User Manual

Photometer DTN-405

(en) English

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IVD

CE

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Warranty

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.
The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of DIALAB, and at the customer´s expense.

Conformity

The DIALAB Photometer DTN-405 analyzer complies with the following directives, regulations and/or norms:
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
It also complies with the European standard:
EN 61010-1:2010;
EN 61010-2-101:2022;
EN 62304:2006,
EN 62366-1:2015,
EN 13612:2002,
EN 61326-1:2012
EN 61326-2-6:2012.
EN IEC 61010-2-010
Conformity is certified provided the equipment is installed in accordance with the conditions described in the manual.

Images

The images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Training

Do not carry out operation tasks or maintenance actions unless you have received training from DIALAB GmbH. Leave tasks that are not described in the user documentation to trained DIALAB Service representatives.

Incident reporting

Report serious incidents or potential serious incidents related to the product in accordance with the requirements of the manufacturer and your competent authority.

Contact information

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INTENDED USE

The Photometer DTN-405 is part of the DTN- Photometer Series:

Intended purpose

The DTN Series photometers are semi-automatic photometric accessory instruments for in vitro diagnostics designed to measure absorbance and calculate quantitative clinical chemistry results in human serum, plasma, and/or urine in combination with the DIALAB-IVD reagents listed below and in accordance with their respective intended uses
Calcium, Arsenazo
Creatinine, mod. Jaffe
Glucose, GOD-PAP
GPT (ALT), mod. IFCC
Protein Total, Biuret
Urea UV Auto, Urease/GLDH

In accordance with the intended use of the respective reagent, the results are intended to aid in the assessment of physiological or pathological processes or conditions and, where applicable, to monitor therapeutic measures. The photometers do not perform independent diagnostic interpretation. The results must be evaluated by qualified personnel, taking into account additional clinical and diagnostic information. The DTN series is intended exclusively for professional use by qualified personnel in a clinical laboratory setting.

SYMBOLS AND ABBREVIATIONS

Symbols used on products

Symbols on the instrument

Serial number:
This symbol indicates the product's serial number, allowing a specific product to be identified.

In-vitro diagnostic medical device
The symbol identifies the product as an accessory to one or more *in* vitro diagnostic devices. The symbol may also be used for *in* vitro diagnostic devices themselves.

Manufacturer
This symbol indicates the manufacturer of the product. The manufacturer's name and address are provided.

CE marking

in accordance with Regulation (EU) 2017/746 (IVDR).

Symbols on the secondary package

Store in a dry place!
Protect from moisture!

Fragile – handle with care!
The instrument should be handled with care during transport to prevent damage.

Orientation of the package during transportation.
The packaging must remain upright. Do not tip over.

This symbol indicates that the stack height must not exceed 8 layers to avoid damaging the photometer.

Temperature limit: This symbol indicates the temperature range to which the product can be safely exposed.

Abbreviations

The following abbreviations are used:

Abbreviation	Definition
ABS	Absorbance
EN	European standard
IVD	In vitro diagnostic medical device
IVDR	In vitro diagnostics regulation (EU) 2017/746

STORAGE AND HANDLING

Storage conditions

Store the DTN-405 photometer at a temperature between 0°C and 40°C and at a relative humidity of ≤85%.

Handling

Handle the DTN-405 photometer with care during transport and storage to prevent damage. Keep the instrument protected from moisture and ensure that the packaging remains upright; do not tip it over. When the instrument is stored in its original packaging, the maximum stacking height must not exceed 8 layers. Retain the original packaging materials for possible return shipment, transport, or future maintenance.

SAFETY GUIDE

To avoid serious or fatal injury, read and comply with the following safety precautions.

General

Before you begin installing and working with the photometer, you should read the safety precautions and regulations listed in this chapter.

Operator qualifications

Please note that the photometer must only be operated by qualified personnel who have completed the necessary training provided by a Dialab representative.

Qualification of the service technician

For the installation, maintenance and repair of the photometer, a service technician must have been trained by the manufacturer or their representative for the photometer. A service technician is also expected to be familiar with the normal operation of the photometer, as described in the user manual, and the specific procedures, as described in the service manual.

Electrical

Please observe the following points to ensure the safe use of the photometer:

To avoid the risk of electric shock and/or damage to the photometer, **the user** must not open the photometer housing. Only authorized personnel, e.g. **service technicians**, may open the photometer for maintenance or repair.

Touching the main circuit board whilst the photometer is switched on can result in serious injury or death. If you encounter any problems, please contact your supplier.

Software

Only use the preinstalled SW that the instrument comes with. The local responsible Dialab representative will inform about available updates

Serial connection is not encrypted, Sensitive Data can therefore be captured by tampering with the cable. Security should be setup accordingly.

Mechanics

The mechanical parts of the photometer do not pose a hazard when the photometer is closed. If the photometer's covers are removed, the mechanical parts may cause injury or the photometer may be damaged if the following instructions are not followed: DO NOT wear loose clothing or jewelry that could become caught in the mechanisms. DO NOT put your fingers or hands in the path of or into other parts whilst the photometer is in operation. DO NOT attempt any mechanical repairs unless the photometer is out of operation or switched off.

Lamp

The light source becomes extremely hot during operation; never touch the lamp when it is switched on! Looking directly into the lamp's light path can cause eye damage.

If the lamp needs replacing, always switch off the photometer and wait until the lamp has cooled down.

Biologically hazardous materials

As with all photometers, patient samples and serum-containing quality control (QC) products tested with this system, as well as all waste from the waste container, should be treated as potentially biohazardous. All materials and mechanical components associated with the sampling and waste system should be handled in accordance with your institution's biohazard procedures. When handling these components, use the personal protective equipment recommended by your institution.

Detailed recommendations:

- **Samples**

  Treat all samples as potentially biologically contaminated and infectious. Should sample material contaminate the photometer, wipe it up immediately using standard personal protective equipment (gloves, lab coat, etc.) and clean the contaminated area with a disinfectant.

- **Liquid and solid waste**

  Avoid direct contact with liquid and/or solid waste. Both should be treated as potentially biohazardous.

  Dispose of liquid and/or solid waste in accordance with the relevant regulatory requirements. Information on the concentrations of heavy metals and other toxic components in the individual reagents can be obtained from the reagent manufacturer.

- **Biologically hazardous parts**

  Avoid direct contact with the pump tubing and all parts of the sample flow path. Treat these areas as potentially biohazardous and/or infectious.

- **Reagents**

Avoid direct skin contact with reagents. Direct skin contact may cause skin irritation or damage. Specific instructions can be found on the reagent packaging, in the manufacturer's instructions for use, or in the safety data sheets.

Avoid direct skin contact with the cleaning solution. Direct skin contact causes skin irritation or damage. Specific instructions can be found on the packaging and in the manufacturer's instructions for use or safety data sheets.

CAUTION! Precautions

Required for samples, reagents, calibrators and controls.

The DTN-405 photometer is an open reagent system. However, the following points should be noted before carrying out the tests.

In general, all reagents and samples must be stored and prepared in accordance with the manufacturer's instructions.

Additional precautions

- **Flammable substances**

Avoid using hazardous flammable materials near the photometer.

- **Accuracy/precision of measurement results**

To use the photometer correctly, measure controls and monitor the photometer during operation.

An incorrect measurement result may lead to a misdiagnosis and thus pose a risk to the patient.

Handle all reagents in accordance with the manufacturer's recommendations. Specific instructions can be found on the reagent packaging, in the instructions for use or in the safety data sheets.

Ensure that the sample/reagent mixture does not contain blood clots, dust or other insoluble contaminants. If the sample contains insoluble contaminants, it may not be possible to obtain accurate readings.

- If you notice any unusual odors or smoke, immediately switch off the power supply and unplug the mains plug from the socket. Contact your specialist dealer or the relevant customer service department immediately. Continued operation under these conditions may result in fire, electric shock or fatal injury.
- No sample material (blood), reagents or metallic objects such as paper clips or pens must enter the interior of the device. This can cause short circuits, smoke or fires. If foreign objects or liquids have entered the device, immediately switch off the power supply, unplug the mains plug and contact your specialist dealer or customer service immediately.
- The operator must not touch any components inside the device. Touching live parts, particularly with wet hands, increases the risk of electric shock.
- When carrying out maintenance and inspection work on the device, protective gloves must be worn

and the prescribed tools and spare parts must be used. Wash your hands thoroughly with a disinfectant liquid soap once the work is complete. Failure to comply poses a risk of infection through contact with sample material, as well as a risk of electric shock or burns.

- Exercise extreme caution when handling patient samples. Wearing protective gloves is mandatory to avoid the risk of infection. Should samples come into contact with the eyes or open wounds, rinse the affected areas immediately with plenty of water and seek medical attention without delay.

Handling reagents and cleaning solution

- Avoid direct skin contact with reagents. Direct skin contact can cause irritation or damage to your skin. Specific instructions can be found on the packaging of the reagents, in the manufacturer's instructions for use or in the safety data sheets.
- Avoid direct skin contact with the cleaning solution. Direct skin contact causes skin irritation or damage. Specific instructions can be found on the packaging and in the manufacturer's instructions for use or the safety data sheets.

- **Tubing**

- In order to ensure optimal , make sure that none of the tubings is kinked or bent.
- Make sure that the aspiration tube is properly positioned.

- **Mains voltage, connection and earthing**

- Take care not to plug the appliance into a socket with an AC voltage exceeding 220 V. Failure to do so may result in fire or electric shock.
- Once the appliance is installed, use the three-core power cable supplied with the appliance and ensure it is properly earthed. Failure to do so may result in fire or electric shock.
- Take care not to damage the insulation sheath of the power cable. Do not pull on the power cable with force or hang heavy objects from it. Otherwise, a power failure or short circuit may occur, which could lead to electric shock or fire.
- The power supply must be disconnected when connecting peripheral devices. Failure to do so may result in electric shock or other problems.

Please report any serious incidents or potential serious incidents relating to the photometer in accordance with the manufacturer's requirements and to your competent authority.

Product safety labels

	This symbol indicates that the marked part is hot during operation of the photometer. Do not touch the marked part, as you may burn yourself. The symbol is located on the lamp holder of the optical system.
	Warning! This means that the marked area may cause injury and/or damage to the photometer. The symbol is located next to the power socket and some external interfaces.
	The precautions should be followed carefully to ensure that your photometer functions correctly and to avoid unnecessary injury.
	The symbol indicates biological risks and is affixed at the point where the photometer comes into contact with the clinical reagent. The symbol appears in black text on a yellow background.

Safety information for disposal

To protect the environment and human health, it is recommended that consumables, wear parts, liquid waste and end-of-life equipment are not disposed of in the environment.
Ensure that the disposal of liquid waste, consumables, wear parts and end-of-life equipment is carried out in accordance with applicable laws and regulations.

OVERVIEW OF THE SYSTEM

The DTN-405 photometer is a universal, semi-automatic clinical chemistry analyser. Its advanced Windows CE-based software offers user-friendly features designed to meet the specific requirements of a clinical chemistry laboratory:

- Monochrome LCD
- Choice between monochromatic and bichromatic measurements
- The following measurement methods are available:
  - End-point method (end-point)
  - Fixed-time method (2-point method)
  - Kinetic method (Kinetic)
  - Bichromatic method (dual wavelength)
  - Absorbance measurement (Extinction)
  - Multi-standard calibration (multi-point calibration curve)

The DTN-405 photometer is equipped with an internal printer.

Structure of the photometer

This section explains the structure of the **DTN-405 photometer**.

Front view

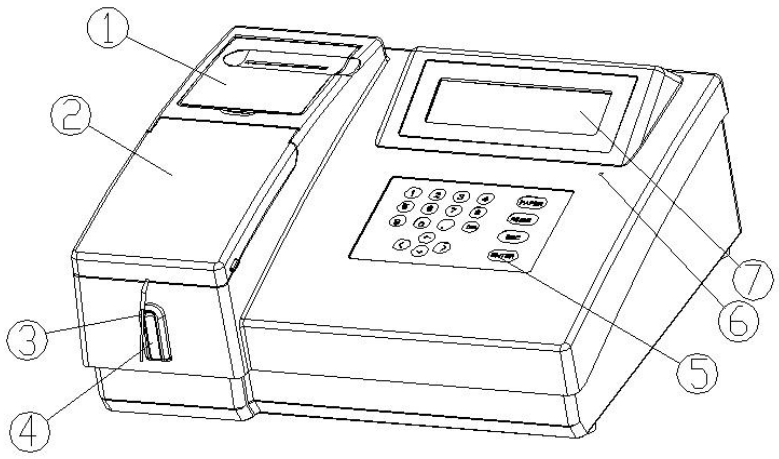


Figure 1 Front view

(1)、 Printer cover
(2)、 Lamp cover
(3)、Suction hose
(4)、Suction button
(5)、Keypad
(6) Power On LED
(7)、LCD

Keypad

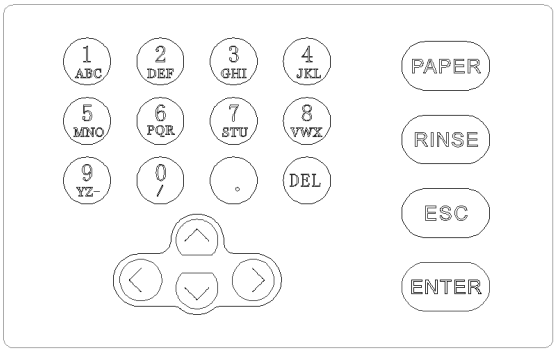
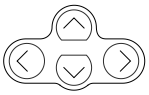


Figure 2 Keypad



Arrow keys: The cursor moves in four directions on the screen: up, down, left and right.

Manual feed button: Feed paper manually (this is also the shortcut for parameter printing)

Flush button: Clean the pipe.

Exit key: Exit the menu and cancel the operation.

Confirm button: To validate the input and save.

Rear view

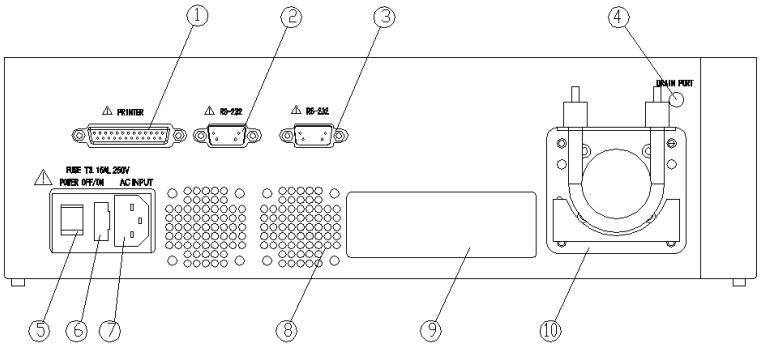


Figure 3 Rear view

1) Parallel connection for printer
2) RS-232 serial interface
3) Serial RS-232 interface
4) Drain hole
5) On/off switch
6) Fuse
7) AC input
8) Fan
9) Label
10) Peristaltic pump

Internal printer

The DTN-405 photometer features an internal thermal printer.

Flow cell and cuvette

1) As shown in Figure 4-5 below, the flow cell or cuvette is located under the lamp cover. The cover can be opened upwards.

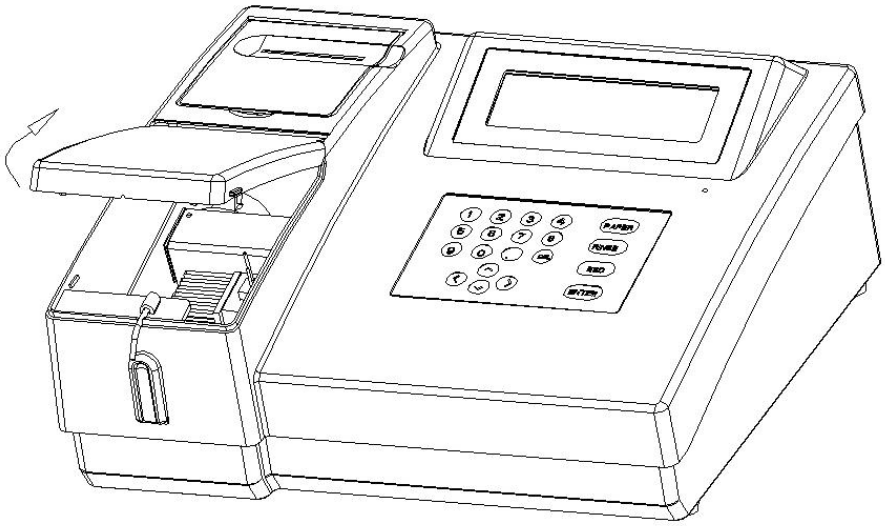


Figure 4 Opening the lamp cover

2) Internal part of the photometric system

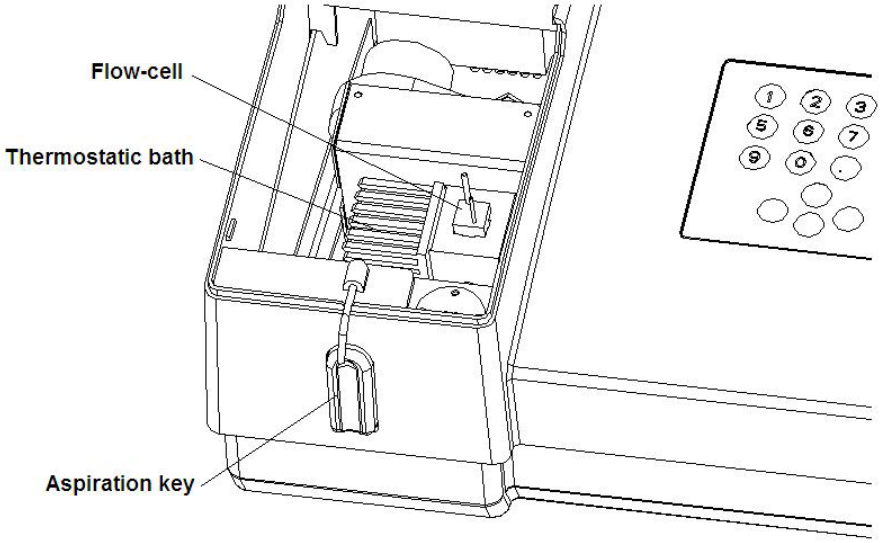


Figure 5 Internal part of the photometric system

Note

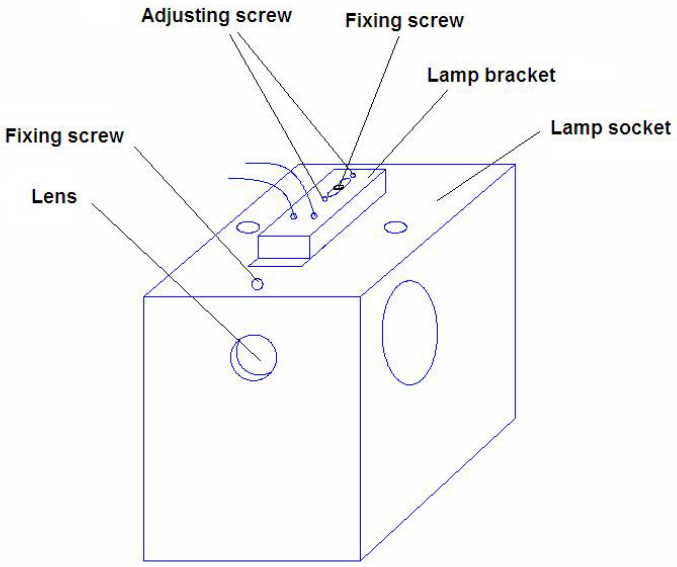
Keep the surface of the flow cell or cuvette clean.

Do not touch it with your fingers.

3) Using a cuvette instead of the flow-through cuvette
   (1) Remove the flow cell from the temperature-controlled holder.
   (2) Place the cuvette containing the sample into the holder.
   (3) The procedure is the same as that used for measurement with the flow cell.

Lamp and peristaltic pump

1) Open the lamp cover.
2) When changing the lamp, disconnect the connecting cable between the lamp holder and the power supply, unscrew the fixing screws on the lamp holder, remove the lamp holder, change the lamp, reinsert it as before and tighten the fixing screws on the lamp holder. Connect the cable between the lamp holder and the power source securely.
3) The lamp and peristaltic pump are shown in the following illustrations:



Lens	Lens
Fixing screw	Fixing screw
Adjustment screw	Adjustment screw(s)
Lamp bracket	Lamp bracket
Lamp socket	Lamp holder

Figure 6 Light source system

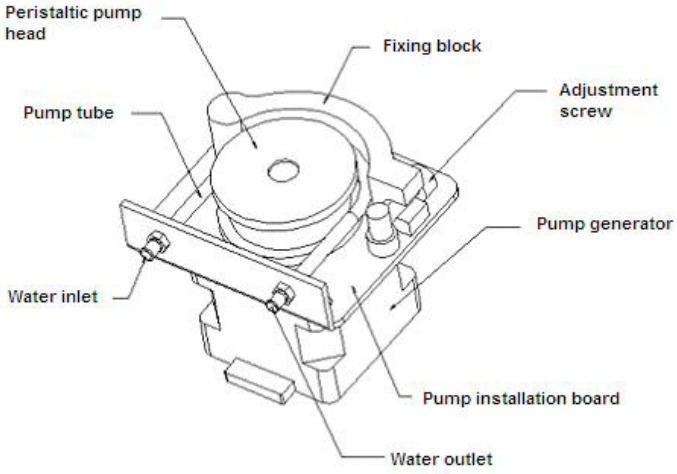


Figure 7 Peristaltic pump system

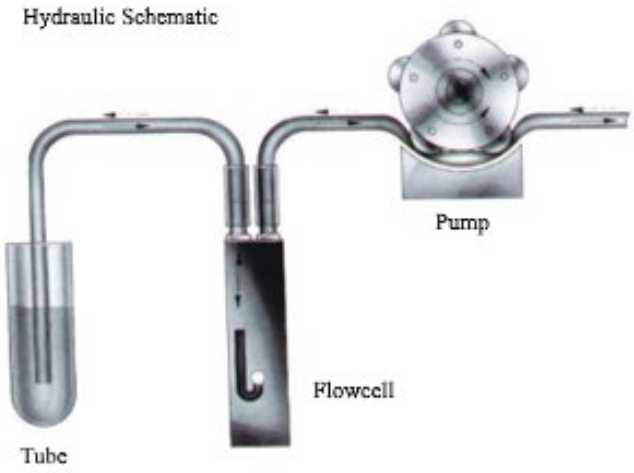


Figure 8 Peristaltic pump system

INSTALLATION

General

Unpacking the device

Carefully unpack the photometer and remove it from the plastic sleeve. Keep the boxes and packaging material until you have checked that nothing is missing, there is no (internal) transport damage and the photometer is working properly.
The box should contain the following:
DTN-405 photometer
User manual
Packing list
Power cable

Site preparation prior to installation

The DTN-405 photometer should be set up on a level surface that is not subject to strong vibrations (e.g. from centrifuges, etc.) or direct sunlight. The ventilation openings in the base plate and on the rear of the photometer must not be blocked.

Bringing into operation

Setting up the instrument

1) Plug one end of the power cable into the socket on the device.
2) Plug the other end of the power cable into the socket on the power supply unit.
AC 110/220 V ±10%
50/60±1 Hz
80VA
Warning/Note
The socket must be earthed (earth potential <5V).
The AC power supply must be stable.
Connection to circuits shared with high-power devices is not permitted. It is recommended to operate the system via a constant-voltage power supply.
In areas with unstable voltage, please use a UPS power supply to ensure normal operation of the device. Hold the plug firmly when unplugging the power cable. Never pull directly on the cable Switch off the photometer if smoke, an unusual smell or unusual noises occur from inside the photometer, and contact your supplier

As shown in Figure 9 below, open the lamp cover.

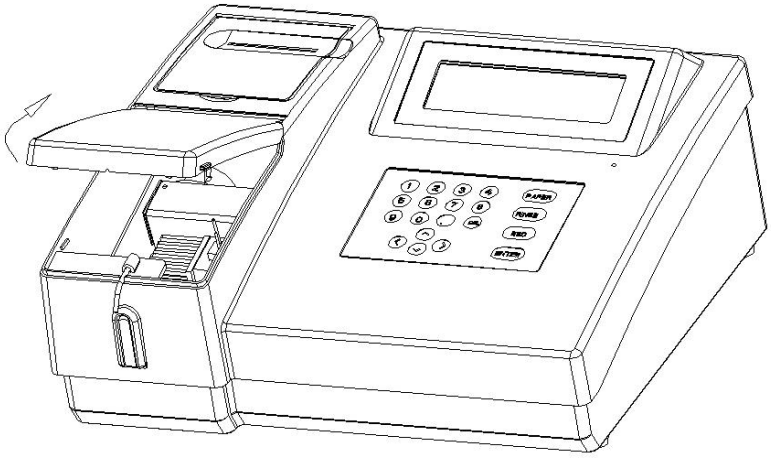


Figure 9 Opening the lamp cover

1) Remove the adhesive tape used to secure the flow cell.
2) Remove the packaging material.
3) Place the flow cell in the holder.
4) Feed the suction hose through the fixing hole on the unit
5) Close the cover.

Warning:
Do not touch the surface of the flow cell with bare hands and keep it clean.
Ensure that the suction tube is correctly positioned. Incorrect positioning can lead to mechanical stress or kinks, which may impair suction performance. This can result in the formation of air bubbles during the suction process and lead to elevated blank values.

THEORY OF OPERATION (BASIC ANALYTICAL PRINCIPLES)

Test principle:

Lambert-beer law is the basis for the absorbance measurements from which values are obtained with the device.
The chemical reaction that leads to a change in absorbance depends on the reagents used.
Mixing the reagent and sample causes a color change that can be measured using a tungsten halogen lamp.
The tungsten halogen lamp emits radiant light centered on the filament, which becomes parallel light through the convex lens, and the protective glass plays the role of protecting the convex lens. The parallel light enters the colorimetric cell containing the sample liquid to be tested, part of the light energy is absorbed by the liquid, and the emitted light is called outgoing light. On the top, the photoelectric receiving Unit converts the optical signal into an electrical signal, which is input to the front-end board for processing. The color of the filter should be complementary to the color of the solution being tested.

FUNCTIONS

For each specific IVD instrument function, information shall be provided on the following:

a) the subsystems and their purpose;

The instrument consists of an optical system, a hydraulic system, a computer control system and software.

Specifications

Resolution	0.001 Abs (display), 0.0001 Abs (internal calculation)
Light source:	Halogen tungsten lamp
Wavelength:	5 filters: 340, 405, 500, 546, 578; three additional filters can be added as an option.
Temperature control:	Ambient temperature, 25, 30, 37°C
Flow cell:	Flow cell
Interface:	Unidirectional RS232 communication
Display:	LCD display
Printing:	Internal printer
Operating environment:	10°C–30°C; relative humidity ≤70%
Storage environment:	-20°C–55°C; relative humidity ≤93%
Weight:	7 kg
External dimensions:	360 mm (L) × 318 mm (W) × 160 mm (H)
Power supply:	AC 110/220 V ±10%, 50/60 Hz ±1 Hz
Input power:	80VA
Fuse type:	Φ5×20
Fuse specification:	3.15A 250V

LIMITATIONS:

- The DTN-405 Photometer is designed exclusively for measuring clear, colored solutions (absorbance photometry). The use of reagents based on the principles of immunoturbidimetry or particle-enhanced agglutination is impermissible. Light scattering caused by latex particles or immune complexes leads to erroneous measurement results.
- Only reagents whose ingredients do not chemically attack the fluidic components of the instrument (flow cell, tubing) may be used. Reagents containing highly concentrated organic solvents, strong acids, alkalis, or aggressive surfactants for sample pretreatment are excluded from use.
- Since the DTN-405 Photometer is a semi-automated system requiring manual mixing and aspiration, only reagents explicitly validated and approved for this device shall be used
- The DTN series is technically capable of programming and executing user-defined photometric measurement methods for other reagents. However, for in vitro diagnostic use, only the DIALAB-IVD reagents specifically listed in these instructions for use, in combination with the DTN series, have been evaluated by the manufacturer. The use of other reagents falls outside the intended use of the DTN series. The analytical and clinical performance, safety and suitability of such reagent-instrument combinations have not been evaluated by DIALAB. The technical feasibility of a measurement does not constitute confirmation of the suitability or validity of the reagent-instrument combination in question. Prior to such use, the user or the responsible healthcare organisation must assess which regulatory, performance-related and quality assurance requirements must be met in the specific case of application.
- When using reagents containing strongly adherent dyes or highly viscous components, there is a risk of sample carry-over in the flow cell. In these cases, the user must ensure that an extended washing protocol is performed between individual measurements to prevent cross-contamination and the distortion of subsequent readings.

OPERATION PROCEDURE

Switching on

Switch on the DTN-405 using the power switch on the rear panel. The following message appears on the screen:

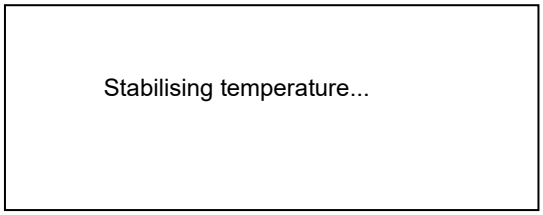


Figure 10 Temperature stabilisation

The instrument waits approximately 3 minutes for the lamp to stabilize before displaying the main menu.

The main menu is then displayed on the screen as shown in the following figure.

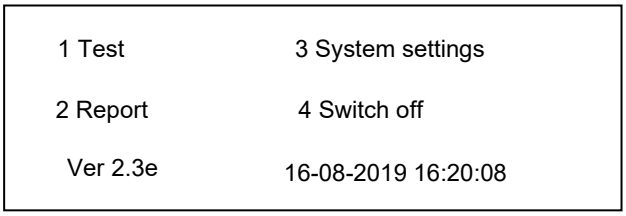


Figure 11 System main menu

Description of the main menu

1. **Test**: Editing of parameter settings, calibration settings and quality control settings. The parameters can be saved automatically. From here, you can then access the test menu.
2. **Report**: Printing of results by test and patient numbers, deletion of test results and browsing of the current month's quality control information.
3. **System Settings:** Configuring basic system parameters such as printer settings, power on/off, time settings and the external connection to an LIS system for transferring test data**.**
4. **Power Off:** The power-off function initiates a flushing process of the hydraulic system (consisting of the flow cell and tubing). If the device is switched off directly via the main switch, residues remain in the hydraulic system. It is recommended to always flush the system via the software function to ensure the accuracy of the results**.**

How do you operate the software?

The individual menu items are numbered. They can be selected either using the arrow keys or directly by pressing the corresponding number on the keyboard;

◄► the symbol on the right-hand side of the menu item name indicates that you can use the left and right arrow keys on the keyboard to change the settings.

▲▼ You can select a specific menu item by using the up and down keys on the keyboard.

System settings

The system parameters are used to configure the device's basic settings, such as the date and time. Press **the 3 key** to open the system settings menu (Figure 12).

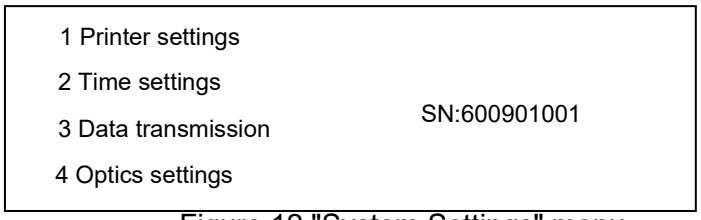


Figure 12 "System Settings" menu

1. Print settings

Press **the 1 key** in the System Settings menu; the device will switch to the following menu (see Figure 13).

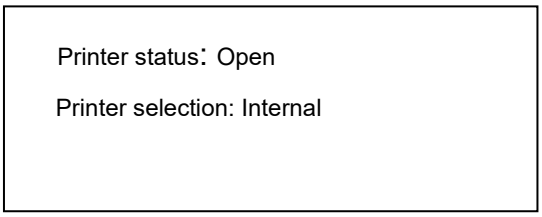


Figure 13 Printer settings

The device is equipped with an internal thermal printer. The printer status is used to switch the global print function on (open) and off (close) via the '◄► ' button. Additionally, during the test, you can choose whether to print the results of the test currently being performed, regardless of the global setting. (Please refer to the print settings during testing for detailed settings)

2. Setting the time

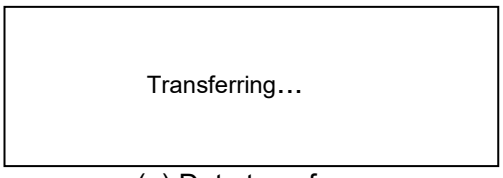
Press **the 2 key** in the system settings menu and the device will switch to the following menu

Figure 14 Setting the time

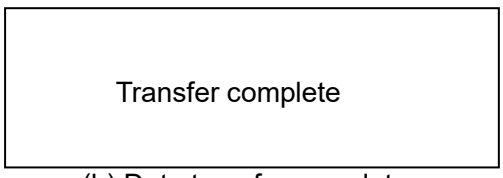
◄► , use the keys on the keypad to select the item to be changed, press the number key to change the current date or time, press the **ENTER key** to save, and press **the ESC key** to return to the system settings menu.

3. Data transfer

In the System Settings menu, press the 3 key (before doing so, ensure that a communication cable is connected between the device and the externally connected PC, and that the serial port on the externally connected PC is set to receive mode). The device will enter the following menu (see Figure 15(a)). Once the data transfer is complete, the device will indicate that the data has been transferred; see Fig. 15.



(a) Data transfer:

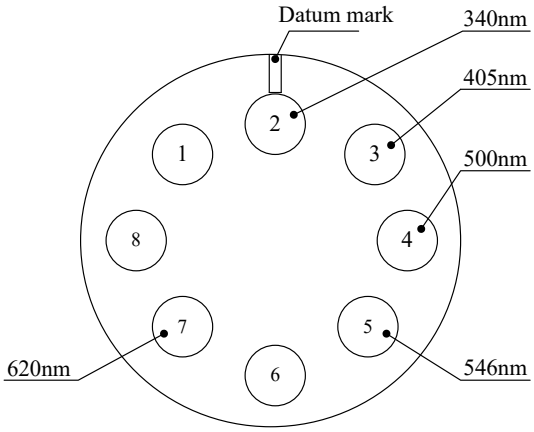


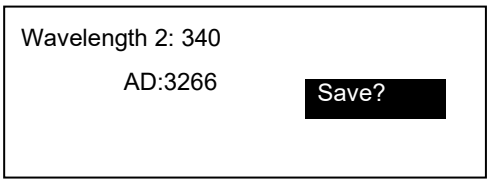
(b) Data transfer complete

Figure 15 Data transfer

4. **Optical settings**

In the system settings menu, press the 4 key to access the optical settings menu, as shown in Figure 16 (a). The wavelengths to be selected correspond to the wavelengths of the built-in filters, as shown in the following figure.





(a) AD display menu (b) Filter wheel arrangement (facing the installation side)

Figure 16 Optical settings

1. Checking the AD value

The AD value is an internal measurement that reflects the condition of the built-in optical filters and the lamp. It is always determined with water in the flow cell. The AD value should be between 2500 and 3800.

To do this, press the RINSE button to draw in a specific volume of distilled water ( ). Press the left or right button (◄►) to switch between wavelengths and check the AD value for the current wavelength.

2. Saving the AD value

As the AD value is used as a reference value for the calculation, it cannot be saved at will. You must only save the AD value again when the filters are replaced or when "Retest" is displayed continuously during the water blank test.

Wait until the AD value has stabilised, then press the ENTER key to save the AD value for the current wavelength; the "Save?" prompt will then disappear

Note:

This procedure affects test performance and is therefore only used to determine whether the lamp needs replacing or whether the blank value with water is outside the specified range.

Ensure there is sufficient water in the flow cell during this procedure.

Pressing the "ENTER" key saves only the AD value of the current filter; other filters retain their saved values

Test menu

The test menu contains test settings and test execution. Test settings include the test method, test name, unit, temperature, wavelength, blank value, delay time, test time and aspiration volume, the range of the normal reference value, the factor, standard and quality control, etc. Test execution includes blank value test, calibration test, control test and sample test.

Test settings

Select test

The tests are displayed in the main menu with their corresponding test numbers. The desired test can be selected using the directional key, the number key or the name search:

1) Select using the arrow keys: Use the up, down, left and right keys to select tests; the selected test is highlighted, and the corresponding number is displayed in the top left-hand corner of the screen.

Select after entering: The input methods are displayed in the top right-hand corner of the screen; they are "123" and "ABC". Use the "." (decimal point) key to switch between them. "123" means entering numbers. Numbers can be entered directly, whereupon the test is selected and highlighted based on the test number. “ABC” means selecting the test by entering the name of the relevant test. Enter the name as shown on the keypad and it will be displayed in the center of the top of the screen. Once you have finished entering the text, press the ENTER key to automatically select the relevant test.

Confirmation of test parameters

Select a test, press the Enter key to call up the menu to confirm the test parameters, as shown in Figure 17, press◄► the key to select "QC", "STD", "Edit" and "Ok", press the Enter key to call up the corresponding programme.

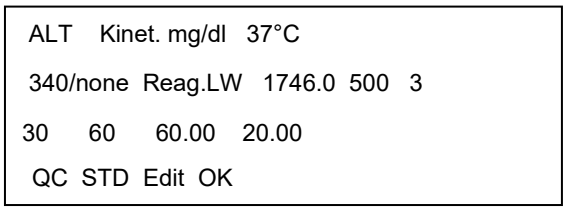


Figure 17 Parameter confirmation menu

The meaning of the individual parameters is as follows:
1st line: Test name, test method, unit, temperature
2nd line: First/second wavelength, type of blank value, factor, aspiration volume
Decimal places
Row 3: Delay time, test time, upper normal range, lower normal range
4th line: QC settings, default settings, parameter settings, test menu
Call up

Press the◄► key to switch between "QC", "STD", "Edit" and "OK"; press the **Enter key** to access the relevant programs.

Editing test parameters
Select the "Edit" menu, press **the ENTER key** to set the parameters for the relevant test.

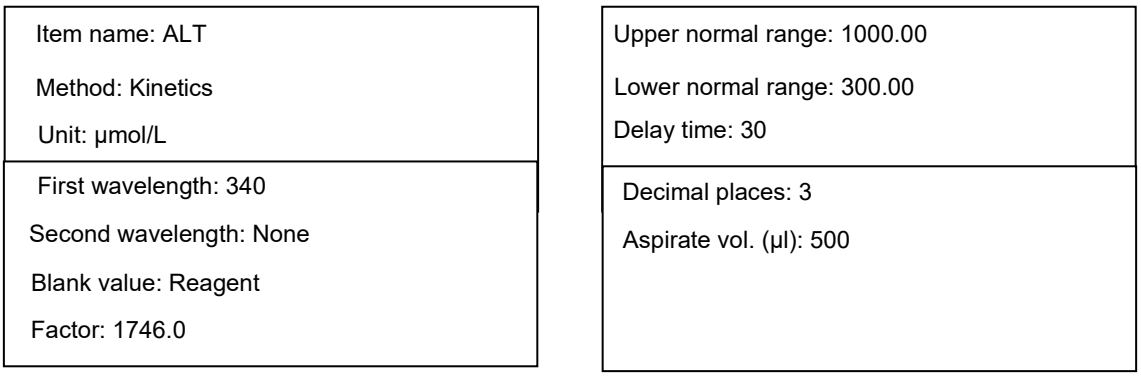


Figure 18 Menus for editing parameters

Basic procedure:

1) Select the parameter to be edited. Move the cursor by pressing on the keyboard to highlight the selected parameter.
2) **Editing settings:** If the ← symbol appears to the right of the selected item, editing is carried out directly via the keyboard. If, however, the → symbol appears, press the confirmation key to access the next submenu. Decimal places can only be entered if the field provides a decimal separator; otherwise, only whole numbers are permitted.
3) **Quick navigation:** To skip the current page without making any changes, press the ENTER key. This takes you directly to the next settings page or the next step.
4) **Printing the test parameters:** Once configuration is complete, the selected parameters can be printed from within the settings menu by pressing the PAPER key.
5) **Save and exit:** On the last page of the test settings, press the ENTER key to automatically save the configured parameters and return to the test menu.

Setting the parameters:

1) Test name: The system allows 60 tests to be saved
2) Method: Select the test method, such as end-point method, two-point method, or kinetics. Select the method using the '◄► ' option.
   a） **End-point method:** After a required incubation time, the reaction reaches its maximum color development or end-point. The color of the reaction remains stable and constant for a certain period. During this time, an absorption measurement is taken. Both monochromatic measurement (one wavelength) and bichromatic measurement (two wavelengths) can be selected.
   b） **Kinetic method:** Kinetic determinations are tests in which enzyme activity is measured continuously over a specific period and finally normalised to 1 minute
   c） **Two-point method**: After a predefined incubation time, two absorbance measurements are carried out at different, programmed time intervals. The final result is calculated from the difference between the two measurements. Each of the measurements taken is an average of a large number of measurements carried out in rapid succession.
3) Unit: Select the unit for the test result: mg/dL, mg/L, g/dL, μg/dL, g/L, μmol/L, mmol/L, mol/L, U/L, IU/L, U/g Hb and blank value. Select the unit using the◄► button.
4) Temperature: Select the test temperature: ambient temperature, 25, 30 and 37. Select the temperature using the◄► button.
5) Primary wavelength: Select the primary wavelength of the test in accordance with the test requirements: by default, you can choose from 5 wavelengths: 340 nm, 405 nm, 500 nm, 546 nm and 578 nm. Select the primary wavelength using the '◄► ' button.
6) Secondary wavelength: Select the secondary wavelength for the test in accordance with the test requirements. The following options are available: 340 nm, 405 nm, 500 nm, 546 nm, 578 nm and none. If testing is carried out at only one wavelength, the secondary wavelength must be set to "none". Select the secondary wavelength using '◄► '.

7) Blank value: Select the blank value test; the following options are available: none, reagent blank and sample blank. First select the method using◄► . If the endpoint method is selected, reagent blank and sample blank can be selected. With the two-point method, only a reagent blank can be selected. With the kinetic method, no blank setting can be selected.
8) Factor: Calculation factors can be entered here; negative and positive values can be switched using the key ◄► . The system supports the direct entry of factors and the determination of calculation factors via system calibration (standard test).
9) Upper limit of the normal range (reference range).
10) Normal range low: The lower limit of the normal range (reference range).
11) Delay time: Enter the delay time for the test. The delay time is the time from the completion of the aspiration to the actual measurement (when using the flow cell).

Note:

- ***A certain delay time is necessary to temper the samples and to eliminate tiny bubbles in the flow cell.***
- ***For most endpoint method tests, the delay time is 5 seconds.***
- ***For kinetic methods below 25°C, the delay time should not be less than 10 seconds;***
- ***For kinetic methods below 30°C, the delay time should be no less than 12 seconds;***
- ***Kinetic method below 37°C, delay time should be no less than 15 seconds.***

12) Test time: Enter the reaction time of the test (end-point methods do not require this parameter).
13) Decimal places: Number of decimal places in the result. The maximum is 4.
14) Aspiration volume: The volume of solution aspirated by the peristaltic pump. This parameter specifies the volume of liquid to be tested each time. To ensure the accuracy of the test, the aspiration volume is generally at least 400 µl. Once you have set all parameters, press the **ENTER key** to automatically save the parameters and return to the test parameter confirmation menu. Press the **ESC key** to return without saving.

Note: Generally, an aspiration volume of 500 µl can ensure a cross-contamination rate of less than 1%. The aspiration volume can be increased or decreased and is specifically controlled by entering a number on the keypad.

Calibration settings

In the parameter confirmation menu, select "STD" and press the ENTER key to access the standard parameter settings menu as shown in the figure below.
Method: The calculation methods for the standard test are linear regression or non-linear regression. Select the appropriate option using the keys:◄► .
Number of standards: The number of standards used for calibration. The maximum number of standards is 8.
Replicates: The number of times the test was performed for each standard.
Concentration: The concentration of the standards used for calibration.

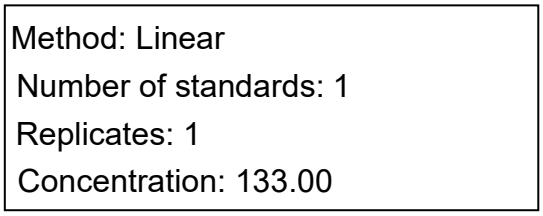


Figure 19 Setup menu for standard parameters

Note:

- ***If non-linear regression is selected, the number of standards should be greater than 3; otherwise, calibrate using the linear regression method.***
- ***If more than two standards are selected, all are measured with the same number of repetitions***
- ***If more than three standard concentrations are entered, the standards must be programmed in ascending or descending order of concentration; otherwise, calibration will not be successful. To ensure an ascending calibration series, the device displays the previous concentration on the right-hand side of the screen from the moment the concentration of the third standard is entered***

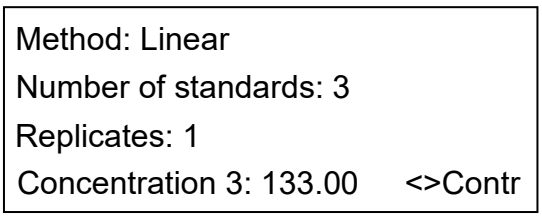


Figure 20 "Standard Concentration" menu

Once you have set all parameters, press the **ENTER key** to save the parameters automatically and return to the test parameters menu. Press **the ESC key** to return without saving.

QC settings

In the parameter confirmation menu, select the "QC" option and press **the ENTER key** to access the quality control parameter settings menu as shown in Figure 21.
Control: Two controls can be defined for each test. Use the◄► to select the relevant control.
Mean: Target concentration of the control
SD: Standard deviation.
Batch number: Corresponding batch number of the control used.

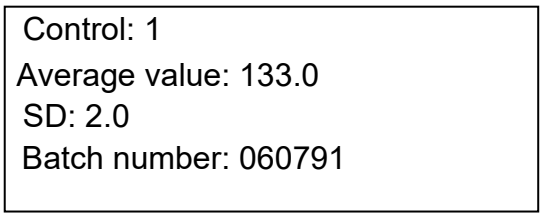


Figure 21 Quality Control Parameters menu

Once you have set all parameters, press the **ENTER key** to save the parameters automatically and return to the Test Parameters menu. Press the ESC key to return without saving.

Printing parameters

In the parameter confirmation menu or the parameter settings menu, press the **PAPER** key to print the parameters for the current test.
Once you have set all parameters, select "Ok" in the Test Parameters menu. Press the **ENTER key** to access the Test menu. Press the ESC key to return to the selection menu.

Programming new tests

The device can store 60 tests, including 47 fixed tests and 13 user-defined tests, whereby the user-defined tests can also be created directly on the basis of the 47 fixed tests. The user-defined methods are located below the fixed tests

1) Move the cursor to the end of the list of fixed tests. The list of all tests is numbered consecutively. The user-defined tests start with the first number in the list that has no label
2) Press the Enter key to select the test, then go to Edit so that you can carry out the programming.
3) For the alphanumeric test name, the number keys are assigned multiple characters. Press the relevant key several times to cycle through the sequence of all characters available on that key ( )
4) Set the test parameters, press the **ENTER key** to automatically save the user-defined element name and parameters, and start the test process.

Running the test

After configuring the test parameters, press the ENTER key to automatically save the settings and start the analysis process. The system first performs the filter change according to the selected wavelength and initialises the other parameters. The corresponding status message is displayed as shown in Figure 22. The filter change takes only a short time, usually just a few seconds; the system then automatically switches to temperature control mode.

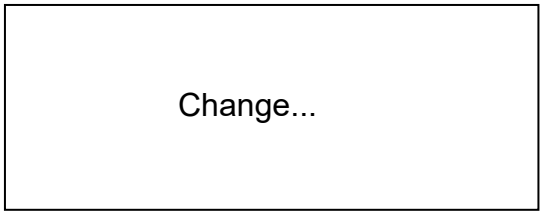


Figure 22 Filter change display

Once the filter change is complete, the system switches to temperature control, as shown in Figure 23. The temperature stabilisation time depends on the temperature difference before and after the test/filter change. It is usually between a few seconds and 3 minutes.

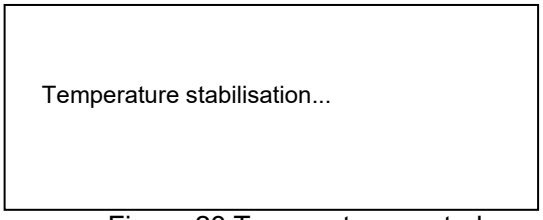


Figure 23 Temperature control

Blank measurement

Once the filter change and temperature control have been completed, the system automatically switches to blank measurement. Depending on the test parameters set, the system determines whether the reagent blank should be measured. If no blank or sample blank is selected in the blank settings in the "Parameter Settings" menu, only water is measured as the blank. If reagent blank is selected, a water blank and a reagent blank are measured.

Figure 24 Blank value measurement

As described in Figure 24, first carry out the water blank measurement. To do this, please select “Please aspirate” to the right of the water blank value (Water-BL). Prepare distilled water and press the sample aspiration button; the system will test automatically and display the results of the water blank value. If the water blank value is too high, “Please aspirate” and “retest” will be displayed and the measured AD value will be shown below, see Figure 25. The water blank measurement must be repeated. If “Please aspirate” and “retest” is still displayed after repeating the process several times, it is recommended that you check the light path of the flow cell

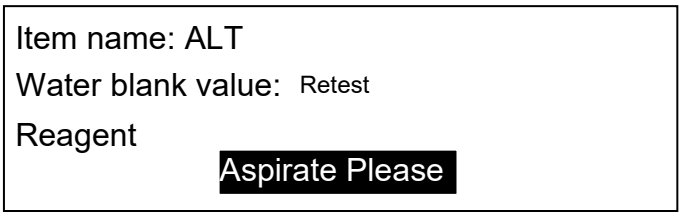


Figure 25 Anomaly in the water blank value

After testing the water blank, the reagent blank can be measured and the results are then displayed.
After testing the reagent blank, the system automatically switches to the test selection menu (see Figure 25).

The cursor points to "Test sample"; use the ▲▼ key to select whether to test a standard, QC or a sample. Press the ENTER key to start the corresponding test process, and press the ESC key to return to this test selection menu in the relevant test menu.

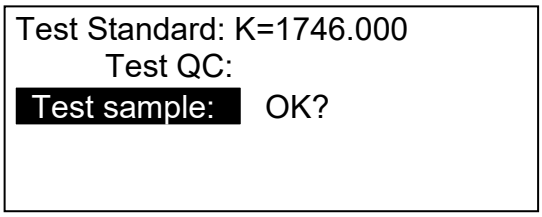


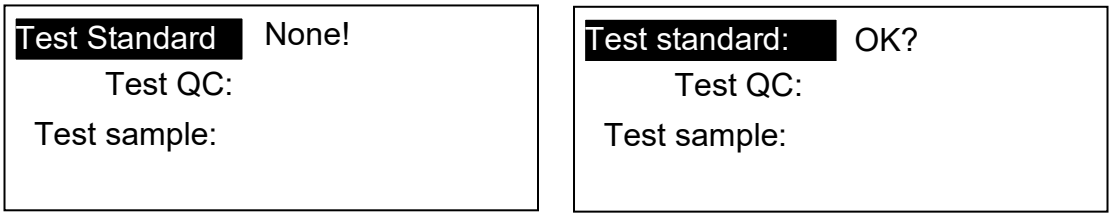
Figure 26 "Test" selection menu

Measurement of the standards

The system offers two options for determining the standard factors. The first method involves manually entering the factors during parameter configuration; in this case, “K=xxx” is displayed in the test selection menu (see Figure 26). The second method involves determining the standard factors via a standard measurement. This section describes the basic procedure for such a standard measurement in detail.

1) Test selection

Move the cursor in the test selection menu to the “Test standard” option. The system will now check the correctness of the configured standard parameters. If the settings are incorrect, the message “None!” appears (see Figure 27a), which means that a standard measurement is either not required or is not possible due to incorrect parameters. If the settings are correct, the prompt “Ok?” appears (see Figure 27b). Confirm with the ENTER key to start the test procedure. Otherwise, move the cursor to select another test or press the ESC key to return to the main menu.



(a) Standard parameters contain errors (b) Standard parameters are correct

Figure 27 Testing the standard

2) Test

After confirming with “OK”, the standard test menu appears; see also the following figure. In the menu, the name of the current test is displayed under “Test”. “STD” indicates the number of the current standard, and the corresponding concentration value is displayed on the right-hand side. Example: “Concentration: 133.00”. The current status of the test process and the test result are displayed under "Status". "Please aspirate", "Testing..." and "Save?" are displayed in sequence in the middle section of the menu.

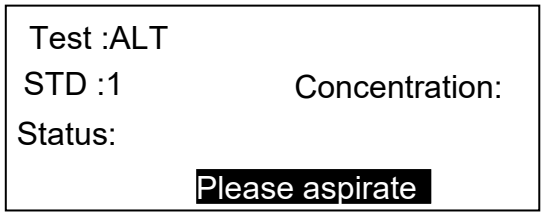


Figure 28 Standard test menu

3) Saving the results

After testing the standards, the system calculates the respective standard factors. The calibration values K and b are displayed in the "Test Result" column and can be saved by pressing the ENTER key. The results of subsequent tests are calculated based on this calibration result until the standard factors are reset or recalibrated and saved, as shown in Figure 29. Press the **ESC key** to cancel saving. If recalibration is required, please select "Standard Test" from the test selection menu to perform the calibration .

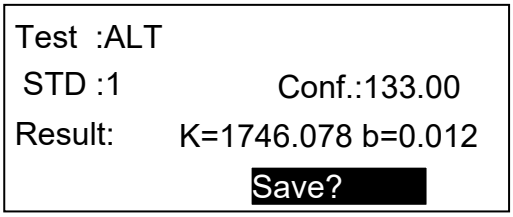
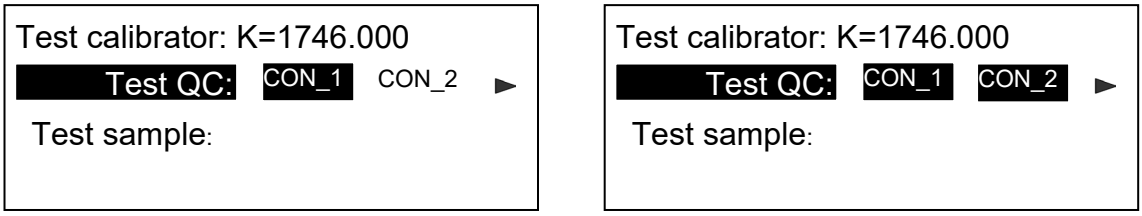


Figure 29 Saving standard tests

Measurement of controls

1) Test selection
In the test selection menu, move the cursor to "Test control The programmed control(s) are displayed on the right-hand side (see Figure 30). Up to 2 controls can be programmed per test (see **Confirmation of test parameters**)
Select the desired control and press the **ENTER key** to call up the control measurement, as shown in Figure 30.



(a) Select a single quality control (b) Select a double quality control
Figure 30 Selecting the quality control test

2) Test
In the test menu for the QC checks (Figure 31), the name of the current test is displayed under "Test". "QC" shows the number of the current check (1 or 2), and the corresponding batch number is shown on the right-hand side. Example: "Batch: 070691"; under "Status", the current status of the test process and the test results are displayed. "Please aspirate", "Test..." and "Save?" are displayed in sequence in the central area of the menu.

Figure 31 Quality control test menu

3) Saving the results
After testing the controls, the system calculates the results. The results are displayed and assessed according to the stored acceptance criteria (“C>2SD” means that the QC result is greater than two standard deviations; otherwise, this information is not displayed), and “Save?” appears on the display. Press the **ENTER key** to save the quality control results. If 2 controls are set, test the two controls in sequence. Valid quality control results are saved, with only one quality control result for the same test and the same batch number being saved each day), as shown in Figure 32. Press **the ESC key** to repeat the quality control.

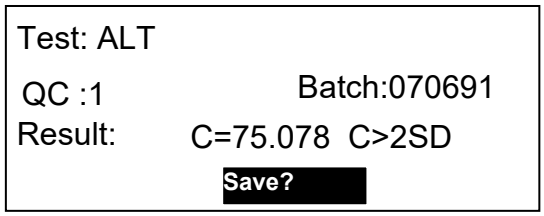


Figure 32 Saving quality control tests

Measuring the samples

From the menu, select "Test Sample"

1) Overview

If a blank value is defined in the settings, the blank value is measured before the sample; see also 33(a). If no blank value is defined, the system goes directly to the test menu; see Figure 33(b)

The name of the selected test is displayed for both “Blank” (default value) and “Test”.

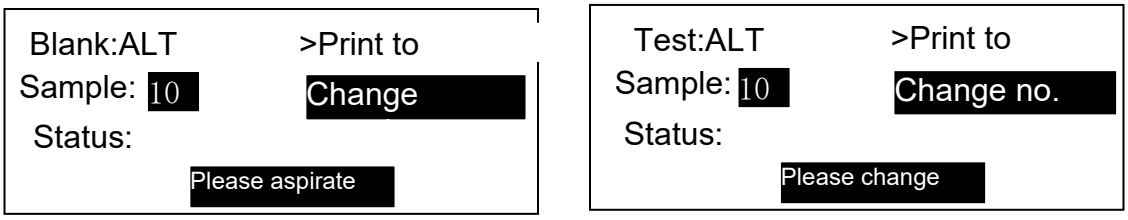
By selecting "Print to" or "Print from" in the top right-hand corner of the window, immediate printing via ► can be enabled or disabled.

"Sample" displays the next sample number to be tested; this can be changed before testing by selecting "Change No.".

"Status" displays the current status of the test and "Result" displays the measured absorbance and concentration of the sample.

Follow the instructions such as "Please aspirate", "Testing..." and "Print..." in the central section of the display.

If "Overwrite?" is displayed after the test, this means that this item already contains the test result for the same sample number on the same day. Press the ENTER key directly to overwrite the existing result. Enter a new sample number and then press the **ENTER key**; it will be saved as a new sample.



a) Measuring the blank value (b) Testing the sample

Figure 33 Example of a test menu

2) Performing a test

a） Confirm the sample number (the sample number displayed is the number of the sample to be tested) and enable or disable the instant print function using the ‘►’ button, as shown in Figure 33.

b） If "Please aspirate" is displayed, prepare the sample and press the aspirate button. The device aspirates the liquid according to the set aspiration volume and the test process begins automatically. "Testing..." is displayed on the screen, and the elapsed time is shown in seconds under "Status", see Figure 34.

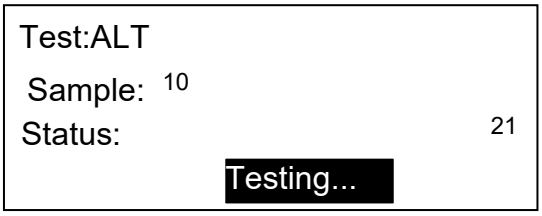


Figure 34 Performing a test

c） Once the test is complete, the test results are saved automatically. If a result already exists for the same sample number with the same test for the same day, “Overwrite?” is displayed. Press the ENTER key to overwrite the existing result directly. Enter a new sample number and then press the **ENTER key** to save the result under a new sample number,

d） Print the results. If the instant print function is selected, you can enable or disable it using the ‘►’ button.

e） Once the current test and printing are complete, the sample number automatically increments by 1 and the next sample can be tested.

f） Follow the on-screen instructions to ensure that samples can be tested continuously at . If you need to measure a control, perform a calibration or stop the test whilst samples are being tested, press the **ESC key** to return to the test selection menu and select the appropriate option.

Report

The report menu allows you to view and print measurements from a specific period in report form. You can choose to list by patient samples, controls or tests.

Press the **2 key** in the system's main menu to access the report menu, as shown in Figure 35. These are the Sample Report, Test Report and Control Report, and you can select the relevant menu items using the number keys **1**, **2** and **3**.

Sample report: Search the test results by date and sample number;
Test Report: Search test results by date and test;
Control Report: Search the control results by month, item number and quality control batch number.

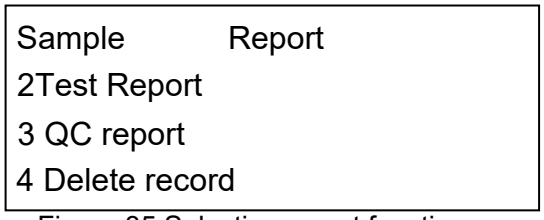


Figure 35 Selecting report functions

Note: The DTN-405 photometer can store a maximum of 2200 test results. If the test data exceeds the system's storage capacity, the system will automatically delete some of the older data. In this case, please wait a moment to allow the test to complete automatically, then restart the test.

Report by sample number

Enter the time range and the sample number to search for the test results. Enter the start date and the end date; the end date must be after the start date or on the same day. Enter the sample number you wish to search for in "Sample Number". " -" means from number A to number B, and B must not be smaller than A. If A is equal to B, a single sample number is searched for. In Figure 36, the test results for sample numbers 1, 2 and 3, which were tested on 9 November 2006, are searched for.

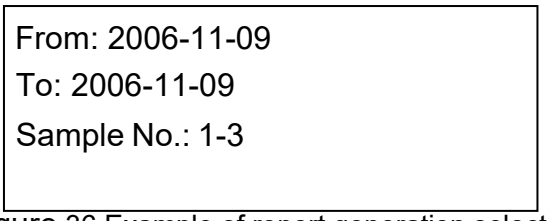
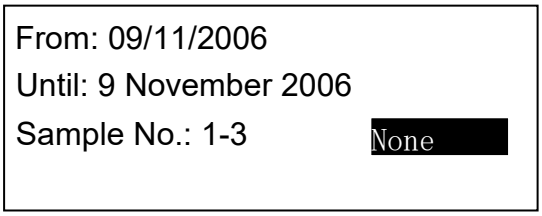
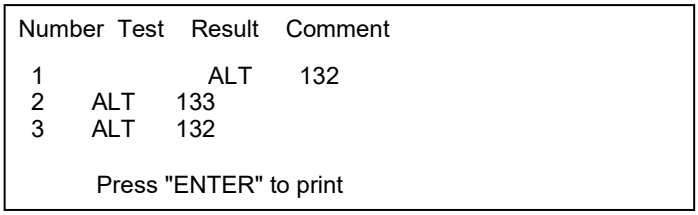


Figure 36 Example of report generation selection

After entering the time range and sample number, press the ENTER key to search for results that meet the criteria. If no records are found under the defined conditions, 'None' is displayed on the right-hand side of the window, as shown in Figure 37(a). Records that meet the criteria are displayed as shown in Figure 37(b).



(a) No results



(b) List of results

Figure 37 Example of a report by sample number

In the search results display window, as shown in Figure 37(b), the following functions are available:

- Page up/down: A single page can only display 3 records, and records spanning multiple pages can be viewed

by turning the pages using the key.
- Print: Press the ENTER key to print all search results.
- Delete: Press the DELETE key to delete all search results.
- Return: Press the ESC key to return to the search window.

Note regarding the "Comment" in the display and print report:
If the values are within the normal or reference range, no comment is displayed.
"H"----Test result is higher than the maximum reference value.
"L" --- Test result is lower than the minimum reference value

Report after test

Enter the time range and the test number to search through the test results. You will find the test number displayed to the left of the test in the test list. Enter the start date and/or the end date, bearing in mind that the end date must be after the start date or on the same day as the start date. Enter the test number you are looking for in the "Test number" field. The test name corresponding to the selected test number is displayed on the right-hand side. Alternatively, the test name can be entered directly if “ABC” is displayed in the top right-hand corner of the screen. The decimal point key “.” is used to switch between numbers and letters. If the entry is made, for example, as shown in Figure 38, the system will search for all results of the ALT test from 9 November 2006.

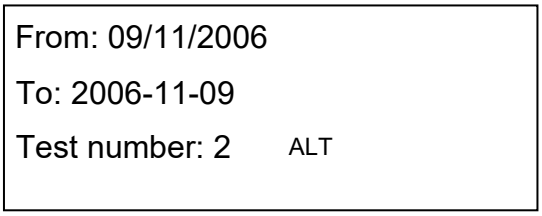
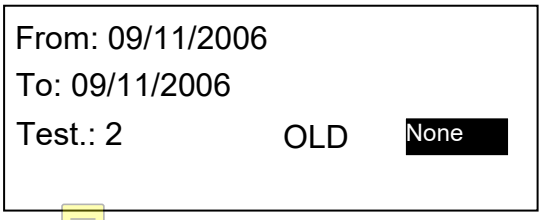
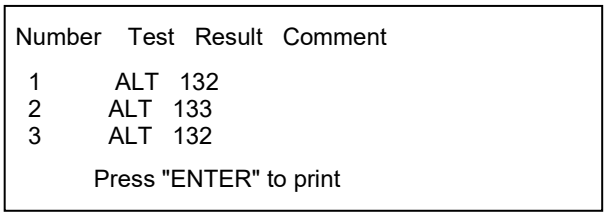


Figure 38 Search by test number

After entering the time range and test number, press ENTER to search for results that meet the defined selection criteria. If no records are found, ‘None’ is displayed in the bottom right-hand corner of the window, as shown in Figure 39(a). Records that meet the defined conditions are displayed, as shown in Figure 39(b).



(a) No results



(b) List of results

Figure 39 Example of a report by test number

In the search results display window, as shown in Figure 39(b), the following functions are available:
- Page Up/Down: A single page can only display 3 records, and records across multiple pages can be viewed by turning the pages using the key.
- Print: Press the ENTER key to print all search results.
- Delete: Press the DELETE key to delete all search results.
- Return: Press the ESC key to return to the search window.

Note regarding the "Comment" in the display and print report:
If the values are within the normal or reference range, no comment is displayed,

. "H"----Test result is higher than the maximum reference value.
"L" --- Test result is lower than the minimum reference value.

QC Report

Enter the month and day, the test number and the batch number of the control to search for the results of the controls. Alternatively, the test name can be entered directly if "ABC" is displayed in the top right-hand corner of the screen. The decimal point key "." is used to switch between numbers and letters. Enter the required batch number for the control in the "Batch number" field, see Figure 40. The system searches for the results of the ALT test quality control with batch number 070691 from November 2006.

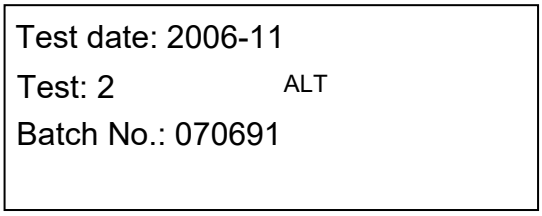
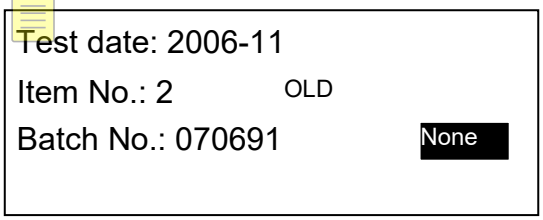
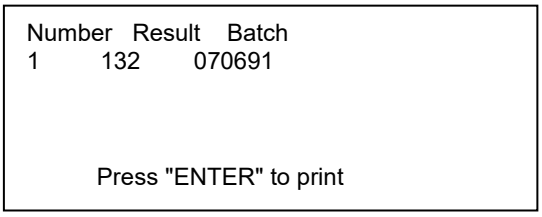


Figure 40 Search for QC Report

After entering the month, test number and batch number of the control, press ENTER to search for results that meet the defined selection criteria.
If no records are found, "None" is displayed in the bottom right-hand corner of the window, as shown in Figure 41(a). Records that meet the defined conditions are displayed as shown in Figure 41(b).



(a) No results



(b) List of results

Figure 41 Example of a QC report

In the search results display window, as shown in Figure 41(b), the following functions are available:

- Page up/down: A single page can only display 3 records, and the records across multiple pages can be viewed by turning the pages using the key.
- Print: Press the ENTER key to print all search results.
- Delete: Press the DELETE key to delete all search results.
- Return: Press the ESC key to return to the search window.

Note regarding the "Comment" in the display and print report:
If the test result is within the defined limits, nothing is displayed.
"H"----Test result higher than 2SD.
"L" --- Test result lower than 2SD.

Delete data set

All stored test and control results for the device can be deleted using this command, as shown in Figure 42

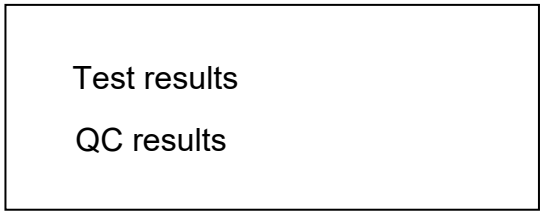


Figure 42 Search criteria for quality control

All test results or quality control results are deleted here. Individual results can be deleted as described in Sample report section

Switching off the device

Once you have completed all the tests, return to the main menu and press the **4 key** to run the shutdown program. When the message ‘Shut down?’ appears on the screen, as shown in Figure 42, press the **ENTER key**. If you press the **ESC key**, the device will not shut down and you will return to the main menu.

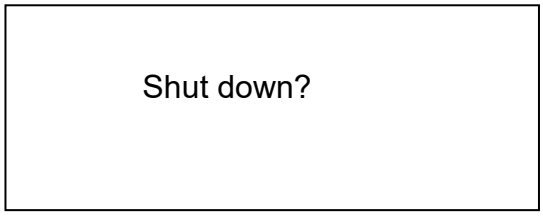


Figure 43 Confirmation of shutdown

Once you have confirmed shutdown, the information shown in Fig. 44 will appear on the display. This indicates that the device is ready to aspirate distilled water for cleaning the flow cell.

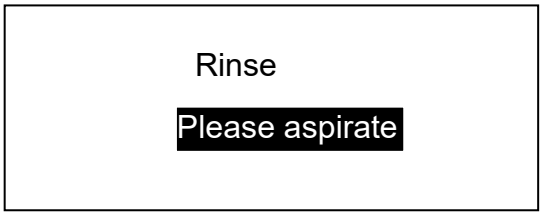


Figure 44 Ready to aspirate distilled water

Prepare sufficient distilled water, press **the aspirate button** or **the RINSE button** to clean the flow cell. The following information is displayed on the screen (Figure 45).

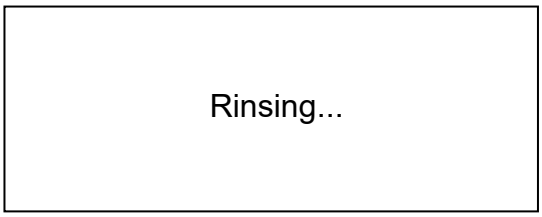


Figure 45 Cleaning the flow cell

After cleaning the flow cell, the system displays "Please switch off!", see 46.

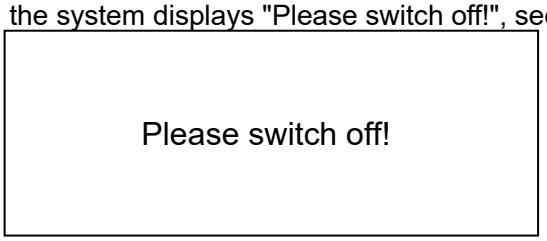


Figure 46 Switching off

Now switch off the mains switch.

Maintenance

Overview

The **DTN-405 photometer** is a clinically precise analyzer, and daily maintenance must be carried out properly to keep the instrument in good condition.

Cleaning the appliance

Cleaning the device surface

- Keep the area around the device clean.
- A neutral cleaner and a damp cloth can be used to clean the surface of the device.
- Please use a soft cloth to clean the liquid crystal display.

Warning: Please avoid contact between the instrument and solvents or aggressive cleaning agents

Cleaning the flow cell

The flow cell must be kept clean to ensure the accuracy and reliability of the test results.

1. Cleaning the exterior

a） The flow cell must be positioned in accordance with the requirements. (see 1.5.5)

b） If the outside of the flow cell is dirty, a soft cloth moistened with alcohol can be used for cleaning.

2. Cleaning the inside

c） Place the container of distilled water under the suction tube, press the **RINSE button** and start the rinsing function. Press **the RINSE button** again to stop the rinsing process. Rinsing usually continues for half a minute.

d) Glassware cleaner or diluted hydrochloric acid (0.1 N), diluted Tween 20 (2–3 drops/L) can be used to clean the flow cell. Press the RINSE button to draw in the cleaner, then press the RINSE button again to stop the peristaltic pump. Allow the cleaner to act in the flow cell for 5 minutes, then use distilled water to rinse continuously for 1 minute. This process may be repeated if necessary.

The flow cell must be cleaned under the following conditions:

- When the instrument is switched on, the water blank value is too high.
- Between tests.
- Before switching off.

Warning: Do not leave any reagent residues in the flow cell for an extended period.

Maintenance of the device

Replacing the fuse

The fuse is installed in the fuse box next to the mains switch on the rear of the instrument.
Fuse specification: 3.15A 250V.
Users are advised to use a voltage-regulated power supply.

Warning:
The fuse with the above specifications must be used.
Before replacing the fuses, ensure that the power cable has been disconnected. Failure to do so may result in serious injury

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Replacing the peristaltic pump tube

It is recommended that the pump tube be replaced after 6 months of operation.

- Turn the peristaltic pump tube lock clockwise and open the rear plate of the pump tube.
- Remove the tube from the rotor.
- Loosen the fastening at the pump tube connection and fit a new pump tube
- Slide the pump hose onto the rotor and lock it in place (turn the locking mechanism of the hose pump anti-clockwise).

Note: If the pump hose is not installed correctly, the unit will not draw in liquid.

Replacing the Suction Hose

If the suction hose (or flow cell) is blocked by various residues, a syringe can be used for cleaning. If the suction hose is severely damaged or blocked, you can replace the hose. Proceed as follows:

- Remove the flow cell
- Pull the hose off, taking care with the connectors.
- Fit the new hose.

Simple troubleshooting

Fault	Solution
The device will not switch on	- Check that the mains adapter is not loose - Check the fuse - Check the power supply
The photometer lamp is not lit	- Check the power supply - Check the lamp and replace it if necessary
The internal printer cannot print	- Check the plug
No liquid in the flow cell	- Check that the peristaltic pump is running normally. - Check the connections of the suction hose, pump hose and flow cell. - The suction hose is too long or too short. - The suction hose may be blocked and should be cleaned - The flow cell is heavily soiled
The photometer is not measuring	- Check the photometer bulb - Try a different wavelength
The blank value is too high	- Clean the flow cell. - Draw in fresh distilled water. - Check the photometer bulb
The reproducibility of the result is poor	- There are bubbles in the flow cell, and it should be washed. - Check the flow cell. - The amount of reagent used is too small and the aspiration volume should be increased. - Replace the photometer bulb. - The reagent is contaminated.
The aspiration volume of the flow cell is not constant.	- Check whether the aspiration tube is blocked. - The peristaltic pump tube may need to be replaced. -
The quality control is not within the target range	- Check the expiry date of the reagent. - Check that the settings are correct and whether the parameters need to be revised. - Ensure that the QC controls are not contaminated. - Measure the control again using other methods. - Check the flow cell and use a new reagent and a new control