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SZABO-SCANDIC HandelsgmbH

Quellenstraße 110, A-1100 Wien

T. +43(0)1 489 3961-0

F. +43(0)1 489 3961-7

mail@szabo-scandic.com

www.szabo-scandic.com

[linkedin.com/company/szaboscandic](https://www.linkedin.com/company/szaboscandic) 

HumaFIA

| User Manual



CE

REF 16090/1



HumaFIA

Semi-automated time-resolved fluorescence immunoassay analyser

Catalogue numbers covered

16090

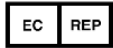
Name and Address of Manufacturer



HUMAN Diagnostics Product (Beijing) Co., Ltd.

Address: Unit 703, Yongchang Industry Park, No.3 Yongchang North Road, BDA 100176, Beijing, China

Name and Address of Authorized Representative



HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Address: Max-Planck-Ring 21, 65205, Wiesbaden, Germany, Tel: +49-6122-99880, E-Mail: human@human.de

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Software 1.5.930

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1 SAFETY INSTRUCTIONS

1.1 Introduction

This manual is considered part of the instrument and must be available to the operator and the maintenance personnel. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid damage to the instrument or personal injury, carefully read chapter 1.4 *General safety warnings*, describing the appropriate operating procedures. Please contact your HUMAN authorized local Technical Service in the event of instrument failure or other difficulties with the instrument.

1.2 User warranty

HUMAN warrants that instruments sold by one of its authorized representatives shall be free of any defects in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item within this warranty period at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability to replace any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer instructions, altered in any way not specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.

1.3 Use of the instrument

This instrument must be used for its intended purpose (see chapter 2.1 *Intended purpose*). It must be operated in perfect technical conditions, by qualified personnel, in such working conditions and maintained as described in this manual, in chapter 1.4 *General safety warnings*. This manual contains instructions for qualified professional operators.

1.4 General safety warnings

Use only chemical reagents and accessories specified and supplied by HUMAN and/ or mentioned in this manual. Place the product so that it has proper ventilation. The instrument should be installed on a flat, stationary working surface, that is free of vibrations.

Do not operate in area with excessive dust. Operate at temperature and at a humidity level in accordance with the specifications listed in this manual. Do not operate this instrument with covers and panels removed.

Use only the power cord specified for this product, with the grounding conductor of the power cord connected to earth ground.

Use only the fuse type and rating specified by the manufacturer for this instrument. The use of fuses with improper ratings may pose electrical and fire hazards. To avoid fire or shock hazard, observe all ratings and markings on the instrument. Do not power the instrument in environments that are potentially explosive or at risk of fire.

Prior to cleaning and/or performing maintenance on the instrument, switch off the instrument and remove the power cord. Only cleaning materials described in this manual may be used, as other materials may damage parts. It is recommended to always wear protective clothing and eye protection while using this instrument. All warning symbols that appear in this manual must be carefully observed.

The instrument is exclusively used for clinical diagnostics.

For users in the European Union only: Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

1.5 Disposal management concept

The applicable local regulations governing disposal must be observed. It is the user's responsibility to arrange for proper disposal of the individual components.

All parts which may contain potentially infectious materials must be disinfected by suitable, validated procedures (autoclaving, chemical treatment) prior to disposal. The instruments and electronic accessories (without batteries, power packs etc.) must be disposed of according to the applicable local regulations for the disposal of electronic components.

Batteries, power packs and similar power sources must be removed from electric/electronic parts and disposed of in accordance with applicable local regulations.

1.6 Biohazard warning

Analytical instruments for in vitro diagnostic application involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore, every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious.

The BIOHAZARD warning label must be affixed to the instrument prior to its first use with biological material!



Figure 1 Biological hazard symbol

1.7 Instrument disinfection

Before performing any servicing on the instrument, it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. Decontamination must be performed by authorized, well-trained personnel, and in observance of all necessary safety precautions.

2 SYSTEM DESCRIPTION

2.1 Intended purpose

HumaFIA is a semi-automated time-resolved fluorescence immunoassay analyser, intended for quantitative measurements of physiological or pathological parameters in human serum, plasma, or whole blood, depending on the test parameter. The instrument is a closed system intended to be used only in combination with HumaFIA SR reagents, as an aid to diagnosis, for screening or monitoring. For laboratory professional use only.

2.2 Instrument structure

The instrument consists of the instrument shell, power supply, cassette reader by fluorescence technique, display and a data management unit.

The instrument shell consists of two parts: the upper and lower shell. The upper shell can be removed from the instrument so that it provides an easy access for service personnel.

The instrument is controlled by an internal software which can store up to 10,000 test results. The power supply switch is located on the back of the instrument.

2.2.1 HumaFIA instrument



Figure 2-1 HumaFIA instrument with cartridges, to be inserted into the Cassette input slot

2.2.2 HumaFIA power supply



Figure 2-2 Power supply

2.2.3 HumaFIA calibration card

The calibration card [CAL] contains the calibration curve for one parameter, which is shown on the card. Further, the LOT number of the corresponding cartridge kit is shown below the parameter name. Insert the calibration card into the analyser to upload the calibration curves into the analyser. The calibration card is then not needed anymore, since the calibration curve for this LOT and parameter is already stored in the analyser. Nevertheless, keep the calibration card until the kit is used up. For further details on upload, see chapter 3.3.5 *Calibration cards overview in the QC module*.



Figure 2-3 Calibration card, with LOT and parameter information

2.2.4 HumaFIA power bank

The HumaFIA power bank (73 Wh) is an optional accessory that allows the analyser to run for several hours even when no mains power is available. It can be combined with a solar panel to function as a stand-alone power system.



Figure 2-4-1 Power bank, 20100 mAh, 73 Wh
REF: 18250/70



Figure 2-4-2 Solar panel, foldable, 36W
REF: 18250/73

2.2.5 HumaFIA test cartridges

Each test cartridge has the same shape that fits into the slot marked *Cassette* input on the front of the analyser. The sample volume gets administered at the sample port of the cartridge. The reading of the test occurs inside the analyser in the rectangular window of the cartridge.

The analyser automatically reads the barcode on the cassette and matches the type of cartridge with the user's selection in the software. Also, the expiration date of the LOT is checked. The test type and LOT number are shown next to the barcode.

Insert the cartridge with the sample port end first into the analyser, as indicated by the arrow.



Figure 2-5 Cartridges of various parameters, with barcode containing LOT information

2.2.6 HumaFIA data cable



Figure 2-6 Data cable, to connect HumaFIA with a PC for data exchange

2.2.7 HumaFIA Standard Cartridge

The Standard Cartridge is a service tool. The Standard Cartridge allows a service engineer or an experienced user to check the correct function of the HumaFIA optical system.



Figure 2-7 Standard Cartridge, REF: 16090/510

To run the Standard Cartridge on HumaFIA, first insert the corresponding calibration card. Run the Standard Cartridge in the QC module, see chapter 3.3 *QC module*.

2.3 Technical data

Display	800 x 480 pixels, / 7-inch touch screen
Operating system	Linux
Sample reading time	Less than 3 seconds
Sample requirements	Depends on parameter type (serum, plasma, whole blood)
Environmental conditions	20-25 °C operation temp. 20-90 % relative humidity, non-condensing. Air pressure 86.0-106.0 kPA Avoid strong magnetic disturbance, keep away from explosive gas, dust, direct light and water immersion.
Storage conditions	10-40 °C (when the analyser is not connected) <93 % relative humidity, non-condensing. Air pressure 50.0-106.0 kPA
Printer	Internal thermal printer
Sample identification	External (optional) barcode scanner
Power supply	100-220 V, 50-60 Hz, max power consumption 60 VA. DC 12V 5A. Three-wire power cord of good grounding performance.
Dimensions	300 x 305 x 120 cm
Weight	4.2 kg

Table 2-1 Specifications

2.4 Method: time-resolved fluorescent immunoassay

2.4.1 Fluorescent immunoassay lateral flow cartridge

Lateral flow assays with dry reagents are simple to use, but very specific due to their antibody detection method.

Principle: The test uses a sandwich detection method to determine an analyte like CRP in a specimen. If the analyte is present in the sample, the Eu^{3+} labelled antibody will capture analytes flowing downstream in the nitrocellulose membrane. The immunocomplex is then captured in the test area by a fixed antibody, forming antibody-antigen-antibody complexes. The more antigen/analyte in the sample, the more immunocomplexes are captured in the test area. This leads to a stronger intensity of the Eu^{3+} fluorescence signal, which is processed by the instrument displaying the analyte concentration of the sample.

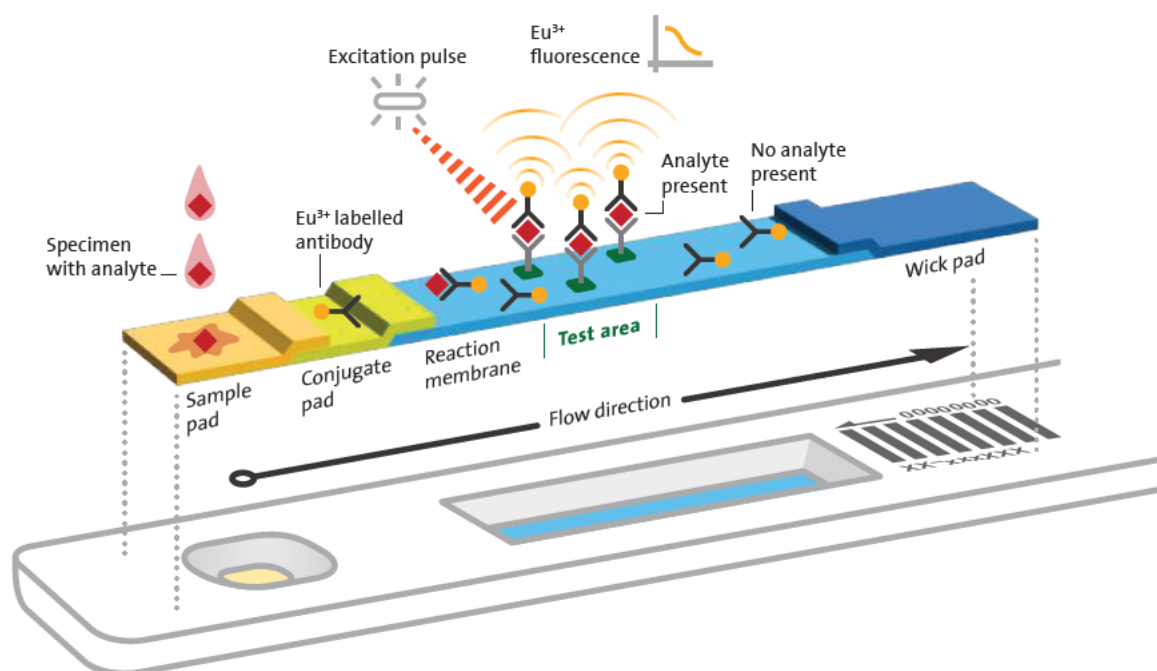


Figure 2-8 Reaction principle

Stable dry reagent cartridges are ready to use (4-30 °C) for easy storage and transportation. Whole blood, serum and plasma are supported sample types. Refer to the corresponding IFU for each parameter.

2.4.2 The time-resolved technology of HumaFIA

The highly sensitive time-resolved fluorescent immunoassay (TR-FIA) technology is based on fluorescent europium Eu^{3+} chelates, with large Stokes shifts, narrow emission bands and long fluorescence lifetimes. Conventional fluorescence dyes emit only during a short period of time after the excitation pulse. However, in that first time span auto-fluorescence emission occurs, too, which contributes to the background signal of conventional tests.

Time-resolved technology, based on Eu^{3+} with long fluorescence lifetimes, allows the detection of fluorescence to start just after auto-fluorescence has completely decayed. This guarantees very sensitive tests with a low limit of detection (LOD).

Since this process takes place in 0.5 ms, the read-out time of the test by the instrument takes only a few seconds.

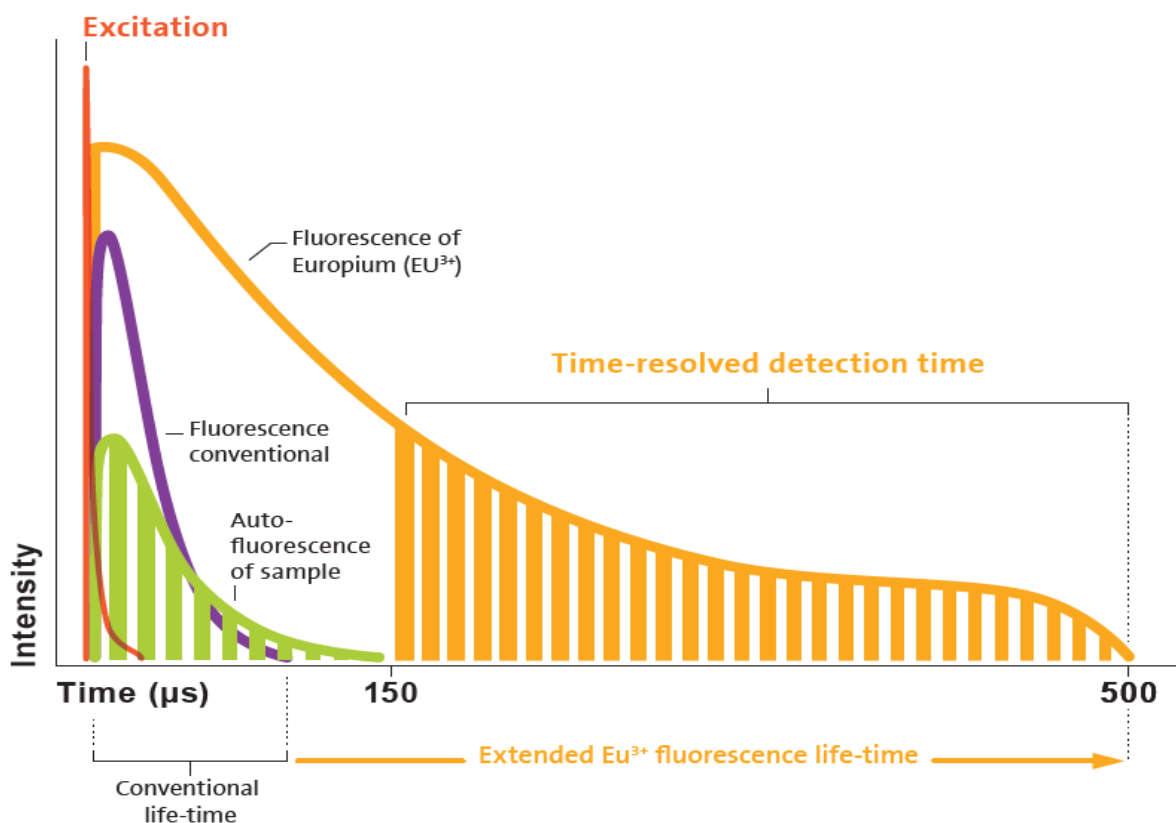


Figure 2-9 TR-FIA method explanation, graph for illustration purposes only

2.5 Installation

This chapter provides instructions for the unpacking and installation of the HumaFIA analyser. Follow the procedures below to ensure proper operation and service. Carefully read and follow all the instructions in this User Manual before operating the analyser. This immune-fluorescence analyser is a precision instrument: Handle with care.

Dropping or improperly handling the instrument will disrupt or damage the calibrated mechanical and electronic components. Inspect the instrument for any visible signs of damage incurred during shipping. If there is any damage, file a claim with the carrier or your distributor immediately. Check the accessories received against the packing list. Contact Service if anything is missing.

1. Unpack the instrument.
2. Place the instrument on a surface with easy access to a ground power outlet and ensure that the distance between the instrument and the power outlet is greater than 20 cm.
3. Place the instrument in a way that the user can easily access the power switch. In an emergency, the user can turn off the instrument with the switch or unplug the power cord.
4. The workbench should be at least 400 mm (L) x 450 mm (W) x 450 mm (D) and should be able to hold more than 5 kg.
5. Keep enough space in front of the instrument for easy operation. Place the instrument in a stable way to avoid impact or collision.
6. Connect the power cord to the instrument power interface.
7. Do not remove the instrument randomly.
8. Keep the room well ventilated for cooling.

To ensure the accuracy of the instrument and the comparability of the measured data, the optical part of the instrument needs to be tested. See the description of use of the Standard Cartridge, chapter 4.9.1 *Run Standard Cartridge as quality check*.

Basic steps to run a sample, explained in detail below in the description of the software

1. Turn on the analyser.
2. Insert the calibration card to upload the calibration curve (see 3.3.5 *Calibration cards overview in the QC module*).
3. Select a sampling mode.
4. Add patient name or ID.
5. Add sample to cartridge and wait for incubation (see IFU for each parameter).
6. Insert cartridge into analyser for reading.
7. Automatic data storage, optional print-out of result.
8. Turn off the analyser.

2.5.1 Turning the instrument ON

Connect the power cord. Turn on the power switch on its back. Each time the instrument is turned on, it will conduct a self-check. The system will check its hardware automatically. Once the self-test is finished, the system will enter the Login interface of the instrument. Select **Admin** and type in the numbers **12345678** as password.

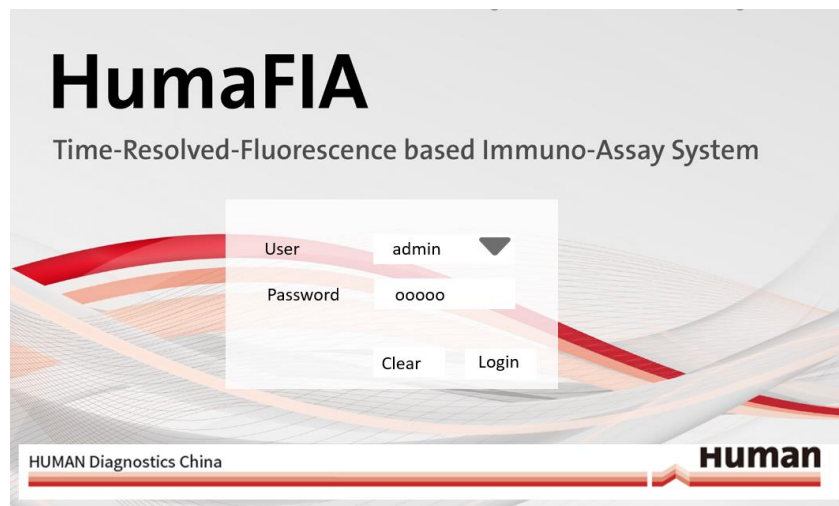


Figure 2-10 Start screen

Note: Not all functions/options are available in **Admin** mode and even less are available in **User** mode. Contact your supplier to introduce changes which are only possible in **Service** mode.

Select the user level, type in the password, and click **Login** to enter the home screen (see chapter 2.6.1.4 *Home screen*).

2.5.2 Turning the instrument OFF

After completing the tests, turn off the power switch at the back of the instrument.

2.6 Software user interface

This chapter contains information about the structure and use of the software implemented menu structure. This integrated software controls instrument operations, including calculation and evaluation of measured data, displaying results and information screens, storage and retrieval of data.

2.6.1 User interface

The user interface of the HumaFIA analyser is designed to be intuitive and easy to use and provide access to all user level functions. The user can interact with the HumaFIA by using only the touch screen and the virtual on-screen keypad, or by using an external keyboard.

2.6.1.1 Using the touch screen

The touch screen is a capacitive sensor behind glass. It must be operated by finger, or a conductive stylus designed for capacitive touch screens, as it is not sensitive to pressure. The touch screen allows selection of menu items and 'pressing' of buttons by gently tapping the surface over the selected item. The touch-screen device used in the HumaFIA analyser was selected for its reliability, endurance, and compatibility with the medical laboratory environment. Simple operations are supported, but multi-touch gestures or multiple tapping are not supported. The surface glass material is resistant to liquids. However, it should be dry when in use, otherwise it may not work reliably. Use a damp cloth to clean the glass surface when the analyser is turned off.

2.6.1.2 Button colours

Activated buttons are displayed either in red with white icons or in dark grey with white icons, while inactive. Upon selection they turn to opposite colours. In case a button is not selectable, it remains greyed out.

2.6.1.3 Entering information

HumaFIA sometimes requires the operator to enter information such as sample ID or patient data. To enter information into a data field, simply tap or click on its box. The data field will change colour, indicating that data entry is active for that field. Enter information using the virtual on-screen keypad or with an optional external keyboard.

Data is not saved until the user presses **Enter** or **Save** or **Accept** to proceed.

2.6.1.4 Home screen

The Main menu will appear after start-up or when the HUMAN logo is pressed in the menu headline.

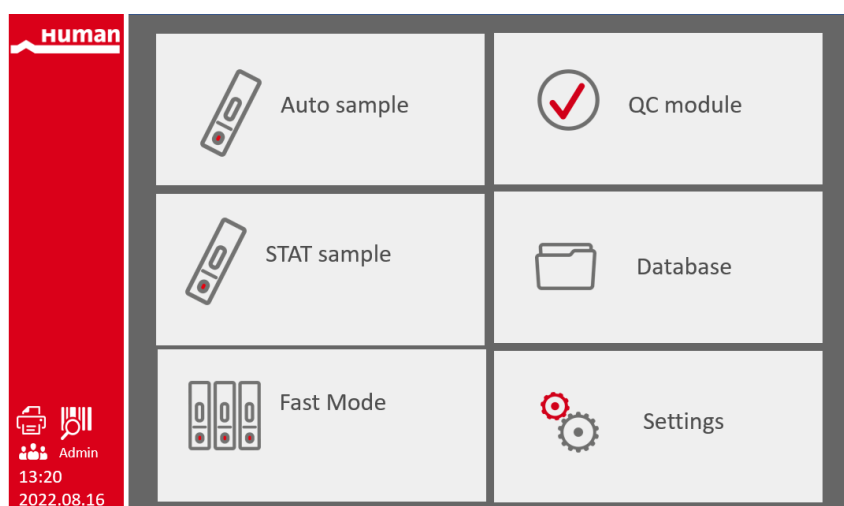


Figure 2-11 Home screen

Description of the home screen interface

Red bar on the left side:

- Instrument time and date
- User mode of the instrument (Admin, User or Service mode)
- External barcode reader connection status
- Printer connection status

Six grey buttons:

- The grey buttons lead directly to the function after which they are named.

2.6.2 Menu tree

The following is a list of the HumaFIA analyser menu tree.

2.6.2.1 Home screen interface

Figure 2-11 shows the main interface, which appears automatically after logging into the system.

The menu shows 3 sampling modes and 3 modules to operate the system. Each is explained below and in a separate chapter (3.2 *Sampling modes*, 3.3 *QC module*, 3.4 *Database interface* and 4.1 *Settings interface*).

- **Auto sample** with incubation: Insert the test cassette after adding a sample, incubation and reading are done automatically.
- **STAT sample** only reading: Incubation of samples is done outside the analyser. The timing can be managed manually. Insert cartridge only for reading.
- **Fast mode**: workflow planning by software with definition of start-point of incubation, request for reading and monitoring of incubation time.
- **QC module**: Allows the user to set the QC LOT number, reference value and deviation, check the L-J curve, and check the quality control result value (this module will be released in a second phase).
- **Database module**: To view the sample result value, query result.
- **Settings module**: for settings of date and time, but also of flags, reference values, printer settings, connectivity, and database selection for review of results.

Access the home screen from any screen on the analyser by pressing on the HUMAN logo in the upper left corner of the permanent header.

2.6.2.2 Permanent header



Figure 2-12 Permanent header is displayed on each HumaFIA screen

The first line shows the HUMAN logo and then the selected user (e.g., Admin) followed by the status of various connectivity ports, software checks and settings.

The 6 main categories or modules of the software are shown in the second line of the permanent header: Auto sample, STAT sample, Fast mode, QC module, Database and Settings. Each module is explained in a separate chapter (3.2 *Sampling modes*, 3.3 *QC module*, 3.4 *Database interface* and 4.1 *Settings interface*).












Status of	White	-Symbol colour and meaning-	Yellow
 Printer	Printer is connected.		Printer is not working.
 External barcode reader	Barcode reader is connected.		Barcode reader is offline.
 Calibration card	Uploaded calibrations are valid and match the selected tests.		Uploaded calibrations are not valid or do not match the selected tests.
 Sample, cartridge	Warning, error message		
 Quality control module	Controls are valid and within target value range.		Controls are expired or out of the target value range.
 Database	Storage capacity available		Storage capacity low
 Settings	Warning, error message		
 Alarm triangle	Warning, error message		
 Temperature, monitored by sensor on HumaFIA system.	Within limits of sample incubation of 18-28 °C.		Ambient temperature sensor out of acceptable range: <18 °C or >28 °C. Risk of wrong values.
 Time	In the format hh:mm:ss, to change it, see chapter 4.3 <i>General (Date, Time, Language, Brightness, Temperature, Delete)</i> .		
 Date	In the format YYYY-MM-DD, to change it, see chapter 4.3 <i>General (Date, Time, Language, Brightness, Temperature, Delete)</i> .		

Table 2-2 Meaning of the symbols shown in the status line of the permanent header

Use the scroll bar on the right side of most screens to reach more patient results or data if they are not initially displayed. Pressing on the HUMAN logo always directs to the home screen.

3 ROUTINE UTILIZATION AND MEASUREMENT

3.1 Instrument operation and sample preparation

The HumaFIA analyser is a semi-automated instrument. The user must prepare the sample, incubate the cartridge (automatically inside the analyser or manually outside), insert a sample cartridge in the analyser at the Cassette input slot of the analyser, and start the reading of the results. See below for more details.

For sample preparation, incubation and cartridge handling, follow the instruction for use of each HumaFIA parameter, since sample types, anticoagulants, sample volumes and use of buffer are also parameter dependent.

3.1.1 Specimen

1. Typically, whole blood, serum and plasma can be used.
2. The serum or plasma should be separated by centrifugation within 2 hours from the time of blood collection.
3. Test the sample immediately or within 2 hours of sample collection. If testing cannot be completed within 2 hours, store the serum or plasma at +2 - +8 °C for 8 hours; if longer storage is required, store the serum or plasma below -20 °C for up to 3 months. Do not heat inactivated samples. Discard haemolysis samples.

3.1.2 Procedure

Follow the procedures exactly as described:

1. Before sample testing, read the instructions and applicable Instrument User Manual carefully. Before using a refrigerated test cartridge, allow it to reach the operating temperature (18-28 °C). Place the test cartridge on a level, horizontal surface.
2. Check that the LOT number of the test cartridge matches that of the calibration card.
3. Insert the calibration card into the calibration card port of the instrument for tests.
4. Refrigerated serum or plasma specimens must reach room temperature before testing. Frozen plasma or serum samples should be vortexed and centrifuged after thawing. The supernatant liquid should be obtained and reach room temperature before testing.
5. If required, pipette serum/plasma/whole blood into the vial of diluent (see parameter IFU). Reclose the cap of the vial and mix the sample mixture by inverting the vial 10 times.
6. Pipette exactly 80 µl of the (diluted) sample into the sample port of the test cartridge. Start the timer, a few minutes (according to IFU) are needed for the reaction.
7. Insert the test cartridge into the analyser after reaction time has elapsed, select the accurate sample type as described below for one of the three modes to run a sample. The test cartridge type is detected and checked automatically by the analyser. Once the test is read by the analyser, the result will be displayed on the screen and can be printed when the analysis is complete.
8. After the assay is completed, remove the cartridge from the analyser.
9. Dispose of the used cartridge and pipette tips in accordance with any applicable regulations.

3.1.3 Calibration

Master curve calibration: Every HumaFIA SR reagent kit has a calibration card [CAL] that contains LOT-specific information for the calibration. After upload of the calibration curve from the card, the calibration for this LOT is stored on the instrument. All subsequent samples may be tested without further upload. Content of calibration cards can be uploaded any time.

3.1.4 Calculation of results

The HumaFIA system automatically calculates the analyte concentration of each sample. See upload of calibration curve, chapter 3.3.5 *Calibration cards overview in the QC module*.

3.1.5 Quality control

For quality control, use the corresponding quality control products provided by HUMAN:

- Once every day, before testing.
- If there are any unexpected test results.
- After each upload of a calibration curve.

Quality control results that do not fall within reference ranges may indicate invalid test results.

3.1.6 Reference value

Reference values are provided in the IFU and can be stored at the analyser as reference value/range for each parameter.

It is recommended that each laboratory establish its own expected values for the population it serves.

3.1.7 Interpretation of results

If the concentration in the sample exceeds the linear range, dilute the sample with 5 % BSA normal saline solution before testing. HumaFIA offers a software option to calculate values for prediluted samples automatically. Each sample can be diluted up to 3 times.

The test results should not be used as the sole basis for diagnosis and should be combined with other clinical and laboratory data for clinical diagnosis. If the test results do not match the clinical assessment, further tests should be performed.

3.1.8 Limitations

Certain samples containing antibodies directed against reagent components may cause interference. For this reason, assay results should be interpreted taking into consideration the patient's clinical history, and the results of any other tests performed.

If a sample contains a high concentration of triglyceride, cholesterol, bilirubin or haemolysis, the test result will be affected.

As with any assay employing mouse antibodies, interference by human anti-mouse antibodies (HAMA) in the sample is possible. The test has been formulated to minimise this interference; however, specimens from patients who have been routinely exposed to animal products or to animal serum may contain heterophile antibodies which may cause erroneous results. For further details see IFU.

Note: The inner packaging/pouch of each cartridge must be tightly sealed without leakage. The surface of the test card should be smooth, without burrs, and uniform in colour.

Safety Notes: All patient specimens, calibrators and controls should be handled as potentially infectious. All donor units of human origin have been tested for HBsAg, HIV and HCV-antibodies and found to be non-reactive using approved methods. All materials of animal origin avoid many risks associated with the use of human serum (e.g. Hepatitis B and C, HIV). Nevertheless, all materials of human or animal origin should still be treated as potentially infectious material.

3.2 Sampling modes

The HumaFIA software provides 3 modes to run a sample.

- Auto sample mode
- STAT sample mode
- Fast mode

3.2.1 Auto sample mode, with internal incubation

Upon selection of **Auto sample**, the following screen is displayed:

Human		24°C	2023.01.04 13:04:37				
Auto sample	STAT sample	Fast mode	QC module	Database	Settings		
Patient, ID	Parameter	Result	Date&Time, sample	Timer	Lot	Cut-off	
Add sample							
Musterman, Otti, 22202301030006	hs-CRP [mg/L]	>10.00 ↑	2023.01.03 17:23, S	--:--	20220501	<3.00	
Musterman, Otti, 22202301030006	CRP [mg/L]	70.33 ↑	2023.01.03 17:23, S	--:--	20220501	<10.00	
Muster, Otto, 225	hs-CRP [mg/L]	>10.00 ↑	2023.01.03 17:22, B	--:--	20220501	<3.00	
Muster, Otto, 225	CRP [mg/L]	>200.00 ↑	2023.01.03 17:22, B	--:--	20220501	<10.00	
, , 22202301030004	hs-CRP [mg/L]	>10.00 ↑	2023.01.03 16:41, P	--:--	20220501	<3.00	

Figure 3-1 Auto-sample mode for automated incubation and reading of tests

Auto sample mode allows the automated sampling for a test. The analyser automatically manages the incubation time and the reading of test results after the incubation of the test is completed inside the analyser.

If the incubation time is 1.5 minutes, e.g. for the CRP parameter, no other test can be run during that incubation/testing time.

Use the **Add sample** button to add a new test to the worklist by selecting a patient name/ID and parameter type. Refer to chapter 3.2.4 *Add sample, patient data and parameter type* below.



Pressing **Insert cartridge for incubation** closes the sample detail interface and starts the software timer.

Add the patient sample to the cartridge and place the cartridge in the analyser before pressing this button.

Pressing this button starts the automatic incubation timer. After incubation time, the reading of the test is triggered automatically by the software. The result accuracy depends on the correct incubation time. Therefore, the timing is very important when preparing the cartridge and starting the software timer.

The remaining incubation time is shown on the column **Timer** next to the hourglass, in the format mm:ss. In the column **LOT**, the LOT number of the used cartridge kit is shown. The column **Cut-off** displays the clinical cut-off value.

After automatic reading of the results by the analyser, the results are shown together with the corresponding unit in brackets. Results in black are normal, while results in red will get flagged with an arrow, since they are out of the normal range. An arrow up is an indicator that the values are higher than normal. An arrow down indicates a result below the normal range. The date and time of the reading is shown, together with the sample type. S = serum, B = whole blood, P = plasma.

Note: 3-in-1 tests, like cTnI/Myo/CK-MB are displayed in 3 lines. Each parameter of the 3-in-1 cartridge is shown in a separate line on the screen. The parameter names start and end with two dots (e.g. ..cTnI.., or ..Myo..).

3.2.2 STAT sample mode, flexible testing

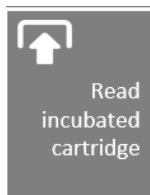
Select **STAT sample** on the home screen or in the permanent header to reach the following menu.

Patient, ID		Parameter	Result	Date&Time, sample	Lot	Cut-off
Add sample						
Musterman, Otti, 22202301030006		hs-CRP [mg/L]	>10.00 ↑	2023.01.03 17:23, S	20220501	<3.00
Musterman, Otti, 22202301030006		CRP [mg/L]	70.33 ↑	2023.01.03 17:23, S	20220501	<10.00
Muster, Otto, 225		hs-CRP [mg/L]	>10.00 ↑	2023.01.03 17:22, B	20220501	<3.00
Muster, Otto, 225		CRP [mg/L]	>200.00 ↑	2023.01.03 17:22, B	20220501	<10.00
, , 22202301030004		hs-CRP [mg/L]	>10.00 ↑	2023.01.03 16:41, P	20220501	<3.00

Figure 3-2 STAT sample mode for flexible reading of tests

STAT mode allows to incubate the sample outside the analyser and run another sample in between, if the incubation time of the sample still allows it. The analyser does not monitor the incubation time in this mode. Therefore, the operator must assure correct incubation time by manual methods, such as a timer.

First, define the next sample with the button **Add sample**. This leads to the process described in chapter 3.2.4 *Add sample, patient data and parameter type*.



Pressing **Read incubated cartridge** on the previous screen **Add sample** closes the sample detail interface and starts the reading of the cartridge.

Insert the incubated cartridge into the analyser and press this button exactly when the incubation time is up.

Pressing this button immediately starts the reading of the result. The result accuracy depends on the correct incubation time. Therefore, the timing is very important when preparing the cartridge, starting the timer and then starting the reading.

Note: 3-in-1 tests, like cTnI/Myo/CK-MB are displayed in 3 lines. Each parameter of the 3-in-1 cartridge is shown in a separate line on the screen. The parameter names start and end with two dots (e.g. ..cTnI.., or ..Myo..).

3.2.3 Fast mode sampling

Select **Fast mode** on the home screen or in the permanent header to access the following menu.

Human		24°C	2023.01.04 12:52:37			
Auto sample	STAT sample	Fast mode	QC module	Database	Settings	
Patient, ID	Parameter	Result	Date&Time, sample	Lot	Cut-off	Timer
Add sample						
1	22202301040001	cTnI	--,--	S		Incubation -14:41
2	22202301040002	PCT	--,--	P		Next sample 01
3	22202301040003	hs-CRP/CRP	--,--	B		Next sample 01

Figure 3-3 Fast mode, for reading of a series of tests

Fast mode allows the user to run a series of tests and delivers a test result every 20 seconds.

The workflow management software supports fast testing by managing:

- when to add the sample to the cartridge
- when to insert the fully incubated cartridge into the analyser for reading
- the correct incubation time to guarantee a quality result

In this way, a series of tests, even of different parameter types, can easily be managed.



First, define a worklist of patients via the **Add sample** button to add samples. This leads to the process described in chapter 3.2.4 *Add sample, patient data and parameter type*.

Pressing **Add test to Fast mode list** on the previous screen closes the sample detail interface and adds the samples to the work list from bottom to top, one by one.

To run a sample in **Fast mode**, follow these steps for each test.

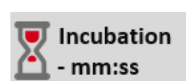


In the **Fast mode** worklist, in the column **Timer**, the button **Next sample** appears. The number of seconds indicates when it is possible to start the next (or first) sample in **Fast mode**. If the number of seconds equals 00 or if **80µl vol. added** is shown, it is possible to start that test.



The next step is to add 80 µl of the sample to the cartridge. Once this is done, press this button immediately. Now the monitoring of the incubation time for this test starts.


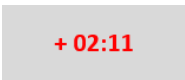
Note: Depending on the parameter, the sample volume of 80 µl consists of blood/serum, or of a dilution of blood/serum (see IFU of parameter).





For this test, now the remaining incubation time is shown in the format mm:ss. When the incubation time for this test is almost up, the next button appears.



Now the user has 10 seconds to insert the cartridge into the analyser and press the **Read** button. For valid results, press the **Read** button when the timer is equals 00. Reading takes only a few seconds, then the result of this parameter is displayed.

	If the timing was correct, --:-- appears, indicating that the incubation time was correct and within the acceptable range.
	If a number in red appears, like +02:11, the incubation time was 2 minutes and 11 seconds too long, indicating that the result is not valid and must possibly be repeated.

To run a series of tests, the workflow described before can be started for the next test.

	This button is displayed to prepare the next test in the Fast worklist once the incubation time for the previous test started. The workflow programme runs a timer, allowing the user to prepare for the next test. If the timer display equals 00, the system is ready for the next cartridge to be prepared.
	Now for the second test, 80 µl of the sample must be pipetted into the cartridge. Once this is done, press this button immediately. Now the monitoring of the incubation time starts for the second test of the worklist.

The series as described above for the first test will be processed for the second test and subsequent tests until the **Fast** worklist has been processed.

Once the **Fast** worklist is empty, the following sample information is provided in each line: the patient's name, ID, parameter type and in brackets the unit, the result, the date, and time of reading the test, plus used sample type (B=whole blood, S=serum, P=plasma). Further, the LOT and cut-off value for this parameter are also displayed as a reference. The analyser displays only results without linearity flags, as these flags indicate that the test was not valid and must be repeated. If there is a red number in the **Timer** column, the incubation time was not correct.

The following acoustic alarms can be enabled in the settings:

Acoustic alarm	Function
2 short beeps	Next sample can be selected
Long beep	Incubation time almost finished, 10 seconds before incubation time ends
Very long beep	Incubation time finished
Short beep	Reading of the cartridge is finished, result is displayed

Table 3-1 Acoustic alarm settings, can be enabled and modified in the settings menu

Note: 3-in-1 tests, like cTnI/Myo/CK-MB are displayed in 3 lines. Each parameter of the 3-in-1 cartridge is shown in a separate line on the screen. The parameter names start and end with two dots (e.g. ..cTnI., or ..Myo..).

3.2.4 Add sample, patient data and parameter type

In each of the three sampling modes, the same procedure is used to add a patient ID, select a parameter and sample type, or choose a predilution. Further patient data like last name and name, birthday, sex and a comment can be added to a sample.

The next screen allows the user to add a patient sample to the worklist in **Auto sample**, **STAT sample** and **Fast mode**. The screen is always the same, only the button to close the screen is different, depending on the sample mode. See Figure 3-4 below:

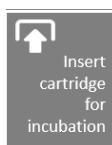
Patient data	Pre-Dil.	Sample	Parameter	Add ID	Add sample		
Family name	Yes 1:3	Serum	PCT	032			
Given name	yes	Blood	cTnl, D-Dimer	1	2	3	Cancel
Birthday / Gender	no	Serum	PCT, Vitamin-D	4	5	6	Delete
Keyboard		Plasma	CRP, cTnl/Myo/CK-MB	7	8	9	Insert cartridge for incubation
Patient bar-code		Capillary Blood	NT-proBNP, other	0			Exit

Figure 3-4 Add a new sample to **Auto sample**, **STAT-sample** or **Fast-mode** process to run a test

3.2.4.1 Confirmation of patient data in each of the 3 testing modes

The previous screen is closed by pressing one of the following buttons, depending on the sample mode:

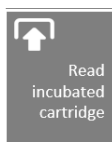
Auto sample



Pressing **Insert cartridge for incubation** closes this screen in **Auto sample** mode and starts the software timer.

Add the patient sample to the cartridge and insert the cartridge into the analyser just before pressing this button.

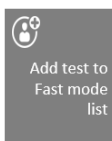
STAT sample



Pressing **Read incubated cartridge** closes this screen in **STAT sample** mode and starts immediate reading of the test.

Insert the incubated cartridge into the analyser and press this button exactly when the incubation time is up.

Fast mode



Pressing **Add test to Fast mode list** closes this screen in **Fast mode** and fills the **Fast** worklist. One by one, new tests/patients are added to the worklist, from bottom to top.

Incubation and reading can be initiated on the next screen.

3.2.4.2 Add an ID

To add a new patient sample, press **Add ID** to assign an ID number. A new ID number is then generated automatically.

3.2.4.3 Select a parameter

Parameter	
PCT	
cTnI	
hs-CRP/CRP	
PCT	
STD	other

Select the **parameter** type by using the dark grey buttons. Available parameters are displayed in white letters since a valid calibration curve has been uploaded before. If the button is red, upload the calibration curve first. If the required parameter is not in the list, press **other**. When the correct one is shown in the light grey field, press **Exit** to transfer the selected parameter to the previous screen.

Pre-Dil.	Sample
no	Serum
yes	Blood
no	Serum
	Plasma
	Capillary Blood

Select the sample type, the types shown in white are available for the selected type of parameter.

Set the predilution function (Pre-Dil.) to **yes** if the sample needs to be diluted to obtain a result within the linearity range. Check the IFU of the parameter to use validated dilution factors.

3.2.4.4 Option to auto-calculate pre-diluted samples

In case very high values are expected, the system has an option to auto-calculate values for prediluted samples. If **yes** is selected for **Pre-Dil.** (see screenshot above), the predilution factor is automatically considered when processing the result.

Caution: The results are only correct if the predilution matches the dilution rate displayed by the software. To carry out a predilution, dilute the sample with 5 % BSA normal saline solution according to the IFU.

3.2.4.5 Add patient data

There are two ways to add patient data:

- A) manually by keyboard
- B) via the optional barcode reader

Once the patient data is added successfully, the **Family name**, **Given name**, **Birthday** and **Gender** are shown in the light grey fields.

A) Keyboard

If selected, the following screen is shown:

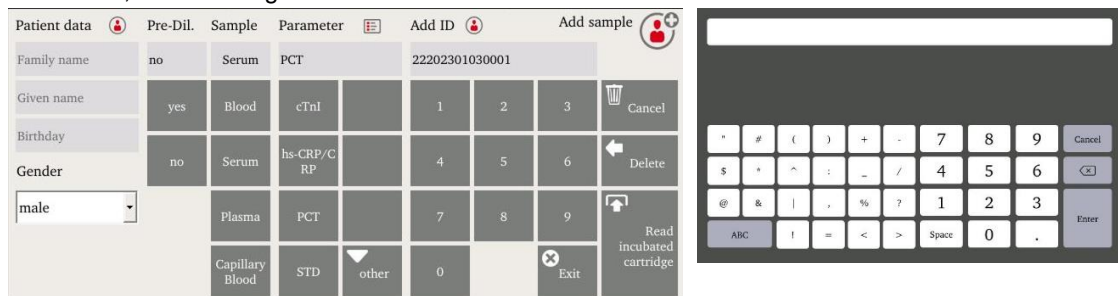


Figure 3-5 Software keyboards

Select the light grey field named **Family name** to add the data with the keyboard. Same for **Given name**, and **Birthday**. The gender can be selected in the drop-down menu below **Gender**. Press **Enter** to close the screen and transfer all the typed-in data to the previous screen.

B) Optional barcode reader

Patient data can be uploaded with a barcode reader.

3.3 QC module

According to Good Laboratory Practice (GLP), the daily use of control materials is a must to ensure that the system and reagents work properly.

The QC module allows the upload of target values of control material, the measurement of QC samples and the operation of a service function tool, the Standard Cartridge (see chapter 4.9 *Service and maintenance*).

The upload of target values must always be done in advance, otherwise it is not possible to run control material through a cartridge. See chapter 3.3.1 *Upload of new control material*.

For more information on preparation of the control material, like reconstitution or pipetting control volumes to the test cartridge, follow the instructions of use for the control and corresponding test parameter. Control materials are used in the same way as samples of the same parameter type.

To run daily controls two modes are available.

1. Run controls in **Auto mode**: This option is recommended if only a few control materials are to be checked and no hands-on time during incubation and reading is of advantage.
2. Run controls in **Fast mode**: This option is recommended if control materials of various levels and parameters need to be run in a short time.



Figure 3-6 Quality control main screen

The LOT number, target values (range) and parameter of the uploaded controls are shown in one line. Note that each level of the control is displayed in a separate line.

The column **Result** shows the last recorded value, and date and time information are available in the column **Date Time**.

The flag in the column **Range** shows a **P** for passed if the result matches the target value. If the flag in the column **Range** is in red and shows a **CH** or **CL**, the result of the control was too high (CH) or too low (CL).

To delete a control because it has expired or for other reasons, press the dark grey button in front of the control to be deleted.

An hourglass is shown if a control is currently running in **Auto mode** and stays in the analyser for incubation and reading. The number next to the hourglass indicates the remaining incubation time in mm:ss.

The latest result of a control reading is shown in the last line.

Note: To delete a control result, press the dark-grey button on each listed control result.

3.3.1 Upload of new control material

The control kits contain a target value sheet that provides the range which the parameters must match, and a LOT number.

Human				18°C	2023.01.06 10:57:59	
Auto sample	STAT sample	Fast mode	QC module	Database	Settings	
Select	Parameter	LOT, valid	Level	Target value	Low range	High range
	1	cTnI	20220609	Low	2.00	1.00 3.00
	2	CRP	20220205	Low	5.00	1.00 9.00

Select Controls for Auto mode

Page up

Page down

Insert Control for incubation

Exit

Figure 3-7 Upload of control data from target value sheet

To upload all data (LOT, level, target values) of a control, the target value sheet of the control is needed.

First, press **Card name**. This opens the next window for selection of a control parameter, like PCT in this example.

Select the level of the control.

Type in the LOT number.

Select the Expiration date.

Type in the target value (according to the units of parameter).

Card name	<input type="text" value="PCT"/>
Level	<input type="text" value="Low"/>
LOT	<input type="text" value="Enter Lot"/>
Expiration date	<input type="text" value="Expiration date"/>
Target value	<input type="text" value="Target value"/>
Low range	<input type="text" value="Low range"/>
High range	<input type="text" value="High range"/>
<input type="button" value="Add"/> <input type="button" value="Cancel"/>	

To complete the upload of new controls, press the **Add** button.

To delete a control, press the dark grey button to the left of the control. This might be necessary when the control has expired. The software displays a red flag **Exp** if the control is not valid anymore. A **V** indicates a valid control.

Follow the instruction of use of the control kit to prepare the control.

3.3.2 Run controls in Auto mode

Press **Select controls for Auto mode** on the QC module screen to access the screen below. This allows the user to select the next control for analysing in **Auto mode**.

Human				24°C	2023.01.03 16:26:01		
Auto sample	STAT sample	Fast mode	QC module	Database	Settings		
Select	Parameter	LOT, valid	Level	Target value	Low range	High range	
	1 质控卡	20220609	Low	8.81	7.93	9.69	Select Controls for Auto mode
	2 质控卡	20220609	High	0.06	0.06	0.07	Page up
	3 cTnI	20220609	Low	2.00	1.00	3.00	Page down
							Insert Control for incubation
							Exit

Figure 3-8 Select a control material to run it in **Auto mode**

The screen provides a list of all uploaded control materials. Each level of a control is considered as a separate control material to be analysed/run.

Select the control by pressing the dark grey button in the line of the control material to be run next. An **X** indicates the selected control material. Only one control material can be selected.

Add the reconstituted control material according to the IFU of the control and parameter to the cartridge. Then press the button **Insert Control for incubation** to run the control in **Auto mode**. This screen closes and the result is displayed on the previous screen after incubation and reading.

Note: The red **Exp** flag in the column **LOT** indicates that this LOT of control material is expired and must be replaced by a new LOT.

3.3.3 Run controls in Fast mode

Press **Add Controls to Fast mode list** in the QC module screen to access this window, which allows the user to select the next control material to be added to the **Fast mode** list.

Human					19°C	2023.01.06 10:58:53	
Auto sample	STAT sample	Fast mode	QC module	Database	Settings		
Select	Parameter	LOT, valid	Level	Target value	Low range	High range	
<input checked="" type="checkbox"/>	cTnI	20220609	Low	2.00	1.00	3.00	Add Controls to Fast mode list Page up Page down Add selected Controls Exit
<input checked="" type="checkbox"/>	CRP	20220205	Low	5.00	1.00	9.00	
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							

Figure 3-9 Select one or more controls to be added to the **Fast mode** list

The screen provides a list of all uploaded control materials. Each level of a control is considered as a separate control material to be analysed.

Note: The red **Exp** flag in the column **LOT** indicates that this LOT of control material is expired and must be replaced by a new LOT.

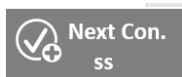
Select the controls by pressing the dark grey button in the lines of the control material to be analysed next. An **X** indicates the selected control materials. A series of control materials, even of different parameters, can be selected and added to the **Auto mode** list on the screen shown below.

Press the button **Add selected Controls** to add these control materials to the Fast mode list. This makes it possible to run the controls in a series. A new line is added and if there is an available time-slot to read a control after incubation time, **Next Con.** is shown in this line, further details below.

Human					19°C	2023.01.06 11:01:24	
Auto sample	STAT sample	Fast mode	QC module	Database	Settings		
Param.	Result	Range	Level	Date Time	Timer	Lot	
<input checked="" type="checkbox"/>	cTnI	1.00 3.00	Low		Incubation -14:13	20220609	Select Control for Auto mode Add Controls for Fast mode Load newControl Database Load Standard Cartridge Load new
<input checked="" type="checkbox"/>	CRP	1.00 9.00	Low		Read -17	20220205	
<input checked="" type="checkbox"/>	CRP	1.00 9.00	Low		80µl vol. added	20220205	
<input type="checkbox"/>							
<input type="checkbox"/>							

Figure 3-10 Worklist of controls to be run in **Fast mode**

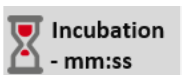
Follow these instructions for each selected control material to run controls in **Fast mode**:



In the **Fast mode** worklist in the column **Timer**, the button **Next Con.** appears. The number of seconds indicates when the first (or next) control material can be started in **Fast mode**. If the number of seconds equals 00, testing can be started. In this case, the button **80µl vol. added** is shown.



The next step is to add 80 µl of the control to the cartridge. Once this is done, press this button immediately. This starts the monitoring of the incubation time for this control reading. For details, see IFU.



For this control, the remaining incubation time is now shown in the format mm:ss. Once the incubation time for this control is almost up, the **Read** button appears.



Now there are 10 seconds left to insert the cartridge into the analyser and press the **Read** button. For optimal results, press the **Read** button when the timer equals 00. Reading takes only a few seconds, then the result of this control parameter is displayed.



If the timing was correct, --:-- appears, indicating that the incubation time was correct, or in the acceptable range.



If a number in red appears, like **+02:11**, the incubation time was 2 minutes and 11 seconds too long, indicating that the result is not valid and that the test must be repeated.

To run a series of control materials, start the workflow described above for the next control.



Once the incubation time for the first control has started, this button shows up to signal that the next control in the Fast worklist can be prepared. The workflow programme runs down a timer allowing the user to prepare the next control. When the timer equals 00, it means that the user can select this control to be pipetted.



Now for the second control, the control volume of 80 µl must be pipetted into the cartridge. Once this is done, immediately press this button. Now the monitoring of the incubation time starts for the second control of the worklist.

The series as described above is processed for the first and all subsequent controls until the **Fast** worklist is empty.

Once the **Fast** worklist is empty, the following information of the control material is displayed in each line: LOT, date and time of the reading, control low and high target values, control level and the recorded result of a control parameter.

Note: A red number in the **Timer** column indicates an incorrect incubation time. The measurement must be repeated with another cartridge.

3.3.4 Database in the QC module

All results of the QC control measurements are shown on the following screen, which can be accessed by pressing the **Database** button on the QC module main screen:

Human							24°C	2023.01.03 16:58:13
Auto sample	STAT sample	Fast mode	QC module	Database	Settings			
Delete	Parameter	LOT	Level	Target value	Low range	High range	Result	Date Time
6	CRP	20220205	Low	5.00	1.00	9.00	52.30 ↑	2023.01.03 16:50
5	hs-CRP	20220205	Low	5.00	1.00	9.00	>10.00 ↑	2023.01.03 16:50
4	CRP	20220205	Low	5.00	1.00	9.00	26.71 ↑	2023.01.03 16:46
3	hs-CRP	20220205	Low	5.00	1.00	9.00	>10.00 ↑	2023.01.03 16:46
2	CRP	20220205	Low	5.00	1.00	9.00	19.01 ↑	2023.01.03 16:44
Page up		Page down		Exit				

Figure 3-11 Database of QC results

Datasets can be deleted by pressing the dark grey button of the dataset to be deleted. With the buttons **Page up** and **Page down** further datasets are accessible.

3.3.5 Calibration cards overview in the QC module

Press the button **Load new Calibration card** on the QC module main screen to get an overview of all calibration cards that have been uploaded to the analyser, their LOT, expiration date and parameter.

Human							24°C	2023.01.04 12:23:33
Auto sample	STAT sample	Fast mode	QC module	Database	Settings			
Delete	Cal. Parameter, Exp	LOT	Card ID	Batch ID				
1	cTnI, 2022.10.08	20211009	10	7				Load new Calibration card
2	PCT, 2023.04.30	20220501	2	10				Page up
3	cTnI, 2023.04.30	20220501	10	11				Page down
4	CRP, 2023.04.30	20220501	1	4				Add Calibration Card
								Exit

Figure 3-12 Overview of uploaded calibration cards in QC module

Add Calibration Card uploads the data of the calibration card currently inserted into the analyser. This happens automatically as soon as the calibration card of a parameter is inserted into the analyser. Datasets can be deleted by pressing the dark grey button of the dataset to be deleted.

Note: Only calibration cards of parameters are shown. The Standard Cartridge is not displayed here.

3.4 Database interface

The previous chapters explain how to collect test results in 3 sample modes. The following section describes how to retrieve the recorded results and associated information.

Note: The database is quite big and not all data might be relevant. Chapter 4.7 *Selection of data fields in the database* describes how to set which data to display.

The database displays all recorded data defined to be displayed in **Settings/ Data selection**.

3.4.1 General operations

By use of the **Page up** and **Page down** buttons further datasets can be reached. Swipe across the screen from left to right to display more data.

In case certain data should be exported or deleted, first use the filter functions as described below:

The **Export all** button will export all data selected by the filters. If no filter is applied, all data are exported to USB.

The **Delete all** button will delete all data selected by the filters. If no filter is applied, all data will be deleted. Be cautious!

Some fields, for example in the column **Printed** or **Exported**, are set to **no** by default. Pressing the field changes this setting to **yes**.

To delete a complete data set, press the wastebasket icon next to the patient's name.

Human				24°C		2023.01.03 16:54:13							
Auto sample		STAT sample		Fast mode		QC module		Database		Settings			
Family n., Given n.	ID	Param. [unit]	Result	Cut-off	Temp [°C]	Timer	Printed	Date	Time				
	22202301030004	hs-CRP [mg/L]	>10.00	<3.00	24.00	--:--	no	2023. 01.03	16:41				
	22202301030004	CRP [mg/L]	41.57	<10.00	24.00	--:--	no	2023. 01.03	16:41				
	22202301030003	cTnI [ng/mL]	1.235	<0.100	24.00	--:--	no	2023. 01.03	16:39				
	22202301030002	PCT [ng/mL]	2.72	<0.50	24.00	--:--	no	2023. 01.03	16:38				
	Delete all		Page up		Page down		Export all		Clear all filters		Search		Import

Figure 3-13 Review of recorded results in **Database**

3.4.2 Filter functions of the database

To select datasets for operations like storing, printing, exporting, or just comparing, it is helpful to select the datasets of interest only. Press **Search** to access the following screen, which shows all possible search functions/filters:

The screenshot displays the 'Human' database filter interface. At the top, there is a red header bar with the text 'Human', '24°C', and '2023.01.03 17:07:10'. Below the header, there is a search form with various filters. The filters are organized into two columns. The left column includes:

- Date Time: 2023, 01, 03, 00, 00
- Family n., Given n.
- ID: Input id
- Param.: CRP
- Result: L
- Timer: Time ealy

 The right column includes:

- Lot: Input lot
- S-Type: Blood
- Expried
- Out of linearity range: LH

 At the bottom right of the filter form, there are 'Search' and 'Cancel' buttons. Below the filter form, there is a table with columns for 'time' and other data. The table shows the following times: 6:41, 6:41, 6:39, 6:38. At the bottom of the interface, there is a navigation bar with buttons for 'Delete all', 'Page up', 'Page down', 'Export all', 'filters', 'Search', and 'Import'.

Figure 3-14 Filter functions in database

With a filter, the user can select all samples recorded between **Date/Time 1** in the first line and **Date/Time 2** in the second line (year, month, day, hour, minute).

Furthermore, a filter to select one or a combination of the following criteria is available:

- Family name
- Given name
- Patient ID
- Parameter
- Result flags
- Comment on correct/wrong reading times
- LOT
- Sample type
- Expired or non-expired readings
- Flagged results out of linearity range

4 ADVANCED OPERATION

WARNING: The following operations are only for experienced users. If the settings are modified, warnings may disappear, data will not be shown anymore, or clinical reference values will change. This may lead to wrong flagging and result interpretation. Therefore, it is recommended to only make changes if the user fully understands the settings.

4.1 Settings interface

Click **Settings** in the main menu to enter the display shown below:

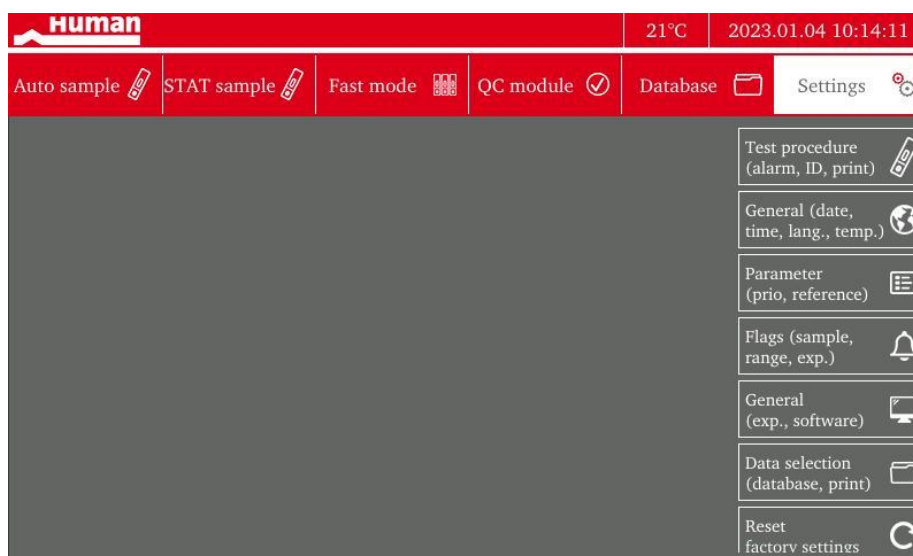


Figure 4-1 Settings screen, shown are the groups of settings which can be modified

Settings can be defined for the following groups of settings:

- **Test procedure:** set alarms, define how to generate the ID, or whether each result gets printed
- **General:** formats for date, time and temperature, and language
- **Parameter:** parameters to be displayed first, create customised parameters and reference numbers
- **Flags:** selection of flags that should be displayed
- **General (2):** run a software update, enable auto-warnings
- **Data selection:** which data fields are displayed in the database
- **Reset factory settings:** delete all data and settings to restore factory setting
- **Connectivity:** definition of IP address and ports for communication channels

Note: The **Connectivity** button can be reached by swiping upwards on the buttons on the right side. It is below the **Reset factory settings** button.

Each module is explained below in a separate chapter.

4.2 Settings for the test procedure

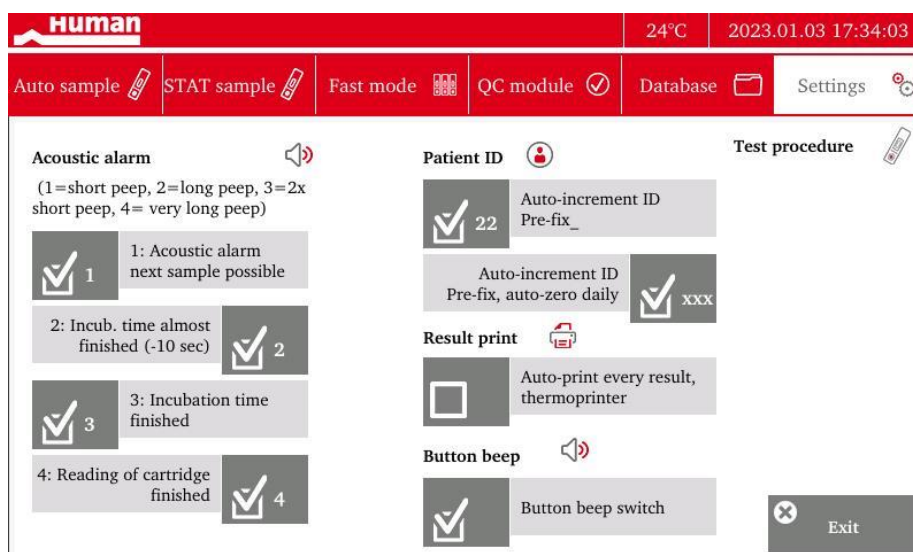


Figure 4-2 Settings of acoustic alarm, patient ID and printing

Acoustic alarms can be defined. Each alarm can be enabled/disabled. The type of alarm can be chosen by adding a number into the activated field:

- 1 for a short beep
- 2 for a long beep
- 3 for 2 short beeps
- 4 for a very long beep

Enabling **Patient ID** will automatically assign a consecutive patient ID to each new patient. Further, it is possible to set a prefix number for the first digits of patient ID. These digits will be separated from the rest by an underscore. For example, if the user sets 101 as a prefix number, the first patient will be assigned the ID 101_1, the second, 101_2, etc. This might help to select and filter data more easily later.

Result print can be enabled to be done automatically on the integrated thermoprinter after a result is generated if **Auto-print every result (thermoprinter)** is enabled.

If **Auto-print every result (external printer)** is activated, the printout to an external printer is activated. However, this option is only available if a printer driver for an external printer is loaded. This function is currently not available.

Exit applies the selected settings and closes the window.

4.3 General (Date, Time, Language, Brightness, Temperature, Delete)

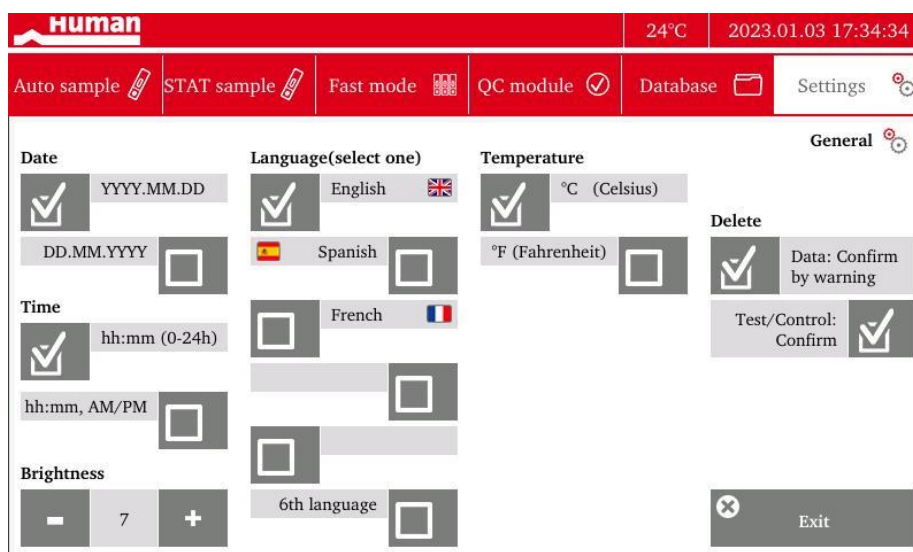


Figure 4-3 Settings of, Date, Time, Language, Brightness, Temperature, and Delete warnings

Date format can be set to YYYY.MM.DD or DD.MM.YYYY. D stands for day, M for month, and Y for year.

Time format can be set to hh:mm (0-24h) or hh:mm, AM/PM. h stands for hour, and m for minute.

Brightness can be increased with + or decreased with –.

Language can be changed if the desired language is installed on the analyser. If another language is needed, ask your service engineer to upload it. The analyser can only support 5 languages at the same time.

Temperature format can be set to °C or °F. Pressing the headline **Temperature** for a few seconds leads to a screen where the user can adjust the temperature. If the temperature displayed on the screen is too high, adjust it by lowering the temperature and vice-versa. For example, type **-4** to lower the temperature by 4 °C. Press **Set** to apply the temperature change and press **Back** to return to the **General** settings screen.

Delete

- **Confirm by warning:** If this option is enabled, a warning will show up to confirm the deletion of data.
- The **Test/Control confirm** option enables all the warnings related to the use of tests and controls, such as a hint for an expired reagent.

Exit applies the selected settings and closes the window.

4.4 Selection of parameter list

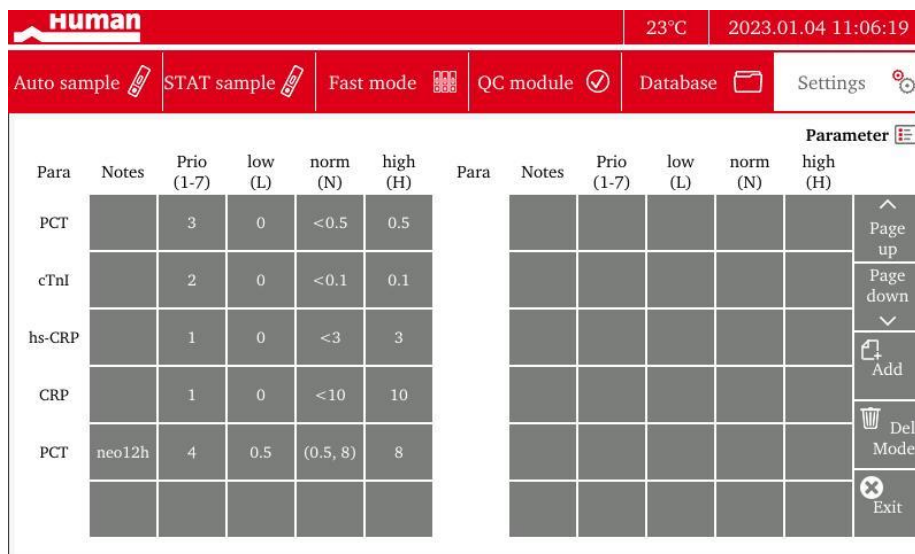


Figure 4-4 Setting to prioritise selection of 7 parameters

On many screens, only 7 parameters are displayed for selection. All further parameters can only be seen by pressing **Other**. This screen allows the user to define the order in which the parameters are shown.

The column **Prio** allows the user to change the display order of the parameters. 1-7 defines the position on the first page, all others are on the page **others**. Use the keyboard to type in the numbers into the selected field.

A single digit indicates the priority/position of a single parameter test.

If a parameter is part of a combined test, two digits will be displayed. The first digit stands for the position of the parameter as a single test, while the second indicates the position of the combined test. For example, if the column **Prio** displays 1.7 for parameter cTnI, the single cTnI test will be shown in position 1, while the combined test cTnI, Myo and CK-MB will appear in position 7 (the parameters Myo and CK-MB will also have a 7 as second digit).

For each parameter, low and high cut-off values can be defined. In-between these two values, the result is considered to be normal and shown in black. If the result is higher, a red arrow is shown next to the result on the measurement screens.

<low is the range where a patient shows abnormally low values. In this case, a red arrow down appears.

<norm indicates the range of a parameter where a patient is healthy, or normal.

<high is the range where a patient shows abnormally high values. In this case, a red arrow up appears.

The rest of the parameter list can be reached by pressing **Page up/Page down**.

Pressing **Add** opens up the following screen and allows the user to create customised reference ranges for one of the uploaded parameters. In the example below, a customised parameter for PCT in neonates is created. Neonates, for example, have different reference ranges depending on their age (in hours). Here, a reference range for neonates who are 12 hours old is created. PCT is selected as **Card name** and **Parameter**. The name of the new parameter is **neo12h**. Any name can be chosen. Then, the range for normal values is set to be 0.5 to 8.0 ng/ml. Pressing **Add** on the pop-up window creates the new parameter with a customised reference range.

The last step is to define a priority for the new parameter.

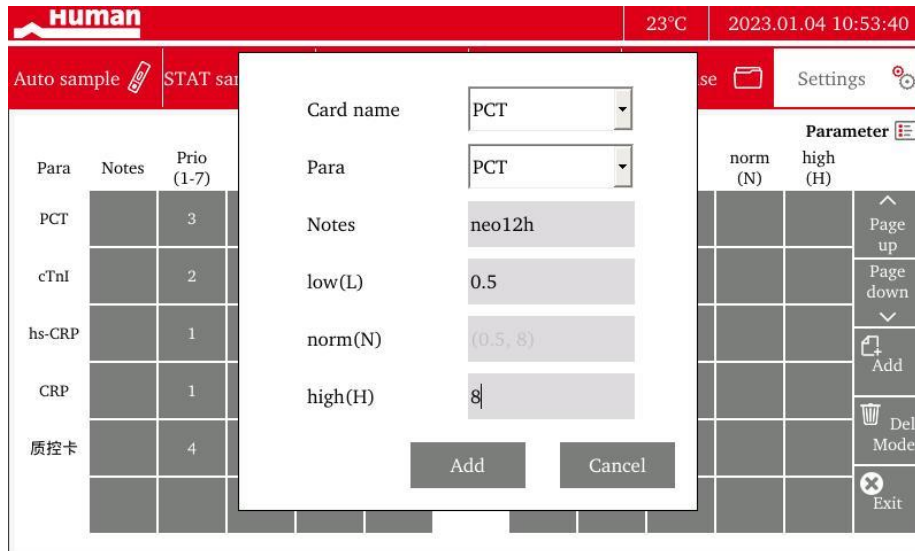


Figure 4-5 Add a customised reference range

Del Mode allows the user to delete any parameter calibration information by pressing the corresponding line in the **Notes** field. End this mode by pressing **Exit**.

Exit applies the selected settings and closes the window.

4.5 Settings to enable flags

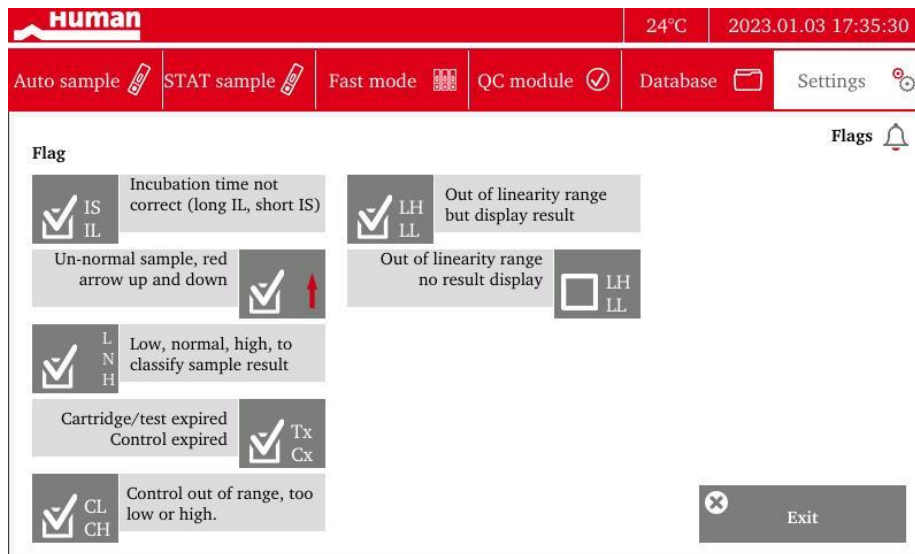


Figure 4-6 Settings option to enable flags

All flags shown in the result data can be set to be displayed or hidden by enabling or disabling the flag.

IS and **IL** flags are shown if **Incubation time not correct (long IL, short IS)** is activated. If these flags show up, the measurement must be repeated due to an incorrect incubation time.

A red arrow flag indicates that a result is out of normal range and is shown if **Abnormal sample, red arrow up and down** is activated.

L, **N** and **H** flags are shown if **Low, normal, high, to classify sample result** is activated.

Tx and **Cx** flags are shown if **Cartridge/test expired Control expired** is activated, indicating the test LOT (Tx) or the control LOT (Cx) is expired.

CL and **CH** flags are shown if **Control out of range (too low or high)** is activated. This indicates that the control result is out of the target value range.

LH and **LL** flags are shown if **Out of linearity range but display result** is activated. In this case, the results are still displayed in the result screens, even if the results are out of linearity. If not enabled, results out of linearity range are not shown.

Exit applies the selected settings and closes the window.

4.6 General (2) settings, software update, auto-warnings

Note: This setting is only accessible in **Service Mode**. Switch from **User** or **Admin** to **Service Mode** first.

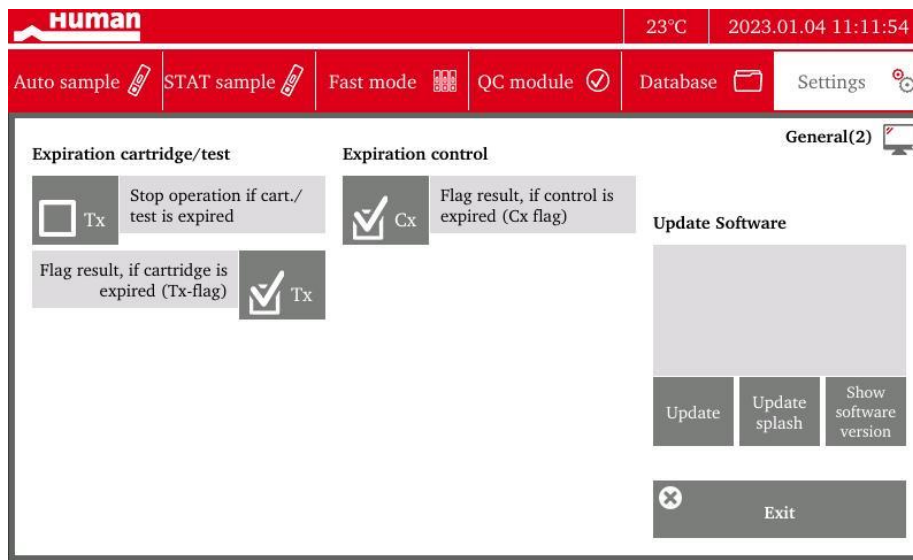


Figure 4-7 Running a software update and enabling of warnings

Expiration cartridge/test

If the setting **Stop operation if cart./test is expired** is enabled, the software stops the operation of expired test LOTs. This guarantees that only valid reagents are used for correct results.

If the setting **Flag result, if cartridge is expired (Tx-flag)** is enabled, the results are flagged with **Tx** if a test LOT in use is expired.

Expiration control

If the setting **Flag result, if control is expired (Cx-flag)** is enabled, the control results are flagged with **Cx** if a control LOT in use is expired.

Update Software

A new software version must be transferred to a USB stick and imported into the system. The USB stick will immediately start flashing if accepted. By pressing the button **Update**, a software update will automatically be uploaded from the USB drive.

Note: Only the USB ports next to the serial-connection port can be used to upload a software update.

Show software version opens a screen that shows the current software version running on the system.

Exit applies the selected settings and closes the window.

4.7 Selection of data fields in the database

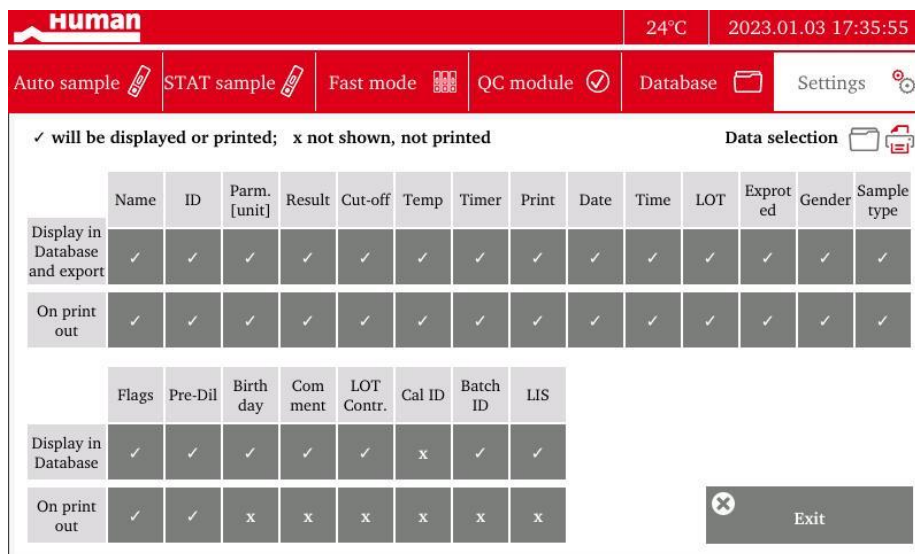


Figure 4-8 Customise the display of data fields in the database module

The database is quite big and stores many data fields. This setting page allows the user to customise what is displayed in the database or printed by activating (✓) or disabling (x) the options on the corresponding data field.

Exit applies the selected settings and closes the window.

4.8 Settings to establish connectivity channels

Note: This setting is only accessible in **Service Mode**. Switch from **User** or **Admin** to **Service Mode** first.

The screenshot shows the 'Human' interface with a red header. The top right corner displays '24°C' and '2023.01.04 11:41:55'. Below the header is a navigation bar with icons for 'Auto sample', 'STAT sample', 'Fast mode', 'QC module', 'Database', and 'Settings'. The main content area is titled 'Connectivity' and contains several input fields and checkboxes. The 'IP address' field is filled with '192.168.1.50', 'Subnet mask' with '255.255.255.0', and 'PC Port' with '0'. The 'LIS port (Ethernet port)' checkbox is checked, while 'DHCP' and 'Serial port (PC interface)' are unchecked. At the bottom, there are buttons for 'Apply', 'Connect', 'Cancel', and 'Exit'.

Figure 4-9 Setting an Ethernet connection and other data-ports

To connect to the internet, add the IP address, Subnet mask, PC IP address, and PC Port information. Press each field to enter the values.

Apply closes the data upload.

Connect starts the connection based on the uploaded data.

Activating the setting **LIS port (Ethernet port)** ensures that the system starts the LIS communication automatically after the start of the instrument.

If the setting **Serial port (PC interface)** is enabled, the system starts the data transfer via the HumaFIA data cable with the PC the HumaFIA is connected to, automatically after the start of the instrument.

If the setting **Serial port** is enabled, the system starts the Serial port communication automatically after the start of the instrument.

Exit applies the selected settings and closes the window.

4.9 Service and maintenance

The HumaFIA analyser is enclosed in a sealed housing and does not produce liquid waste during tests. The instrument does not come into contact with blood samples as long as cartridges are handled correctly, and sample spillage is avoided. The only service tool is the Standard Cartridge kit which is explained below. The following maintenance must be carried out:

- Remove dust from the surface of the device.
- Turn off the power switch when all tests on the current day are finished.

4.9.1 Run Standard Cartridge as quality check

The Standard Cartridge kit is a service tool that allows the user to check the optical system of the analyser. It is recommended to run it as a quality check of the instrument on a daily basis. Further, if the controls of various parameters are out of range, contact the service engineer and check the analyser with all 5 levels of the Standard Cartridge kit. It should also be used during the service maintenance scheduled every 6 months.

The kit contains a specification sheet that includes reference values for each of the 5 levels of the Standard Cartridge. The cartridges are numbered 1-5 depending on the level.

The Standard Cartridge is used like control material. Therefore, use the **QC module** screen to operate it.



Figure 4-10 QC module to operate the Standard Cartridge

In a first step, the target values of this Standard Cartridge must be uploaded. This happens automatically as soon as the calibration card of the Standard Cartridge is inserted into the analyser.

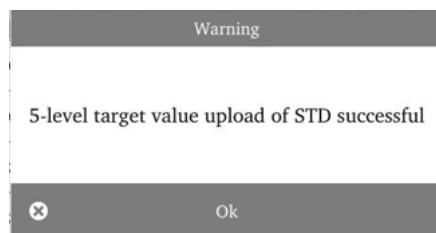


Figure 4-11 Successful upload of target values of the Standard Cartridge

Press **Load new Standard Cartridge** in the **QC module** screen to access the following screen. Then press **STD-test** which leads to the pop-up window showing the LOT of the Standard Cartridge. Next to **Gradient**, select the level of the Standard Cartridge that should be used next.

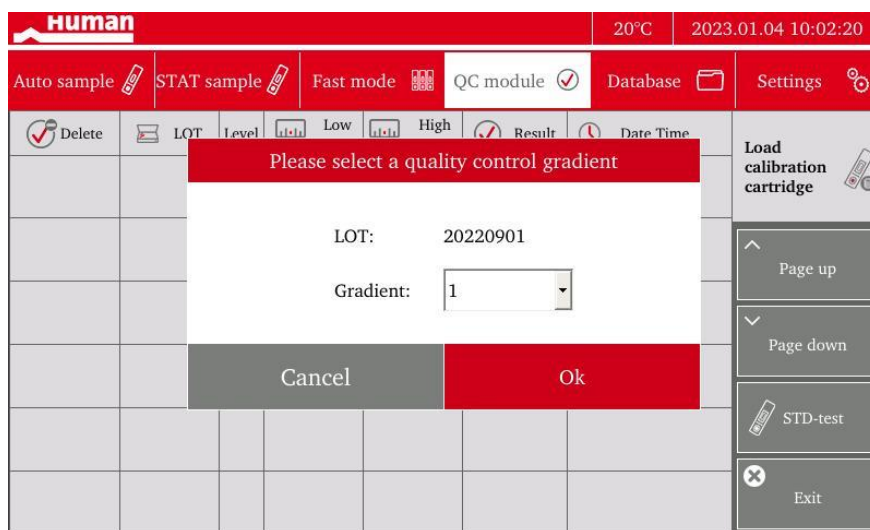


Figure 4-12 Read Standard Cartridges (STD)

Pressing **Ok** starts the reading of the Standard Cartridge of the selected level. Repeat the process for each level of the 5-level Standard Cartridge control material. The results of the current reading together with the uploaded target value range are shown. Reproducibility of STD readings should be very high, as shown in Figure 4-13.

Human						24°C	2023.01.04 12:16:37
Auto sample		STAT sample		Fast mode	QC module	Database	Settings
Delete	LOT	Level	Low range	High range	Result	Date Time	Load calibration cartridge ^ Page up v Page down STD-test X Exit
3	20220609	2	3.41	4.61	3.93	2023.01.04 12:16	
2	20220609	2	3.41	4.61	3.93	2023.01.04 12:09	
1	20220609	1	7.49	10.13	8.96	2023.01.04 11:20	

Figure 4-13 Results and target value ranges of Standard Cartridges

If the result is within specifications, the message **QC PASSED** appears. If not, rerun the Standard Cartridge or use a new LOT. Compare the uploaded target values to the values on the target value sheet in the kit to ensure that they have been uploaded correctly. If the problem remains, contact a service engineer.

5 TROUBLESHOOTING

This manual includes troubleshooting information for all simple faults. If an issue persists, contact the local after-sales service centre, the local agent, or the manufacturer. This device is supplied with a Certificate of Conformity. Keep the Certificate of Conformity properly. This analyser must be maintained regularly by the user and technical service.

List of troubleshooting measures

Fault Content	Meaning
<p>Self-test of analyser during start-up fails.</p> <p>Warning 621 Self-test revealed problem with storage</p> <p>Warning 620 Self-test revealed problem with connectivity</p>	<p>A component of the analyser is faulty. Make sure the cartridge slider is empty.</p> <p>Check the issues mentioned in the warning messages.</p> <p>In case the self-test alarm persists, contact a service engineer.</p>
<p>Controls of a certain level are not in range.</p>	<p>Replace the control material and repeat the control measurements.</p> <p>In case the problem persists, run the Standard Cartridge kit or contact a service engineer.</p>
<p>Standard Cartridge kit does not match all 5 levels.</p>	<p>Faulty optical components, contact a service engineer.</p>
<p>Red number in column Timer in Auto-sample or in Fast mode. A red number like 02:11 and an IL or IS flag are displayed with the following warning:</p> <p>Warning 300 Incubation time too long. Incorrect result. Please re-run sample.</p>	<p>Monitoring of the incubation time by HumaFIA revealed an incorrect timing. IL: Incubation time too long, IS: Incubation time too short.</p> <p>Repeat the measurement with a new cartridge.</p>
<p>Warning 400 Control is expired, please use new LOT</p>	<p>The used control material is expired. Replace it with a new LOT and upload new target values.</p>
<p>Warning 402 More than 24h no control measurement</p>	<p>GLP recommends the daily use of controls. Run a control every 24 hours.</p> <p>To disable this warning, see chapter 4.6 <i>General (2) settings, software update, auto-warnings</i>.</p>
<p>Warning 403 Test cartridge is expired, please use new LOT</p>	<p>Test cartridge LOT is expired, replace it with a new LOT and upload new calibration data.</p>
<p>Warning 404 No recording of present parameter possible. No valid control measurement during last yy days. Please run control!</p>	<p>GLP recommends the daily use of controls. Run a control, after the control successfully matches the parameter range, the software will allow the user to run this parameter again.</p> <p>To disable this warning, see chapter 4.6 <i>General (2) settings, software update, auto-warnings</i>.</p>
<p>Older data disappears.</p> <p>Warning 501 Maximum data volume reached. Overwriting of oldest data will start. Please export/delete data!</p>	<p>Warning 501 informs on low data storage. If this message is ignored, the oldest data sets will be overwritten.</p>

<p>Warning 100 Ambient temperature out of specifications. Please re-run sample at 18 to 28 °C room temperature</p>	<p>HumaFIA has a temperature sensor which monitors the ambient temperature. If the temperature is out of the specified range, all results will be flagged, and a warning is shown. The results might be incorrect due to improper incubation temperature.</p>
<p>Warning 502 Result out of linearity range. Please re-run sample as a pre-diluted sample (Auto/STAT)</p>	<p>HumaFIA offers a software option to auto-calculate prediluted samples in Auto-sample and in STAT sample mode. Results out of linearity are outside the analyser specifications and might be incorrect. Rerun sample as prediluted sample.</p>
<p>Warning 611 External barcode reader not connected</p>	<p>Check the cable connection and status LED of the external barcode reader. Refer to the user manual of the external barcode reader for further assistance.</p>
<p>Warning 612 LIS, Ethernet connection not active</p> <p>Warning 613 Serial port (PC interface) not active. Please check cable</p> <p>Warning 614 Serial port not active. Please check cable</p>	<p>Check the cable and connections on both sides (analyser and external connector). Contact a service engineer for further assistance.</p>
<p>Warning 615 External printer off-line. Please check printer status</p>	<p>Check the cable and connections on both sides (analyser and external printer). Refer to the user manual of the printer for further assistance.</p>
<p>Warning 301 Pre-diluted sample result is low, please re-run sample in un-diluted mode</p>	<p>As predilution requires a manual pipetting step, it is of advantage to use undiluted samples whenever possible. If the result is in the normal linearity range, it is recommended to run the sample as a normal sample a second time.</p>
<p>Warning 610 Maintenance necessary. Ask for technical support!</p>	<p>It is recommended to run a maintenance cycle every 6 months. To disable this warning, see chapter 4.6 <i>General (2) settings, software update, auto-warnings</i>.</p>

Table 5-1 Troubleshooting

6 LATEST INFORMATION/UPDATES

Information about the latest software and manual version is accessible via:

<https://www.human.de/sw-FIA01>

or by scanning the following QR Code with a mobile device supporting QR Codes. This QR code can also be found as a label on the device.



If the information about the latest versions is not accessible via internet, it can be obtained free of charge from your local distributor.

If the installed software is not the latest one, contact your local distributor.

If you cannot download the latest manual, contact your local distributor.

HUMAN Diagnostics Product (Beijing) Co., Ltd.
Address: Unit 703, Yongchang Industry Park, No.3 Yongchang North Road,
Beijing Economic and Technological Department Area, Beijing 100176, China
Tel: +86-10-63579937, E-Mail: customerservice@human-china.com