

Vario Photometer plus
DP 550
Operating Manual
Version 5.16 / 5.16 SI
Edition 2024-02

Dear customer,

We are pleased that you have chosen the Vario Photometer plus from Diaglobal GmbH and thank you for the confidence you have placed in us.

The Vario Photometer plus belongs to a new generation of small mobile devices developed by Diaglobal GmbH and specially designed for on-site analysis.

With the software version V5.3 and higher, an automatic test of the device function has also been integrated. Therefore, the Vario Photometer plus complies with the requirements of the guidelines of the German Medical Association.

With the Vario Photometer plus, 9 clinical-chemical parameters can be determined. The device can be supplied with SI units of measurement on request (see chapter 9, Technical Data, table Measuring Ranges).

The kits and accessories required for the test are also available from Diaglobal GmbH.

All the best for your work with the new Vario Photometer plus!

Yours
Diaglobal GmbH

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1. General information on the Photometer

Device name: Vario Photometer plus

Model: DP 550

Features: In-vitro diagnostics, measuring device for the determination of selected clinical-chemical parameters in blood, serum/plasma and cerebrospinal fluid

Manufacturer:



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The Vario Photometer plus fulfils the basic requirements of Appendix I of Directive 98/79/EC regarding in-vitro diagnostics.



The conformity of the device with Directive 98/79/EC is confirmed by the use of the CE marking.

2. Installation

For trouble-free operation of the device, the following environmental conditions must be met:

- Ambient temperature: 0 °C ... 40 °C
- No direct exposure to sunlight or similar sources of radiant heat
- Free from excessive dust
- Free from vibrations
- Free from interference by electromagnetic waves
- Operation on a horizontal surface

Please observe the following instructions for use:

Insert a rechargeable battery or normal battery if the device is to be operated independently of a power supply or connect the photometer to a power supply unit.

Press the **<ON/ENTER>** key (Fig. 1) to activate the internal device check which is automatically carried out by the device.

The device is then immediately ready for measurement.

3. Description of the device



Fig. 1

3.1 Power supply

The Vario Photometer plus can be operated as desired using a power supply, a (9V block) battery or (model 6F22 or PP3) rechargeable battery.

3.1.1 Mains power operation

The photometer is supplied with a power supply unit for operation on a mains voltage in the range of 100 V ... 240 V AC. The mains plug is marked with a Diaglobal logo (sticker).

The connector plug of the power supply unit is connected to the power supply socket on the back of the device.

3.1.2 Mains-independent operation

To insert the rechargeable battery or the normal battery:

Unscrew the knurled screws on the bottom of the device and remove the battery compartment cover. Connect the battery to the push-button contact and insert it into the device. Replace the battery compartment cover and screw in the knurled screws.

Notes:

- The Vario Photometer plus can be operated using a power supply without the need to remove the rechargeable battery or the normal battery.
- The rechargeable battery cannot be charged while it is installed. A separate battery charger is required for this purpose.
- If the photometer is operated with a rechargeable battery, we recommend fully charging it before use and carrying a charged spare battery with you.

3.2 Measuring system

The optical section is shown in Fig. 2.

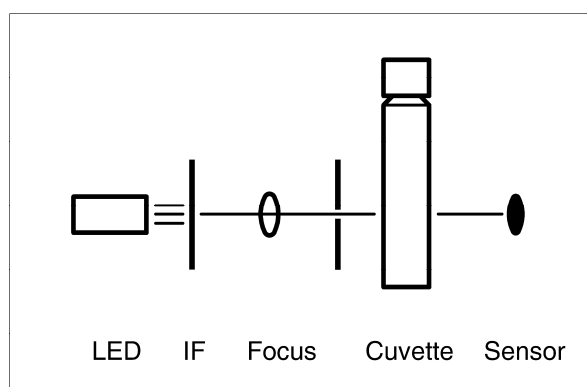


Fig. 2

The light emitted by an LED is first selected into its wavelength ranges (365 nm / 520 nm / 546 nm) by an interference filter IF (FWHM \sim 5 nm) and then bundled and directed onto the cuvette in the shaft. After passing through the cuvette, a broadband photosensor converts the light falling on its sensor surface into a current, proportional to the intensity.

4. Service

4.1 Adjustment and calibration

The device is adjusted and calibrated at the factory on delivery, adjustment by the customer is not necessary.

Adjustment is carried out via the interface socket on the rear panel. It can only be carried out at the factory, adjustments by the customer are not possible.

Information on calibrating the device can be found in chapter 6 Quality control according to the Guideline of the German Medical Association.

4.2 Maintenance

The device is maintenance-free. Maintenance after the warranty period is recommended, but not mandatory.

Due to the integrated test of the unit functions (chapter 8.5) and regular tests with control material, maintenance is only recommended if one of these two test functions indicates an error message.

4.3 Cleaning instructions

Commercially available decontaminating solutions commonly used in clinical chemistry laboratories, such as Mikrozid® AF Liquid, Bacillol® plus, 3 % Kohrsolin® or similar, are recommended for cleaning the device and the surface. Before cleaning the unit with a soft cloth and the decontaminating solution, it must be switched off and the electrical power supply must be disconnected.

Make sure that no liquids get into the device. There is no protection against penetrating liquids (Code IP X0).

The cuvette shaft must not be cleaned by the user of the device, as this may damage the device. If cleaning is necessary, especially because of leaking liquids or broken glass, please contact Diaglobal GmbH.

4.4 Malfunctions

If any malfunctions or problems occur, simply call us. Most questions can be answered on the phone. Non-functional units should be sent to our Berlin address. We will provide a loan device for the duration of the repair.

4.5 Disposal

Diaglobal GmbH will take back and dispose of units that are no longer needed or cannot be repaired, free of charge.

5. Required reagents and laboratory accessories

5.1 Expiration date of consumables

It is important to ensure that all consumables may only be used within the expiration date.

5.2 Reagents / parameter list

The following tests can be measured with the Vario Photometer plus:

Parameter	Sample material			Tests / pack	Art. no.
	Blood	Serum	Plasma		
CK from blood ^{1) 2) 3)}	+	+	+	20	CK 321
CK from serum ²⁾	-	+	+	20	CK 121
Urea ^{1) 3)}	+	+	+	20	HST 321
Haematocrit	+	-	-	40	HCT 142
Lactate	+	-	+	40	LAC 142
Lactate-rapid	+	-	+	40	LAC 342
Bilirubin	-	+	+	40	BIL 142
Neonatal Bilirubin ^{1) 3)}	+	+	+		
Glucose	+	+	+	40	GLU 142
Haemoglobin (SLS-method)	+	-	-	40	HB 342
Haemoglobin (HiCN-method)	+	-	-	40	HB 142
Erythrocytes	+	-	-	40	ERY 142
Creatinine ²⁾	-	+	+	20	KRE 121

¹⁾ Mini centrifuge required (Art. no. DZ 002)

²⁾ Dry Block Thermostat required (Art. no. DZ 003)

³⁾ From blood, with subsequent sample preparation (centrifugation with mini centrifuge)

5.3 Control materials

Art. no.	Description	Contents
HEM QS	Haemoglobin control Haemolysate for accuracy and precision control of haemoglobin determination in blood in the normal range	5 x 1 mL
ERY QS	Erythrocytes- and Haematocrit control Control blood for accuracy and precision control of haematocrit and erythrocytes determination in blood in the normal range	5 x 1 mL
GLU QS	Glucose control 100 mg/dL	3 x 4 mL
LAC QS	Lactate control set 2 mmol/L ; 4 mmol/L ; 10 mmol/L	3 x 4 mL
BIL QS	Bilirubin control Lyophilisate for accuracy and precision control of bilirubin determination	20 caps

5.4 Laboratory aids and accessories

Art. no.	Description	Contents
LH 006	Cuvette rack	1
LH 007	Micropipetter (pipetting aid)	1
LH 009	Cellulose swabs	500
LH 011	Alcohol pads, non-sterile	100
LH 026	Capillaries 10 µL, with ring mark	250
LH 028	Capillaries 100 µL, with ring mark	250
LH 029	Capillaries 20 µL, with ring mark	250
LH 037	Microvettes 200 µL, Li-heparinised	100
LH 050	Reaction tubes to separate the plasma	500
LH 046	Capillaries 20 µL, heparinised, end-to-end	100
LH 060	Capillaries 60 µL, heparinised, end-to-end	5 x 20
LH 055	Pipette tips 50-1000 µL blue, for pipette LH 500	2 x 500
LH 500	Pipette fix 500 µL	1
DZ 002	Mini centrifuge	1
DZ 003	Dry Block Thermostat	1

All reagent kits, control materials and other materials are supplied by Diaglobal GmbH and can be stored and transported together with the Vario Photometer plus in a practical case.

6. **Quality control according to the Guideline of the German Medical Association ¹⁾**

The Vario Photometer plus has been specially developed for near-patient immediate diagnostics with unit-use reagents (German Medical Association, part B, chapter 2.1.5). According to the guideline of the German Medical Association, there is therefore no obligation to participate in surveys (German Medical Association, part B, chapter 2.2, paragraph (3) a). The user only has to carry out internal quality checks.

Internal quality assurance is carried out in the form of a weekly accuracy check (calibration) with subsequent documentation of the measured value. The corresponding protocol forms are available from Diaglobal free of charge.

We recommend using the Diaglobal control solutions LAC QS and GLU QS to check the accuracy of lactate and glucose determinations.

We recommend using the Diaglobal control caps BIL QS to check the accuracy of bilirubin determinations.

We recommend using the blood control HEM QS and ERY QS with target values in the normal concentration area for checking the accuracy of determinations of haemoglobin, haematocrit and erythrocyte counts.

For all other parameters we recommend using the universal control sera from the company, Roche, www.roche.de:

PreciControl ClinChem Multi 1 Order-No.: 05 947 626 190 (4 x 5 mL) for normal range

PreciControl ClinChem Multi 2 Order-No.: 05 947 774 190 (4 x 5 mL) for pathological range

In agreement with the requirements of the German Medical Association, a test of the device function (see operating instructions, chapter 8.5) is integrated in the Vario Photometer plus, therefore a daily test by means of a standard manual test (German Medical Association, part B, chapter 2.1.5, paragraph (2) is not necessary.

The Vario Photometer plus is suitable for the speedy detection of gestational diabetes and fulfils the requirements of the Maternity Guidelines ²⁾ and the S3-Directive ³⁾. Glucose can be measured from whole blood as well as from venous plasma. The displayed measured value is - according to the requirements - always related to venous plasma.

¹⁾ Guideline of the German Medical Association for the quality assurance of laboratory medical examinations
Deutsches Ärzteblatt | Volume 120 | Issue 21-22 | 30 May 2023

²⁾ BAnz. Nr. 36, S914

³⁾ AWMF-Register Nr. 057/008

7. Measuring procedure

7.1 Endpoint measurement

The absorbance is measured after reaching the endpoint.
It is measured against the reagent's blank count.

Parameters: Haemoglobin (HB), Haemoglobin SLS (HB SLS),
Erythrocytes (ERY), Haematocrit (HCT)

Calculation: Concentration = $\Delta A \times \text{Factor}$

The erythrocyte and haematocrit counts are determined using stored reference curves.

7.2 Endpoint measurement with consideration of the sample blank value and pre-programmed measuring time

After measuring the sample blank value, the colour reaction in the cuvette is started and the endpoint absorbance is measured after a specified time has elapsed.

Parameters: Bilirubin (BIL), Neonatal bilirubin (BIL N), Creatinine (CRE)

Calculation: Concentration = $\Delta A \times \text{Factor}$

Measuring time: 2 Minutes

The samples are measured in succession:

Sample 01: Measurement 1 (sample blank value)

Sample 01: Measurement 2 (result)

Sample 02: Measurement 1 (sample blank value)

Sample 02: Measurement 2 (result)

etc.

Parameter: UREA

Calculation: Concentration = $\Delta A \times \text{Factor}$

Measuring time: 10 minutes

Blank values of the samples are measured one after the other:

Sample 01: Measurement 1 (sample blank value)

Sample 02: Measurement 1 (sample blank value)

Sample 03: Measurement 1 (sample blank value)

etc.

Results are measured one after the other:

Sample 01: Measurement 2 (result)

Sample 02: Measurement 2 (result)

Sample 03: Measurement 2 (result)

etc.

7.3 Multipoint measurement with consideration of the sample blank value and recognition of the endpoint

After measuring the sample blank value (= measurement 1) the colour reaction in the cuvette is started. The reaction process is monitored by the device (= measurement 2). The measuring process is terminated as soon as the endpoint is reached.

The time needed to reach the endpoint depends on the temperature. It is normally 2 - 6 minutes for the lactate test. If temperatures are close to freezing point, measuring times can take up to 20 minutes, depending on the parameters.

You can choose between single and series measurements up to a maximum of 20 samples.

For single measurements, the samples are processed one after the other.

For series measurements, all A1 values are measured first.

Parameter: Lactate (LAC)

Calculation: Concentration in plasma = $\Delta A \times \text{Factor}$

7.4 Multipoint measurement with consideration of the sample blank value and calculation of the endpoint

After measuring the sample blank value (= measurement 1) the colour reaction in the cuvette is started. The course of the reaction is monitored by the device. The endpoint is calculated using several absorbance values recorded at different times.

Parameter: Glucose (GLU), Lactate-rapid (LAC-rapid)

Measuring time: Glucose: 2 minutes

Lactate-rapid: 1 minute

7.5 2-point kinetic (fixed time interval) reaction with fixed incubation time and fixed measuring time, T = 37°C

7.5.1 Creatine Kinase from blood <CK 321>

The reaction is started in the cuvette with the starter cap. The measurement starts simultaneously on the photometer by pressing the **<ON/ENTER>** key. After incubation of 5 minutes, the first absorbance (A1) is measured. After another 10 minutes, the second absorbance (A2) is measured.

For series measurement, the photometer specifies a time interval (15 seconds). For series lengths of $N < 6$, the **<ON/ENTER>** key must be used to switch to the A2 measurement. For $N = 6$, the device performs the switchover automatically. The measured enzyme activities of the individual samples can be accessed with the arrow keys.

Calculation: The Creatine kinase concentration is calculated from the difference of the absorbances (ΔA) using a calibration factor. Because the determination is made from blood, the haematocrit value must be considered.

Enzymatic activity (U/L) = $\text{Factor} \times (\Delta A) / (1 - 0,01 \times \text{HCT})$

Individual haematocrit values can be considered, they will be requested before calculation. The default setting is an HCT value of 40%.

Please note: If the sample material is serum/plasma, the HCT value must always be set to 0%.

7.5.2 Creatine Kinase from serum/plasma <CK 121>

The reaction in the cuvette is started by adding the sample. The time measurement starts simultaneously on the photometer by pressing the **<ON/ENTER>** key. After incubation of 5 minutes, the first absorbance (A1) is measured. After another 10 minutes, the second absorbance (A2) is measured.

For series measurement, the photometer specifies a time interval (15 seconds). For series lengths of $N < 6$, the **<ON/ENTER>** key must be used to switch to the A2 measurement. For $N = 6$, the device performs the switchover automatically. The measured enzyme activities of the individual samples can be accessed with the arrow keys.

Calculation: The creatine kinase concentration is calculated from the difference of the absorbances (ΔA) using a calibration factor.

Enzyme activity (U/L) = Factor x ΔA

8. Measurement

8.1 Switching the device on

Press the **<ON/ENTER>** key

8.2 Self-test when switching on

When the device is switched on, a self-test of the digital and analogue circuitry is conducted. The operational device check proceeds automatically after it is switched on. It takes approx. 5 seconds, after which the unit is ready for measuring.

Note:

If it becomes obvious during the test that one of the device functions does not correspond to the required settings, **<SERVICE>** will appear in the display.

In this case, switch the device off.

Please call Diaglobal GmbH service (Tel. +49 (0) 30 6576 2597) or contact your specialist retailer.

8.3 Test selection

Press the **<ON/ENTER>** key.

The desired test is selected from the menu with the right or left arrow key:

LAC - CK 321 - HCT - UREA - GLU - HB-SLS - ERY - LAC-rapid - CK 121 - HB - BIL - BIL N - CRE - ABS365 - ABS520 - ABS546

Pressing the right arrow key activates the next test while pressing the left arrow key returns to the previous test. The selected test is shown in the upper right corner of the display.

Confirm test selection with the **<ON/ENTER>** key.

8.4 Switching the device off

To switch the device off, press both arrow keys simultaneously.

8.5 Integrated operational device checks

Self-test when switching on

Testing of the digital and analogue circuits of the device is automatically performed by the device when it is switched on.

Please see chapter 8.2, Self-test when switching on.

Differential measurements

All measurements are based on differential measurements. I. e. after selecting the desired test, the device requests a zero measurement with a blank value cuvette. This creates a reference base to the measured value so that minor deviations can be compensated.

Measuring range controls

The measuring ranges of all measurement results shown in the display are verified by an integrated measuring range control. If the measuring range is exceeded, an error is displayed.

The measuring ranges that are separately defined for each parameter are documented on the respective package inserts as well as in this operating manual, chapter 9, Technical Data.

Plausibility controls

For multi-point measurements, the absorbance measured first forms the reference basis. The programme verifies the plausibility of the individual measured values. If specific requirements (e.g. $A_2 > A_1$ for ascending reactions) are not met, an error message is displayed.

8.6 Notes on taking samples and carrying out measurements

To carry out the measurements, please also refer to the tutorials on our website, www.diaglobal.de.

For safety instruction, see chapter 10.

This chapter addresses the most common errors that can occur during taking samples and measuring samples. Errors in taking samples will always lead to incorrect measurement results.

1. Before measuring, cuvettes stored in a refrigerator must be brought to room temperature. If the cuvettes are too cold, they will become misty with water on the outer wall due to the humidity, which will lead to incorrect measurement results.
2. Never touch the lower part of the cuvette (where the liquid is) with bare hands. If this should happen accidentally, clean the vials with a fluff-free cloth before use.

Cleaning with a fluff-free cloth is recommended in any case. Even if the package is still new and unopened. Fingerprints on the cuvette lead to incorrect measurement results.

3. If the blood is taken from the heel using the microvette (neonatal bilirubin), make sure that there is enough blood (approx. 60 μL) in the microvette, as 20 μL serum/plasma is needed for the measurement. Close the microvette well after taking the blood sample and return it to the small sample tube for centrifugation.
4. After centrifugation of the microvette, please make sure that the centrifugate has separated completely and that the supernatant is clear and free of any solid particles. If not, repeat the centrifugation. If the supernatant is not free of suspended matter or if particles of the centrifugate accidentally enter the capillary, the measurement result will be incorrect.
5. If blood is taken from the fingertip or earlobe, note that the first drop that forms spontaneously must be wiped away with a cellulose swab. It contains a high proportion of tissue fluid, which will corrupt the measurement result.
6. The second drop that forms is for blood sampling. To support blood collection, it may be pressed carefully (!). The emphasis on *carefully*, otherwise too much tissue fluid will get into the blood sample again.
7. Make sure that the blood drop that forms is large enough to fill the capillary with the required sample volume in one go. Repeated filling of the capillary leads to air bubbles that cannot be removed from the capillary. If air bubbles form, discard the capillary and start sampling again.

8. The capillary must be filled exactly up to the black ring mark.

Please note: A deviation of only 1 mm from the ring mark is sufficient to obtain a completely incorrect measurement result!

If the sample is above the black ring mark, this will lead to incorrect positive measurement results. A cellulose swab can be used to carefully soak up too much blood.

If the sample is below the black ring mark, this will lead to incorrect negative measurement results. In this case, correction is hardly possible due to the air bubble that will form when trying to collect more blood.

9. Before the capillary is placed in the cuvette, the lower area must be carefully wiped on the outside with a cellulose swab to remove sample particles attached to the capillary. Otherwise, this would lead to incorrect positive measurement results.
10. With the help of the micropipetter, the sample is completely transferred into the cuvette. The complete transfer of the sample is done by ejecting it several times with the help of the push button on the micropipetter.

Please note: The micropipetter is only used when the capillary is filled with the sample. It is not needed for filling the capillary. The capillary is filled by the capillary action alone.

11. During series measurements, make sure that the order of the samples is not reversed. Otherwise, the device cannot assign the samples correctly, which leads to unreliable measurement results.
12. When changing the cap with the starter cap, make sure that the substance in the starter cap has completely dissolved. Failure to do so will result in a non-linear kinetic reaction process, which will lead to an error message in the display or unreliable measurement results.

9. Technical data

Storage temperature:	-20 °C ... 70 °C
Operating temperature:	0 °C ... 40 °C
Dimensions:	200 x 100 x 50 mm
Weight:	450 g
Measuring principle:	Absorption measurement with single beam photometer (Fig. 2), chopped operation
Projector:	LED
Spectral apparatus:	Interference filter
Measuring wavelengths:	365 nm / 520 nm / 546 nm
Spectral half-width value:	~ 5 nm
External light influence:	Negligible
Interface:	V24 (9600, 8, n, 2)
Power supply:	6 V ... 12 V DC
Current consumption:	max. 250 mA
Warm-up time:	0 min
Interference suppression:	According to DIN VDE 0871 and DIN VDE 0875
Inaccuracy:	< 0.5 % at A = 1.000
Relative photometric short-time standard deviation:	< 0.1 %

Measuring ranges:	<u>DP 550</u>	<u>DP 550 SI</u>
CK in blood / CK 321	0.0 - 3000 U/L	0.0 - 3000 U/L
CK in serum / CK 121	0.0 - 2500 U/L	0.0 - 2500 U/L
Urea	0.5 - 200 mg/dL	0.8 - 35 mmol/L
Haematocrit	5 - 90 %	5 - 90 %
Lactate	0.2 - 30 mmol/L	0.2 - 30 mmol/L
Lactate-rapid	0.2 - 20 mmol/L	0.2 - 20 mmol/L
Bilirubin	0.5 - 25 mg/dL	8.5 - 428 µmol/L
Neonatal Bilirubin	2.3 - 50 mg/dL	39 - 850 µmol/L
Glucose	20 - 630 mg/dL	1.1 - 35 mmol/L
Haemoglobin (SLS-method)	0.0 - 50 g/dL	0.0 - 31 mmol/L
Haemoglobin (HiCN-method)	0.0 - 50 g/dL	0.0 - 31 mmol/L
Erythrocytes	1.0 - 10 Mio/µL	1.0 - 10 Mio/µL
Creatinine	0.0 - 5 mg/dL	0.0 - 440 µmol/L
ABS 365 nm	A = 2.500	A = 2.500
ABS 520 nm	A = 2.500	A = 2.500
ABS 546 nm	A = 2.500	A = 2.500

10. General guidelines, standards and notes

1. Directive 98/79/EC on in-vitro diagnostic devices
2. EN ISO 9001, Quality Management Systems, Model for quality assurance in design, development, production, installation and customer service
3. EN ISO 13485, Medical devices, Requirements for regulatory purposes (application of EN ISO 9001)
4. EN ISO 14971, Medical devices - Application of risk management to medical devices
5. EN 61010 -1, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
6. EN 61010 -2-101, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in-vitro diagnostic (IVD) medical equipment
7. EN 61326 -1, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
8. EN 61326 -2-6, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements – In-vitro diagnostic (IVD) medical equipment
9. EN 592, Instructions for use for in-vitro diagnostic instruments for professional use

National directive (Germany)

Guidelines for Quality Assurance of Laboratory Examinations of the German Medical Association of 30 May 2023

Note on electromagnetic compatibility

The photometer meets the requirements for electromagnetic radiation and interference immunity as described in the IEC 61326 series of standards.

Do not use this device near sources of intense electromagnetic radiation because they may interfere with correct functioning. A distance of at least 1 m should be maintained between an operational (switched on) mobile phone and the photometer during measurement.

Note on the unit's internal quality control

The functionality of the device is checked when it is switched on. In addition, electronically controlled checks are carried out for individual tests during the measurement, which leads to an error message if specified requirements are not met.

Safety instruction

Personal protective equipment (gloves, gown) must be worn when handling potentially infectious materials (patient samples).

11. Appendix: "Step-by-step measurement"

See the following pages