pH X-act

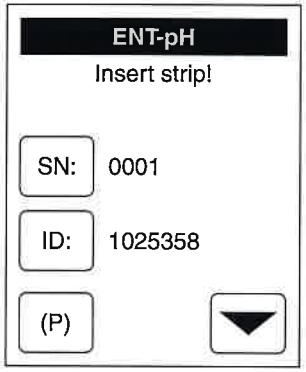
User manual

Enteral UK
Part of the GBUK Group

pH X-act

1. Quickstart

Unpack the instrument and place it on an even, hard surface. Connect the power supply and turn the equipment on with the On/Off-switch (Pic. 4-⑧). After the self test the start screen will appear on the display.



Display 1: Start menu

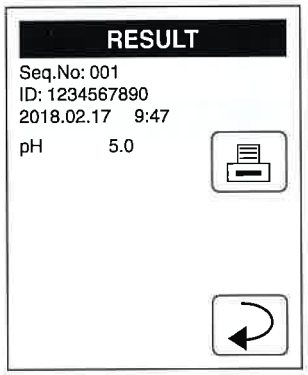
- Apply sample to the test strip.
- Blot by touching the edge of the strip to a paper towel to remove excess sample.
- Place the strip on the strip holder.
- Slide or push the strip to the end of the channel. Do not touch the reagent pads on the test strip.

The instrument will automatically detect an applied strip. The measurement cycle will be started. A progress bar on the display shows the remaining measurement time.

Note: If "Autostart" (Chapter 9.5 "How to deactivate and activate the autostart") is deactivated, the measurement must be started using the start control panel  .

Notice:
The strip will be drawn into the instrument after a few seconds.

At the end of the measurement the result will be displayed on the screen and transferred to the printer and interfaces.



Display 2: Result

By pressing the printer symbol the result can be printed again. Choosing the return panel will lead back to the start screen.
Another analysis may be started by applying the next test strip.

Notice:
To start a new measurement it is not necessary to go back to the start screen. A new strip is detected at any time and the measurement is then started automatically.

2. Introduction and intended use

The pHX-act instrument is a portable and easy to use analyser for the rapid semiquantitative determination of gastric acidity. It is designed to read only pH test strips.

2.1. Medical Purpose

The medical purpose of the pHX-act is the semiquantitative determination of gastric acidity.
For further information about medical use, test population, and sample materials please refer to the instructions for use of the corresponding pH test strips from Enteral UK.

2.2. Intended use

The pHX-act is intended to be used only with compatible pH test strips from Enteral UK. Suitability for instrumental read-out on the pHX-act instrument is described in the corresponding instructions for use of the Enteral UK pH test strips.
The pHX-act is intended to be used as an aid in the control of correct enteral feeding tube placement prior to feeding.
The pHX-act is intended to be used only with gastric juice samples which are not strongly colored and with a volume sufficient to properly wet all test pads of the strip.

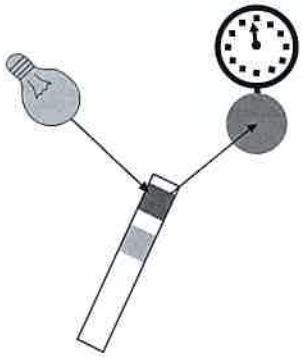
2.3. Intended user(s)

The pHX-act instrument is intended to be used by healthcare professionals that have been assessed as competent to confirm enteral tube position checks, through theoretical and practical training. (In the UK instructions issued by the National Patient Safety Agency must be followed).

2.4. System description

2.4.1. Measuring principle

The test strip moves below a fixed measuring head on a sled with an embedded reference pad. The reflectometric analysis of the test strip and the reference field take place during withdrawal and release of the sled.



Pic. 1: Measuring Principle

The strip is illuminated with an LED and a detector registers the intensity of light reflected by the test strip at three different wavelengths. Using an internal calibration, the results are calculated from the reflection values.

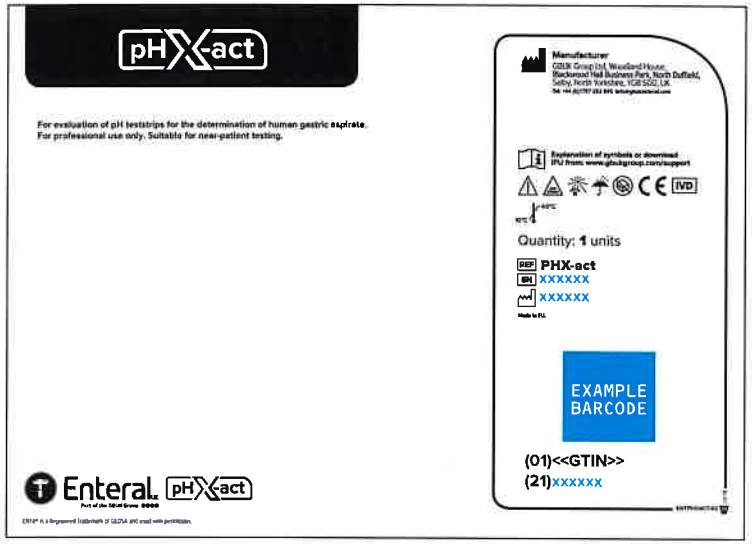
2.4.2. Functional principle

A measurement is started by placing a strip on the holder. If the Autostart-feature is turned off, the measurement is started by pressing the start panel in the display. The result is shown on the display, printed out and released via the interfaces after the measurement has been completed. After three minutes the instruments will go to stand-by. Touching the screen will reactivate the instrument. All user inputs are performed via the touch-screen (Chapter 3.9 "Use of the instrument").

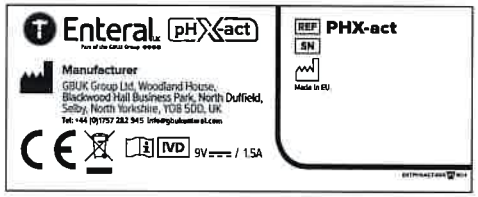
2.4.3. Safety warnings

The following safety warnings are used throughout the manual:
- DANGER: defines a danger which can result in serious injury or death.
- ATTENTION: defines a possible danger which can result in simple - mild injury. This symbol is also used to indicate user errors which can result in malfunction or damage to the device.
- NOTE: provides necessary additional information.

2.4.4. Labels on the device and symbols



Shelf Box Label



Type Plate Label

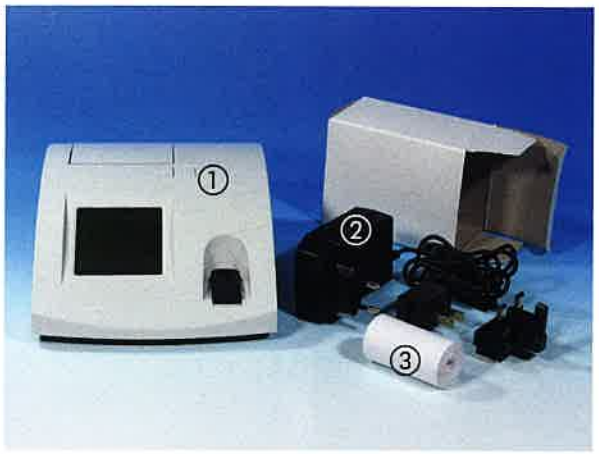
2.4.5. Symbols explanation

⚠	Caution: Further information in user manual
	The medical device that has not been subjected to a sterilization process.
	Keep away from sunlight.
	Keep dry.
	Temperature limits.
	Should not be used if the package is damaged.
	The medical device is intended for one use, or for use on a single patient during a single procedure.
	Indicates the need for the user to consult the instructions for use.
	Do not dispose of the device in common household waste.
	Medical device manufacturer.
REF	Manufacturer's catalogue number.
LOT	Manufacturer's batch code.
SN	Serial number of the device.
	Date on which the medical device has been manufactured.
	Date after which the medical device is not to be used.
IVD	In vitro diagnostic device.
CE	Indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
9V ⎓ / 1.5A	Power input specifications.

3. Unpacking and set up

3.1. List of delivered parts

① pHX-act reflectometer
② Power pack 100 – 240 V, 47/63 Hz, 9 V, incl. adapter
③ Printer paper (1 roll)
+ User manual (this booklet)
+ Quick Reference Guide



Pic. 2: Content

Read the operating manual carefully before the first startup in order to ensure an error free operation.

3.2. Consumables

Printer paper , pack of 5 rolls, REF pHX-act-pp5
Check solution for quality controls, dropper of 10 ml, REF pHX-act-bsol
6 AA type batteries (optional)

3.3. Advice on surrounding

If the device is exposed to higher temperature fluctuations (e.g. after transport or distribution), it must be switched on not before sufficient acclimatization is given. The device should not be used close to electrical fields (e.g. by microwaves, radio units et cetera). In worst case the measurement results can be affected.

3.4. Setting up the instrument

Place the instrument on a hard, even surface where humidity and temperature are fairly constant. Make sure that the instrument is allowed to acclimate to room temperature prior to use.
Make sure that you

- Do not place the instrument near strong electromagnetic fields
- Do not place the instrument near heating plates, ovens or radiators
- Do not expose the instrument to strong light sources (i.e. direct sunlight)

3.5. Description of instrument parts

Pic. 3: Front view

Pic. 4: Backside view

Actuator	Function
1. Touch-Screen	Control of equipment functions
2. Test Strip Sled	Test strip retainer and autonomous start of analysis
3. Printer Flap	Opening the printer flap for paper replacement
4. Serial Interface	Connection of a computer (cable length[1] max. 3 m)
5. USB-Interface	Connection of a computer (cable length[1] max. 3 m)
6. PS/2 Interface	Connection of a keyboard
7. Mains Connection	Contact for the provided power pack
8. On/Off Switch (I/O)	Turning the equipment on and off

[1] We recommend to use shielded cables.

3.6. How to plug the instrument in

Pic. 5: Power pack

Pic. 6: DC in

Four adapters are provided for adapting the power pack to the available mains connection. The adapter matching the mains connection is plugged on to the power pack (Pic. 5). After plugging the power pack cable into the jack "DC IN" (Pic. 6) and connecting the power pack to the power socket the instrument is ready for operation.

3.7. How to load the printer paper

Pic. 7: Printer A

Pic. 8: Printer B

Open the printer flap by pressing the rectangular key next to the printer flap (Pic. 7).

Pic. 9: Printer C

Pic. 10: Printer D

Unroll the paper roll by 5 cm and place the roll in the paper compartment with the end on the lower side. Fix the end of the paper to the housing with your finger while closing the flap (Pic. 9 + Pic. 10).

3.8. How to install batteries (optional)

The instrument can be operated with 6 type AA batteries independent of the mains supply. The battery compartment is on the underside of the equipment. Notice the designated polarity (+/-) marked on the battery compartment while inserting the batteries.

Pic. 11: Battery compartment

3.9. Use of the instrument

All user inputs are done via a touch-screen (touch-display). All functions are activated directly by slight pressure with the finger on explicit pictograms or text representing the menu items.

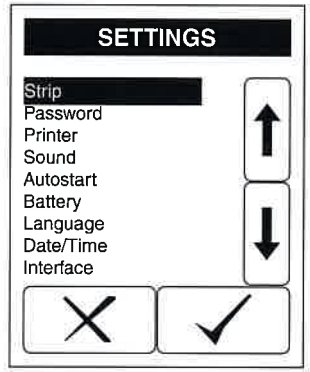
3.9.1. Buttons

Framed areas react to pressure and trigger the action linked to it. The caption of an area describes its function.
Examples:

[✓] Confirm / perform action
[✗] Cancel action
[⏻] display of equipment settings

3.9.2. Scroll Menu

Press the up-and-down arrows on the right side of the screen to scroll through a list of information on the left side of the screen. The desired information on the left side is highlighted.

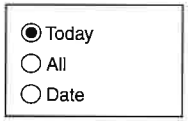


Display 3: Selective lists

Pressing will [✓] select the highlighted line. You can leave the menu by pressing [✗].

3.9.3. Round buttons

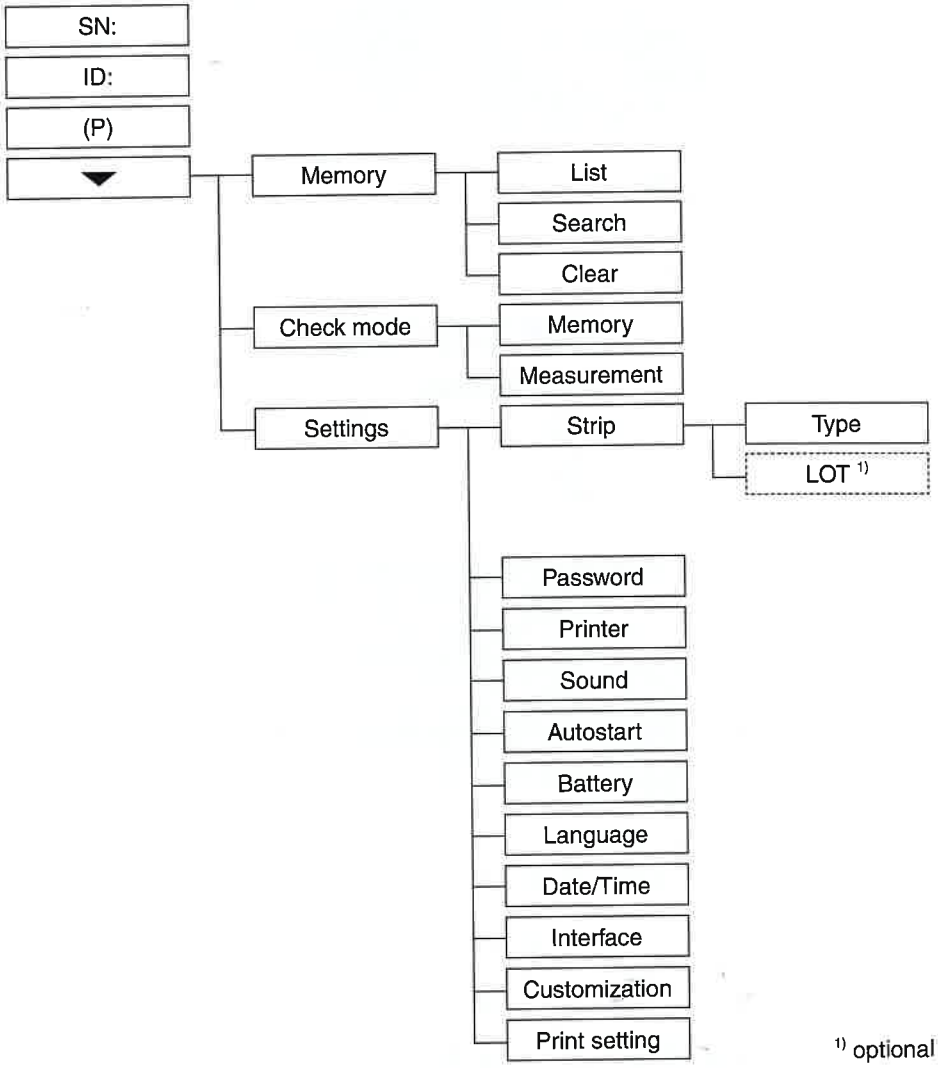
These buttons typically appear on screens that require a selection among serial items. The button with a filled circle is the current selection.



Pressing the circle will activate a selection. Save your selection by pressing [✓]. Pressing [✗] will quit the menu without performing any changes.

4. User menu

4.1. Flow-chart of the menu structure



1) optional

4.2. Description of the menu items

- SN:
  Chapter 5.5 "Changing the sequence number ("SN")"
- ID:
  Chapter 5.4 "Entering the patient identification"
- (P):
  Standby
- ▼:
  Main menu
- Memory:
  Chapter 7 "Recall results"
- Check mode:
  Chapter 8 "Quality control testing"
- Settings:
  Chapter 9.1 "How to modify strip settings"
  Chapter 9.2 "How to protect settings from unauthorized access"
  Chapter 9.3 "How to turn the printer on and off"
  Chapter 9.4 "How to enable and disable acoustic signals"
  Chapter 9.5 "How to deactivate and activate the autostart"
  Chapter 9.6 "How to set energy saving options for the battery mode"
  Chapter 9.7 "How to change the language"
  Chapter 9.8 "How to set time and date"
  Chapter 9.9 "How to activate data transfer"
  Chapter 9.10 "How to change the text of the printout header"
  Chapter 9.11 "How to print the settings"

5. Analysis of test strips

5.1. How to perform a measurement

In order to start the measurement, the test strip is placed on the strip holder. The instrument automatically detects a new strip and starts the measurement. A progress bar appears, that indicates the remaining analysis time. After a few seconds the test strip is drawn into the instrument.

NOTE:
Make sure to remove excess sample by blotting the test strip carefully on a lint-free cloth.

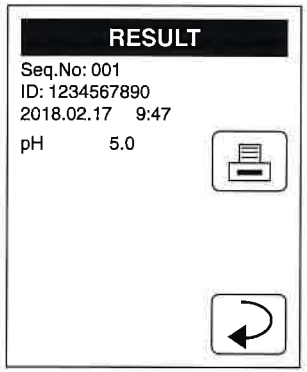
NOTE:
If auto mode (Chapter 9.5 "How to deactivate and activate the autostart") is deactivated, the analysis needs to be started by pressing [ ] on the touch-screen.

After the measurement, the instrument will release the analyzed test strip which can now be discarded. The result is displayed on the screen and is transferred via the interfaces and/or printed according to equipment settings.
For additional information on the test strip, please read the instruction leaflet that comes with the strips.

DANGER:
Gastric juice and used test strips bare the danger of infection. Always use protective gloves during handling and disposal. The disposal of used test strips should be performed according to the regulations of the handling of potentially infectious material.

5.2. Display of results

The sequence number (Seq.No.) as well as the patient identification (ID) will be displayed with the results.



Display 4: Result

The printout is light-sensitive and may turn yellow when exposed to light during storage. For archiving purposes the printouts should be kept in a dark place (patient file) or as a photocopy.
The result displayed may be printed again by pressing [ ]. The return panel [ ] will lead back to the start screen.

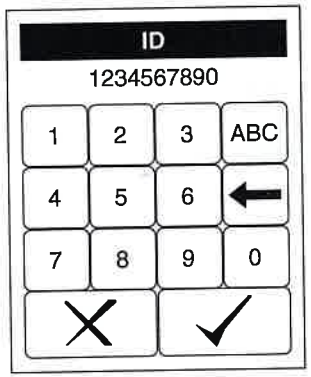
5.3. Measurement errors

If the display shows "Measuring Error ..." instead of a result please read the instructions in Chapter 13 "Error Messages and Fault Clearance".
Repeat the measurement. In case of permanent errors please contact your service provider.

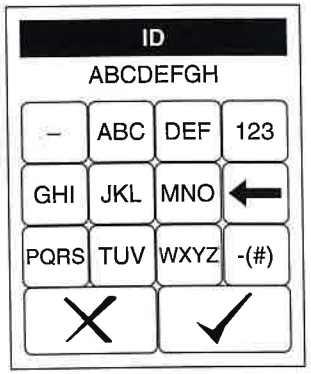
5.4. Entering the patient identification

The patient identification needs to be entered before starting the analysis. This can be done as follows:

- Directly on the equipment: Pressing [ID:] in the start menu brings up an alpha-numeric keypad. Enter the ID using the keys. To enter characters (i.e. "Miller") press [ABC] to change the character entry. Repeated pressing on the same field within 0.5 seconds switches through the characters displayed on the key. Wrong entries may be erased by pressing [←].



Display 5: Entering ID (numerics)



Display 6: Entering ID (letter)

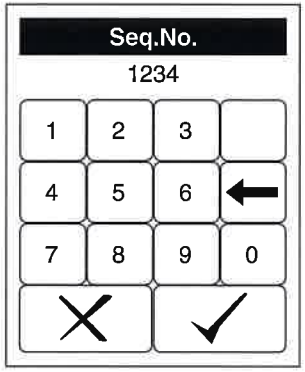
- Using a standard PC-keyboard: Connect the keyboard to the PS/2 jack in the backside of the instrument. User inputs on the keyboard will automatically be interpreted as Patient Identifications.
- Using a bar code reader: Connect the barcode reader to the PS/2 jack in the backside of the instrument. Barcode readings will automatically be interpreted as Patient Identifications.

After entering the patient identification start the measurement. The Patient Identification is saved together with the test results.

NOTE:
A new ID cannot be entered before the present analysis has been completed.

5.5. Changing the sequence number ("SN")

Pressing [SN:] in the start menu brings up a numerical pad. Enter a new sequence number using the keys on the pad. All following measurements will now be counted from this number on.



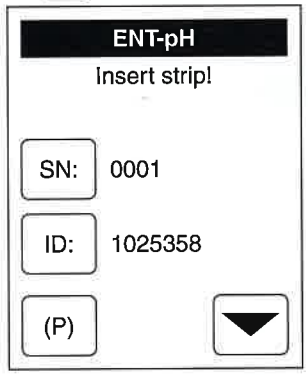
Display 7: Seq.-Input

5.6. Transferring data to a PC

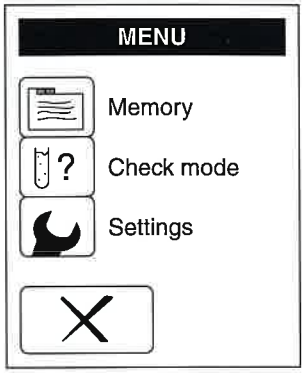
The results may be transferred to a PC via the USB- or RS232-interface.
A detailed description of the interface can be found in Chapter 12 "Interface description".

6. Enter the main menu

Pressing ▼ on the start screen will bring up the main menu.



Display 8: Start menu

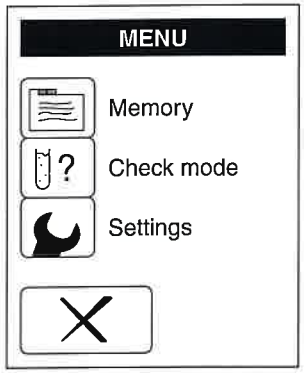


Display 9: Main menu

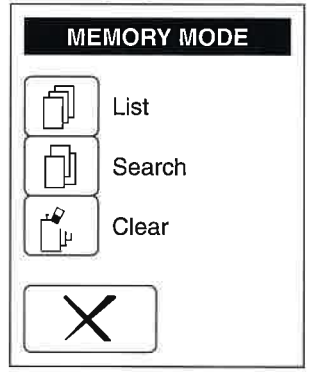
From here the other functions e.g. memory (Chapter 7 "Recall results"), the test mode (Chapter 8 "Quality control testing") as well as the settings (Chapter 9 "Equipment Settings") can be reached.

7. Recall results

The instrument has memory for 200 measurements. Every result is automatically saved after the analysis. After 200 measurements, new data will overwrite the eldest saved dataset.
Access the memory by pressing ▤ in the main menu ▼.



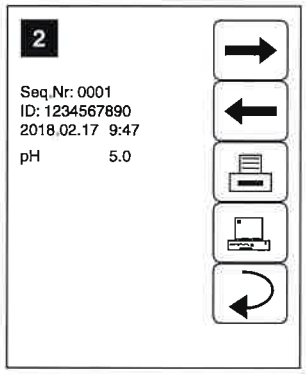
Display 10: Main menu



Display 11: Memory mode

7.1. How to scroll through memory

Pressing ⧉ will bring up Display 12. Scrolling through the memory is possible by pressing the arrows on the right side. The next → or previous ← result will be displayed.

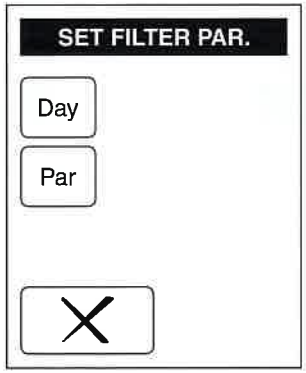


Display 12: Memory contents

It is possible to print ⎙ and send 💻 the dataset displayed. The memory menu will reappear upon pressing return ↩.

7.2. How to find specific results (filtering)

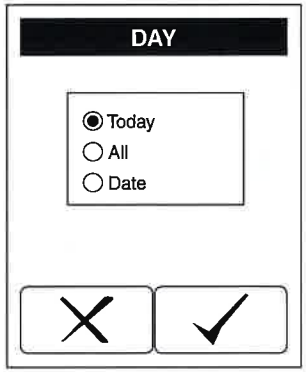
To find a result, you may select the date of the measurement and a specific parameter (Display 13).



Display 13: Filtering

7.2.1. Selecting the date

By pressing [Day] you will reach the menu displayed below (Display 14).

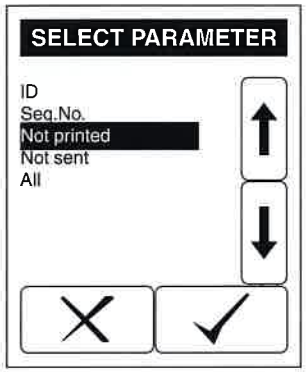


Display 14: Select day

Set the day with the buttons. Selecting "Date" will bring up a screen with the list of available dates (only days with measurements are shown on the screen). Select the desired date with the up-and-down arrows and confirm your selection by pressing [✓]. After confirmation your selection will be displayed on the screen "SET FILTER PAR."

7.2.2. Selecting search criteria

Pressing [Par] in Display 13 brings up Display 15.

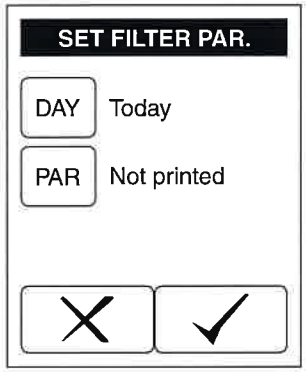


Display 15: Select parameter

Use the arrow keys to select the desired criteria and confirm with [✓]. The filter criteria will be displayed on the filter settings screen (Display 16).

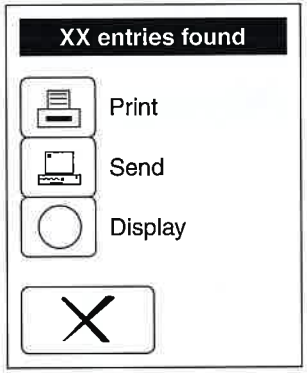
7.2.3. Display suitable matches

After setting "Day" and "Parameter" the search may be started by pressing [✓] (Display 16).



Display 16: Filtering

When suitable matches are found, an option will appear, allowing to print the datasets, send them to a PC or display them on the screen (Display 17).



Display 17: Search result

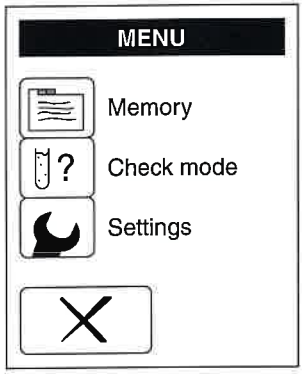
If no matching results are found, the equipment returns to the memory menu.

7.3. How to delete results from memory

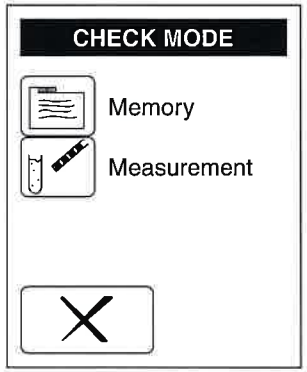
Pressing will delete all data in the memory. You need to confirm this again on a further screen. The quality control measurements are not affected by this action.

8. Quality control testing

Every facility has to implement its own QC policy.
Do not use water as control.
Upon pressing on the start menu the "Check mode" screen will appear (Display 18 + Display 19).



Display 18: Main menu



Display 19: Check mode

8.1. How to review old QC measurements

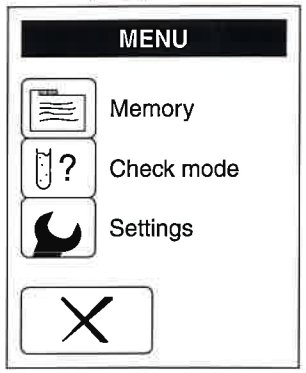
The equipment saves the results of the last 20 QC measurements in a separate memory. They may be displayed by pressing (Display 19) and may be printed for documentation purposes.

8.2. How to perform a QC measurement

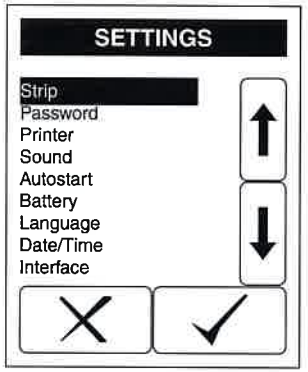
Prepare the control as described in the instruction leaflet. Use the control exactly as patient samples and perform the measurement.
In case several results do not match the expected results (indications in the checking solutions' package inserts), please contact your service provider.

9. Equipment Settings

Enter the main menu by pressing the menu key ▼ to reach the "SETTINGS" display press ↵ (Display 20 + Display 21).



Display 20: Main menu



Display 21: Settings

9.1. How to modify strip settings

In the "Strip" menu, settings for result displaying and the test strip type can be chosen.

9.1.1. Type

When the equipment has data for various approved strip types, the strip type can be chosen in a selective list.

9.1.2. Test Strip LOT

The LOT-administration is deactivated in the default setting. See Chapter 11.2 "How to enable LOT information (LOT activate)".

9.2. How to protect settings from unauthorized access

Select "Password" in the settings menu if you want to protect the instrument settings with a PIN. An option panel with the possibilities "ON" and "OFF" will be displayed. Selecting "ON" will enable the PIN-protection.

After enabling the PIN-protection a numerical pad will appear. Enter a 4-digit PIN and confirm by pressing [✓]. The PIN will be asked for upon the next attempt to change the settings.

ATTENTION:
A forgotten PIN cannot be reconstructed. Only a complete reset of the instrument will delete the PIN-protection. This will result in loss of all results and settings!

9.3. How to turn the printer on and off

Selecting "Printer" in the settings menu will bring up an option panel. Choose the desired option and confirm.

9.4. How to enable and disable acoustic signals

Select "Sound" in the settings menu to enter the settings for acoustic signals.

9.4.1. Acoustic confirmation of user inputs

In the preprogrammed settings all user inputs are confirmed with an acoustic signal. Disable or enable these signals by choosing "ON" or "OFF" in the box "Touch".

9.5. How to deactivate and activate the autostart

Select "Autostart" in the settings menu. In basic mode the instrument automatically detects an applied test strip and starts the measurement. This function may be deactivated via an option panel.
If Autostart is deactivated the analysis must be triggered by pressing a panel in the Start menu.

9.6. How to set energy saving options for the battery mode

Select "Battery" in the settings menu. Settings in this menu will only apply when the instrument is operated with batteries.
To increase the lifetime of the batteries, the LCD backlight and the printer can be turned off using the option panels.

9.7. How to change the language

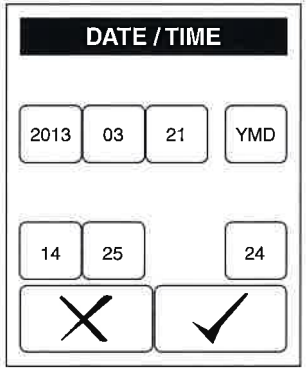
Select "Language" in the settings menu. The language of the menu can be switched to the languages in the respective selective list.

9.8. How to set time and date

Select "Date/Time" in the setting menu. To change, press on the respective number. A numerical pad appears. Enter the correct number and confirm by pressing [✓].
The date may be formatted in three ways. The active format is shown on a button [YMD] on the right hand side of the date (Display 22). Select a date format by pressing this button.

Displayed Format Abbreviation	Meaning	Example
YMD	Year - Month - Day	2007-12-17
DMY	Day . Month . Year	17.12.2007
MDY	Month / Day / Year	12/17/2007

The time format may be changed to 12 or 24 hours with the button displayed next to the time [24].



Display 22: Date / time

9.9. How to activate data transfer

Select "Interface" on the settings menu. The data transfer via the interfaces can be activated or deactivated via an option panel.

9.10. How to change the text of the printout header

Select "Customization" in the settings menu. The first two lines of the printout may be filled with a user-specific identifier. Each line contains 23 characters.
To enter the text an external keyboard or the alphanumerical pad on the display can be used. The keys on the touch-screen are linked to several letters. Repeated pressing within half a second switches through the letters displayed on the key.

9.11. How to print the settings

Select "Print Settings" in the settings menu to print the equipment settings for documentation purposes. Thermo printings fade with time. Therefore, please store it in a dark place or copy the printout.

10. Disinfection

DANGER:
Gastric juice and used test strips bare the danger of infection. Always use protective gloves during handling and disposal. The disposal of used test strips should be performed according to the regulations for the handling of potentially infectious material.

10.1. How to clean and disinfect the housing

Use commercially available disinfection wipes to clean and disinfect the instrument from the outside. Do not use liquids that can enter the instrument as these may cause permanent damage of the instrument.

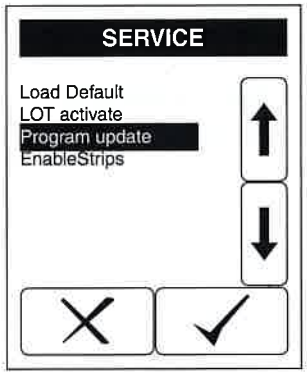
10.2. How to clean and disinfect the strip holder

Wipe off residues from the strip holder with a lint-free cloth after each measurement. This prevents carry-over and drying of sample residues.
To remove the strip holder for more comprehensive cleaning, make sure to turn the instrument off. Pull the strip holder from the metal strip below. Wipe down the strip holder with disinfection wipes. When removed from the instrument, you may also use water with a soft brush and/or liquid disinfectants.
After cleaning, insert the holder on the metal slit. The rectangular notches of the transport mechanism and the strip holder must be placed on top of each other (Pic. 12). Use reasonable force to push the strip holder completely onto the metal slit. Doing so the metal slit and the strip holder will be pushed back completely into the housing.
If you get an error message after turning the instrument on: Turn the instrument off and push the strip holder again on the metal slit with more force.

Pic. 12: Test strip holder (bottom view)

11. Service menu

The instrument has a password protected service menu. To enter the service menu press the touch-screen three times during the self test after turning the equipment on (Display 23). Upon request input the PIN "1111".
A selective list with different menu items appears.



Display 23: Service menu

11.1. How to reset the system (Load Default)

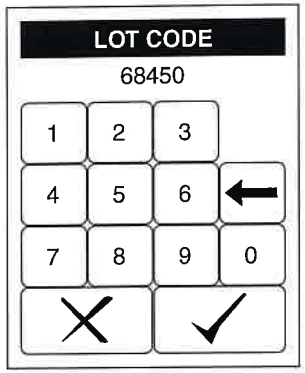
Select "Load default" from the service menu. The instrument will be reset to delivery status. All settings modified by the user will be cleared!

11.2. How to enable LOT information (LOT activate)

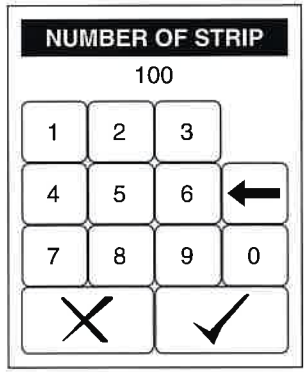
Select "LOT activate" from the service menu to enable the entry of LOT information. The LOT will be reported with the results.

11.2.1. Entry of test strips' LOT

If LOT-control is activated, the actual LOT-number of the test strips can be entered using "Strip" in the menu "Settings" (Display 24).
When selecting "LOT number" a numerical pad will appear, which can be used for entering the LOT printed on the strip packaging.
After entering the LOT, information on the number of strips from that LOT is requested. For example, if three boxes of the same LOT are present, please enter "300" for the number of strips (Display 25).



Display 24: LOT code



Display 25: LOT size

NOTE:
The instrument counts the number of strips. If the number of measurements reaches the previously entered number of strips of that LOT the instrument requests to enter a new LOT number. Then, please enter the LOT number of the strips you want to use.

11.3. How to update the instrument

Select "Program update" from the service menu. The instrument now expects the upload of a new firmware. Follow the instructions that come with the update-file to finalize the update process.

11.4. How to enable strips

In principle the instrument is able to read different test strips. Select "Enable Strips" to make additional strips available. After entry of the correct code, the strip can be selected in the menu "Strip".

12. Interface description

The instrument may be connected to a computer via the RS232- or the USB-interface (work station or laboratory information system).

12.1. Serial interface

Protocol RS232, 19200 Baud, 8 bit, no parity (Pic. 4-④)
Connection plug arrangement:

PIN	Signal	Description	Direction
1	Nc	Not wired	
2	RxD	Data reception	Input
3	TxD	Send	Output
4	Nc	Not wired	
5	GND	Signal ground	--
6	Nc	Not wired	
7	Nc	Not wired	
8	Nc	Not wired	
9	Nc	Not wired	

12.2. USB 1.1-interface

USB-jack Type B (Pic. 4-⑤). The instrument will be identified as a serial interface. Please contact your service provider if you need a driver for your PC.

12.3. Transmission protocol

The data is released via the interfaces as plain text. The received dataset corresponds to the format of the printout.

12.4. PC-keyboard

A PS/2 jack (Pic. 4-⑥) is provided for connection of a keyboard.

13. Error Messages and Fault Clearance

Messages are displayed in plaintext and are self-explanatory.

Error Message / Error	Cause	Solution
"Dry Strip"	The test strip wasn't dipped completely	Repeat measurement with a new strip
"Wrong Strip"	A wrong test strip has been detected (wrong type)	Use correct test strips
"Wrong Position"	The strip hasn't been pushed into the strip retainer far enough	New measurement, place strip in right position
"No Paper"	Paper roll empty or printer flap open	Replace paper and close printer flap
"Battery Low"	Batteries are low	Exchange batteries or use power pack
"Instrument doesn't start"	Power supply not installed or defect	Check whether all connections are plugged in and whether the power socket is functioning

In case a fault cannot be cleared by the aid of the instructions above, please contact your service provider.

14. Warranty

The warranty for this equipment has a duration of 24 months from the date of purchase. The original copy of the bill serves as a certificate and must be submitted in case of assertion of a warranty claim. The warranty expires in case of improper handling and/or maintenance of the equipment; it does not comprise defects due to the external power supply.
The warranty is limited to the repair of faulty parts or – at our sole discretion – to the delivery of a faultless substitute. The warranty period of 24 months is not affected by claiming on the warranty during this period. There is no right of withdrawal.
Further claims are excluded. Hereunto we count in particular all claims for damages evolving from consequential damages or indirect damages.
Additionally the relevant version of our general sales terms and delivery conditions apply as printed on all price lists.

15. Technical information

15.1. Technical data

Name of device: pHX-act, REF PHX-act

Required electric supply:
Mains transformer:
Input 100~240 V
Output 9 V⎓1.5 A
Alternative: battery operation with 6 mignon batteries 1.5 V (AA).

Dimensions:
Height: 7.5 cm
Width: 16 cm
Depth: 20 cm

Weight:
710 g (without batteries and power pack)

Range of ambient air temperature:
10 °C–40 °C

Humidity:
20 %–80 % (non-condensing)

Test strips programmed for evaluation:
enteral-pH Test 2.0-9.0

15.2. Security standards

The instrument is a medical device and is in compliance with the IVD directive 98/79/EC as device itself as well as in combination with the designated test strips. It is ROHS-conform and complies with directive 2011/65/EU.

15.3. Table of results

Param.	Gradation
pH	2.0
	2.5
	3.0
	3.5
	4.0
	4.5
	5.0
	5.5
	6.0
	6.5
	7.0
	7.5
	8.0
	8.5
	9.0

15.4. Performance Characteristics

15.4.1. Analytical performance

A study with buffer solutions in the pH-range 2–9 in steps of 0.1 pH units was performed. The average accuracy of the instrumental strip reading with respect to pH-meter reading was 0.2 pH-units.

15.4.2. Clinical performance

A study with 113 human gastric aspirate samples was performed. 98 % of the instrumental strip reading results were accurate within ± 0.5 pH units with respect to pH-meter reading.

15.5. Electromagnetic Compatibility

The instrument as a medical device is subject to particular precautions with regard to electromagnetic compatibility (EMC) and has to be installed and put into operation as described in Chapter 3 "Unpacking and set up". High frequency communication equipment (mobile phones, etc.) can influence the functionality. By using other cables or equipment than mentioned in Chapter 3.5 "Description of instrument parts", there is a consisting danger of other influences on the instrument. Furthermore, by using other equipment the effective radiant power could increase or the interference resistance could decrease. Please do not arrange the instrument in a pile when using it. If there is an urgent need to pile the

instrument, an extra observation of instrument is necessary which controls and ensures the conventional use.

Essential performance features:
The instrument does not display wrong measuring results in tested conditions from EMC-test.

Electromagnetic transient emissions		
The instrument is destined for an electromagnetic environment as described below. The user of instrument should ensure that instrument is used in such environment.		
Transient emissons measurement	**Accordance**	**Electromagnetic environment - guideline**
RF-Emissions according with CISPR 11	Group 1	The instrument needs RF-energy only for its inner functions. Therefore the amount of RF-Emission is very low and it is improbably that instruments in closer surrounding get disturbed.
RF-Emissions according with CISPR 11	Class B	The instrument can be used in all institutions including residential area and areas which are directly connected to the public power supply, no matter if public power supply supplies buildings for residential purpose.
Emissons of harmonic components according with IEC 61000-3-2	Class A	
Emissions of voltage fluctuation / flicker according with IEC 61000-3-3	in accordance	

Electromagnetic interference resistance

The instrument is destined for an electromagnetic environment as described below. The user of the instrument should ensure that instrument is used in such environment.

Interference resistance-test	IEC 60601-Immunity test level	Compliance-level	Electromagnetic environment – guideline
Electrostatic discharge according with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The floor covering should be made of wood, cement or ceramic tile. If floor covering is made of synthetic materials, air humidity must be 30 % at least.
Electrical fast transients / bursts according to IEC 61000-4-4	± 2 kV for power line ± 1 kV for input- and output power	± 2 kV for power line ± 1 kV for input- and output power	The quality of supply voltage should be like the typical voltage for business or hospital environment.
Surges Line-to-line according with IEC 61000-4-5	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-ground	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-ground	The quality of supply voltage should be like the typical voltage for business or hospital environment.
Voltage dips, short interruptions and variation of supply voltage according with IEC 61000-4-11	< 5 % UT (> 95 % break in of UT) for 1/2 period 40 % UT (60 % break in of UT) for 5 periods 70% UT (30 % break in of UT) for 25 periods < 5 % UT (> 95 % break in of UT) for 5 s	< 5 % UT (> 95 % break in of UT) for 0,5 period 40 % UT (60 % break in of UT) for 5 periods 70 % UT (30 % break in of UT) for 25 periods < 5 % UT (> 95 % break in of UT) for 5 s	The quality of supply voltage should be like the typical voltage for business or hospital environment. If the user of the instrument requires continued function in case that energy supply is interrupted, we recommend to supply it with power from an uninterruptible power supply or a battery.
RATED power frequency magnetic field (50/60 Hz) according with IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields should have the typical values like for business or hospital environment.

ANNOTATION UT is the alternating current voltage of net before the use of the immunity test level.

Electromagnetic interference resistance

The instrument is destined for an electromagnetic environment as described below. The user of instrument should ensure that instrument is used in such environment.

Interference resistance-test	IEC 60601-Immunity test level	Compliance-level	Electromagnetic environment – guideline
			Portable and mobile radio equipments should not be closer to the instrument than the recommended protection ratio which can be calculated with the equation that is applicable to the transmitter frequency. **Recommended protection ratio:**
Conducted disturbances induced by RF fields according with IEC 61000-4-6	3 V rms-value 150 kHz to 80 MHz	3 V	$d = 1{,}2\sqrt{P}$

Blazed disturbances induced by RF fields according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\ \sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}3\ \sqrt{P}$ for 800 MHz to 2,5 GHz with P as rated power of transmitter in watt (W) according to description of transmitters manufacturer and d as recommended protection ratio in meters (m). The field intensity of stationary radio transmitter should be lower than the level of compliance[b] in all frequencies according to an analysis on site[a]. In the vicinity of instruments which have following symbol disturbances are possible. 

ANNOTATION 1 In case of 80 MHz or 800 MHz the higher frequency rang is valid.

ANNOTATION 2 These guidelines are not applicable for all cases. The propagation of electromagnetic volumes is influenced by the absorbtion and reflection of buildings, items and humans.

[a] The field intensity of stationary transmitter, e.g. base stations for cordless telephones and mobile radio equipment, amateur radio stations, AM and FM radio and television station, can not be predestinated precisely. For the identification of the electromagnetic environment regarding the stationary transmitter, a survey about the electromagnetic phenomena of area should be made. If the measured field intensity at the place where the instrument is used is higher than the compliance level mentioned in the list above, an extra observation of instrument is necessary as an evidence for the conventional functionality. In the case that unusual performance features occur, additional actions like changing the direction of instrument or moving the instrument to another place are necessary.

[b] Across the frequency range from 150 kHz to 80 MHz the field intensity should be lesser than 3 V/m.

Recommended protection ratio between portable and mobile RF-telecommunication device and the instrument

The instrument is destined for the use in electromagnetic environments where RF-disturbances are controlled. The user can avoid electromagnetic disturbances by observing the minimum distance – dependent on the output power of telecommunication device, see list below - between portable and mobile RF-telecommunication devices (transmitter) and the instrument.

Rated power of transmitter W	**Protection ratio, dependent on transmitter frequency** m		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\ \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\ \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not listed above, the recommended protection ratio d in meter (m) can be calculated by using the equation from the particular column, where as P is the maximum rated power of transmitter in watt (w) according to description of manufacturer.

ANNOTATION 1 In case of 80 MHz or 800 MHz the higher frequency rang is valid.

ANNOTATION 2 These guidelines are not applicable for all cases. The propagation of electromagnetic volumes is influenced by the absorbtion and reflection of buildings, items and humans.

15.6. Waste disposal

Waste disposal according to EU Directive 2012/19/EU. In compliance with national legal regulations (EU Directive 2012/19/EU), GBUK Enteral disposes old instruments free of charge. Note: Disposal using public waste disposal facilities is not permitted.

16. Additional Information

16.1. Manufacturer Information

GBUK Group Ltd,
Selby, YO8 5DD, UK
Tel: +44 (0)1757 282945
www.gbukenteral.com

NOTE:
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and / or the patient is established.

16.2. Version history

pHX-act strip reader, version 1.0, 12.3.18