CE [IVD]

GP Reader NT

User's Guide

CE [IVD]

REF 740450

Notices

REVISION HISTORY

V 1.0 | 14.03.2023	First release
V 2.0 | 30.05.2023	Second release - text and image updates
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1 GENERAL

1.1 CONTACT INFORMATION

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1.2 DOCUMENT CONVENTIONS

This manual uses the following typographic conventions:

⚠️	This icon calls attention to important safety notes
Warning!	A Warning indicates the potential for bodily harm and tells you how to avoid the problem.
Caution	A Caution indicates potential damage to the instrument and tells you how to avoid the problem.
Notice!	Bold text is primarily used for emphasis.
ⓘ	This icon calls attention to important information.

About This Manual

The intent of this User's Guide is to instruct the user how to set up and operate the GP Reader NT. To help you to read and understand this manual, certain document conventions have been used.

Each major topic starts on a new page under a major heading and includes e.g. **Document Conventions** described above, relating to that topic. One or more subheadings may appear below each major heading.

1.3 INTENDED USE STATEMENT

GP Reader NT (REF 740450) is a bench top instrument for the quantitative measurement of fluorescence signals from multichannel lateral flow cassettes.

GP Reader NT is intended to be used in conjunction with GastroPanel Quick Test NT (GPQT NT) (REFs. 602410, 602420) for diagnosing *Helicobacter pylori* infection and atrophic gastritis (AG) from patients with dyspeptic symptoms or at risk to develop malignant cellular changes in stomach mucosa.

In addition, GP Reader NT with (GPQT NT) aids in screening conditions that necessitate additional examination or treatment from healthy stomach mucosa. GP Reader NT is to be used by healthcare professionals, either in a laboratory-based or point of care (POC) setting. For *in vitro* diagnostic use.

1.4 QUALITY CONTROL

It is considered good laboratory practice to run laboratory samples according to the instructions and specific recommendations included in the test kit package. Failure to conduct Quality Control checks could result in erroneous test results.

1.5 REPACKAGING AND SHIPPING

If you need to ship the instrument to Biohit for service or repair, contact Biohit for a Return Materials Authorization (RMA) number, and be sure to use the original packaging. Other forms of commercially available packaging are not recommended and can void the warranty. If the original packaging materials have been damaged or lost, contact Biohit for replacement packaging.

1.6 WARNINGS

Operate the instrument on a flat surface and away from excessive humidity.

When operated in a safe environment according to the instructions in this document, there are no known hazards associated with GP Reader NT. However, the operator should be aware of certain situations that could result in injury.

1.7 HAZARDS AND PRECAUTIONS

1.7.1 Hazards

Warning! Power Rating. The GP Reader NT power supply must be connected to a power receptacle that provides voltage and current within the specified rating for the system. Use of an incompatible power receptacle may produce electrical shock and fire hazards.

Warning! Electrical Grounding. Never use a two-prong plug adapter to connect primary power to the GP Reader NT power supply. The use of a two-prong adapter disconnects the utility ground, creating a severe shock hazard. Always connect the power cord directly to a three-prong receptacle with a functional ground.

Warning! Internal Voltage. Always turn off the power switch and unplug the power cord from the mains electricity supply before cleaning the outer surface of the instrument.

Warning! Electrical Shock. Never touch the power plug, power line or power switch when hands wet. Never operate the GP Reader NT with wet hands.

Warning! 2D Barcode Stray Light. The integrated 2D barcode reader can be activated by the user. Avoid direct or reflected light entering the eyes.

Warning! Liquids. Avoid spilling liquids on the instrument; fluid seepage into internal components creates a potential shock hazard. Disconnect the instrument from the mains power supply and wipe up all spills immediately. Do not operate the instrument if internal components have been exposed to fluid.

Warning! Potential Biohazards. Test cassettes with specimens may pose a biohazard. Adequate safety precautions should be taken as outlined in the assay's package insert. Always wear appropriate clothing and personal protective equipment (PPE) to protect from contamination to skin or eyes.

Warning! Software. The operator should use the latest version of the firmware and software.

Warning: Use. The instrument produces a magnetic field. Persons with cardiac pacemakers or metal prosthetic devices must not use the instrument. The permanent magnetic field may interfere with the functioning of the cardiac pacemaker and metal prosthetic device and could result in personal injury.

1.7.2 Precautions

Caution: Service. GP Reader NT should be serviced only by Biohit authorized service personnel. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.

Caution: Environmental Conditions. The operating environment should remain between 18°C and 28°C with a relative humidity of <80% [etc] to ensure the correct functioning of the instrument. Note that the GPQT NT lateral flow test can be adversely affected by temperature and users should observe the additional recommendations in the kit insert.

Caution: Sodium Hypochlorite. Do not expose any part of the instrument to diluted sodium hypochlorite solution (bleach) for more than 5 minutes. Prolonged exposure may damage the instrument surfaces. Be certain to remove all traces of sodium hypochlorite and thoroughly wipe down all surfaces.

Caution: Chemical Compatibility. Some chemicals may cause irreparable damage to GP Reader NT. Never use acetic acid, dimethylsulfoxide (DMSO), or organic solvents. Contact Biohit prior to using chemicals that may cause damage to the instrument.

Caution: Warranty. Failure to follow preventive maintenance protocols may void the warranty.

Caution: Failure. Do not drop or knock the instrument when handling it as it has not been designed to withstand such impacts. Damage caused by such impacts will void the warranty.

Caution: Disposal. This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to current WEEE ("waste electrical and electronic equipment"-directive).

1.8 CE MARK

1.8.1 Directive 2014/30/EC: Electromagnetic Compatibility

The system has been type-tested by an independent, accredited testing laboratory and found to meet the requirements of IEC/EN 61326-1 and IEC/EN 61326-2-6: Class A for Radiated Emissions and Line Conducted Emissions.

• IEC 61326-1:2012, EN 61326-1:2013
• IEC 61326-2-6:2012, EN 61326-2-6:2013

1.8.2 Directive 2014/35/EU Low Voltage (Safety)

IEC 61010-1: 2010/AMD1:2016 Safety requirement for electrical equipment for measurement, control and laboratory use. Part 1, General requirements.

IEC 61010-2-101:2018 Safety requirement for electrical equipment for measurement, control and laboratory use. Part 2-101, Particular requirements for in vitro diagnostic (IVD) medical equipment.

The instrument itself works with 12VDC voltage, which is produced by an external CE-marked commercial voltage adapter. The Low Voltage directive does not apply to the instrument itself.

1.8.3 Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

Disposal Notice: This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to current WEEE-directive. You may also send the instrument to be disposed of by Biohit, if needed.

1.8.4 Directive 2011/65/EU Restriction of Hazardous Substances (ROHS)

EU rules restrict the use of hazardous substances in electrical and electronic equipment to protect the environment and public health.

1.8.5 Directive 98/79/EC for *In vitro* Diagnostic Medical Devices

Product registration with competent authorities.

1.8.6 Regulation (EU) 2016/679

General Data Protection Regulation (EU) must be followed to protect natural persons regarding the processing and free movement of personal data.

1.8.7 Labeling and Symbols

ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.

ISO 18113-1:2022 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements.

1.9 USER SAFETY

This device has been type tested by an independent laboratory and found to meet the requirements of the following:

IEC 61010-1: 2010/AMD1:2016 "Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements."

1.10 SYMBOLS USED ON THE INSTRUMENT

Symbol	Description
∿	Alternating current
⎓	Direct current
▣	Protected by double or reinforced insulation
⚠ (biological hazard)	Warning, biological hazard
⚠ (!)	Caution (refer to accompanying documents)
⚠ (optical radiation)	Caution, optical radiation
CE	CE mark
IVD	In vitro diagnostic medical device
REF	Catalog number
LOT	Batch code
SN	Serial number
▲	Manufacturer
⊿	Manufacturing date
📖	Consult instructions for use
⊗	Separate collection for electrical and electronic equipment

1.11 WARRANTY

The warranty time for GP Reader NT is a period of 12 months and will commence from the date the relevant product is shipped by Biohit.

Biohit shall remedy all defects discovered in any Product (the "Defective Product") that result from unsuitable materials or negligent workmanship which prevent the mechanical functioning or intended use of the Products including, but not limited to, the functions specified in Biohit's specifications for the Product.

ANY WARRANTY WILL, HOWEVER, BE DEEMED AS VOID IF FAULT IS FOUND TO HAVE BEEN CAUSED BY ACTS OF NATURE, MALTREATMENT, MISUSE, ABUSE, LACK OF ROUTINE MAINTENANCE, ACCIDENTAL DAMAGE, INCORRECT STORAGE OR USE OF THE PRODUCTS FOR OPERATIONS OUTSIDE THEIR SPECIFIED LIMITATIONS OR OUTSIDE THEIR SPECIFICATIONS, CONTRARY TO THE INSTRUCTIONS GIVEN IN THE INSTRUCTION MANUAL. IF THE PRODUCT IS MODIFIED IN ANY WAY, OR DISASSEMBLED BY ANYONE OTHER THAN BIOHIT, ALL TERMS OF THIS WARRANTY ARE VOID.

In accordance with the terms of the warranty Biohit shall be obligated to replace any defective product returned by the end-user, distributor or agent of Biohit, within a reasonable time.

The product has been manufactured according to ISO 9001/ISO 13485 quality management protocols and has passed all relevant Quality Assurance procedures related to these products.

In case of interpretation disputes the English text applies.

2 INTRODUCTION

This chapter introduces the GP Reader NT, describes its hardware and software structure, product with specifications, and contact information for technical support.

2.1 GP NT READERS IN BRIEF

GP Reader NT (REF 740450) is a bench top instrument for the quantitative measurement of fluorescence signals from multichannel lateral flow cassettes.

GP Reader NT is intended to be used in conjunction with GastroPanel Quick Test NT (GPQT NT) (REFs. 602410, 602420) for diagnosing *Helicobacter pylori* infection and atrophic gastritis (AG) from patients with dyspeptic symptoms or at risk to develop malignant cellular changes in stomach mucosa.

In addition, GP Reader NT with GPQT NT aids in screening conditions that necessitate additional examination or treatment from healthy stomach mucosa. GP Reader NT is to be used by healthcare professionals, either in a laboratory-based or point of care (POC) setting. For *in vitro* diagnostic use.

A GPQT NT cassette containing four test strips, one for each of the the four different markers of pepsinogen I, pepsinogen II, gastrin-17, and *H. pylori*, can be read by the GP Reader NT within 30 seconds, converting the readings to concentrations and displaying the results on the display of the reader.

The reader is equipped with a touch screen user interface for operating and displaying the results. An embedded printer is used for printing the results. The results are saved in the memory of the instrument for further use. All the results can be exported to external USB memory, if needed. Connectivity to laboratory information system (LIS) is supported as well.

The reader is also equipped with an internal and external QR-code scanner for reading the LOT-specific kit calibration data of the GP NT cassettes.

2.2 WORKING PRINCIPLE

The microcontroller comes with photodetection and motor drive circuitry, which allows for stepper motor linear actuator control to scan the strips. During scanning, the microcontroller controls the light emitting diode (LED) to excite light, which is focused on to the sample strip after passing through the lens and filter, and the substances in the sample are thus excited to generate fluorescent signals. After passing through the lens and filter, the fluorescence signal is received by a high-sensitivity photodiode and then converted into an electrical signal. The analog signal is amplified, filtered, and converted to a digital reading representing the emitted fluorescence intensity value. The microcontroller controls the linear stepping motor actuator and the analog-to-digital conversion to work synchronously until the measurement of the fluorescence intensity is completed. The analog-to-digital conversion results of each mapping point are sent to the control software, and finally, the control software converts the results into the corresponding concentration through algorithmic processing before being displayed to the user.

2.3 BASIC FUNCTIONS

This device has the following functions:
1) Graphical touch screen user interface to operate the instrument
2) Scanning of QR-codes of the LOT specific calibration, from the cassette or sticker inside the kit box
3) Measure, convert to concentrations, and display results on the screen
4) Print results; with built-in micro printer
5) Data storage and query
6) Data transfer

2.4 GENERAL PARAMETERS

Instrument specifications
- Size: 291 mm (L) × 290 mm (W) × 150 mm (H)
- Weight: 4.0 kg (reader only)
- Lifespan: 10 years

Software specifications
- Operating system: Android 4.4
- CPU: Arm Cortex-A7, 1.5 GHz Quad-Core Processor

Interface
- Cassette tray (Card slot)
- Touch screen
- 2D barcode scanner (QR-code scanner)
- Embedded printer
- USB-A, USB-B, LAN, COM, WIFI
- DC-IN (12 VDC)
- ON/OFF (power on/off switch)

Package specifications
- Size: 350 mm (L) × 330 mm (W) × 220 mm (H)
- Weight: 4.9 kg

Power supply
- Voltage: AC 100V ~ 240V to 12 VDC for the reader
- Frequency: 50/60 ±1Hz
- Rated power: 30VA

2.5 BASIC PERFORMANCE INDICATORS

- Detection limit   ≤ 1μg/ml (microspheres)
- Stability   ≤± 5%
- Linearity   r > 0.9
- Repeatability   CV% < 1.5%
- Reading speed   ≤ 30s (per test cassette; four test lines)

2.6 HARDWARE

The reader has been designed to function as a standalone instrument and therefore includes a touch screen user interface for operating of the reader, a fluorescence measurement module, an integral printer and bar code reader, audible speaker, and input/output (I/O) function to transfer data and control the reader remotely.

Touch screen		2D-scanners
Printer	Main PCB	Fluorescence reader
I/O		RTC
PSU		Speaker

Figure 2.1. Hardware description – Embedded PC with I/O, Power supply unit (PSU), Speaker and Real time clock (RTC), Touch screen, Printer, 2D barcode scanners, Fluorescence reader (opto-electromechanics).

2.7 SOFTWARE

The user interface of the reader has been designed to be intuitive, easy to use, and to minimize steps needed to carry out basic operations. The large and clear touch screen graphical user interface (GUI) make operating the reader and browsing results simple. The operation structure of the software is shown in figure 2.2.
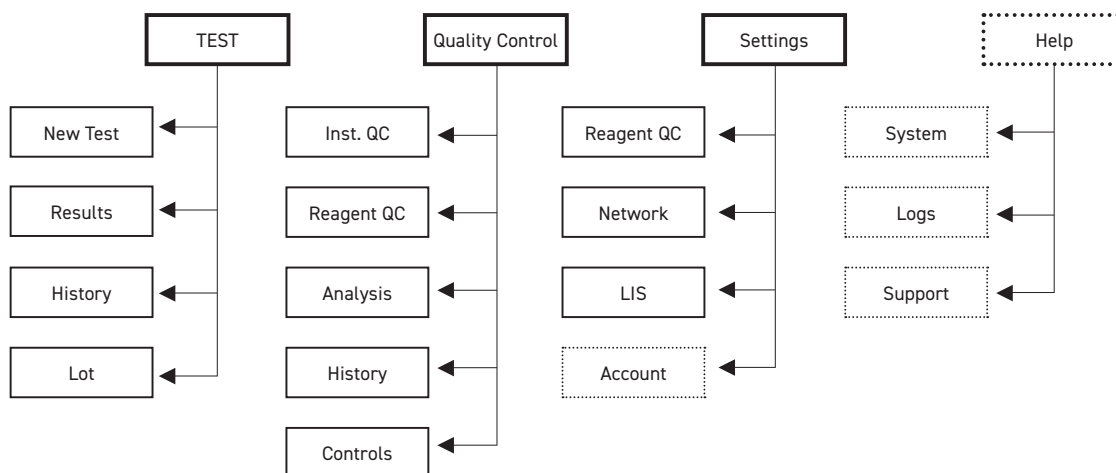
Figure 2.2. Hierarchical structure of the main functions of the GP Reader NT. Access to some functions depends on the user login rights.

Test menu provides all the functions needed to carry out new analyses. **Quality control** provides functions to support on-reader QC. **Settings** provides features to support QC settings, communication, and access control. **Help** provides supports for system management (and is accessible only for administrators).

2.8 PACKAGE CONTENTS

The reader is shipped in a cardboard box, including following items:

- GP Reader NT instrument (REF 740450)
- Power supply adapter (REF 740460) with mains cord (CEE7/7)
- Paper roll (REF GPQT 100110)
- User's Guide
- Quality Certificate

2.9 MAIN STRUCTURE

The main functional and interface elements are illustrated in Figure 2.3.

Figure 2.3. Main components of the instrument

Table 2.1. Description of the instrument interface.

Touch screen	Interact directly with what is displayed
Scanner	Read the barcode of cassettes

Print	Print test results
Cassette	Card slot for cassettes
USB-A	Connect to mobile devices, such as USB flash drives
USB-B	Connect to computer for debugging. Note: Not available for users
LAN	Connect to network or LIS system
COM	Connect to computer
DC-IN	DC power input connector for connecting the power adapter
ON/OFF	Power switch

2.10 ENVIRONMENTAL CONDITIONS

During operation, the device should be placed on a dry, clean, flat, stable surface, away from direct sunlight, sources of vibration and strong magnetic fields. Although the instrument can tolerate wide environmental conditions, (Table 2.2), it is important to adhere to the environmental limits specified by the tests performed (e.g. GPQT NT requires 18 - 28°C - please refer to GPQT NT instructions for use).

Table 2.2. Extreme environmental specifications of the reader.

Operating conditions	Ambient temperature: +10°C to +40°C Relative humidity: < 80% Atmospheric pressure: 86 - 106 kPa
Transportation and storage conditions	Ambient temperature: -20°C to +45°C Relative humidity: < 93% Atmospheric pressure: 86 - 106 kPa

During transportation and storage conditions, the device should be well protected to avoid moisture, solar radiation, or vibration.

2.11 PRODUCT SUPPORT AND SERVICE

If your instrument or software fails to function properly, or you have questions about how to use or maintain your products, or if you need to send an instrument to Biohit for service or repair, please contact Biohit:

Phone: +358 8 773 861
E-Mail: info@biohit.fi
WWW: www.biohit.fi, www.biohithealthcare.com

Please be prepared to provide the following information:

- Your name and company information
- A daytime phone, and/or an e-mail address
- The product name, model, and serial number; from the sticker at the bottom of the reader.
- The onboard software version (Help > System)
- For troubleshooting assistance or instruments needing repair, the specific steps that produce the issue

Returning Instruments for Service/Repair

- If you need to return an instrument to Biohit for service or repair, please contact Biohit for a Return Materials Authorization (RMA) number and the shipping address.
- Repackage the instrument according to the instructions in Chapter 3, **Repacking the instrument and its accessories**.
- Any laboratory instrument that has been used for research or clinical analysis is considered a biohazard and requires decontamination prior to handling (see Chapter 7, Decontamination). Decontamination minimizes the risk to all who come into contact with the instrument during shipping, handling, and servicing. Make sure that the reader has been decontaminated before shipping the reader to Biohit.
- As the instrument may contain patient results, please export the results out of the instrument to avoid data loss and/or transfer of patient data, which may contravene Regulation (EU) 2016/679.

3 SETUP FOR USE

GP Reader NT and its accessories are securely packaged inside custom-designed shipping materials. This packaging protects the instrument from damage during shipping. Inspect the shipping box, packaging, instrument, and accessories for signs of any damage.

If the reader is damaged, notify the carrier and your manufacturer's representative. Keep the shipping cartons and packing material for the carrier's inspection. The manufacturer will arrange for repair or replacement of your instrument immediately.

3.1 UNPACKING THE INSTRUMENT AND ITS ACCESSORIES

1. Carefully open the top of the box, and remove the power supply, documents supplied, and accessories.
2. Lift the reader out of the box and remove the left and right foam end caps. Place the reader on a flat table.
3. Connect the power cord to the power adapter and connect the power supply to the DC-IN socket at the rear of the instrument. Finally, connect the power cord to the mains.
4. Remove transport support from the cassette slot.

Figure 3.1. Instrument is ready to be used; cassette tray adapter at out position for cassette to be inserted.

3.2 REPACKING THE INSTRUMENT AND ITS ACCESSORIES

1. Before repacking the reader, please make sure to decontaminate the instrument as instructed in Chapter 7, Decontamination.
2. Repack the reader to its original packaging. Other forms of commercially available packaging are not recommended and can void the warranty. If the original packing materials have been damaged or lost, contact Biohit for replacement packaging.
3. Always contact Biohit representative before sending an instrument for return or repair.

4 OPERATION

4.1 SETTING UP THE READER

4.1.1 Operating Environment

The GP Reader NT is designed to operate optimally at normal room temperatures. Although the instrument withstands wide operating temperatures, the GPQT NT assay has its own specific operating tolerance (18 - 28°C) which must be adhered to. In general, as the performance of the reader may be affected by extreme environmental conditions, the following should be avoided:

- **Excessive temperature:** Although the instrument uses inbuild temperature correction very low or high temperature should be avoided.
- **Excessive humidity:** If condensation forms directly on the sensitive electronic circuitry, the performance of the instrument may be compromised or even fail.
- **Excessive ambient light:** Bright sunlight or strong incandescent light may affect the performance of the instrument.
- **Dust:** Operate the instrument only in a clean area. Avoid dirt or dust building up in or on the reader.

Caution! Power Supply. Only use the specified power supply provided with the GP Reader NT to ensure proper operation of the unit. The GP Reader NT has a universal 12VDC, 30AV power supply that functions from 100 to 240 VAC (± 10.0%) @ 50/60Hz without external switching.

Warning! Electrical shock. The GP Reader NT power supply must be connected to a power receptacle that provides voltage and current within the specified rating for the system. Use of an incompatible power receptacle may produce electrical shock and fire hazards.

Never use a two-prong plug adapter to connect primary power to the GP Reader NT power supply. Use of a two-prong adapter disconnects the utility ground, creating a severe shock hazard. Always connect the power supply cord directly to a three-prong receptacle with a functional ground.

The reader is intended to be used indoors. The room should be well ventilated, free of excessive dust, vibration, strong magnetic field, direct sunlight, UV radiation, air flow, high humidity. Significant temperature changes should be avoided.

Place the instrument on a flat laboratory table which is away from any heat sources.

The specific environmental requirements are as follow:

1) The working area should be a dry, clean, flat, stable surface, away from sources of vibration and have enough room for accessories, such as cables, reagent bottles, etc.
2) Leave enough space on each side of the instrument (10 cm at least).

3) The environment should be clean and away from corrosive gas, smog, and dust.
4) Never use electronic instruments in an explosive environment.
5) Never run the instrument in an environment with potentially dangerous liquids or gases.
6) Ensure the environment temperature and humidity are within specified conditions.
7) The instrument should be sited where it is safe to use it and secure from unauthorized access to the data of the reader.
8) Voltage requirement: 100 to 240 VAC, 1.0 A, 50/60Hz. UPS power supply is recommended for unstable electrical premises.
9) The QR-code reader is embedded on the left side of the instrument. Avoid any direct or indirect light exposure to the eyes when using the barcode reader.

4.2 ELECTRICAL CONNECTIONS

1) Connect the mains power cord to the external power adapter.
2) Plug the round end of the power adapter cable into the power supply jack on the rear of the instrument.
3) Plug the 3-prong end of the mains power cord into an appropriate power receptacle.
4) Use the **ON**/**OFF** switch, at the rear of the instrument, to power on the instrument.

4.3 REPLACING PRINTING PAPER

If the paper roll is not in place, or if you need to replace printing paper, do as follows:

1) Open the printer cover.
2) Release the lock (at the center of the cover).
3) Take away the paper roll core and replace it with a new paper roll.
4) Be sure to release the end of the paper before putting it in place and closing the cover. Pay attention to the direction of the paper roll: the paper is released 'over the top' of the roll.
5) Close the lock.
6) Close the printer cover.
7) After powering on the instrument, use the small feed button to make sure that paper emerges smoothly from the printer.

A flashing green light on the paper feed button indicates the paper roll needs replacing.

4.4 START UP THE INSTRUMENT

After powering on the instrument the system will boot up.

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Figure 4.1. Biohit Healthcare logo will be shown on the display during the boot up process.

The Biohit Healthcare logo will be displayed, self-test will be activated during initialization. Wait a moment until the login screen appears as illustrated in figure 4.2.
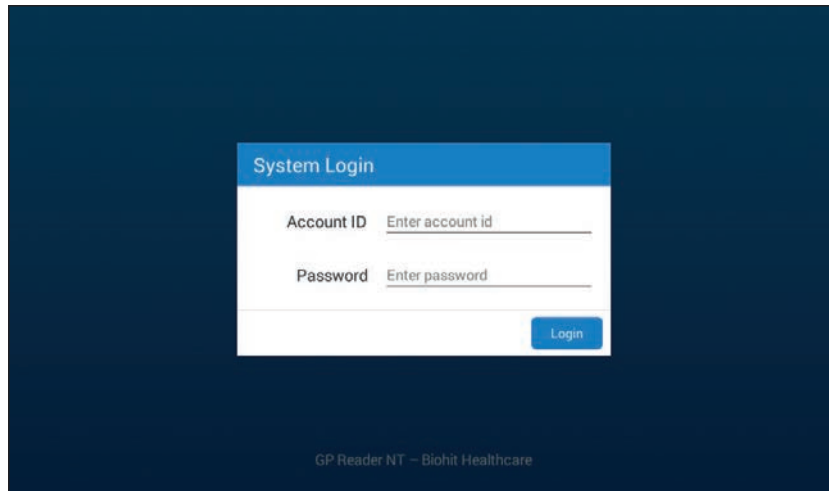
Figure 4.2. Login screen

4.4.1 Log in/out
Enter your login credentials (account ID and password) and tap on the **LOGIN**-button when ready. The MAIN menu will be displayed, as shown in figure 4.3.
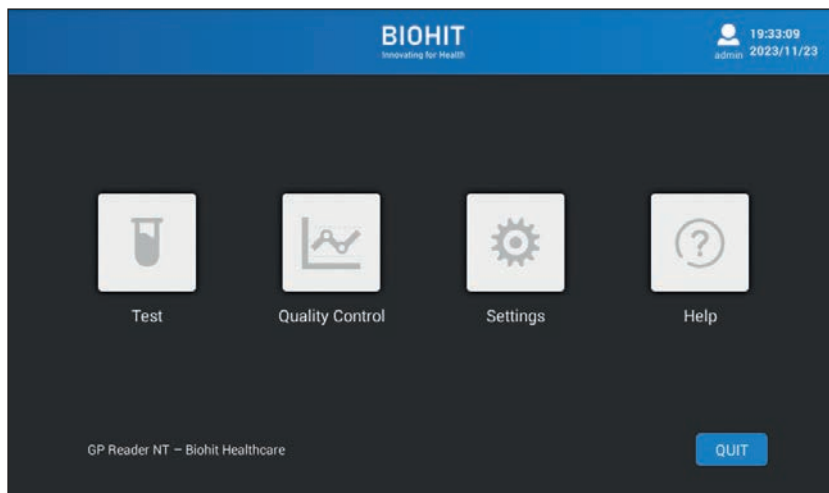
Figure 4.3. The MAIN menu as Administrator login; Help functions are not accessible for Operator login.

Caution: Please, do not press the touch screen too firmly or use sharp objects when operating the device. Pressing too hard or using a hard implement may damage the display.

Please, do not use the ADMIN login to run any clinical samples. Instead, always use a specific 'operator' login to run new tests. If you don't have credentials, please ask a person with administrator rights to create a user login for the user.

Do not use false credentials. To login with your private crendetials, you may either logout by tapping on the user icon at the top right corner of the display, or by restarting the instrument.

Caution: Make sure that the operator and time displayed in the top right corner of the screen are correct, so as not to hamper the traceability of the analysis. If the time is not correct, please contact the administrator to change the time. You may refer to Chapter 5.2 for more information.

QUIT

The **QUIT**-button on the administrator main page can be used to quit the application. However, this functionality is reserved for maintenance use by an authorized Biohit representative only.

4.5 TEST MENU

To carry out a new test, select on the "Test" icon of the MAIN menu - to enter to the New Test page.

Figure 4.4. The test menu with default test parameters displayed.

4.5.1 New Test

The new test page is selected by default when selecting [**Test**] from the main menu.
To carry out a new test, the following parameters need to be entered.

Cassette

GastroPanel quick test NT cassette - GPQT NT (4) - is automatically selected. No need to edit this.

Sample ID

Enter the ID of the sample to be analyzed.

As you select on the editable field, a pop-up keypad will be displayed.

Please follow local and national regulations in using sample/patient identification. Make sure you follow EU General Data Protection Regulation 2016/679 when processing the data of EU citizens.

Reagent Lot

The QR code for the reagent lot is printed on the test cassette and therefore you do not need to enter the Reagent Lot.

However, if the QR code is distorted or unreadable, the QR-code can be selected by tapping on this editable field. A pop-up list will be displayed from which the QR-code can be selected. If the pop-up list does not contain the correct QR-code, you must first scan it from the sticker of the kit box. The scanning function is explained on the **Test** > **Lot** page.

⚠ **Caution: Using an incorrect QR code** leads to false data, so be very careful when selecting the QR-code manually.

Sample Type

Depending on the test kits used, you can measure either plasma "P" or whole blood "WB" samples. Select the correct sample type.

⚠ **Caution:** If you select the incorrect sample type, the results will be compromised and should not be used.

If finger prick sample is used for the test, then select whole blood and enter the hematocrit value of the whole blood sample. If this is not known, you may use the set default values for female or male (please refer to the Instructions For Use of GPQT NT).

⚠ **Caution:** The HCT value directly affects the concentration values. This must be considered in the interpretation, especially if the values are close to the decision endpoints.

Patient

It is important for the physician to know if the sample collected is a fasting (basal) "B" or postprandial (stimulated) "S" sample, as Gastrin-17 concentrations are affected by the acidity of the stomach.

For fasting samples, it is common practice to use a morning sample, drawn after an overnight fast. Sometimes a postprandial (stimulated) sample is requested. In this case the blood sample should be collected about 20 minutes after protein stimulation. Select **Postprandial** instead of **Fasting** in this case.

⚠ **Caution:** Fasting vs postprandial impacts the reference range of the Gastrin-17, and therefore also the interpretation. An incorrect selection may lead to false interpretation.

As certain medicines, such as proton pump inhibitors (PPI) or H2 blockers, reduce the acid content of the stomach, use of these medicines will have an impact on the marker values. If the patient is using these acid blocker medicines, please tick on the **Use of PPI-medication**. Although it does not affect the interpretation displayed, it is useful information for the doctor for diagnosis and further investigation.

⚠ **Caution:** Do not check the Use of PPI medication check box if you are unsure about the use of PPIs. Leaving the check box empty does not cause any issue, but checking it in error may confuse the physician.

Measurement

You may activate the measurement by choosing between two different options, as follows:

Option 1. Now: If you prefer to pipette the sample onto the test cassette and incubate it for 15 minutes (e.g. on the bench top) before before inserting the test cassette into the reader to be measured, please select **Now** as the measurement mode.

⚠ **Caution:** It is important to activate measurement exactly 15 minutes after pipetting the sample onto the test cassette. If the measurement is delayed, the concentrations may not be correct and may lead to false interpretation.

Option 2. On timer: If you prefer the reader to time the incubation and measure the test cassette automatically after 15 minutes, pipette the sample onto the test cassette and insert the test cassette into the reader, then select **On timer** as the measurement mode.The timer will get activated after tapping on the **START**-button, and the reader will trigger the measurement after the set time of 15 minutes (set as the default).

⚠️   **Caution:** It is important to measure the cassette at exactly 15 minutes from pipetting the sample onto the test strips. If for some reason you delay activating the measurement, you can adjust the timer to ensure the correct test time of 15 minutes is achieved.

As soon as you have selected the way to proceed, make sure to place your test cassette in the correct orientation in the cassette holder (see figure 4.5). Open the cassette holder by pressing on the **IN/OUT**-button on the screen or using the mechanical button on the front panel of the instrument.

Figure 4.5. Correct orientation for the inserting the test cassette.

ⓘ   Pay attention to the correct orientation of the test cassette on the slide-in cassette holder.

⚠️   **Caution:** Do not hinder the cassette holder from moving as it may fail to find the correct position when scanning the strips.

The selected measurement mode begins after tapping the **START** button. For the **Now**-mode, the results will be displayed after about 30 seconds, but for the **On timer**-mode, the results will be displayed soon after the set time has elapsed.
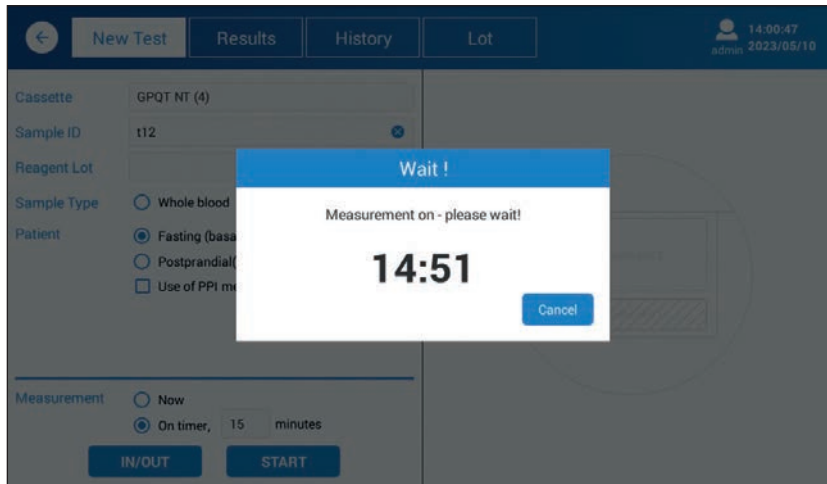
Figure 4.6. Timer activated measurement.

As soon as the measurement has been completed and data processed, the test results will be displayed on the screen, as illustrated in the figure 4.7.
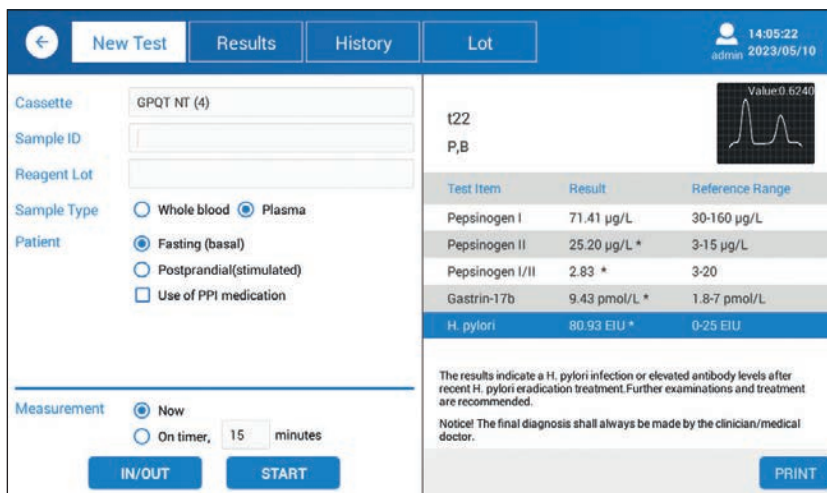

Figure 4.7. Example of test results displayed on the screen.

Check that all selected parameters are correct, as wrong parameters can lead to wrong results.

Results are automatically stored in the memory of the reader. You may also print the results by tapping on the **PRINT**-button.

The displayed results compose the following information :
Sample and patient data as follows:
- Sample ID
- Plasma (P), whole blood (WB) with hematocrit value in percentages (%).
- Fasting (B) or Postprandial (S)
- Use of PPIs

List of markers with concentrations and reference ranges.
Interpretation of the results.

If measured concentration is out of measurement range, less than (<) and higher than (>) marks are used.
If measured concentration is out of reference range, an asterisk (*) is displayed with the value.

A new measurement can be initiated just by entering 1) Sample ID, 2) selecting the sample type and patient parameters, 3) selecting a measurement mode, and 4) activating the measurement by tapping on the **START**-button after inserting the cassette on to the cassette tray.

⚠️ **Caution:** Safely dispose of all reagent strips as per local regulations and procedures.

4.5.2 Results
To view or print previous results, select [**Results**] from the Test menu.
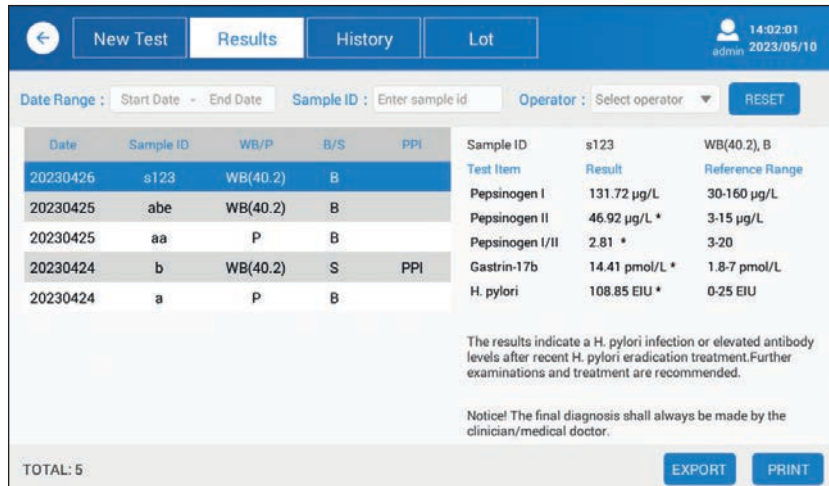

Figure 4.8. Results display.

By selecting on the [**Results**], a list of recent results is displayed. You may view any result on the list by selecting on the row. The results will be displayed on the right panel of the screen.

You may filter the results by Date range, Sample ID or by Operator.

RESET
The **RESET**-button is used to clear the filter settings.

PRINT
The selected results can be printed by selecting on the **PRINT**-button.

EXPORT
If you need to transfer all the measured results for further data processing, you may export the data onto a USB-memory device. Plug in the USB-memory device into the reader's USB port located at the rear of the reader. The structure of the ASCII-data record (CSV-file) is described in the Appendices.

⚠️ **Caution:** Be careful when processing the CSV-file using MS Excel, as it may convert numeric data to a form that may be difficult to convert back to correct results. Always make sure you keep a backup copy of the original file.

ⓘ Please follow local and national regulations in using patient name or other identification of the sample. As the reader contains patient laboratory results, make, sure that the reader is kept in a safe and secure place, which is not accessible by any unauthorized user. Also, if you print or export data on any media, please, make sure that patient rights and consent are obeyed. Make sure EU General Data Protection Regulation 2016/679 is followed when processing data of EU citizens.

4.5.3 Results History

Via the Test menu, you can view the result of each marker one-by-one by using the History page.

Figure 4.9. History display.

You may filter the results by Date range and Lot No.

DELETE

You have the option to delete data by selecting the corresponding check box and tapping on the **DELETE-**button.

⚠️ **Caution:** Be careful when deleting data permanently. Make sure EU General Data Protection Regulation 2016/679 is followed when processing data of EU citizens.

SEND TO LIS

It is possible to send data to laboratory information systems (LIS) by selecting data and tapping on the **SEND TO LIS-**button. The LIS connection must be set up and enabled before data transmission. Please contact Biohit for more information about the supported LIS protocol.

4.5.4 Lot

The **Lot** page of the **Test** menu enables users to scan and view the QR-code of the test kit manufacturing batches.

Figure 4.10. The Lot page.

RESET

The **RESET**-button is used to clear the filter settings.

CODE SCAN

The embedded QR-code scanner on the right side of the reader, enables users to scan the QR-code of the test kit batch. To scan the code, position the QR-code of the kit box cover some 10 cm from the scanner and tap on the **CODE SCAN**-button.

FROM USB

You can also upload the QR-code data from a USB memory device, by inserting a USB memory device containing the "batch_info"-file into the USB port and tapping on the **FROM USB**-button. For more information about this option, please contact Biohit.

DELETE

If there is some particular reason to delete scanned QR-code data from the instrument, select the check box of the QR-code you wish to delete, and tap on the **DELETE**-button.

4.6 QUALITY CONTROL MENU

The quality control features provide on-instrument quality management functionalities.

4.6.1 Instrument QC

The **Inst. QC** can be used to check that the instrument measurement works as expected with the help of a one strip QC Cassette.

Figure 4.11. Instrument Quality check display.

IN/OUT

To toggle in/out of the test cassette tray holder.

START

To start the measurement process.

Open the cassette tray by pressing on the **IN/OUT**-button. Insert the QC Cassette into the first slot of the cassette tray, as shown in figure 4.12. Finally, activate the measurement using the **START**-button.

Figure 4.12. Inserting QC test card into the cassette tray.

Values within the High and Low acceptance limits indicate the measurement QC has passed.

PRINT
The result can be printed out by using the embedded printer, which can be activated by pressing on the **PRINT**-button.

4.6.2 Reagent QC
The inbuild Reagent QC feature can be used to control the test cassette batch variation using control samples (not provided). To use this feature, it is of vital importance that the selected control samples are stored unchanged during the follow-up period.

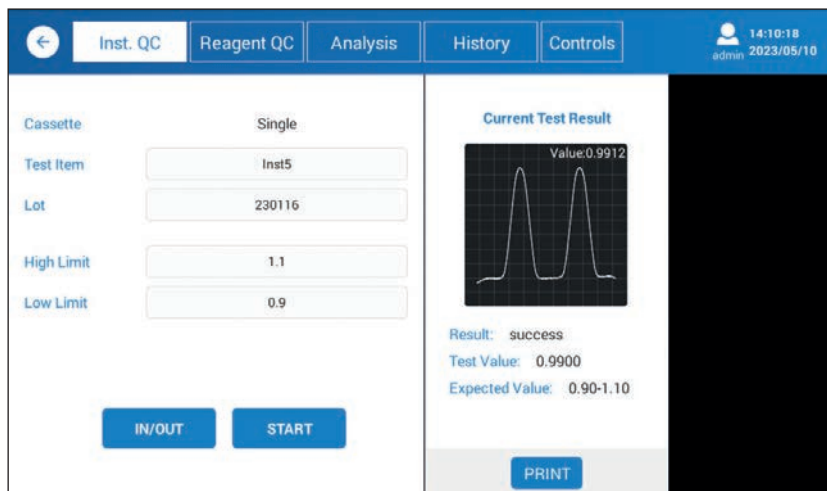 **Caution:** Improper storage of the sample can lead to wrong results.

Figure 4.13. Reagent QC display.

IN/OUT
To toggle in/out of the test cassette tray holder.

START
To start the measurement process.

Before using this feature, you need to define Control Lot and reference ranges for all the four markers using the Control LOT form, as shown in figure 4.14.

Select control lot level for all the different markers. Press on the **IN/OUT** to open the cassette tray and put the test cassette on the tray. Tapp on the **START**-button to activate the measurement.

The measurement results are displayed on the screen. Pass or fail will be used to indicate the outcome of the test.
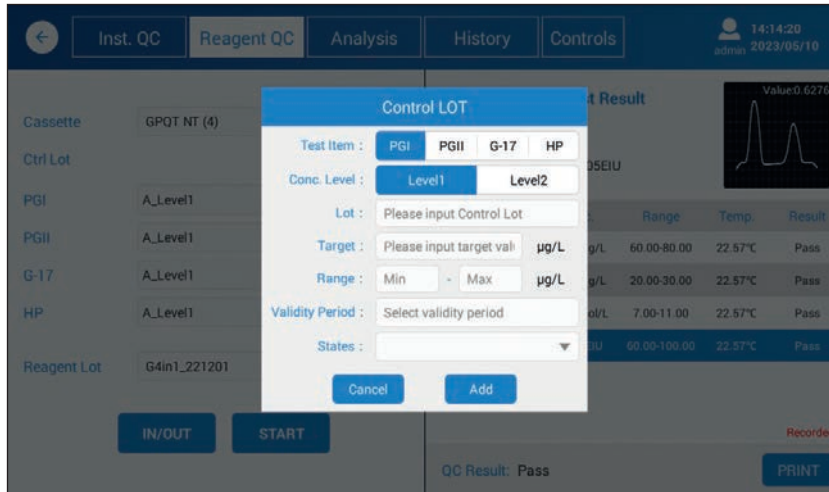
Figure 4.14. Control LOT form

For more information on how to set the Control Lot ranges, please refer to the Controls page.

PRINT
The result can be printed by using the embedded printer, which can be activated by pressing on the **PRINT**-button.

4.6.3 Analysis
The **Analysis** page is used to display the results of the Reagent QC data. Some filters can be used to filter the data displayed.

RESET
The reset button is used to clear the filter settings.

Figure 4.15. Analysis display.

You can filter the results by Test item, Control Level, Date range and Control Lot.

4.6.4 History of QC

The **History** page displays all the quality control data measurement results either for the Instrument QC or Reagent QC, as illustrated by figure 4.16.

The displayed results can be filtered by Date range, Test item, Control level, Control lot, Result and Status.

RESET

The **RESET**-button is used to clear the filter settings.

Figure 4.16. The History page.

SEND ALL TO LIS

It is possible to send data to laboratory information systems (LIS) by selecting data and tapping on the **SEND ALL TO LIS**-button. The LIS connection must be set up and enabled before data transmission.

EXPORT

Selected results can be exported to USB-memory device. To do that, insert USB-memory device to the USB-port and tap on the **EXPORT**-button.

Refer to the Chapter 7, **Appendices** for information about the data structure.

DELETE

You have the option to delete data by selecting the corresponding check box and tapping on the **DELETE**-button.

⚠️ **Caution:** Be careful when deleting data permanently. Make sure EU General Data Protection Regulation 2016/679 is followed when processing data of EU citizens.

PRINT

The selected (checked) value can be printed by using the embedded printer.

4.6.5 Controls

The Controls page displays the data of the control used, as illustrated by figure 4.17.

Figure 4.17. Controls display.

The displayed results can be filtered by Date range, Test item, Control Lot, Level and Status.

RESET
The **RESET**-button is used to clear the filter settings.

ADD LOT
New Control Lot data can be added by tapping on the **ADD LOT-**button.

DELETE
You have the option to delete data by selecting the corresponding check box and tapping on the **DELETE**-button.

4.7 SETTINGS

The settings menu is used to set up parameters for the Reagent QC, Network, LIS and for the Accounts.

4.7.1 Reagent QC (settings)

Figure 4.18. Reagent QC display.

The reader provides some QC control functionalities, as described below.

QC Rule Options

Upper and lower limit rule enables users to set up upper and lower limits as the reference levels to trigger if the value does not fall within these limits.

1_3S rule corresponds to a Levey-Jennings chart having control limits set as the mean plus/minus 3s (3 standard deviations). An analytical run is rejected when a single control measurement exceeds a 3s control limit.

The user interface offers a few different options that affect the calculation of the average and standard deviation.

4.7.2 Network
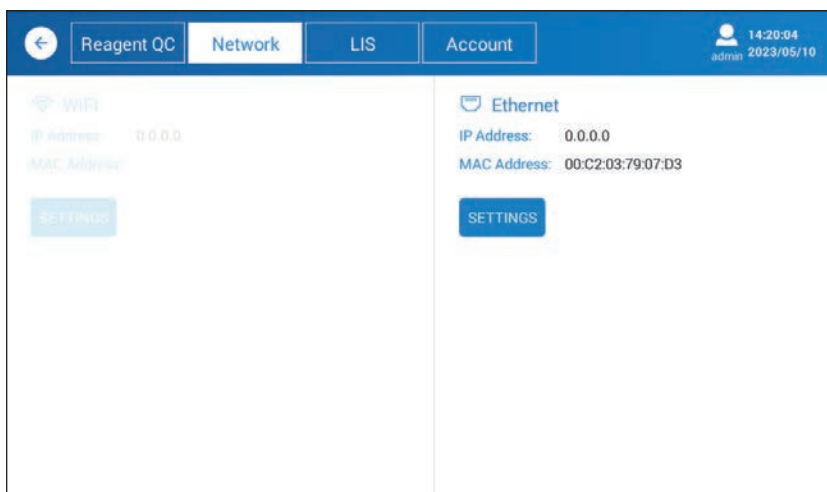
Figure 4.19. Network display.

The **Network** page enables the user to set up both WIFI and Ethernet IP and MAC addresses.

WIFI-SETTINGS

The WIFI is not yet supported, as indicated by the dimmed pane. Contact Biohit for more information.

SETTINGS (Ethernet)
As you tap on the **SETTINGS**-button, the system will display all the networks supported by the operating system. Ethernet is one of the options and when selected, you will see the corresponding settings. When it comes to the address, DHCP is enabled, but can be disabled should you need to define a dedicated address.

To return from the settings, please select the back arrow button.

Settings are supported by the operating system (Android) and changed if updated.

4.7.3 LIS
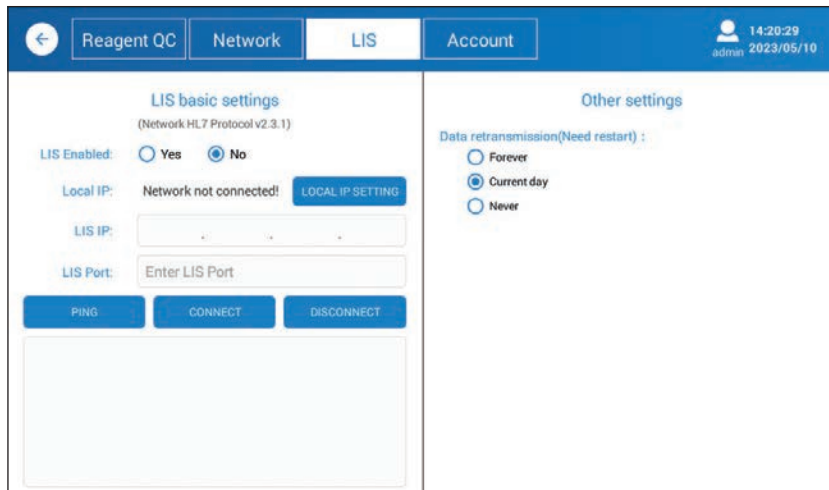
Figure 4.20. LIS display.

As soon as the network parameters have been set and communication enabled, you can set up LIS parameters to connect to the host system.

LOCAL IP SETTINGS is used to setup IP settings – refer to the **Network**.

Enter the host system LIS IP address and the LIS Port.

PING can be used to test the connection between the reader and the host system.
CONNECT is used to connect the instrument to the host.
DISCONNECT is used to disconnect the instrument from the host.

Please contact Biohit for more information about the messages supported by the HL7 protocol (version 2.3.1) supported for the LIS.
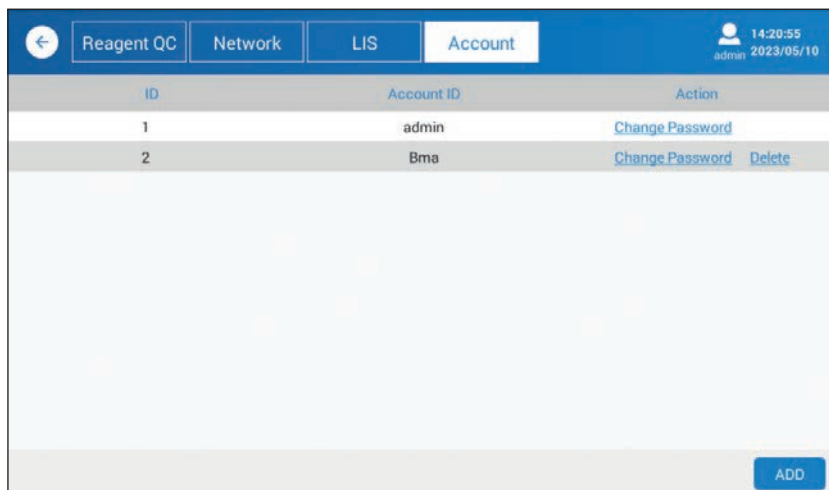
Figure 4.21. Account display.

4.7.4 Account

ADD
It is very important to establish accounts for every operator. To do that tap on the **ADD**-button and define **Account ID** and **Password** for the operator.

Some pages or functions are not accessible for the operator. However, to run clinical samples, this should only be carried out by designated operators only.

As can be seen in Figure 4.21, the Account user interface enables the additions, change, or deletion of user accounts.

Please, do not use ADMIN login to run any clinical samples. Instead, always use user specific login to run new tests.

Warning: Never forget the administrator password, as it may require shipping the instrument back to Biohit.

4.8 HELP

Access to the Help page requires Administrator login.

4.8.1 System

The system page contains important information about the software version and the instrument's serial number. This information should be sent to Biohit if there is any issue with the product.

Always use the latest software version of the application either by contacting Biohit or browsing it on Biohit's website.
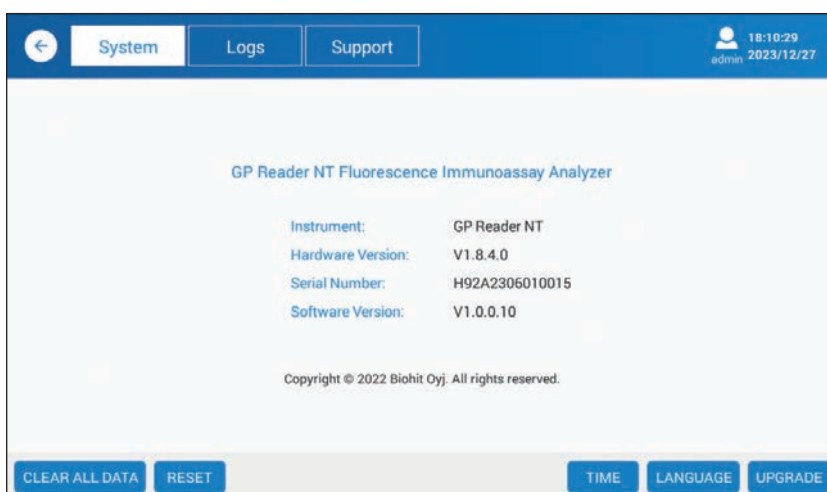
Figure 4.22. System display.

CLEAR ALL DATA
By tapping on the **CLEAR ALL DATA**-button, test data, quality control data and self-check data are deleted, so be careful to confirm the deletion.

Caution: Be careful when deleting patient data. Make sure EU General Data Protection Regulation 2016/679 is followed when processing data of EU citizens.

RESET
Restore default settings.

TIME
To set the system time. Always make sure (from the top right corner of the screen) that the clock is in local time. If not, tap the TIME button to access the system settings to change the time.

LANGUAGE
The language of the user interface can be selected by tapping on the **LANGUAGE**-button. A popup is displayed to select the language. After selecting the language the software will restart and return to the Login page.

UPGRADE

It is important to use the latest version of the software application. Should you upgrade the software application, please proceed as follows:

1. Copy new version of the software application onto a suitable USB memory device.
2. Start the reader and login as Administrator
3. Browse Main menu Help > System
4. Insert USB memory device into the USB port at the rear of the instrument
5. Tap on the **UPGRADE**-button
6. Select Install
7. Restart the reader as operator to use the instrument

Contact Biohit to make sure that you have the latest file version of the software (the .apk-file).

4.8.2 Logs

The instrument collects log data on different actions. The log files are useful for solving issues, if any.

Figure 4.23. Logs display.

EXPORT

|< First page of the log file.

< Previous page of the log file.

> Next page of the log file.

>| Last page of the log file.

In troubleshooting, you may be asked to send log files to Biohit. Connect the USB memory device to the USB A port, select Instrument and tap the EXPORT button. The log file is saved to a USB memory device. You can send the file to BIOHIT by email.

4.8.3 Support

The Support functionality is intended only for the manufacturer, not for the operator or the administrator.
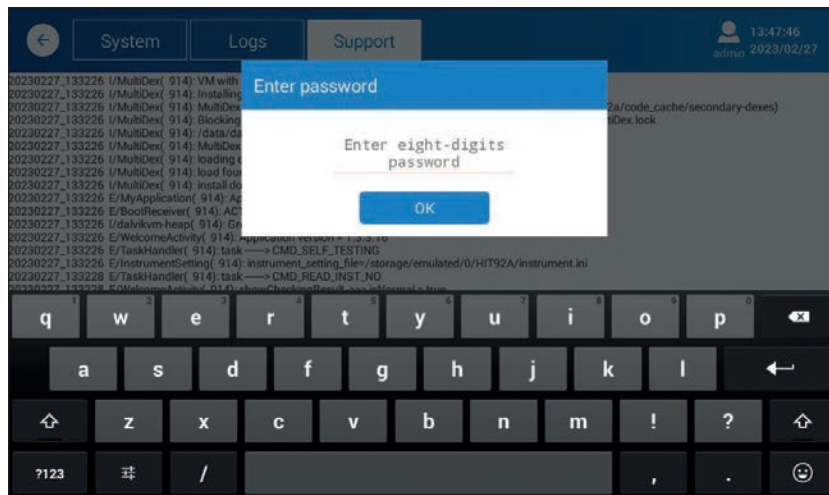
Figure 4.24. Support display.

In case of any questions, please contact Biohit.

5 INSTRUMENT QUALIFICATION

This chapter discusses the tasks and procedures necessary for qualifying instrument operations, and for administors only.

5.1 INSTALLATION QUALIFICATION (IQ)

The IQ is conducted when unpacking and setting up the GP Reader NT according to the following steps.

1) Check that the shipment is free from damage and that it contains all the items listed in the Chapter 2, Package contents.
2) Place the GP Reader .NT in its chosen location on a clean flat table.
3) Connect the power adapter to mains and the power supply to the reader. Switch on the instrument. The reader will boot up displaying Biohit Healthcare logo, and after a while the login prompt will be displayed.

5.2 OPERATIONAL QUALIFICATION (OQ)

Make sure that the following basic functions work as expected:

a) Login procedure
After switching on the power to the reader the login screen is displayed. Login as administrator. Please contact Biohit for the Administrator ID and password, if needed.

At this point, also create login details for the operators (Settings > Account) - refer to section 4.7.4 Account.

b) Time and Date
Check current time and date from top right corner of the display, as illustrated in figure 5.1.

Figure 5.1 See the User login, time and date from the top right corner of the display.

If you need to change the time/date, please browse **Help > System** and tap on the **TIME**-button. Adjust time settings and select the back icon to return.

It is important to keep the clock on time, as it is stored as a timestamp in analyses and file references.

Each operator must use their own identification data for the analyses. You can change the user ID by tapping on the user icon in the top right corner of the screen or by switching the instrument off then on again.

c) Access the functions
Make sure that as an administrator you have access to all the pages of the application – refer to the Chapter 2, Software.

d) QR-code scanner
Test that the QR-code scanner is functioning (lights up) when activated. Browse to **Test** > **Lot** and tap on the **CODE SCAN**-button. At this stage it is not necessary to have test kit box QR-code available.

e) Measurement

To test the measurement operation, please use a previously used test cassette, or carry out a new test on a new test cassette. Follow the measurement process and check the display of results, ensuring that sample information, marker concentrations, reference ranges and interpretation are all displayed. See figure 5.2.

f) Printing

Make sure that the printer paper roll has been installed in the printer. Check that the form feed works (by pressing on the form feed button). Activate printing from the results display by tapping on the **PRINT**-button.
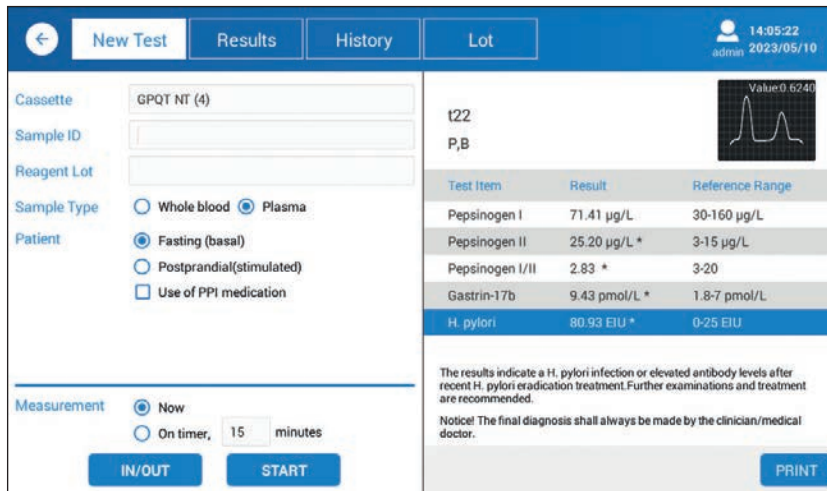
Figure 5.2. Typical display of results, with interpretation.

5.3 PERFORMANCE QUALIFICATION (PQ)

The GP Reader NT has been calibrated at the factory. The construction of the reader optoelectromechanics is well protected with robust design. Therefore, calibration is seldom compromised.

If you suspect that the reader's performance has deteriorated, please contact Biohit.

Always keep the reader clean and verify its performance at regular intervals. The reader has inbuilt QC functionality to use for quality control, or you can establish a method suitable for your laboratory use.

6 PREVENTIVE MAINTENANCE

The instrument requires little maintenance to work in clean environment at normal room temperature conditions. It should be kept free of dust and debris to ensure safe and error-free operation.Through regular maintenance of the instrument you can prolong its life.

Follow these steps to maintain the instrument in good condition:

1) Carefully read the user manual before using the instrument.
2) Remember to switch off the power supply before cleaning the instrument to avoid instrument damage or personal injury.
3) For daily maintenance, keep the instrument clean and free from dust, debris and moisture.
4) Clean the instrument surface on a regular basis. It is suggested to clean the instrument with a piece of moist cloth and mild detergent (such as Mikrozid® AF Liquid or comparable product). Please do not clean the instrument surface with strong detergent/acid/alkali, organic solvents or with alcohol of which concentration is more than 75%, as these solutions may damage the cover and display of the instrument.
5) In case there is any salt, acid, alkali solution or organic solvents spilled on the instrument, clean immediately to protect the instrument.
6) The screen can be cleaned with a piece of soft microfiber or other lint-free cloth, and if needed, use 75% ethyl alcohol or routine laboratory detergent. Please do not directly spray any liquid on the screen.
7) Always keep the cassette holder free from dust and liquid residue. Use absorbent cotton or cotton cloth with SDS solution, 75% ethyl alcohol when cleaning. Never pour any liquid into the reader.
8) In case the instrument will not be used for a long time, unplug its power cord, and cover the device with a piece of soft cloth or a plastic bag to prevent dust from entering.
9) It is suggested to power on the instrument and to run a dummy cassette every 30 days to ensure normal performance of instrument, If the instrument is used infrequently, it is recommended to power on the reader and run a dummy test cassette every 30 days to ensure normal performance of the instrument.

⚠ **Caution:** Do not place any heavy objects on top of the instrument.

⚠ **Warning:** Even if the instrument has passed the security certification and testing, in order to avoid instrument damage or personal injury, do not clean the instrument while it is running or when it is connected to the power supply.

7 APPENDICES

7.1 DECONTAMINATION

If there is any liquid spill or contamination in the cassette holder or other parts of the reader, disinfect the instrument before moving the cassette holder. Disinfect the instrument before moving it to another location or shipping to manufacturer.

Disinfection treatment:
1) Wear protective clothing and medical disposable gloves.
2) Prepare the disinfectant in advance (such as **Mikrozid® AF Liquid** or comparable product).
3) Leave the cassette holder open and remove any test cassette, then disconnect the instrument from the power supply.
4) Moisten the absorbent cotton or cotton cloth with the pre-prepared disinfectant.
5) Gently clean the cassette holder with the absorbent cotton or cotton cloth.
6) Please wait until the cassette tray holder interior is dry and clean it again with 75% ethyl alcohol.
7) Wipe the instrument cover with mild detergent and clean immediately with a cloth moistened with clean water.
8) Please wait until the cassette holder and the instrument surfaces are dry before to connecting the power cable to the instrument.
9) Optional short exposure to UV-light disinfection could be used.

Warning: Only trained professionals are allowed to perform the disinfection treatment, which should be performed in a well-ventilated environment.

7.2 DISPOSAL

During its operating time, the device may come into contact with potentially infectious material, such as blood, and hence a used device can constitute a possible source of infection. Decontaminate the device according to instructions in chapter 7.1 before disposal.

This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to local laws and regulations.

The real time clock (RTC) of the reader is powered by a small Lithium coin battery. Should you need to remove the battery, please contact Biohit for assistance.

Notice: According to EU General Data Protection Regulation, personal data must be removed prior to disposing of the reader.

7.3 TROUBLESHOOTING

7.3.1 Basic malfunctions

The chart below describes common error messages that may be displayed while using GP Reader NT, their causes and troubleshooting methods. If unable to solve the problem after troubleshooting, please contact your local distributor.

Table 7.1. General operating errors

Error	Possible reason	Solution
Unable to start the device.	Power supply is not properly connected to device.	Check and reconnect power.
	Power supply is damaged.	Contact supplier or manufacturer for assistance.
Display is not responding.	Display calibration failure.	Contact supplier or manufacturer for assistance.
	Display broken.	
Unable to complete test.	Instrument heated up / environmental temperature is too high.	Turn off the device, wait for the device to cool down, then restart.
	Other reasons.	Contact supplier or manufacturer for assistance.
Unable to print test report.	Printer has run out of paper / buffer is full.	Change paper roll / wait for printer handling data.

Table 7.2. Troubleshooting

Error	Possible reason	Solution
Beep	GP Reader NT is not operated in accordance with the instructions specified in this manual.	Follow the Error prompt on the screen.
	Power supply is damaged.	Contact supplier or manufacturer for assistance.
QR-code scan failure	Distance and angle between the scanner and the bar code or the QR-code may be wrong.	Re-scan by adjusting the bar code or QR-code distance, angle, or orientation.
	Display broken.	
Data exception	Undetectable QR-code, wrong orientation or false cassette.	Retest cassette.
	Other reasons	Contact supplier or manufacturer for assistance.
Cassette jam	Cassette is not in correct position on the tray.	Make sure that cassette is properly placed on the tray.
Printing failure	The printer is out of paper.	Check whether the printer is out of paper.
	Paper jam.	Check whether the print paper output slot is jammed.
	System error.	Shut down and then restart the instrument.
Instrument not responding	The instrument is in power down mode, or the power cable is not properly connected.	Check the power supply and cable connections.

⚠ **Caution:** Do NOT make any changes to the GP Reader NT. The instrument is not user serviceable. Any problems caused by attempts to open, disassemble, or modify GP Reader NT will void the warranty.

7.4 DATA EXPORT

7.4.1 Test Results

Specification of the test results ASCII CSV-file exported by the GPQT NT Reader.

<**DateTime**><DL><**SampleID**><DL><**Sample**><DL><**PGI**><DL><**PGII**><DL><**PGR**><DL ><**G17**><DL><**HP**><DL><**Interpretation**><DL><**OperatorID**><DL><**LOT**><DL><**TC**>< DL><**FLU**><DL><**SVER**><DL><SN><CR><LF>

<**DateTime**>	DateTime (YYYY-MM-DDThh:mm:ss)	; string
<**SampleID**>	Sample ID	; string
<**Sample**>	WB(HCT) || P - B || S - P	; string
<**PGI**>	Pepsinogen I value (concentration in µg/l)	; string
<**PGII**>	Pepsinogen II value (concentration in µg/l)	; string
<**PGR**>	Pepsinogen I/Pepsinogen II value	; string
<**G17**>	Gastrin 17 value (concentration in pmol/l)	; string

<HP>	*Helicobacter pylori* value (concentration in IU)	; string
<Interpretation>	Interpretation	; string
<Operator ID>	Operator ID (Login ID)	; string
<LOT>	LOT number	; string
<TC>	Temperature in Degrees Celsius *	; string
<FLU>	Fluorescence values (T1/C1-T2/C2-T3/C3-T4/C4) *	; string
<SVER>	Firmware version – Software version (FW-SW)	; string
<SN>	Serial number of the instrument	; string
<DL>	Data delimiter	; char
<CR><LF>	Carriage return (0xD), Linefeed (0xA)	; char

Note:

- TAG-labels shall be used as the header of the record
- File origin Unicode UTF-8
- The data fields are enclosed in parentheses (" ")
- Dot is used as the decimal separator
- Data delimiter as semicolon
- µg/l = micrograms per liter, pmol/l = picomol per liter, EIU = (arbitrary) enzyme immuno unit
- || is used as logical OR
- Dash is used to concatenate Sample data
- T1   PG I Test line intensity value
- C1   PG I Control line intensity value
- T2   PG II Test line intensity value
- C2   PG II Control line intensity value
- T3   G-17 Test line intensity value
- C3   G-17 Control line intensity value
- T4   HP I Test line intensity value
- C4   HP I Control line intensity value
- asterisk (*) marked parameters exported only for administrator (log in with ADMIN rights)

Example:

"DateTime";"SampleID";"Sample";"PGI";"PGII";"PGR";"G17";"HP";"Interpretation";"OperatorID";
"LOT";"TC";"FLU";"SVER";"SN"
"2017-09-20T12:10:00";"S1234";"WB(45)-B";"160.62";"22.38 ";"7.18";"9.68";"138.15";"
The results indicate a *Helicobacter pylori* infection. However, if the *Helicobacter pylori* eradication treatment was given recently, *Helicobacter pylori* antibody levels may still be elevated. It may take several months for antibody levels to return to normal even after successful eradication treatment. There is no atrophic gastritis (loss of gastric cells) of the stomach mucosa.";"T12345";"LTN87623";"27.0";"2151282/1877254-841547/2098513-223420/1717917-1861811/937892";"V1.8.4.0-V1.3.3.9";"SN123456Y2023"
When the data is exported to the USB-memory device, the file is stored in the following folders:

HIT92A/<serial>/<YYYYMMDD_hhmmss>/CSV/, where
<serial> is the serial number of the instrument
<YYYYMMDD_hhmmss>, where
YYYY = year, MM = month, DD=day,
hh = hours, mm = minutes, ss = seconds

and file name:

test_report_<YYYYMMDD_hhmmss>

where,
<YYYYMMDD_hhmmss>, where
YYYY = year, MM = month, DD=day,
hh = hours, mm = minutes, ss = seconds

Example: D:\HIT92A\H92A2103010035\20230213_101911\CSV\ test_report_20230213_101912.csv

7.4.2 QC record

When the QC record is exported, the file is created on the USB-memory to the same folder as the test result. However, the file structure is different.

Specification of the QC record ASCII CSV-file exported by the GPQT NT Reader

<**ID**><DL><**Test Date**><DL><**Test Item**><DL><**Level**><DL><**Concentration**><DL><**Unit**><DL><**QC Range**><DL><**Temp.**><DL><**Lot.**><DL><**Control Lot.**><DL><**Result**><DL><**Status**><DL><CR><LF>

where,

<ID>	Count number	; string
<DateTime>	DateTime (YYYY-MM-DD hh:mm:ss)	; string
<Test Item>	Test item (marker)	; string
<Level>	Level1 or Level2	; string
<Concentration>	Concentration of the marker	; string
<Unit>	Unit of the marker concentration	; string
<QC Range>	QC range	; string
<Temp.>	Temperature in Degrees Celsius *	; string
<Lot.>	Test kit batch id	; string
<Control Lot.>	Control batch id	; string
<Result>	Result	; string
<Status>	Status	; string
<DL>	Data delimiter	; char
<CR><LF>	Carriage return (0xD), Linefeed (0xA)	; char

7.5 ACCESSORIES

Table 7.3 List of additional items

REF	Description	Specifications
100110	Printer paper roll	Thermal, size 57x30x12 mm, BPA-free
100130	Euro plug	ICEE 7/7 - C13, (250 V, 16 A)
740460	Power Supply Adapter	Voltage: AC 100V ~ 240V to 12 VDC for the reader Frequency: 50/60 ±1Hz Rated power: 30W

7.6 ANALYTICAL RESULTS

7.6.1 Calculation of concentrations

The concentrations of the four analytes are calculated as follows:

1) The fluorescence intensity profiles of each are of each of the four test strips are scanned.
2) The two peaks of Test (T) and Control (C) lines are digitally processed and ratio of T/C calculated.
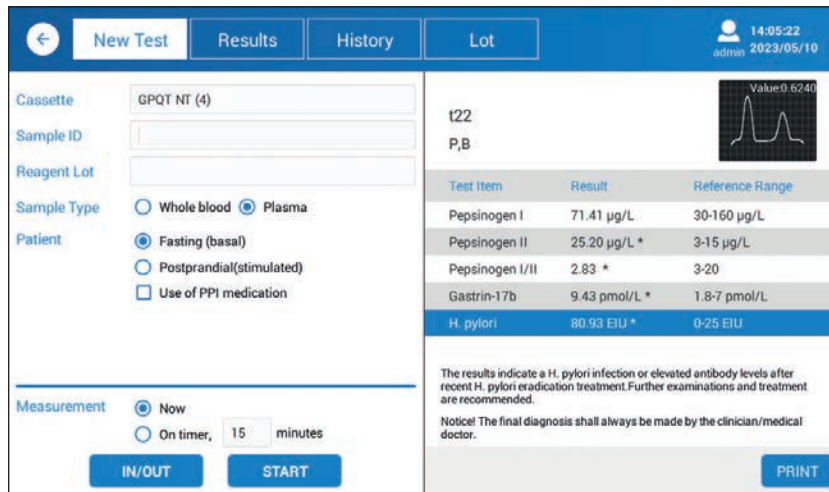3) The LOT specific QR-code from the test cassette is read to transfer T/C-ratio to concentration.

Figure 7.1 Fluorescence intensity readings are calculated from the scanned profiles of the peaks (test line peak T follows the control C line peak).

7.6.2 Display of results

The measured concentration is displayed by default as float number presented with one decimal, unless the number is over 100. The measured values are rounded mathematically.

The predefined measurement ranges have impact on how the results shall be displayed and printed with the embedded printer.
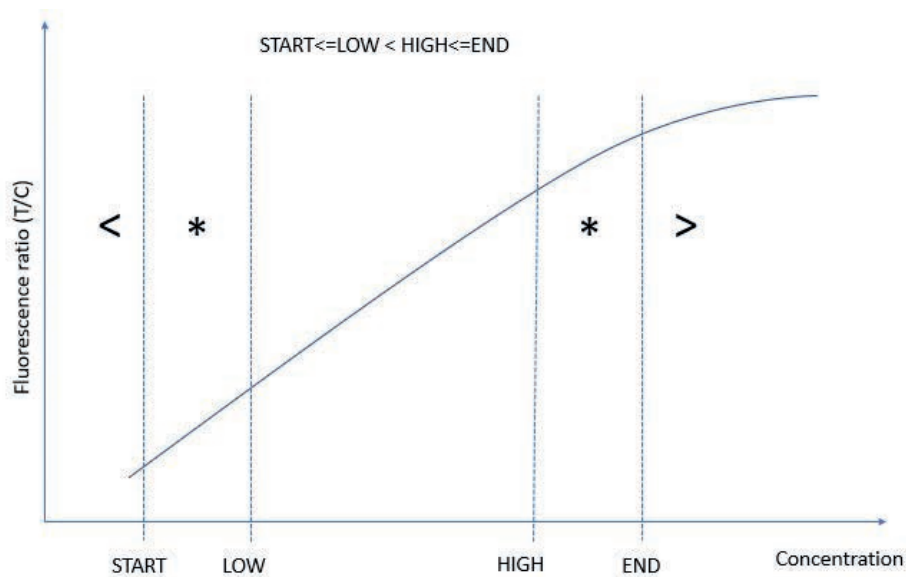

Figure 7.2. Marking of concentration values.

If the concentration is less than the lower limit of the measuring range, "lower than"-symbol '<' shall be used in front of the low-end value.

If the concentration is greater than the upper limit of the measuring range, "greater than"- symbol '>' shall be used in front of the high-end value.

The reference range of the analyte concentrations shall be used to interpret the results.

If the concentration is out of the reference range, "asterisk"-symbol '*' has been added to help highlight the out-of-reference range value.

Asterisk '*' with the *H. pylori*, indicates elevated value due to current or past *H. pylori* infection.

Measurement range: sample concentrations can be reliably interpolated within the measurement range.

Reference range: is the range of values of 'normal' healthy persons.

Out of reference range: Asterisk (*) indicates a value which is not within the reference range. The asterisk will also be added if the result is out of measurement range.

Exclamation "!" symbol is added in front of PGI/PGII-ratio to indicate value which is calculated on measured concentrations of PGI and PGII, but only when the measured value is out of marker specific analytical performance range.

7.6.3 Interpretation of results

The results not only display the measured concentrations of the markers, but also the interpretation, as illustrated in the Figure 7.1.

The interpretation algorithm below is used to differentiate between atrophic gastritis, *H. pylori* infection and a normal mucosal state.
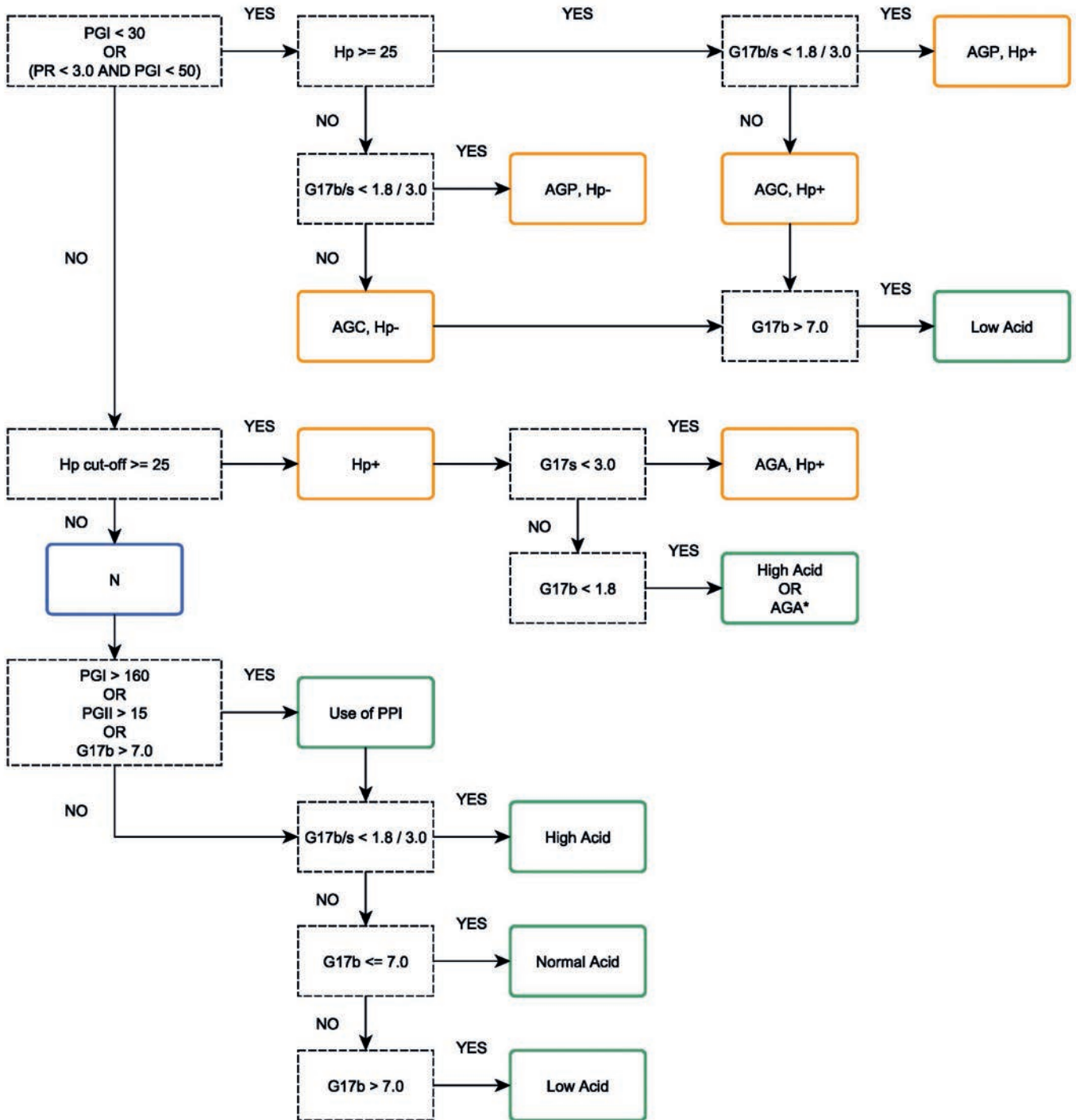

Figure 7.3. The decision tree, with example reference range values.

The abbreviations used in the decision tree are as follows:

PGI   Pepsinogen I concentration (µg/l)
PGII   Pepsinogen II concentration (µg/l)
PR   Ratio of Pepsinogen I/II
G17   Gastrin-17 basal (fasting) or stimulated (postprandial) concentration (pmol/l)
G17b   Gastrin-17 basal (fasting) concentration
G17s   Gastrin-17 stimulated (postprandial) concentration
Hp cut off   *H. pylori* cut-off value (EIU)
Hp-   *H. pylori* antibodies below cut-off
Hp+   Elevated levels of *H. pylori* antibodies
AGC   Atrophic gastritis
AGP   Atrophic pangastritis
AGA   Atrophic antrum gastritis; * if suspected
Acid   Acid status in the stomach
N   No gastritis

NOTES

GP Reader NT

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