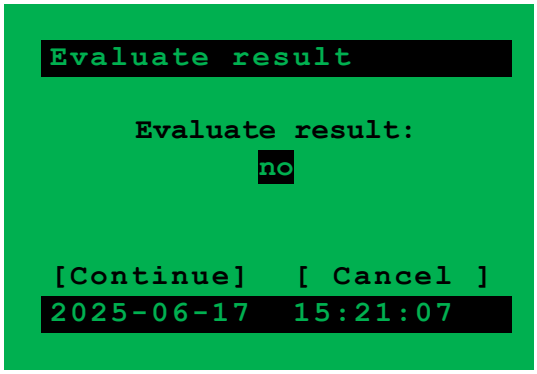


Enter a product name for the new method and confirm with [Continue]. This can also be left blank.

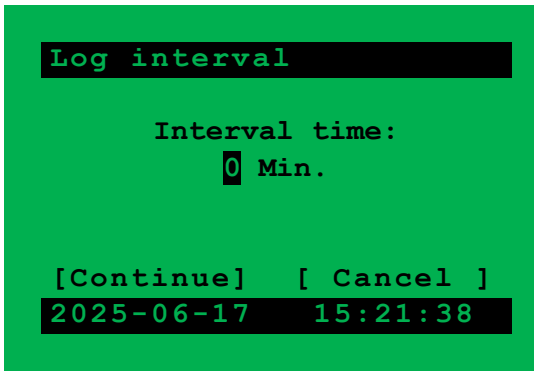
Note that the product name serves as a default and can later on be edited each time a test is run from this method.



Choose whether the test defined in this method should be performed as to the description in the EP/USP pharmacopeia or not. Several settings in the method are fixed to defined values if selecting “YES”.

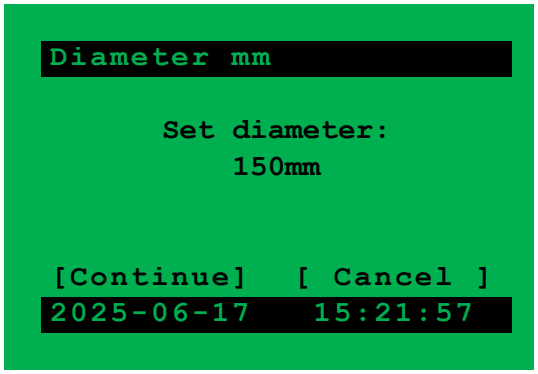


This setting is available only in case “According to EP/USP” has been set to “no” above. Choose whether you want to have an automated evaluation (“Test passed” / “Test failed”) for the test result or not. In case “According EP/USP” has been set to “yes”, the evaluation will be set to “yes” automatically and this screen will be skipped.



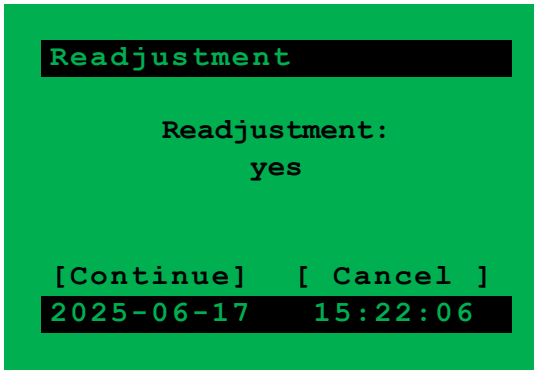
Set an interval time for your log protocol or deactivate this function by setting the time to “0 Min.” When activated a short printout with the current vacuum occurs every xx minutes.

Select [Continue] to confirm.



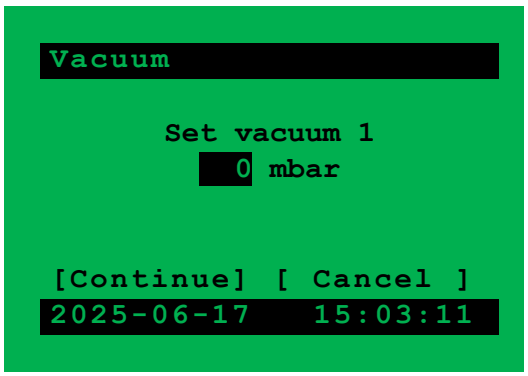
What desiccator to use for this test with this method is determined by the desiccator diameter. Select between 150, 200, 250, 380mm and "other".

Select [Continue] to confirm.



Once the target vacuum has been reached, PT-LT100 can actively maintain the vacuum. If you select "no" here, the instrument will not do this, and the vacuum will deteriorate during the test. By how much depends on the desiccator used and the air-tightness of the system.

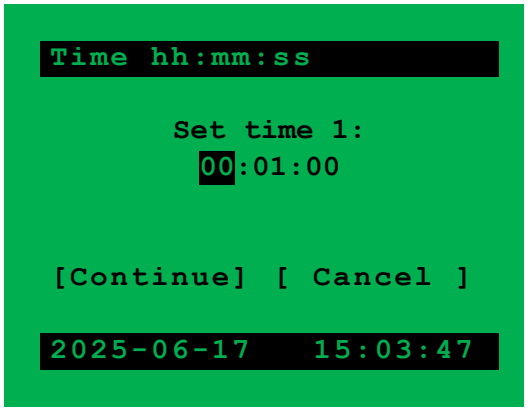
Select [Continue] to confirm.



Now enter the first target vacuum for this method. You can set a vacuum of up to 950mbar.
(See item 2, Technical background: air pressure)

Select [Continue] to proceed.

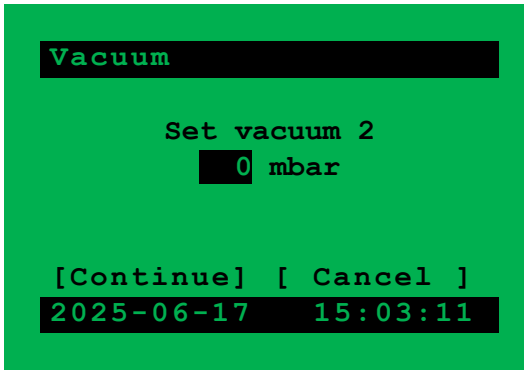
Note: This setting refers to a relative (low) pressure in relation to the actual ambient atmospheric pressure. Note that any pressure difference can only be reached if the absolute ambient atmospheric pressure is higher compared to the value set here.



Enter the first holding time (hh:mm:ss) for the vacuum.

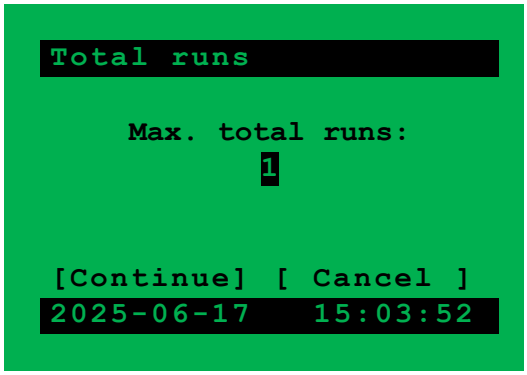
Here the time is set to one minute.

Select [Continue] to proceed.



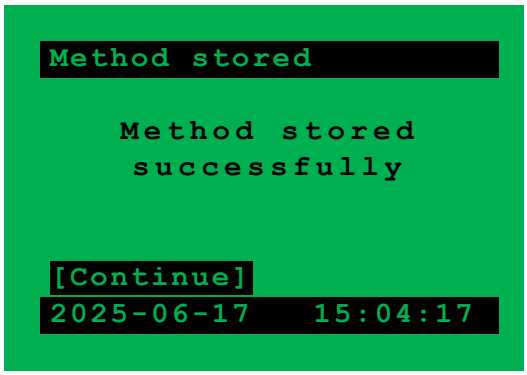
You can set up to four vacuum targets. If you do not want to set additional vacuum targets, enter 0 mbar. This will skip this vacuum target and all subsequent vacuum target and time entries.

Select [Continue] to proceed.



Here you define how many subsequent runs will be performed, from 1 to 9.

Select [Continue] to confirm.



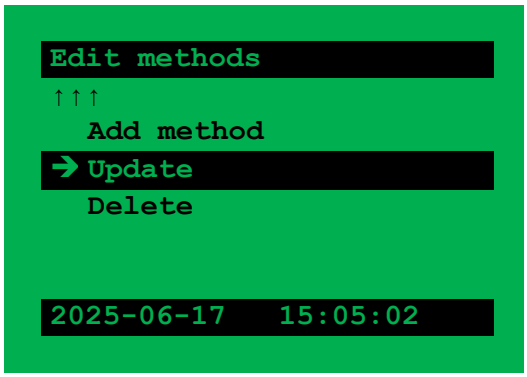
After this last step your method has been stored successfully.

Select [Continue] to return to the “Edit methods” menu.

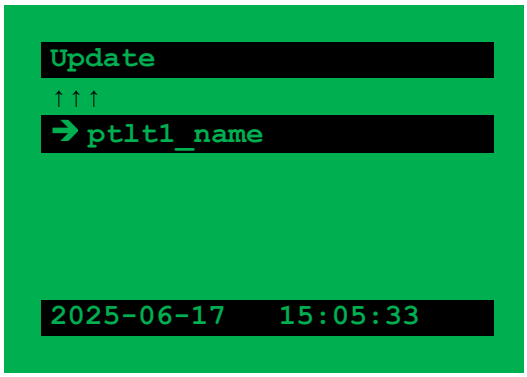
Update a Method

This section describes how to edit or change an already existing method.

Note: the process of updating (i.e. editing) a method is identical to creating a new method.



From the "Edit methods" menu, select [Update] to change an existing method.



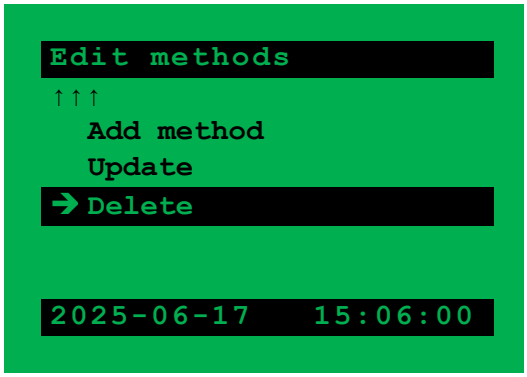
All methods available on this instrument are listed here. Select the method you want to edit.

Now proceed through every screen and make your changes as needed. Refer to the previous section for details about each screen.

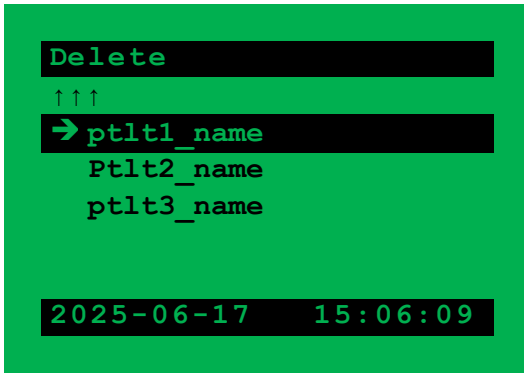
After the last screen, after the message "Method stored successfully" is displayed, you are returned automatically to the "Edit methods" menu.

Deleting a Method

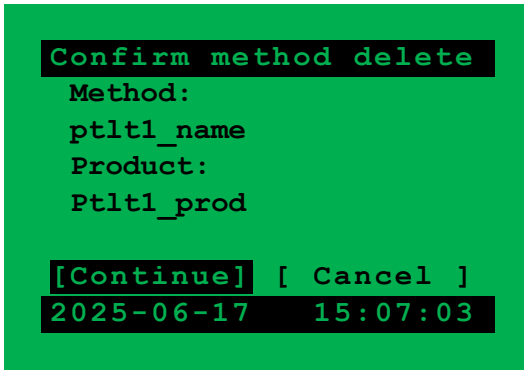
This section describes how to delete a method from the instrument's internal storage.



Select [Delete] to delete an existing method.



Select the method to be deleted from the list.



You now have to confirm that the selected method really should be deleted. You can confirm that you selected the right method from the method and product names displayed here.

Select [Continue] to permanently delete the selected method or [Cancel] to abort.

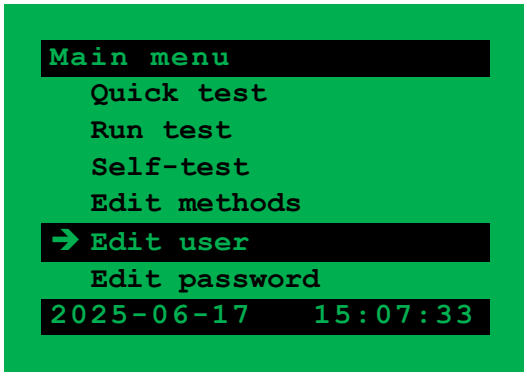
Note: deleted methods cannot be restored. You can create backups of your methods. See below for more details about saving files.

Edit User

This section describes how to add a new user, how to delete users and how to change the user password and permissions.

PT-LT100 is equipped with a flexible user management system that can handle a large number of users with different permissions. The users are created by the administrator ("ADMIN") and he also assigns the permissions.

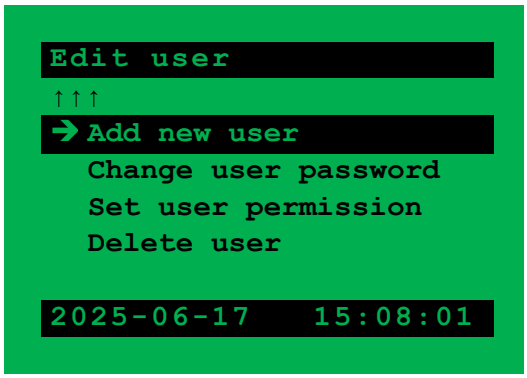
Note: only the administrator has the permission to edit users (and some settings, like Language selection, time and date and qualification interval). The following menu is available only when logged in as user "ADMIN".



From the main menu select [Edit user].

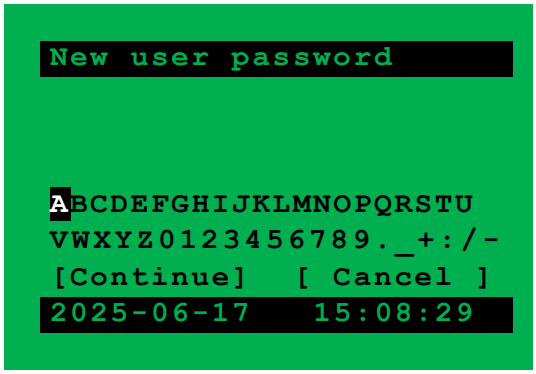
Adding a New User

This section describes how to create a new user.



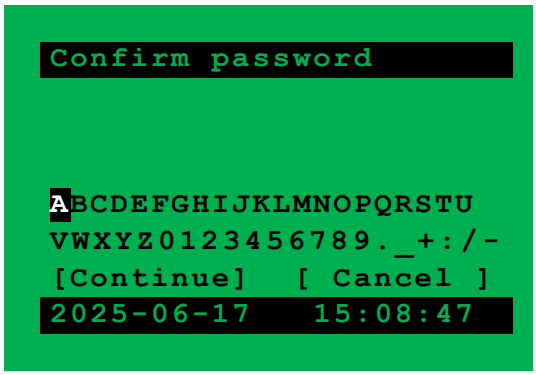
From the "Edit user" menu, select [Add new user].

First enter a name for the new user and confirm with [Continue].

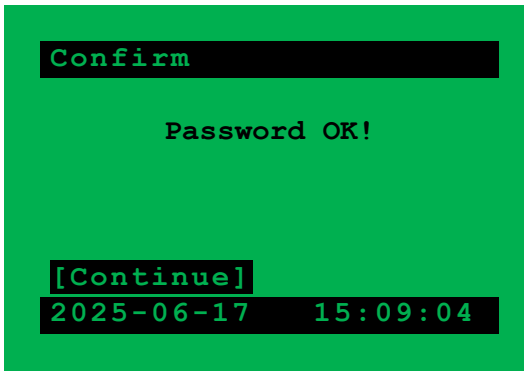


Enter a password for the new user and confirm with [Continue].

Note: There are no password rules. Every input except empty is allowed, which means there is no minimum length, password validity and or password history. Since this instrument does not feature a result archive and thus the potential to manipulate any result data, the user management is kept simple here.

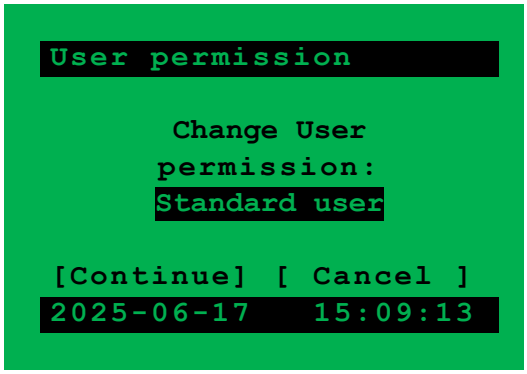


Verify the user password by entering it again and confirm with [Continue].



Provided you entered the password exactly the same twice, your entered password is accepted.

Select [Continue] to confirm.



Select permission level for the new user. Choose between “User disabled”, “Standard user” and “Method user”.

As a "Standard user" you are only able to run tests and quick tests, perform self-test and to edit your own password.

As a "Method user" you have the same permissions as the standard user, but additionally you can edit and change methods.

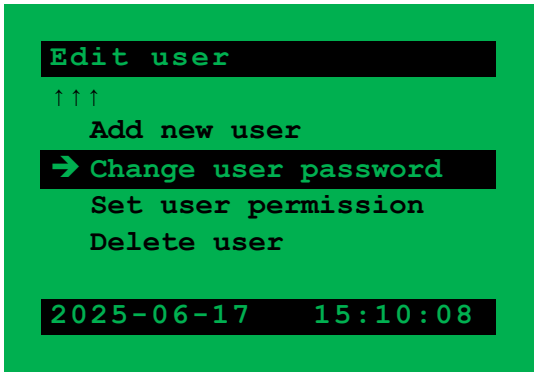
"User disabled" means the user is not allowed to login, but the user is not deleted and can be re-activated by changing the permissions again later on.

This completed the creation of the new user.

Select [Continue] to save the new user or [Cancel] to discard your entries without creating the new user.

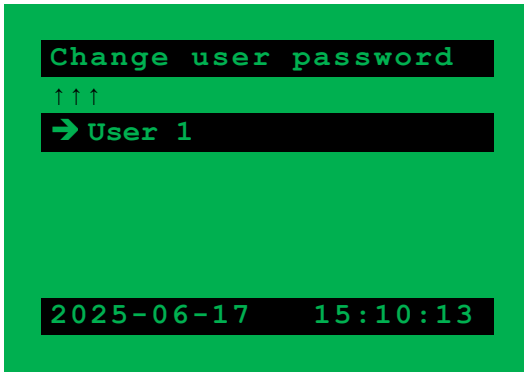
Changing a User Password

This section describes how to change the password of any user. This function is only available for the administrator.



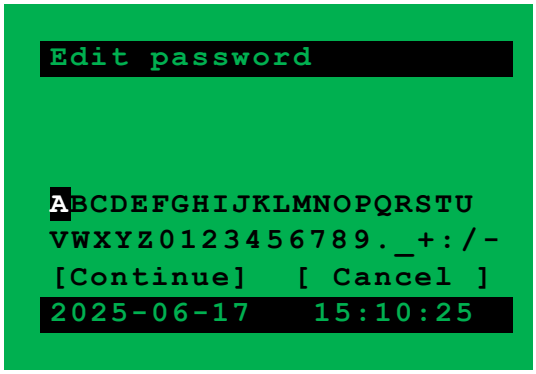
As opposed to the "Edit password" function to change a user's own password, the administrator can change the password of every user. This is useful in case a password has been forgotten.

In the "Edit user" menu, select [Change user password] to change the password of a specific user.

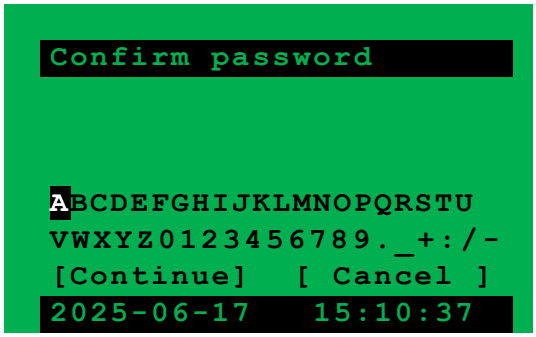


It is not possible to change the password of the user "ADMIN" in this menu. For this, select "Edit password" from the main menu while logged on as user "ADMIN".

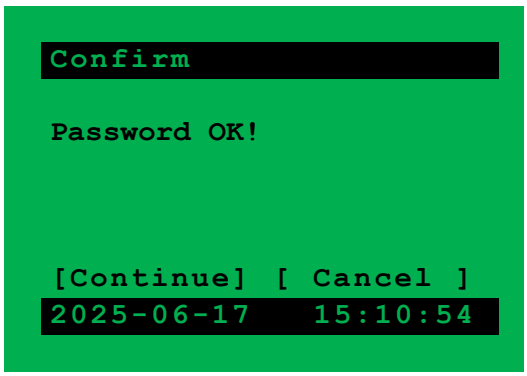
Select the user whose password you want to change.



Enter the new user password and confirm with [Continue].



Verify the new user password by entering it again and confirm with [Continue].

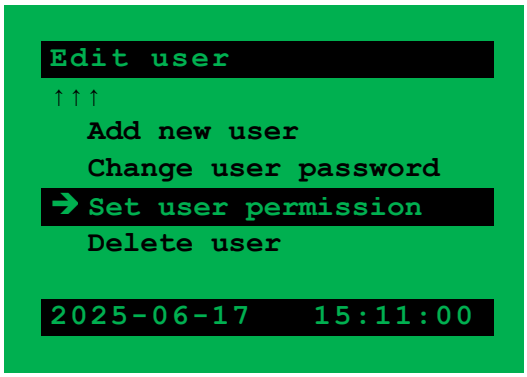


The new password is accepted.

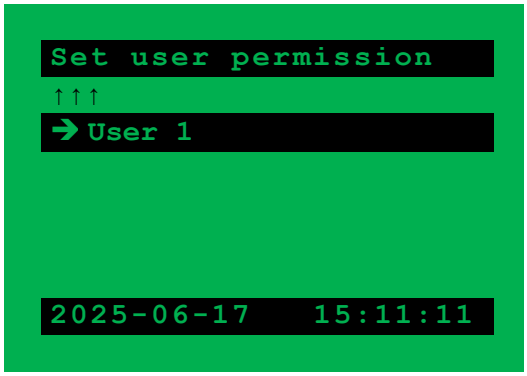
Select [Continue] to confirm.

Changing User Permissions

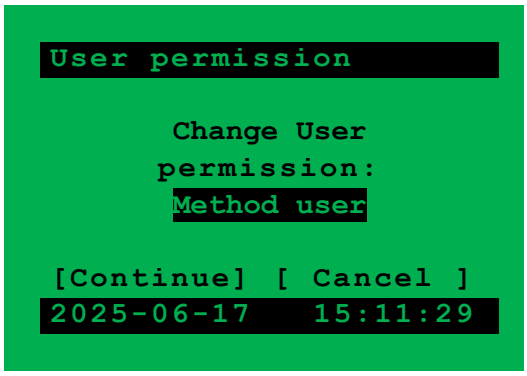
This section describes how to change the permission level of an already existing user.



In the “Edit user” menu, select [Set user permission] to change the user permission of an already existing user.



Select a user from the list to change its permission level.

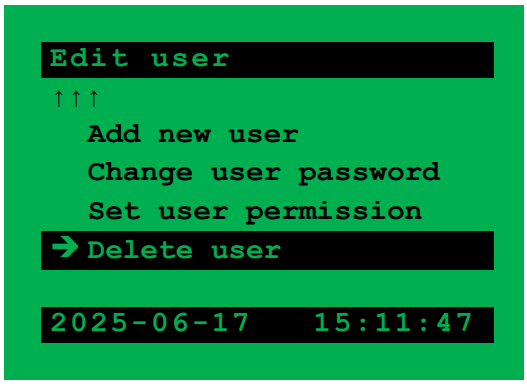


Select the preferred user permission. Choose between “User disabled”, “Standard user” and “Method user”. See above for details on the user levels.

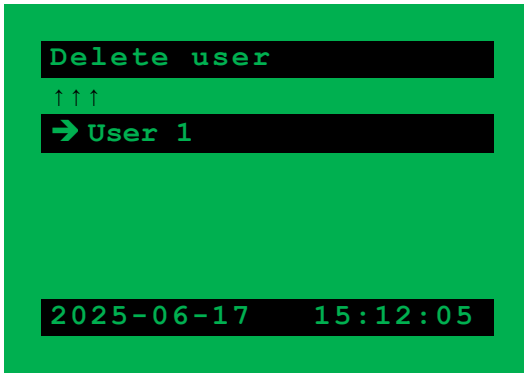
Select [Continue] to confirm

Deleting a User

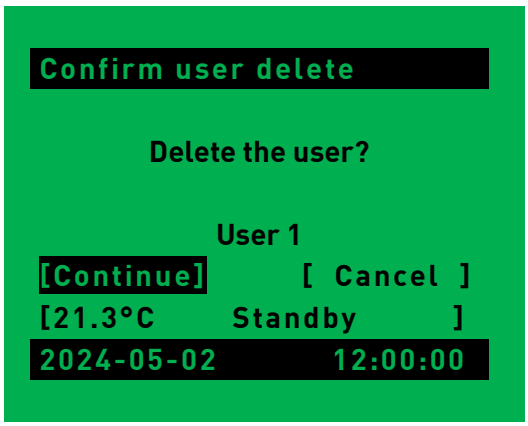
This section describes how to delete a user from the instrument's internal memory. Deleted users cannot be restored. In case you suspect the user may be required again in the future, you can change his permission level to "User disabled" to prevent him from being able to login to the instrument.



To delete a user, select [Delete user] from the "Edit user" menu.



Select a user to delete from the list.



Select [Continue] to confirm the deletion of the user. Or select [Cancel] to abort the process.

6. Settings

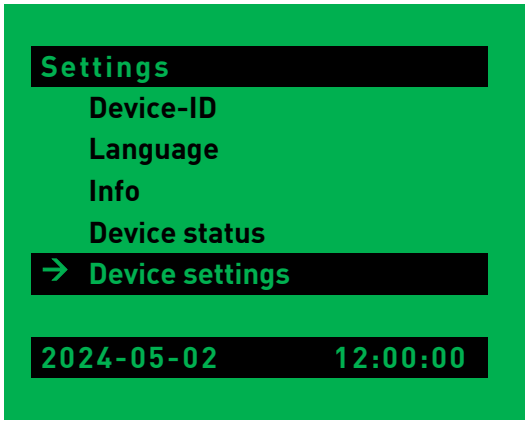
This section describes the “Settings” menu and its various sub-menus.

Device Status (Factory Menu)

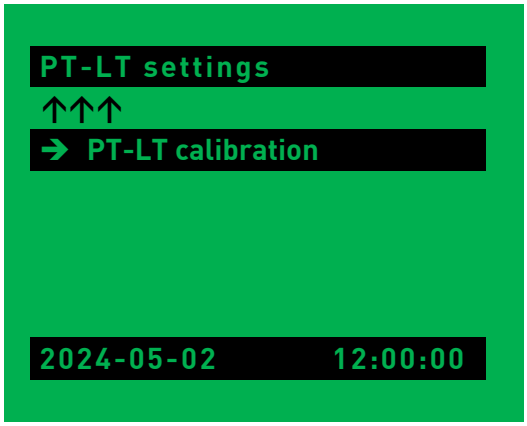
This menu is only visible and accessible when logged in as user “Factory”. This menu is intended for service purposes performed by certified Pharma Test service providers.

Device settings

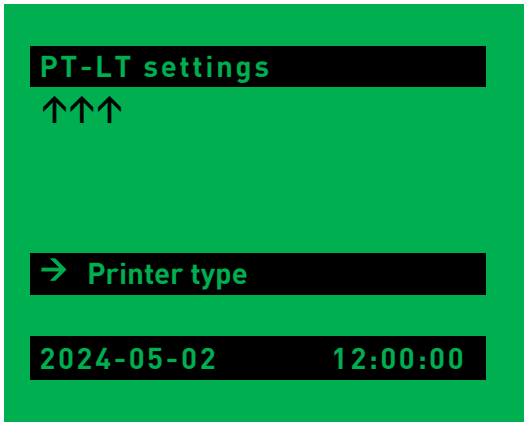
This section describes how to perform the calibration of the PT-LT100 as well as the device settings. The balance type and the printer type can be set here as well.



From the settings menu select [Device settings] (only available as Admin) to do the calibration of the PT-LT100, to change the offset feed and preheat temperature, the standby time as well as the printer type.



In this sub menu the PT-LT100 calibration can be done, different temperature settings like the offset feed and the preheat temperature, the standby time and the printer selection.

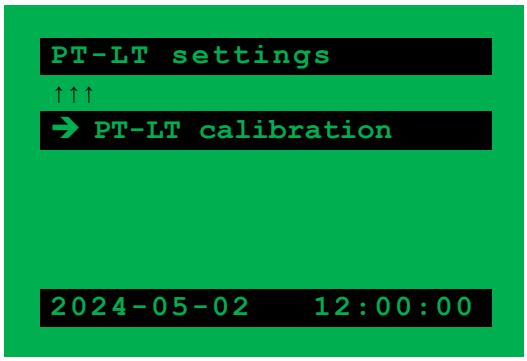


Supplementary information: lower line in the PT-LT100 settings menu.

PT-LT100 calibration

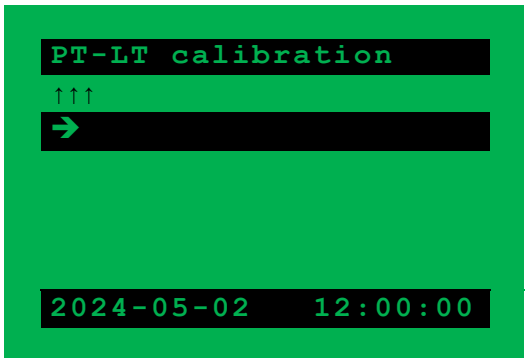
This section describes how to perform the calibration of the PT-LT100.

Note: Only a trained service technician should perform calibration of the instrument. After performing the calibration, a calibration report can be printed.



In this sub menu the PT-LT100 calibration can be performed.

Select "PT-LT calibration" to confirm.



In the "PT-LT calibration" sub menu different features can be calibrated.

Calibrate vacuum

To calibrate the vacuum function, you will need a calibrated vacuum gauge (part no. 382-0350 for a digital gauge and 382-0300 for an analog gauge).

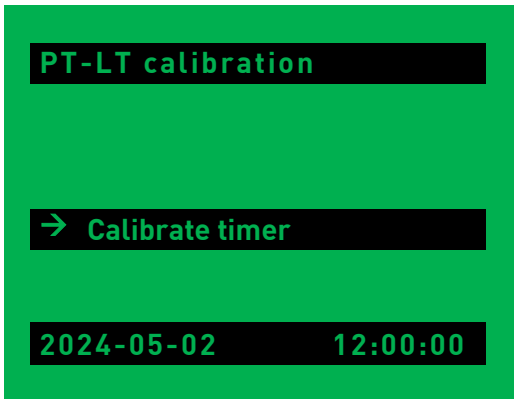
Before you start calibration, please read chapter 2 on air pressure conditions.

Make sure that a desiccator is still connected to the instrument and that the lid is closed tightly. From the device settings menu select "PT-LT calibration". Then select "Calibrate vacuum". Set the nominal vacuum, for example to the maximum of 950 mbar and the hold time to 10 seconds, for example. Select "Continue". Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum. Confirm that during this test a vacuum of 950 mbar was reached. After vacuum release wait for at least 60 seconds. You can then print a calibration report.

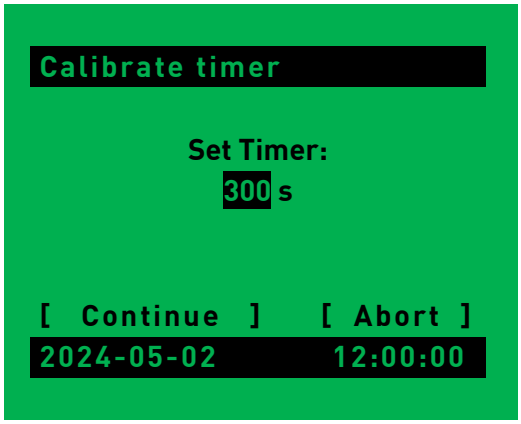
Calibrate timer

To calibrate the timer, you will need a calibrated stopwatch (part. no. 10-61000).

Calibrating the timer is to ensure that the vacuum holding times will be measured correctly.

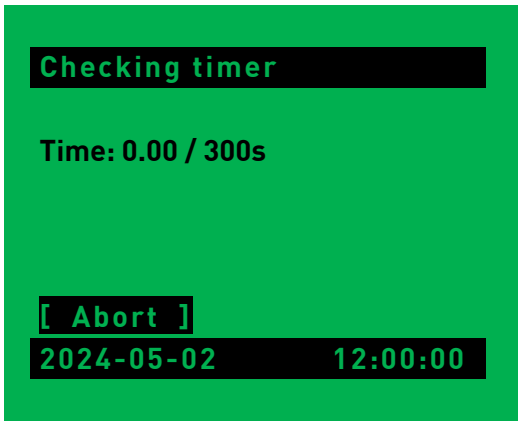


From the "PT-LT calibration" menu choose [Calibrate timer] to check the correct function of the internal timer of the PT-LT100.



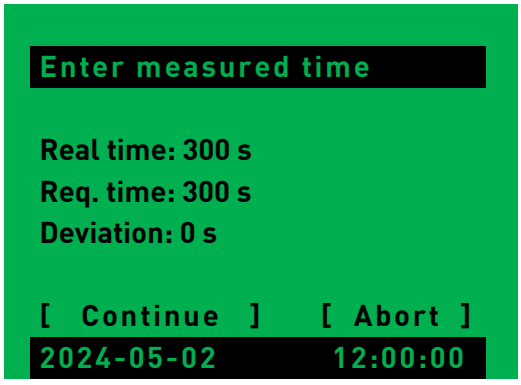
Enter the time which should be counted by the instrument. Choose between 0 s and 1000s. Consider that it is just meaningful to manually measure "long" times.

Choose [Continue] to confirm.



Now the timer starts to count the preset seconds where you simultaneously measure the time with the stopwatch.

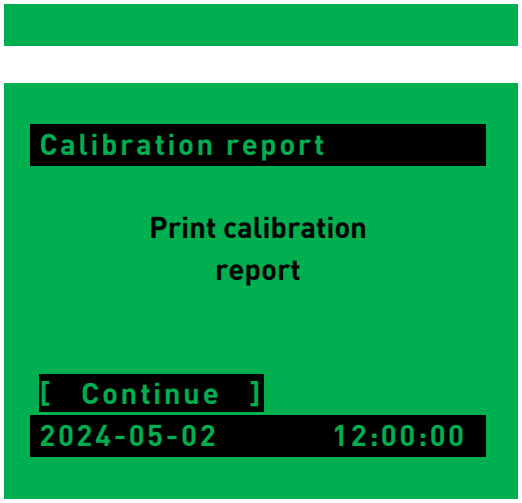
You can [Abort] the test.



After the time has elapsed, the shown screen appears. Here you have to enter the measured "real" time in the first line.

In the last line the deviation between the measured and the required time is calculated according to your previous entry.

Choose [Continue] to confirm or [Abort] to abort.



After finishing the calibration process, choose [Continue] to print out the calibration report

Adjust zero level

Section upcoming

Adjust vacuum

Section upcoming

Vacuum unit

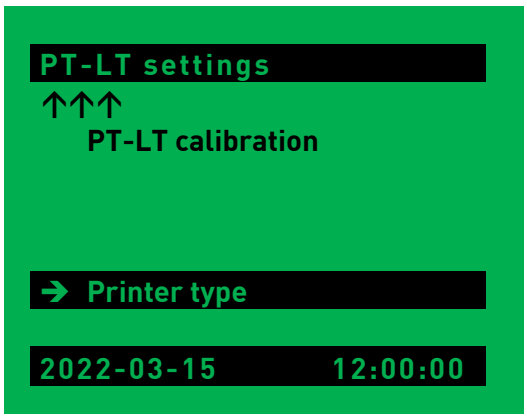
Section upcoming

Balance type

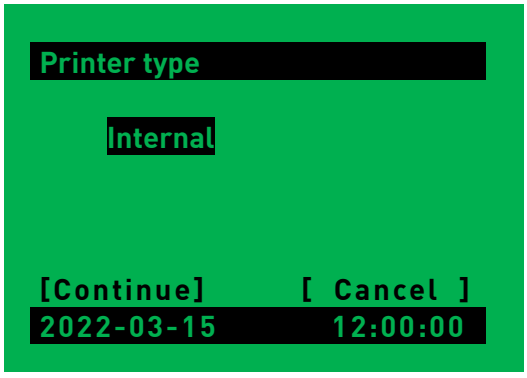
Section upcoming

Printer type

In this device setting the use of a printer can be activated and deactivated.



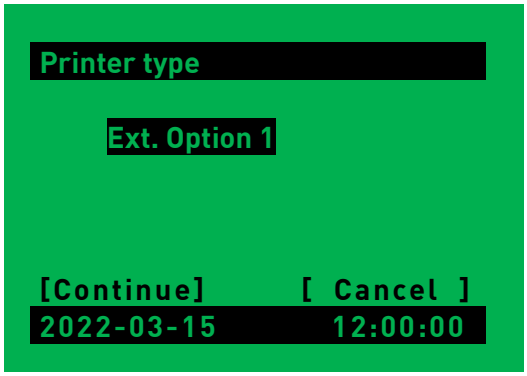
From the "PT-LT settings" menu select "Printer type".



This screen offers three possibilities for the printer. Choose between

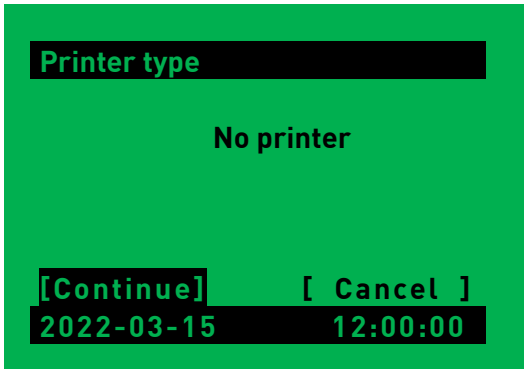
"Internal"

for using the built-in printer. The printer port at the backside can be used parallel. Every data which is sent to the built-in printer is also available at the port at the backside.



"Ext. Option 1"

With this setting a "carriage return / line feed" (CR/LF) is added to every line. This means a serial data capturing by the backside port will appear in a readable form. The built-in printer at the front is not affected by this.



or

"No printer".

With this setting there will be no data output at the serial printer ports. Neither at the built-in printer nor at the backside port.

Choose [Continue] to confirm.

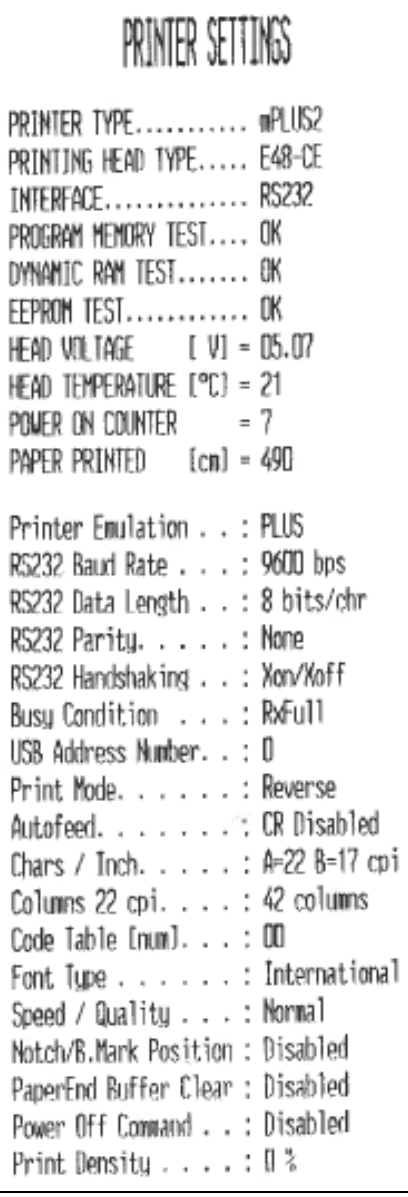
The printout respectively data output is done by the serial port "Printer" at the backside or at the built-in printer at the front.

The serial interface parameters are fixed to **9600-8-N-1**.

As external printer Pharma Test supports the EPSON TM-U220D ticket printer as well as the PT-Node network adapter.

Settings of the Built-in Printer

In case that after any change or repair work, the print layout of the built-in printer is in some way incorrect (for example, the print-out does not fit the paper anymore, shows larger symbols, additional line feeds, etc.), check and correct the internal printer settings:



Hold the paper feed button for approx. 5s during power-up of the PT-LT100.

The printer will print a list with its actual settings. (left picture)

Use a „long press“ of the paper feed button (>1s) to enter the setup

Use a „long press“ to confirm the current setting and to switch to the next parameter.

Use a „short press“ (<0.5s) to change the current setting. Always the last printed setting is the currently selected one!

Do the „long presses“ as often as the printer prints a complete list again. Then the setup is finished. Skip the „Font test“ by a short push.

Set the printer as shown in the left picture.

If you make a mistake, you must start the procedure from the beginning.

Figure 20: Built-in printer settings

7. PT-LT100 Data Capturing

It is possible to record the PT-LT100 results electronically. Connect the PT-LT100 using the "USB Device"-port to a Windows®-PC with a standard USB-A to USB-B cable. An FTDI-driver will be installed automatically, and a virtual COM-port will appear in the Windows®-device manager. This way you can capture the serial output data by using a suitable terminal program of your choice.

Figure 21: Port for PC connection

The serial output is a separate data protocol. It contains the test definition and the raw data of the results. Statistics and derived calculation are not included in this protocol. This data is neither encrypted nor write protected. The end user is responsible for the safe usage of this data.

Parameter	Setting
Speed	115200 baud
Data bits	8
Parity	none
Stop bits	1
Handshake	none

Table 11: Interface parameters

Serial Output Example and Format Explanation

`PT-LT100 -SN1234 -Start`	Start string
`PT-LT100 -SN1234 -FW 2.9`	Firmware version
`PT-LT100 -SN1234 -Date 2024-05-02`	Test run date
`PT-LT100 -SN1234 -STime 16:03:53`	Time of test start
`PT-LT100 -SN1234 -ETime 16:05:25`	Time of test end
`PT-LT100 -SN1234 -Department`	Department label
`PT-LT100 -SN1234 -DeviceID`	Device ID label
`PT-LT100 -SN1234 -User ADMIN`	Actual user
`PT-LT100 -SN1234 -Method pt-lt_name`	Name of method
`PT-LT100 -SN1234 -Product1 pt-lt_prod`	Name of product
`PT-LT100 -SN1234 -Batch1 AABBCCDDEEFF`	Entered batch number
`PT-LT100 -SN1234 -AID 000000000216`	Actual analysis number
`PT-LT100 -SN1234 -End`	End string

8. Troubleshooting

Error	Solution
The PT-LT100 instrument does not turn on.	1.) Mains connection is faulty: Check that the mains connection is present and properly connected to the external power supply and in turn to the instrument.
	2.) The fuse is blown: Check the fuse and replace it if necessary.
The lid of the desiccator cannot be lifted.	Residual vacuum inside the desiccator prevents the opening of the lid: Press <Esc> from anywhere while the instrument is turned on to open the instrument's valves to release and residual vacuum.
The self-test cannot pass or the target vacuum cannot be reached during a test. The self- test cannot be passed, or the target vacuum cannot be reached during a test.	1.) Check that a desiccator is connected
	2.) Check that the desiccator is properly closed. Depending on the type of desiccator used check that any seals are properly inserted and that the seams between body and lid are greased.
	3.) Check all connections between the instrument and the desiccator for leaks
	4.) Read point 2 for the basic conditions for generating a vacuum.

Table 12: Troubleshooting

9. Cleaning and Maintenance

Only trained and qualified personnel should clean and maintain the instrument.

The Plexiglas parts should be cleaned daily. **Never use solvent-containing cleaning supplies like alcohol, ethanol, etc., they will destroy the acrylic glass.** Use exclusively soaps containing cleaning supplies with lukewarm water or cleaning cloth. Do not use the dishwasher to clean the desiccator or parts containing Plexiglas.

Clean the stainless- steel parts using a soft cloth and a suitable cleaner. Stainless steel parts must be cleaned immediately in case liquids are spilled onto the surface. Wipe away the liquid with a cloth.

The instrument does not include any other spare parts, which should be maintained by the user. Any repairs are exclusively allowed to be performed by a certified Pharma Test service partner.

In case the instrument cannot be operated anymore without the possibility of damaging or harming anybody, it must be stopped from operation immediately. This is always the case when:

- The mains cord shows any damage
- The instrument shows visible damage
- Any cable is damaged
- Any supply cable is damaged

10. Safety Information

Before you open the Instrument always remove the mains cord from the mains socket. Only authorized personnel (electrician, Pharma Test service technician) should open the instrument.

Do not use the instrument in case:

- The mains cord shows any damage
- The instrument shows visible damage
- Any cable is damaged

Before transporting the instrument or desiccator, make sure that it is cleaned and emptied from any test substances.

Always use gloves while moving the instrument, even while unpackaging, to avoid bruising hands and fingers.

During operation or cleaning, liquid may spill out of the desiccator. Do not hold eyes and head in direct closeness to the test sample while operation or cleaning or use protective glasses.

In case any spare parts are needed, only use original Pharma Test parts.