Duo Photometer plus
DP 210
Operating Manual
Version 5.12 / 5.12 SI

Edition 2022-01

Dear customer,

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

The Duo 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 Duo Photometer plus complies with the requirements of the guidelines of the German Medical Association.

With the Duo 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 Duo Photometer plus!

Yours
Diaglobal GmbH

Table of contents

1. General information on the Photometer

Device name: Duo Photometer plus

Model: DP 210

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

The Duo 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.

Manufacturer: Diaglobal GmbH
Innovationspark Wuhlheide
Köpenicker Str. 325 / Haus 41
12555 Berlin

Tel: +49 (0) 30 6576 2597
Fax: +49 (0) 30 6576 2517
E-Mail: info@diaglobal.de

http://www.diaglobal.de

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

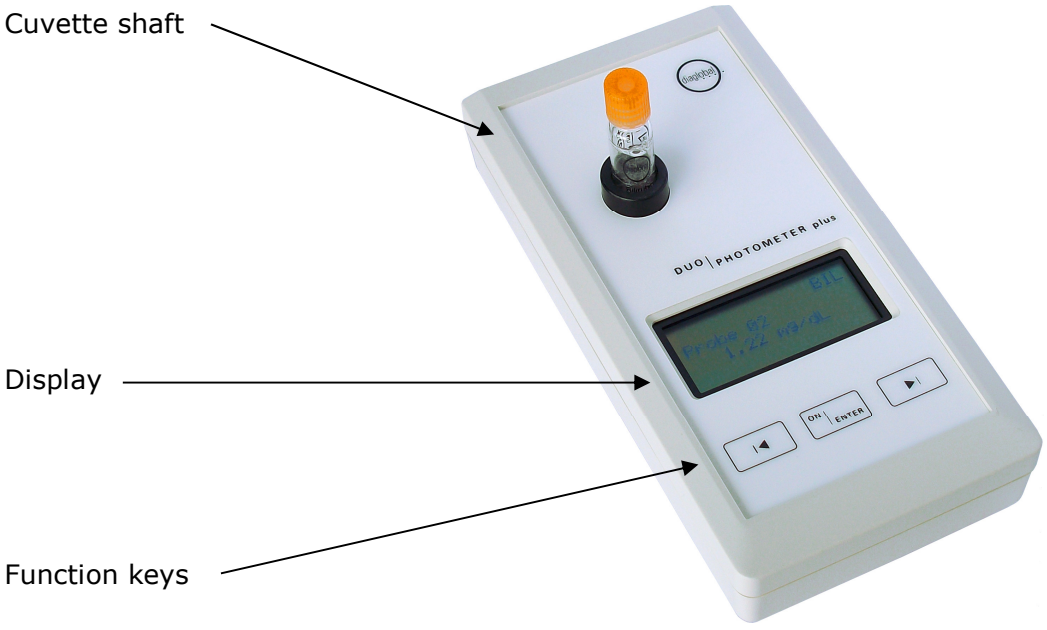


Fig. 1

3.1 Power supply

The Duo 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 Network-independent operation

To insert the rechargeable battery or the normal battery:
Unscrew the knurled screws on the bottom of the unit 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.

Please note:
The Duo 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.

3.2 Measuring system

The optical section is shown in Fig. 2.

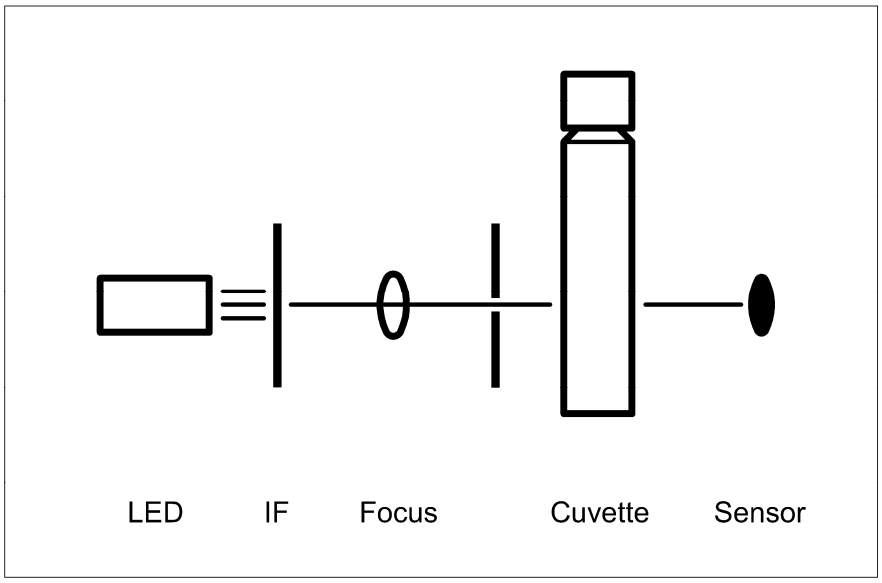


Fig. 2

The light emitted by an LED is first selected into its wavelength range (546 nm) by an interference filter IF (HBW ~ 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 instrument 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 Duo Photometer plus:

Parameter	Sample material			Tests/pack	Art. no.
	Blood	Serum	Plasma		
Bilirubin	-	+	+	40	BIL 142
Neonatale Bilirubin[1) 2)]	+	-	-		
Haemoglobin (SLS-method)	+	-	-	40	HB 342
Haemoglobin (HiCN-method)	+	-	-	40	HB 142
Erythrocytes	+	-	-	40	ERY 142
Haematocrit	+	-	-	40	HCT 142

[1)] Mini centrifuge required (Art. no. DZ 002)
[2)] From blood, with subsequent sample preparation (centrifugation with mini centrifuge)

5.3 Control materials

Art. no.	Description	Contents
HEM QS	Haemoglobin control Haemolysate for correctness 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
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 001	Blood lancets	500
LH 004	Capillaries 10 µL, with ring mark	250
LH 006	Cuvette rack	1
LH 007	Micropipettor (pipetting aid)	1
LH 009	Cellulose swabs	500
LH 010	Cellulose swab box	1
LH 011	Alcohol pads, non-sterile	100
LH 012	Powder-free nitrile gloves size M	200
LH 023	Capillaries 100 µL, with ring mark	250
LH 024	Capillaries 20 µL, with ring mark	250
LH 031	Microvettes CB 300	100
LH 034	Safety Lancets Neonatal, pink 1.2 mm	200
LH 035	Safety lancets extra, orange 1.8 mm	200
DZ 002	Mini centrifuge	1

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

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

The Duo 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 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.

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 Duo Photometer plus, therefor a daily test by means of a standard manual test (German Medical Association, part B, chapter 2.1.5, paragraph (2) is not necessary.

[1)] Guideline of the German Medical Association for the quality assurance of laboratory medical examinations Deutsches Ärzteblatt | Jg. 116 | Heft 51-52 | 23. Dezember 2019

7. Measuring process

7.1 Endpoint measurement

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

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

Calculation: Concentration = Absorbance x 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)

Calculation: Concentration = Absorbance x Factor
Measurement 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.

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:

HB - HB-SLS - ERY - HCT - BIL - BIL N - 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, point 8.2.

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.

Measurement range controls

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

The measurement 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. E2 > E1 for ascending reactions) are not met, an error message is displayed.

8.6 Notes on taking samples and carrying out measurements

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

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. 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:	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:	DP 210	DP 210 SI
Haemoglobin (HiCN-method)	0.0 - 50 g/dL	0.0 - 31 mmol/L
Haemoglobin (SLS-method)	0.0 - 50 g/dL	0.0 - 31 mmol/L
Erythrocytes	1.0 - 10 Mio/µL	1.0 - 10 Mio/µL
Haematocrit	5 - 90 %	5 - 90 %
Bilirubin	0.50 - 25 mg/dL	8.50 - 428 µmol/L
Neonatal Bilirubin	2.30 - 50 mg/dL	39.0 - 850 µmol/L
ABS 546 nm	A = 2.500	A = 2.500

10. General Guidelines and Notes

EC Directives

1. Directive 98/79/EC on in-vitro diagnostic devices

EN / ISO standards

2. EN ISO 9001:1994, 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 directives and recommendations (Germany)

10. Guidelines for Quality Assurance of Laboratory Examinations of the German Medical Association of 23.12.2019

Note on electromagnetic compatibility

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

b) 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.

11. Appendix: “Step-by-step measurement”

Please refer to the illustrations in the "Step by step" instruction manual.

Step by step instructions

Device manual

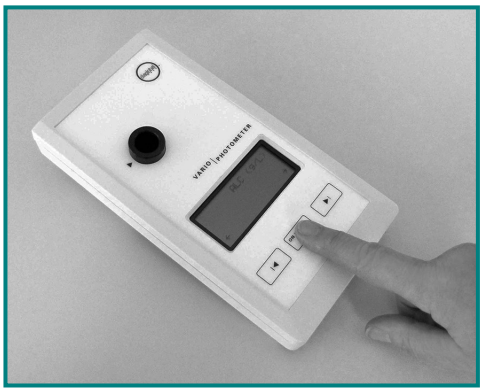
1. Switch on:

Press ON/ENTER key

Wait for device check and confirm with ON/ENTER

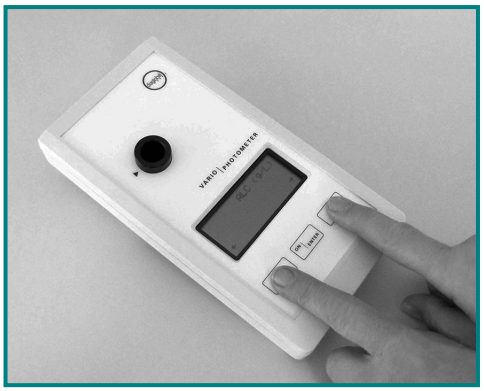
2. Select test:

Press arrow key until required test appears



3. Confirm required test:

Press ON/ENTER



4. Switch off:

Press both arrow keys at the same time

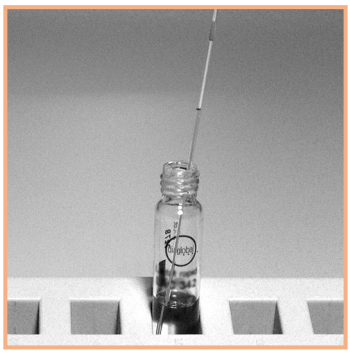
Note:
If SERVICE appears in the display after the device check, the device has a defect.

In this case, please contact our customer service at +49 (0) 30 6576 2597.

Step by step instructions

BIL / BIL N (BIL 142)

Additionally required: Mini centrifuge

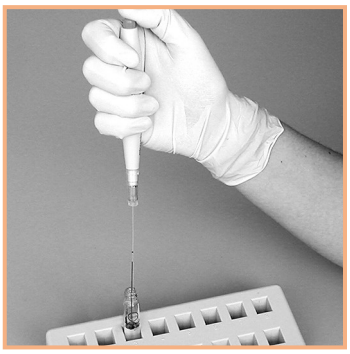


1. Insert capillary with sample (serum/plasma) into cuvette

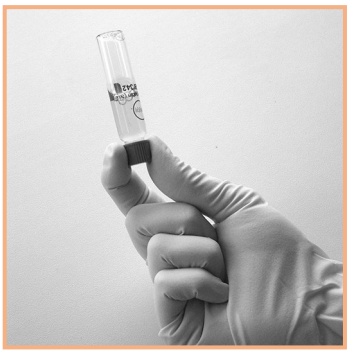
BIL: 100 µL (adults)

BIL N: 20 µL (newborns)

Sampling of BIL N see next page

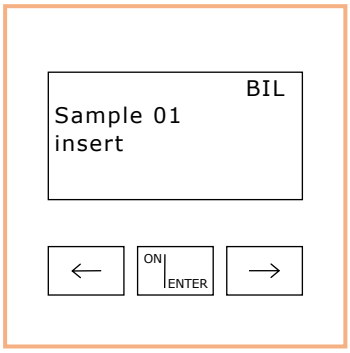


2. Eject sample several times with micropipetter into cuvette



3. Screw cap on

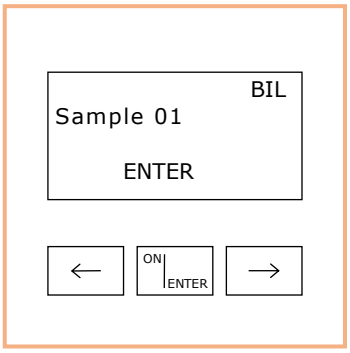
Turn cuvette upside down several times



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

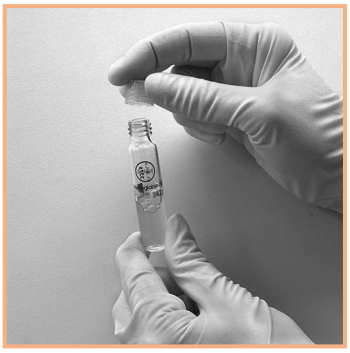
Select the required test, confirm with ON/ENTER



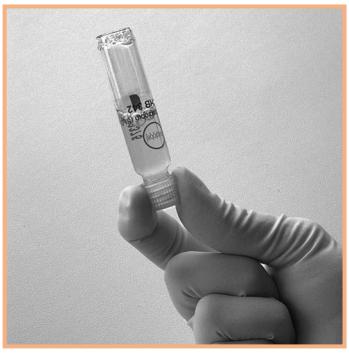
5. Zero point adjustment:

Insert cuvette with sample (Fig. 3) into photometer, zero point is stored in memory

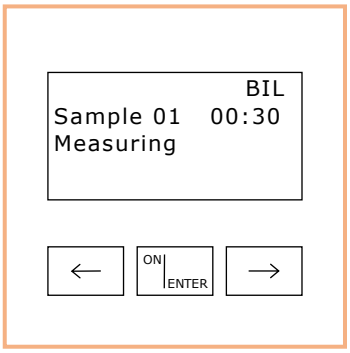
Remove cuvette after signal tone



6. Replace screw cap with starter cap



7. Turn cuvette upside down several times



8. First press ON/ENTER

Then insert cuvette into photometer

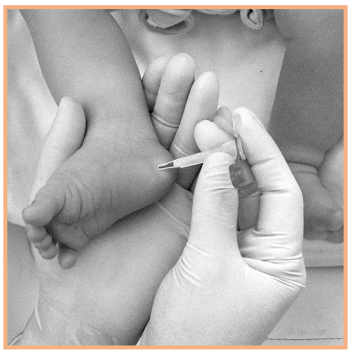
9. Time is displayed, wait for measured value

Step by step instructions

BIL / BIL N (BIL 142)

Sampling of BIL N

Additionally required: Mini centrifuge, Microvette



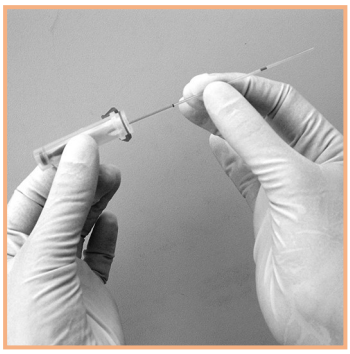
1. After pricking with the lancet, take about 60 µL of blood (approx. 1 drop) from the heel with the microvette

Note: Close the microvette carefully before placing it into the mini centrifuge

2. Insert microvette into mini centrifuge

Centrifugate for 3-5 minutes

Note: Ensure an even loading inside the mini centrifuge



3. Take 20 µL plasma from the microvette

Continue with Fig. 1 on the previous page

Mini centrifuge

Art. No. DZ 002

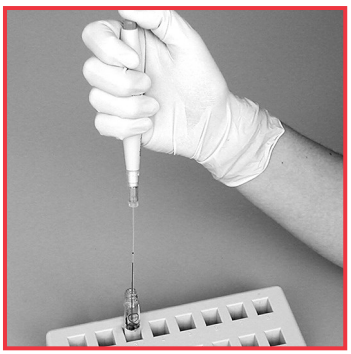
Microvette

Art. No. LH 031
(100 pieces per package)

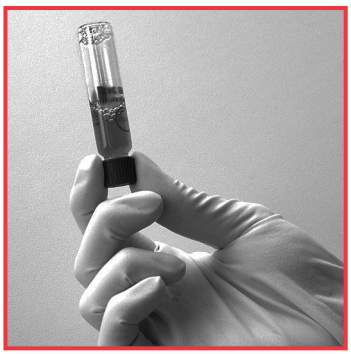
Step by step instructions

HB 142 / HB 342 / ERY 142 / HCT 142

1. Insert capillary with 10 µL blood sample into cuvette



2. Eject blood several times with micropipetter into cuvette

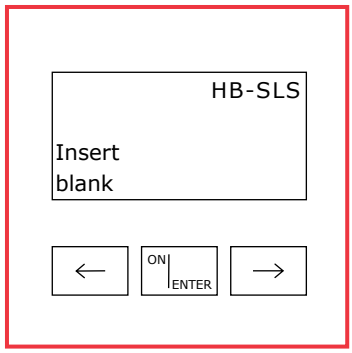


3. Screw cap on

Turn cuvette upside down several times

Wait 3 minutes

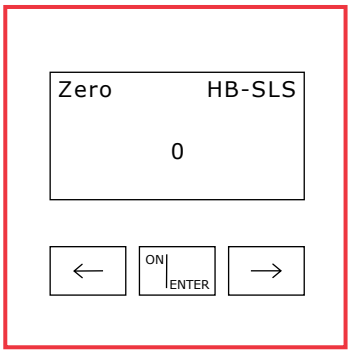
HB 342: wait 30 seconds



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

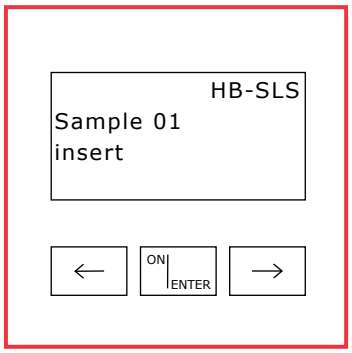
Select the required test, confirm with ON/ENTER



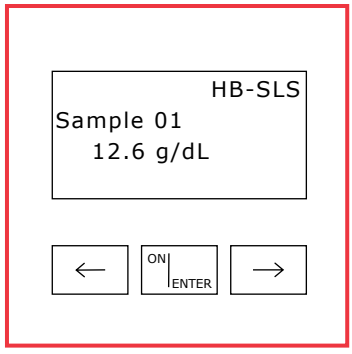
5. Zero point adjustment:

Insert an unprocessed cuvette from package into photometer

Zero point is stored in memory



6. Remove cuvette after signal tone



7. Insert cuvette with blood sample (Fig. 3) into photometer

Read measured value

In regard to series measurement:

After zero point setting any number of additional samples can be measured

Step by step instructions

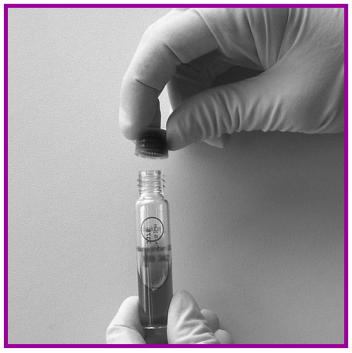
BIL QS

Quality assurance

Photometer testing with control caps

1. 20 control caps with lyophilized control serum

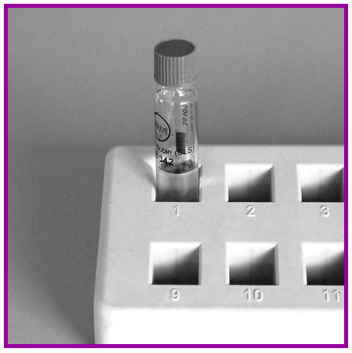
BIL QS: Bilirubin (adults), Bilirubin N (newborns)



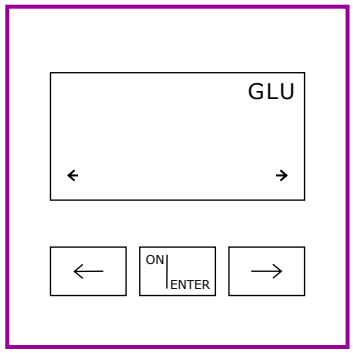
2. Screw the control cap onto a cuvette of the test you want to check

Mix well

Now the cuvette contains a sample with a known concentration



3. Leave the cuvette for 1 minute



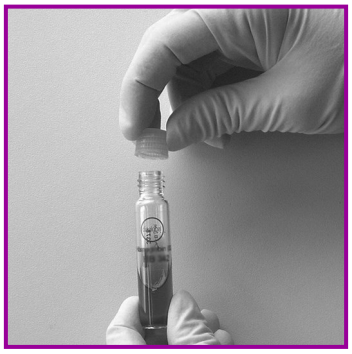
4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

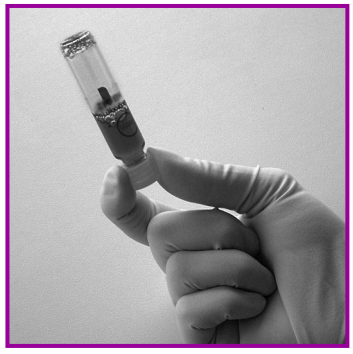
Select the required test, confirm with ON/ENTER

5. Zero point adjustment: Insert cuvette with sample (Fig. 3) into photometer, zero point is stored in memory

Remove cuvette after signal tone



6. Replace control cap with starter cap



7. Turn cuvette upside down several times

8. First press ON/ENTER, then insert cuvette into photometer

Wait for measured value

Compare the measured value with the target value on the package insert