Operator's Manual

InnovaStar®

Valid from Version: 1.24 October 2011

Manufacturer / Copyright:

DiaSys Diagnostic Systems GmbH
Alte Str. 9
D – 65558 Holzheim
Germany

Distributor:

ENG

If you have any questions concerning our products, please dial:
+49 (0)6432 9146 0

Or contact us via:

Fax: +49 (0)6432 9146 32

Email: mail@diasys.de

A) Table of contents

ENG

ENG

B) Table of figures

C)Table of symbols

Symbols on device

Symbol	Description
	ENTER - key for selecting a menu item or changing the menu area
	MENU button for selecting menu items
	Follow operator's manual
	In-vitro-Diagnostics
	Manufacturer
	CE Compliance
SN	Serial number
	Biohazard

Symbols on consumption material

Symbol	Description
	Diagnostic use *in vitro*
	CE Compliance
	Follow operator's manual / package inserts
	Reusable material
	Dispose according to regulations
	Storage temperature
	Item number
	Contents of package
	Batch number
	Use before
 *Only for waste*	Biohazard

Symbols in operator's manual

Symbol	Description
	Attention or Note
Bold/italics	Very important notes

ENG

1. Preface

1.1. Introduction

Congratulations on purchasing an **InnovaStar®** analyzer. We hope you will find working with your analyzer satisfying and successful.

In the following chapter "The **InnovaStar®**" you will find a first overview of your analyzer: what parameters you can measure, what further devices and accessories belong to your analyzer, and an overview of the device's functionality.

Furthermore, you will receive information on safety, on liability and warranty, and on indications or contraindications of your analyzer.

For further and more detailed information, please read the corresponding chapters.

1.2. The InnovaStar®

The **InnovaStar®** analyzer is an instrument for biochemical analysis via in-vitro diagnostics. Turbidimetric and color reactions may be measured.

Figure 1.: Overall view of **InnovaStar®**

1.2.1. Basics

The **InnovaStar®** was designed using the latest technology.
It fulfils all legal specifications required with regard to design and production of analyzers used in clinical chemical laboratories. Absolute compliance with valid norms and statutes is documented on grounds of the visibly attached CE-Label which signifies compliance with all pertaining laws and regulations and, in consequence, safety and confidence.

By employing an altogether newly developed technology for the determination of various blood parameters, it is possible to fulfill all requirements of quality assurance (e.g. RiliBäk (Guidelines of the German Federal General Medical Council for Quality Assurance in Medical Laboratories)) in medical laboratories while maintaining easy handling and minimum operating effort. All users are thus able to achieve analysis results which meet all quality demands.

1.2.2. Device and accessories

Scope of supply:

Designation	Quantity
InnovaStar® incl. slider	1
Power connection cable	1
AC adapter for device and printer	1
Operator's manual	1
Optional	
Thermal Printer DPU 414	1
Printer cable	1
EDP connection cable	1
Sample bar code reader (without picture)	1

Figure 2.: Illustration of instrument

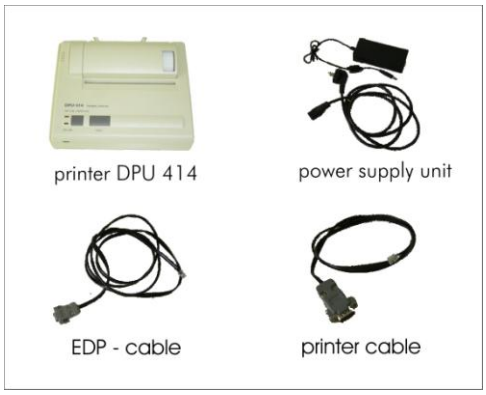


Figure 3.: Accessories

1.2.3. Overview of functionality

The **InnovaStar®** analyzer is designed for measuring various parameters of human sample material. The device shows the measuring results on the built-in display and results are sent to an optional connected printer and/or EDP.
The analyzer also allows you to provide patient samples with a bar code and thus, linking it to the patient in the EDP.

For further information on measuring principle and sample taking, please refer to the appropriate chapters.

1.3. Indication / Contraindication

Indication:
The **InnovaStar®** analyzer is used for measuring various parameters of human sample material. Because of the ongoing development of reagents, it is not possible to supply a complete update list of all parameters in this manual. For further information contact the manufacturer or authorized distributor. Current information is always available at www.diasys.de.

For the selection of sample material, please refer to the information in the package inserts of the reagents. Only this sample materials must be used, or else faulty measuring results may occur.

The **InnovaStar®** analyzer must only be used and operated by trained personnel.

Contraindication:
Using unsuitable sample material can result in faulty measuring results. If in doubt, call the manufacturer!

Operating the instrument for home testing is expressly forbidden!

1.4. Manufacturer's liability

Legal liability and warranty claims are expressly excluded in the following cases:

- gross negligence or willful damage of the device, parts thereof or consumption material
- unauthorized opening of the device by untrained personnel (without proper service training)
- force majeure (e.g. stroke of lightning, water damage, fire)
- nonobservance of user manual and package inserts

1.5. Warranty

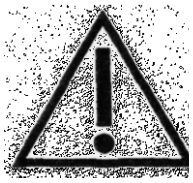
For their products DiaSys Diagnostic Systems GmbH extends a two-year warranty according to EU Directive 1999/44/EG starting with the date of purchase. Consumables (because of shorter shelf-life) and parts subject to wear (they should be replaced on a yearly basis) are expressly excluded from this warranty.

2. Safety

2.1. Introduction

The following chapters concern the safety of the person operating the device.

Read these chapters carefully ***PRIOR*** to starting up the analyzer because they contain general safety warnings, warnings concerning the personal safety of the person operating the device, and warnings for the protection of the device.



Displaying the following safety warnings does not release the person operating the device from adhering to the safety measures of the facility.

2.2. Responsibility / Training of the operator

- The **InnovaStar®** analyzer must only be used and operated by trained personnel. An employee of the manufacturer or of an authorized distributor will introduce the operation procedures.
- Every user is responsible for adhering to safety, health and legal regulations, and operating the device only according to its intended use.
- Interpreting the results and diagnosing on that basis must be left to a medical practitioner. Operating the device for home testing is expressly forbidden.

ENG

2.3. General safety instructions

- Prior to operating InnovaStar®, read the entire operator's manual especially the instructions for sample taking. If you have any questions, please contact the manufacturer or authorized distributor.
- Every person working with the device must be acquainted with the relevant safety rules prior to operating the device and these rules should be kept at hand all the time.
- Please pay attention to all general safety rules for laboratories such as personal protective equipment, and the applicable disinfection and hygiene regulations.
- In case of unintentional skin contact with potential infectious material, e.g. human blood samples, disinfect the place concerned with a suitable antiseptic solution.

- The system solution is not corrosive, toxic or strongly skin irritating. In case of skin contact with system solution, the washing of the concerned place with water is appropriate.
- To avoid risk of electric shock, do not place the instrument or its power supply in water or other liquids! If the cable or the power supply adapter is damaged in any way, you must not continue using the power supply. Never touch the plug of the power supply adapter with wet hands. The power supply adapter must only be used indoors and must be protected from humidity.

2.4. Product specific safety instructions

- The device may only be used for the intended use with special attention to the defined usage restrictions and constraints to be strictly adhered to (in case of need contact the manufacturer).
- In case of not intended use it is pointed out explicitly that the safety measures of the device may be ineffective.
- Operate the device only on smooth, horizontal surfaces. Avoid deviations with regard to temperature, drafts, direct sun light or vibrations. These can result in faulty measuring values.
- In case of malfunction, stop operating **InnovaStar®** immediately! Prior to continuing to operate the device, read the notes concerning cleaning, error messages and troubleshooting. After consulting the manufacturer or authorized distributor you may ship the device for repairs to the manufacturer or authorized distributor.
- Use only original accessories and spare parts to avoid damage to the analyzer and to people. Repairs must only be conducted by the manufacturer or by companies authorized by the manufacturer!
- The use of reagents and consumption materials that are not expressly recommended by the manufacturer can cause severe measuring errors and malfunctions and is therefore not permissible.
- If the user opens the device without authorization, he shall not be entitled to any rights concerning the liability for the device and damages caused thereby.

2.5. Maintenance interval

The **InnovaStar®** needs maintenance by authorized professionals every second year.

Without regular maintenance, false measuring results may occur for which the manufacturer is not liable.
For further information, please refer to the chapter Maintenance / Troubleshooting.
* Explanation of terms: Authorized professionals are people who have gained expert knowledge by completing certified training courses offered by the manufacturer or authorized companies.

3. Description of analyzer

3.1. Introduction

This chapter describes the analyzer's measuring principle, layout, and accessories, and the consumption material.

This chapter will provide you with general information. For detailed instructions and description, please refer to chapter 'Operation'.

3.2. Intended use

The **InnovaStar®** is an analyzer for biochemical in-vitro diagnostics. It must only be used and operated by trained personnel. Operating the instrument for home testing is expressly forbidden.

The sample material is taken out of a closed sample cup collocated in a slider. The containers for the system and waste solution – located on the back side of the device – are capped with separately marked stoppers including feeding hose. Both containers must be replaced at the same time since they are adjusted to each other.

InnovaStar® offers the following features:

- Measurement of various parameters of human sample material (for an overview of the parameters, please contact the manufacturer or authorized distributor).
- Automatic recognition of parameters using a bar code
- Options:
  - Serial printer interface for thermal printer DPU 414
  - Serial RS 232 electronic data processing interface
  - Interface for PS2 keyboard or bar code reader

3.3. Measuring principle

The **InnovaStar®** analyzer uses a spectrophotometer with a wavelength range of 450 nm to 700 nm to collect data.

The photometer unit consists of a halogen lamp, an iris, the flow cell, and the detection unit. The whole photometer unit is tempered at 37 ° C and contains a flow thermostat to incubate the substance to be measured.

The change in absorption – caused by a reaction of the sample with the reagents – detected by the detector corresponds to the concentration of the analyte.

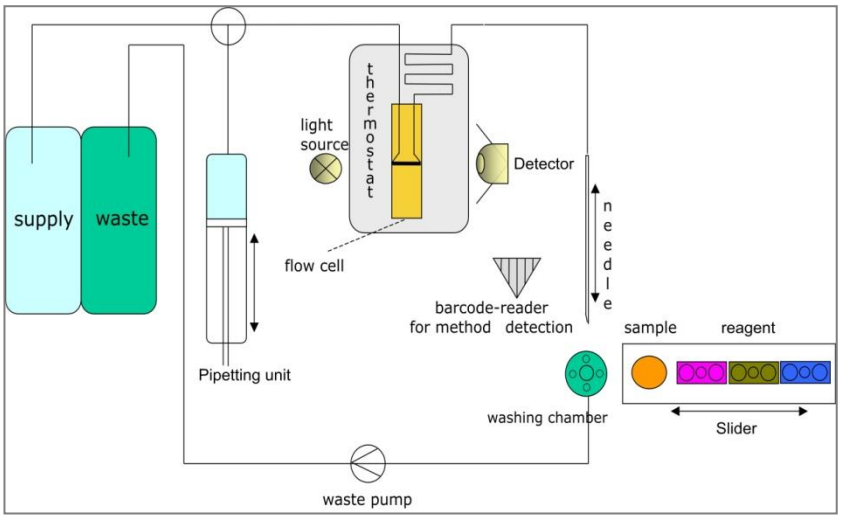


Figure 4.: Diagram device layout

Using the pipette unit consisting of dispenser unit and sampler, **InnovaStar®** is able to dispense and mix exact amounts of sample and reagent.

ENG

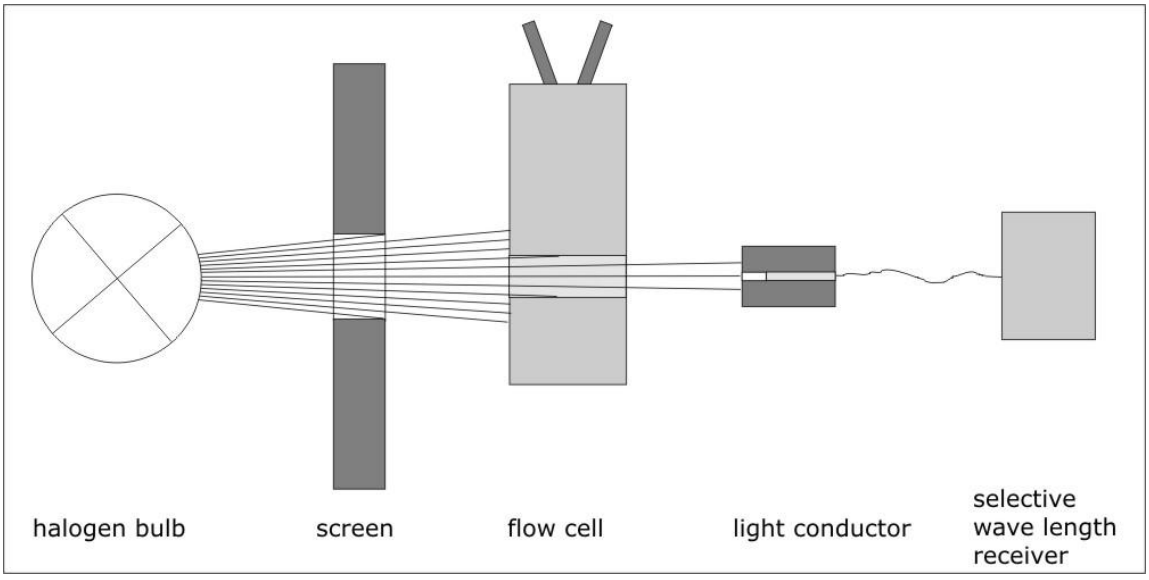


Figure 5.: Diagram photometer

All data needed for analysis is stored on the ParamCard. This card is supplied with each package of reagent cartridges. For further information, please refer to the chapter 'Operation'.

3.3.1. Calibration mathematics

The change in absorption will be used to calculate the concentration of the analyte on the basis of a calibration curve.

3.3.1.1. Linear calibration

Linear calibration is used when the correlation between concentration of analyte and measuring signal is linear. The concentration of the sample will be calculated by the following equation:

$$C_{Sample} = \frac{C_{Calibrator}(A_{Sample} - A_{Blank})}{A_{Calibrator} - A_{Blank}}$$

C_{Sample} = Concentration of sample
$C_{Calibrator}$ = Concentration of calibrator
A_{Sample} = Absorption of sample
$A_{Calibrator}$ = Absorption of calibrator
A_{Blank} = Absorption of blank

3.3.1.2. Point to point calibration

This kind of calibration is applied on InnovaStar® for the calculation of concentrations if a calibration curve with more than two calibrators is used. For this type of calculation a linear relation is assumed for a small segment of the curve. To connect these two calibration points (x_1, y_1 and x_2, y_2) the following equation is applied:

$$\frac{(x - x_1)}{(y - y_{1)}} = \frac{(x_2 - x_1)}{(y_2 - y_1)}$$

If the absorption of a sample (A_{Sample}) lies between the absorption of the two calibrators (A_m und A_n), the following equation is applied to calculate the concentration of the sample (C_{Sample}):

$$C_{Sample} = \frac{A_m - A_n}{C_m - C_n} \times (A_{Sample} - A_n) + C_n$$

C_{Sample} = Concentration of sample
C_m = Concentration of calibrator m
C_n = Concentration of calibrator n
A_{Sample} = Absorption of sample
A_m = Absorption of calibrator m
A_n = Absorption of calibrator n
$A_n/C_n < A_{Sample}/C_{Sample} < A_m/C_m$

3.4. Accessories

As described and shown in chapter 1.2.3, **InnovaStar®** is supplied with standard accessories. In addition, further optional accessories can be ordered. Both manufacturer and authorized distributor will gladly provide information about connecting interfaces.

3.5. Consumables

To operate the analyzer, the following consumables are needed:

- Pre-filled sample cups and capillaries for taking sample
- Reagent cartridges with ParamCard
- Containerkit with system solution

For detailed instructions on how to use these consumption materials, please refer to the chapter 'Operation' of this manual.

4. Operation - Part 1

4.1. Introduction

This part of the operator's manual includes all information useful for day-to-day operation of **InnovaStar®**.
Part 2 provides all additional information which is needed to understand functions, complementary functions and certain sources of possible problems.

The person responsible for the device must be familiar with both parts and must also have the medical knowledge to be able to interpret the acquired values correctly. Conclusions for a therapy may only be drawn by a medical practitioner.

4.2. Safety instructions

As mentioned before, certain safety warnings must be followed during operation in order to guarantee correct and faultless operation:

- The device must only be used for the described indication and must only be used and operated by trained personnel.
- Every user is responsible for adhering to safety, health and legal regulations, and for operating **InnovaStar®** according to its intended use alone.
- Interpreting the results and diagnosis on this basis must be left to a medical practitioner. Operating the device for home testing is expressly forbidden.
- In daily operation, regular checks of the results should be made; if needed, an additional control measurement should be carried out.
- Do not switch off the device or disconnect it from the power supply while it is running. If this happens, malfunctions can occur the next time the device is switched on.
- If you suspect a malfunction or faulty measuring results, please inform the person responsible for the device immediately. If necessary, this person will contact the manufacturer or distributor to solve the problem.
- In case of unintentional skin contact with potential infectious material, e.g. human blood samples, disinfect the place concerned with a suitable antiseptic solution.
- The system solution is not corrosive, toxic or strongly skin irritating. In case of skin contact with system solution, the washing of the concerned place with water is appropriate.
- In case of not intended use it is pointed out explicitly that the safety measures of the device may be ineffective.

4.3. Installing InnovaStar®

Before start-up, check the supplied analyzer and accessories for completeness. If anything is missing, please contact your supplier immediately.

Furthermore, please check all parts for intactness. Proper and safe operation is only guaranteed when using original parts and accessories. NEVER use damaged parts or parts from other manufacturers!

Place the **InnovaStar®** onto a horizontal, smooth and dry surface. Please choose a location where the instrument is protected from direct sunlight and extreme variations in temperature since these can impair measuring results.

Connecting the device to the power supply:
Please make sure that the voltage noted on the power adapter is the same as the voltage of your power grid.
The device is connected to the power supply via the included power supply adapter. Connect the power supply cable to the power supply adapter. Plug one end of the power supply adapter into the power connector at the right side of the device and the other end into the socket.

Connecting the printer:
If **InnovaStar®** is used together with the thermal printer DPU 414, the printer is supplied with power via the second connection of the line cord.
The jack of the printer cable is inserted into the printer interface on the right hand panel of the device's casing and connected to the corresponding interface on the back panel of the printer.

ENG

The following image shows the interfaces on the right hand panel of the casing of the **InnovaStar®**.

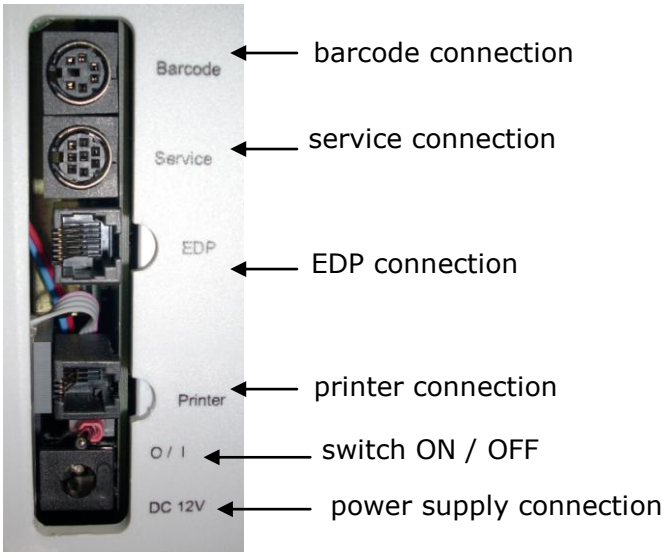


Figure 6.: Connections of **InnovaStar®**

4.4. Initial operation

After the analyzer has been installed as described above, the container kit with system solution must be connected to it.

Proceed as follows:

- Hook the combined supply/waste bottle to the device's back panel. Please make sure that waste and supply tubings are connected correctly!
- Unscrew the purple lid of the container with the system solution.
- Screw the cap on the tubing onto the system solution's container (purple lid: supply, rubber stopper: waste)
- Take care that the rubber stopper is **pressed closely** into the right bottle neck. **Otherwise an overflow of the washing chamber may occur.**

After finishing these steps the installation of the device is completed. Turn on the device by switching the "ON/OFF" switch backwards.

After on the turn-on procedure, rinsing takes place and the thermostat heats up. When the thermostat has reached proper temperature, the analyzer carries out a self test and is then ready for use.
NOTE: This may take up to 15 minutes!
The **InnovaStar®** is operated using the MENU and ENTER buttons. This takes you through to the two main program branches: the Function menu and the Measuring menu (see Fig. 5.1)

ENG

The measuring menu contains all functions that are directly needed for measuring. In the Function menu you find all functions that are not needed in daily operation. Switch between the two program branches by pressing ENTER, in standby mode only. The bottom line of the display shows the current menu.

Both menus are described in detail in chapter 5.2 and 5.3.

4.5. Preparing the measuring process

4.5.1. ParamCard

The **InnovaStar®** uses pre-dosed reagents. For each analysis one reagent cartridge bearing a bar code is needed. With this bar code, the instrument can recognize the reagent cartridge and assign it to the appropriate application and calibration data. The bar code also communicates the lot and expiry information of the used reagents to the device.

Figure 7.: Reagent cartridge with bar code

The application, calibration and LOT data are stored on a parameter card, named "ParamCard", which is included in every reagent package. With every LOT change, this included ParamCard must be read. If there is no LOT change, then the ParamCard shall not be read.

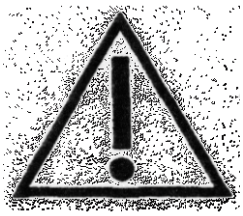
Reading the ParamCard:

1. If the Measuring menu is active, insert the ParamCard into the slot in the upper casing panel. If the function menu is active, select menu item "Read method" by pressing the MENU button before inserting the card.
2. Confirm by pressing ENTER.
3. If the device reads the parameter for the first time, the measuring unit can be chosen.
4. In order to change the measuring unit of one of the parameters all stored lots of this parameter have to be erased in the method memory, as described in 5.3.2.5. Then read the ParamCard of this method again.
5. After the data from the ParamCard has been read, the card can be removed.
6. If a former lot of the same parameter is stored the user is asked whether this lot should be overwritten.

4.5.2. Sample preparation

Please observe the instructions in the package insert of the reagent cartridges concerning sample preparation!

The following notes complement the above notes and they are only valid if capillary blood is used as sample material:



When drawing a capillary blood sample, do not compress the tissue. This practice leads to a dilution of the blood sample with intracellular fluid and can thus lead to faulty results. For taking capillary blood sample, use suitable lancets and if appropriate, measures which stimulate circulation (e.g. massaging the spot) to yield a sufficient sample amount.

On the following page, taking capillary blood by using open-end capillaries is described and shown.

ENG

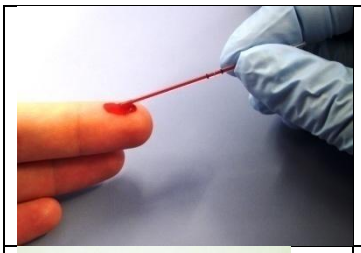
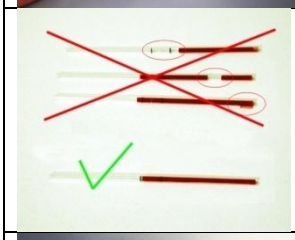
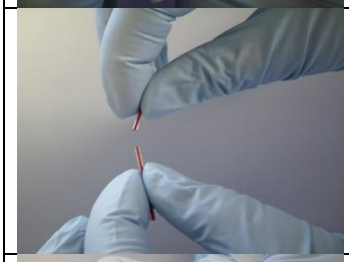
	Taking capillary blood from the earlobe or the tip of the finger and fill the capillary at least up to both markings.
	Make sure, it is properly filled (sufficient amount of blood, no air bubbles, no drops of blood at the end of the capillary etc.)
	Carefully wipe off the outer surface of the capillary
	Break the capillary at the predetermined breaking point (predetermined breaking point is located in the middle between two markings)
	Insert the completely filled capillary into the pre-filled sample cup
	Shake sample cup until the blood has completely left the capillary (during the measurement the capillary remains in the sample cup)

Figure 8.: Sample preparation using open-end capillary

ENG

4.6. Measuring operation

The following steps require complete preparation of the analyzer which implies that the appropriate ParamCards have been read. If this has not happened yet, they must be read now.

To measure a patient sample, proceed as follows:

1. If necessary, select menu item "Measure sample" by pressing the MENU button in the Measuring menu.
2. Prepare sample according to chapter 4.5.2.
3. Insert the prepared sample (closed sample cup) into the first slot of the slider. Ensure that the hinge of the sample cup is located between the position pins. Otherwise sample cup may open during piercing of the lid, which may damage sample needle during further processing.
4. Bring reagent to room temperature. Make sure that the reagent is at the very bottom of the cartridge.
5. Insert the reagent cartridge and the cleaner possibly needed for the parameters to be measured into the slider (onto last position).

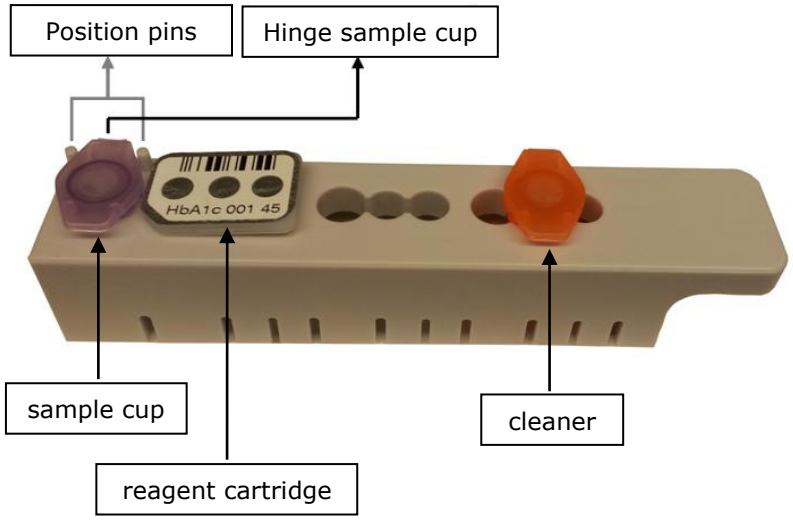


Figure 9.: Assembled slider

6. Insert the loaded slider into the analyzer. The slider has to be pushed into the instrument against slight resistance.
7. The device reads the bar code on the reagent cartridges. It shows the detected parameters for approx. 2 seconds. During this time it is possible to cancel the measurement by pressing the MENU button.
8. Now the selected parameters of the patient sample will be determined. The results are displayed and optionally printed out on the printer and/or transferred to EDP. The sequence of output/transfer depends on the sequence of the reagent cartridges on the slider.

ENG

9. Necessary washing steps with system solution or special cleaning solutions are automatically effected by the instrument.
10. Do not remove the slider before the instrument is requesting the removal.

A further patient sample may be measured. Proceed as described in steps 2 to 6.

Note:
In case of some few parameters the flow cell may require special cleaning. This is done with a cleaner that is supplied with the reagent cartridges for this parameter. For further information, please refer to the package insert.

4.7. Switching off InnovaStar®

The device may only be switched off when no more functions are being carried out. NEVER switch off the device while measuring or rinsing since then malfunctions may occur the next time the device, i.e. when switching the analyzer on again.

If the device is switched off for a longer time (e.g. during vacation), rinse and empty the device before switching it off.

For further information, please contact Service.

5. Operation - Part 2

5.1. Introduction

This part of the operator's manual describes special functions and settings relevant to the user. Furthermore, it gives additional information about quality control and problems which can be solved by the user.

5.2. Menu functions

As described in chapter 4.4, there are two main program branches: the measuring menu and the function menu.
The measuring menu contains all functions directly needed for measuring. The function menu contains all data management and setup functions. Switch between the two main program branches by pressing ENTER, in standby mode only.
The measuring menu is immediately ready for use after the start-up period. It can be browsed by pressing the Menu button repeatedly. If you need to use the function menu, switch to standby mode and select the function menu.

The menu branches show the following menu items:

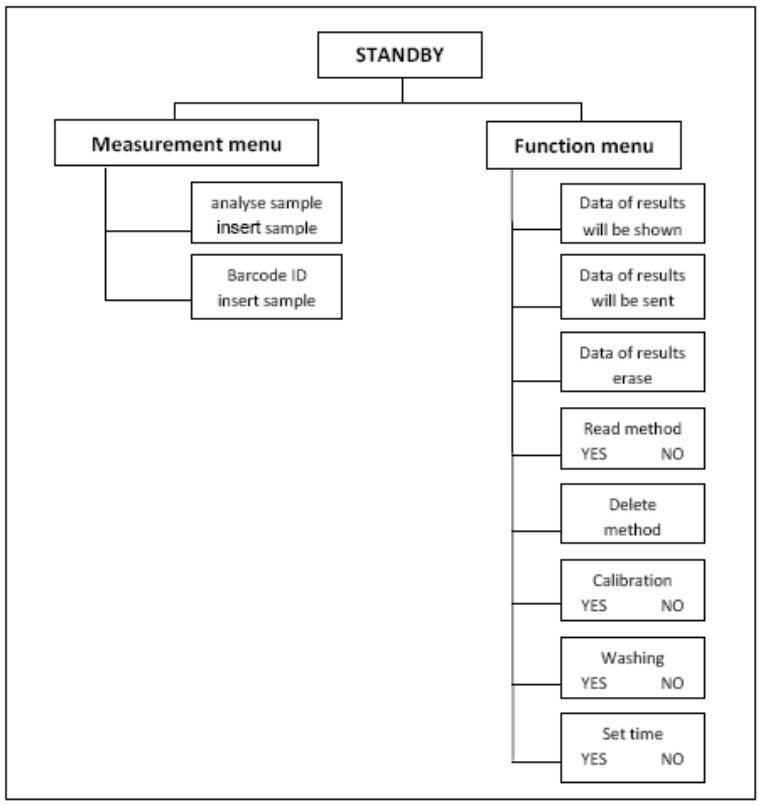


Figure 10.: Diagram menu areas

5.3. Menu items

5.3.1. Standby measuring menu

In this operating mode **InnovaStar®** does not carry out any functions. However, it is possible to switch into the function menu.

5.3.1.1. Sample measuring

InnovaStar® is ready for measuring. As soon as a slider is inserted, the measuring process begins as described in chapter 4.6.
After the sample has been measured, the results are displayed and optionally transferred to a connected printer and/or to an electronic data processing system.
The results of the last sample can be displayed repeatedly by pressing ENTER.

5.3.1.2. Sample measuring with bar code

This menu item is only available if a bar code reader or a PS2 keyboard is connected. The **InnovaStar®** automatically recognizes a supported bar code reader. For further information, please contact the manufacturer or distributor.

Instead of a bar code reader, a PS2 keyboard may be connected. In this case, digits and/or letters can be entered manually to identify a sample (up to 16 characters).
Example: M.Mueller,m,1966
For measuring a sample with bar code identification use following steps:

1. Choose menu "Bar code ID" by pressing the menu-key in the measurement menu.
2. By pressing theENTERkey the analyzer reads the bar code. If you are using a PS2 - keyboard you have to quit your input by pressing the ENTER key at the keyboard. You can abort the input of the bar code by pressing the ENTER key at the device.
3. Please proceed as describedin chapter 4.6.

The read sample identification will be printed out at display, printer and EDP.

5.3.2. Standby function menu

In this operating mode the device does not carry out any functions. However, it is possible to switch into the Measuring menu.

5.3.2.1. Display result memory

Here you can view the results of the latest 50 measurements. The value measured last is displayed first; by pressing "Menu" repeatedly the previous result is displayed and so on. The first line displays both date and time of the measurement or the sample identification entered. In the second line parameter and value appear. By pressing ENTER again, the display disappears and you return to the menu item "Display result memory".

5.3.2.2. Output results

Selecting this menu item and pressing ENTER issues all measured values stored in memory to the printer and to the electronic data processing system.

The results are not deleted. Results which have already been output can be printed or sent again by selecting "yes" after the prompt "Print all?"

5.3.2.3. Delete results

If the result memory is completely deleted, all results are lost and cannot be recovered. Therefore, after selecting this item, the device asks for confirmation "Delete yes/no".

5.3.2.4. Read method

Function and handling of the ParamCard are described in chapter 4.5.1.

5.3.2.5. Delete method

By means of this menu item, the complete method memory or individual parameters/lots can be deleted. This may be necessary if the memory is full or if individual parameters/lots are not needed any longer.

To delete parameters/methods proceed as following:

1. Select menu item "Delete method" by pressing the MENU key in the Functionmenu.

2. Confirm the inquiry "Delete all?" * with "yes" if you want to delete the complete memory. The operation is then finished.
3. If you choose "no" instead of following the above * step, all parameters/lots memorized will be shown stepwise. By pressing "yes" the individual parameter/lot will be deleted. By pressing "no" the next parameter/lot from the memory will be shown.

5.3.2.6. Calibration

Although the ParamCard stored calibration data, it might well become to recalibrate **InnovaStar®**.

The expiry of the calibration on the ParamCard might be one possible reason for recalibration.

For recalibration the analyzer needs up to 5 codes each with 8 digits plus 1 security code with 3 digits. Codes are provided on the homepage: www.diasys.de.
For recalibrating the device use following steps:

1. Choose menu "Calibration" by pressing the MENU key in the function menu.
2. Confirm the menu item by pressing the ENTER key.
3. Choose the parameter which should be recalibrated by pressing the MENU key respectively the ENTER key.
4. Enter the recalibration code digit by digit. By pressing the MENU key you set the number, by pressing the ENTER key you switch to the next digit.
5. If you entered all 8 digits the instrument will check this code.
6. A wrong code will not be processed.
7. The instrument asks if the input of the recalibration codes has been finished. To enter more codes, choose NO by pressing the menu key and enter the next code (see 4.). If all codes have been entered, choose YES by pressing the enter key.
8. Enter the security code (3 digits).
9. After entering the confirmation code, check the code. If the security code is correct, choose YES by pressing the enter key, otherwise choose NO by pressing the menu key for entering the security code again.
10. If the security code has been entered correct, the recalibration is effective. If the security code has been wrongly entered or if not all recalibration codes were entered, the calibration is blocked. Measurements of this reagent lot are not feasible before entering the correct codes again.
11. To check the recalibration the measurement of adequate controls is recommended.

By reading the ParamCard again the recalibration will be erased.

5.3.2.7. Rinse

The top line of the display shows "Washing"; the bottom line shows yes/no according to the buttons. Confirm to rinse the system. To empty the whole system, remove the hose from the system solution supply container of the container kit and effect the washing.

5.3.2.8. Set time

After pressing ENTER, the first row of the display shows the currently valid time set in the analyzer. The second row displays "OK" below the ENTER button and "SET" below the MENU button. By pressing MENU briefly, you can count up the minutes in single steps; holding the button counts up the minutes more quickly towards a later point in time. Setting the time can only be done in this direction. After reaching the desired time, press ENTER to confirm.

5.4. Quality Control

Please observe all national laws and regulations when it comes to the required quality control.

In Germany these regulations can be found in the guidelines of the German Medical Association (RiliBäk). For further information, please refer to www.bundesaerztekammer.de.

6. Maintenance and troubleshooting

6.1. Introduction

This chapter gives information on maintenance of the **InnovaStar®** and about problems which may occur and how you might be able to solve them on your own.

If you are unsure about certain aspects, DO NOT try anything you might consider as appropriate without qualified technical help. DO NOT open the device without an authorized professional*!

6.2. Maintenance

Every two years, **InnovaStar®** must be serviced by personnel authorized and trained by the manufacturer*. Please contact the manufacturer or distributor immediately to make an appointment for service.

6.3. Servicing

The following operations can and should be carried out by the operator. These actions are part of diligent care and serve to enhance the life span of the device. They are NOT maintenance or repair works, these may only be carried out by authorized professionals*!

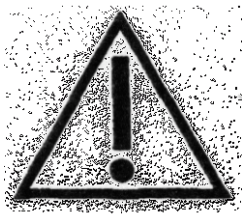
6.3.1. Cleaning and disinfection

Please adhere to the regulations valid in your laboratory with regard to cleaning and disinfection of the device. For disinfection turn off the device and wipe the entire accessible surface with a cloth containing disinfectant. Use a disinfectant for surface disinfection! Also note the instructions of the manufacturer of the disinfectant.

6.3.2. Changing the system solution

A combination of system solution / waste container made specifically for the **InnovaStar®** can be attached to the back side of the instrument. The sizes are designed in such a way that the waste container is full when the system solution is used up. The instrument monitors availability of the system solution but not the liquid level in the waste container.
Clean the grey rubber stopper with a cloth containing disinfectant after every change of the system solution. Use a disinfectant for surface

disinfection. Also note the instructions of the manufacturer of the disinfectant.



Due to the composition of the system solution and the high dilution of human blood sample the majority of pathogenic germs existing in these samples are eliminated. Nevertheless, regard the waste as potential infectious and observe the regulations applying to you for disposal.

***Note:* Do not use other than the prescribed bottles since this may result in malfunctions.**

6.3.3. Put device out of operation

To switch off the device for a longer period of time or finally or for transport, proceed as follows:

1. Rinse the device according to chapter 5.3.2.7.
2. Empty the system by removing the tubing from the supply bottle and repeat rinsing.
3. Switch off the device and disconnect all cables.
4. Remove all consumables (e.g. cartridges, container kit, etc.) from the device.

ENG

Prepare instrument for transport:

5. Decontaminate the device if necessary and put a declaration of decontamination into the original box (available at the distributor or at www.diasys.de).

6. Pack the device into the original box.

Disposing of the device:

7. Put a note on the declaration of decontamination declaring that the device will be disposed.
8. Contact the distributor concerning legal requirements for disposal of the device.

6.4. Troubleshooting

Alarm	Meaning	Action
Container kit has to change	System solution in the supply bottle is empty.	Replace supply and waste bottle. Confirm by pressing ENTER.
Cleaner has to change	Not enough Cleaner in the cup for next measuring.	Insert a new cup with cleaner into slider and insert slider into the analyzer again.
Result "Lim L"	Result is lower than the lower limit of the measuring range.	Check, if the result is plausible! If not, rerun sample! Check: Sample put on correct position of slider? Correct sample cup used? (Color must be as described in package insert) Correct system solution was used?
Result "Lim H"	Result is higher than the upper limit of the measuring range.	Check, if the result is plausible! If not, rerun sample!
Failure reagent	Measurement failed.	Check, if reagent cartridge was used for a second time. Rerun the sample!
Expiry XXX XX/XX	Expiry date for the used reagent cartridge will be reached in a few days.	Keep reagents with a younger lot ready at hand. Please note: Although this alarm occurs the device will measure the sample.
XXX XX/XX expired!	Shelf life of used reagent cartridge is over.	Use a reagent cartridge of a younger lot.

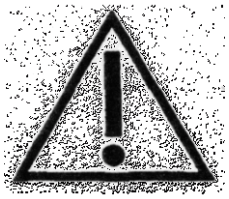
ENG

Alarm	Meaning	Action
Calibration XXX XX/XX expired!	Calibration data on ParamCard expired.	Recalibrate parameter!
Expiry calibration XXX XX/XX	Calibration data on ParamCard will expire in a few days.	Recalibrate parameter. Please note: Although this alarm occurs the device will measure the sample.
Calibration invalid!	Recalibration not successful.	Repeat recalibration or read ParamCard.
Method XXX LOT XX not in memory	No application stored for the bar code read on this reagent cartridge.	Read ParamCard of this reagent cartridge.
Card error: VX	The version of the ParamCard is not compatible with the software version of the analyzer.	Contact your distributor or service.
Card error: XX	Device cannot read the card.	Check wether card is inserted correctly. (Chip must show to the backside of the device.) Call service.
Error dispenser	Dispenser unit cannot reach its position.	Turn instrument off. If the dispenser unit is blocked mechanically, call Service!
Error Spectro	Spectrometer unit does not deliver data.	Turn the device off. Call Service!
Photometer instable!	No stable measurement possible.	Switch device off and on again. If error occurs again, call service.

Alarm	Meaning	Action
Error Cassette	Slider cannot reach its position.	Turn device off. If slider is blocked mechanically, call Service!
Error lifter	Sampler cannot move to its position.	Turn the device off. Call Service!
Failure canula	Canula cannot move to its position.	Switch device off and on again. If error occurs again, call service.
Error T-Sens	Thermostat does not get the set temperature of 37 ° C or 37 ° C are exceeded.	Turn off the device. Call Service!
Fe-RAM Failure	Check sum is not correct.	Delete result memory.
TiO	Bar code reader does not reply.	Insert the reagent cartridge again. If the alarm still occurs call service.

ENG

Figure 11.: List of alarms



If in doubt or if you have any questions, please contact service or manufacturer! The technicians are at your disposal to help you solve your issues to your satisfaction!
Unauthorized opening of the device automatically forfeits your warranty claim!

7. Technical data

Measuring time per sample	Depending on selected parameter Information on individual product information
Measuring range	0-2 absorption units
Wavelength	450-700 nm
Spectral width	3.5 nm
Amount of sample material	Depending on selected parameter Information on package insert
Interfaces	
Printer	V24, RS 232
EDP	V24, RS 232
Operating temperature (during measuring no great variations in temperature allowed!)	+15°C to +30°C
Storage temperature (emptied system)	-10°C to +50°C
Voltage	12 V DC
Power consumption	12 W maximum
Classification according to MPG	In vitro diagnostic (according to guideline 98/79/EC)
Dimensions	
Width	200 mm
Height	150 mm
Depth	170 mm
Weight	approx. 4 kg
Manufacturer	DiaSys Diagnostic Systems GmbH Alte Str. 9 65558 Holzheim, Germany

Figure 12.: List of Technical data

The technical data for the various parameters can be found on the corresponding package inserts.