JINSHAN | Life Insights

CE 0197

pH Capsule Monitoring System

Type JSPH-3

User Manual

PW 03-SM002

User Manual Version: 1.1

Revision Date: 12 July 2018

CONTENT

Legal Statement

Copyright

Trademark

Authorization

Chongqing Jinshan Science & Technology (Group) Co., Ltd. protects all parts, reasonably designed and produced, of OMOM pH capsule monitoring system by means of authorization.

a. No unit or individual is allowed to lend, transfer or sell the product in any form without our authorization.
b. Chongqing Jinshan is not liable for any unauthorized use of licensed products.
c. Our company holds no liability to any consequence caused by man-made sabotage or improper manipulation through directly or indirectly using the wireless monitoring system of OMOM pH capsule.
d. Our company is entitled to make adjustments on this system's design and production within the authorization protection scope without prior notice.
e. Termination of any authorization is deemed unauthorized and any data provided within the validity of authorization must be destroyed immediately otherwise it would be deemed an infringement of right.

Certification

CE_{0197} Registration NO. : HD 60109014 0001.

FCC declaration of conformity

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
- If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
    - ✓ Reorient or relocate the receiving antenna.
    - ✓ Increase the separation between the device and receiver.
    - ✓ Connect the device into an outlet on a circuit different from that to which the receiver is connected.
    - ✓ Consult the dealer or an experienced radio/TV technician for help.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Environmental Protection

a. Please dispose the used battery of the capsule according to local environmental protection law to avoid environmental pollution.
b. Treatment of waste from data recorder of the wireless monitoring system of OMOM pH capsule shall be subject to local electronics discarding legislation.

We reserve the right to change this Manual of wireless monitoring system of OMOM pH capsule at any time without notice.

Safety Signs in the Manual

	**Warning:** Potentially hazardous to human if unattended
	**Caution:** Potentially cause failure or damage the device if unattended.
	**Attention:** Special notice.

Important Safety Statement

Purpose

This manual is applicable to OMOM pH Capsule Monitoring System (model JSPH-3) and is not intended to use for any other purposes.

About this manual

This manual contains all the information to safely and effectively use this product. Please read carefully before proceeding. Pay attention to the safety signs illustrated prior to this section. A comprehensive understanding of these signs is required.

( Warning,  Caution,  Attention)

Clinical Procedures

Allow only personnel received adequate training about operation of pH Capsule Monitoring System to use this product. Clinical techniques are not incorporated herein and shall be decided by physicians.

Risk

Risk of OMOM pH capsule monitoring system is very low. As a medical apparatus, however, it cannot exclude the possibility of the following circumstances. Please take relevant measures.

Possible side effects of endoscopic gastrointestinal tract examination, including:

Perforation, hemorrhage, aspiration, fever, infection, high blood pressure, breath arrest, arrhythmia and heart arrest.

Possible side effects of OMOM pH examination, including:

a. The conveyor cannot be taken out after the capsule is put in place.
b. Capsule detaches early,
c. Capsule does not detach after placement or needs to be taken out as the patient feels sick,
d. Massive hemorrhage caused by esophageal mucosal or submucosal tear, in such case, intervention treatment may be required,
e. Perforation,
f. Possible side effects of nasotracheal incubation: sore throat, throat discomfort, nasopharynx discomfort caused by hemorrhage, and soft tissue injury.

Attention

IF the conveyor cannot be taken out after the capsule is fixed in esophagus, please handle as the appendix A.

Pre-use Inspection

In order to avoid undesirable accident during use, please read this Manual carefully and make inspection before use.

Attention

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- ✓ Reorient or relocate the receiving antenna.
- ✓ Increase the separation between the device and receiver.
- ✓ Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- ✓ Consult the dealer or an experienced radio/TV technician for help.

Warning

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Maintenance

Maintenance of the pH Capsule Monitoring System shall be conducted in strict accordance with Part "Maintenance" of this Manual. Please watch any anomaly, even slight, and inspect the product carefully. Never disassemble or modify the product.

Safety Classification

PH Capsule

a. Classified by electric shock protection type: device fed by internal power supply.
b. Classified by electric shock protection level: BF.
c. Classified by liquid protection level: IPX8.
d. Classified by safety level of use in the presence of inflammable anaesthetic gas mixed with air or with oxygen or nitrous gas: device cannot be used in the presence of inflammable anaesthetic gas mixed with air or with oxygen or nitrous gas.
e. Classified by operating mode: continuous operation.

Data recorder

a. Classified by electric shock protection type: device fed by internal power supply.
b. Classified by electric shock protection level: not applicable.
c. Classified by liquid protection level: IPXo.
d. Classified by safety level of use in the presence of inflammable anaesthetic gas mixed with air or with oxygen or nitrous gas: device cannot be used in the presence of inflammable anaesthetic gas mixed with air or with oxygen or nitrous gas.
e. Classified by operating mode: continuous operation

This device has a limited operation lifespan.

Chapter 1: General Information

Introduction

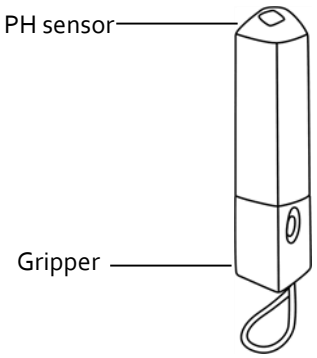
OMOM pH Capsule Monitoring System(hereinafter referred as pH Capsule System) is for examining gastro-esophageal reflux disease (GERD). It may continuously monitor pH variation within esophagus for 96h. pH value monitored by the capsule can be transmitted by means of radio frequency to the data recorder and store in it. After the examination, doctors upload the data to the workstation and analysis the pH variation to make diagnosis.

Components

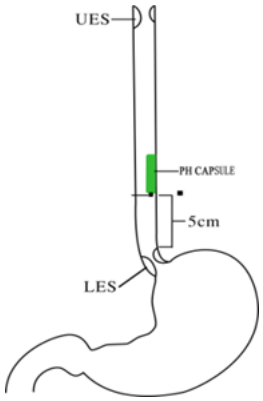
PH Capsule System is comprised of pH capsule, conveyor, data recorder, data analysis workstation and relevant accessories. All components are described in the next sections.

1. pH Capsule

PH capsule is comprised of sensor, gripper and signal acquisition module sealed in polymer enclosure, illustrated as follows:



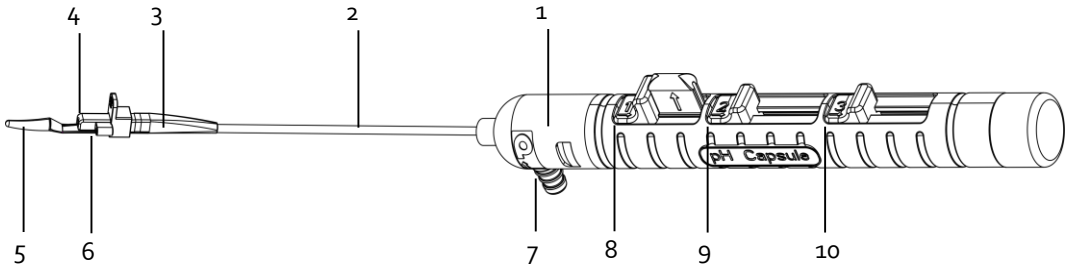
The capsule is powered of by breaker during storage and transportation, starts working once the breaker is removed, and is attached to the esophageal wall with a gripper to acquire and transmit data about esophageal pH in a real time manner, illustrated as follows:



After examination the esophageal mucosal tissue gripped by the capsule dies naturally, and the capsule falls off and is excreted naturally via digestive tract.

2. Conveyor

The conveyor is comprised of handle, duct, releasing device and other parts, illustrated as follows:

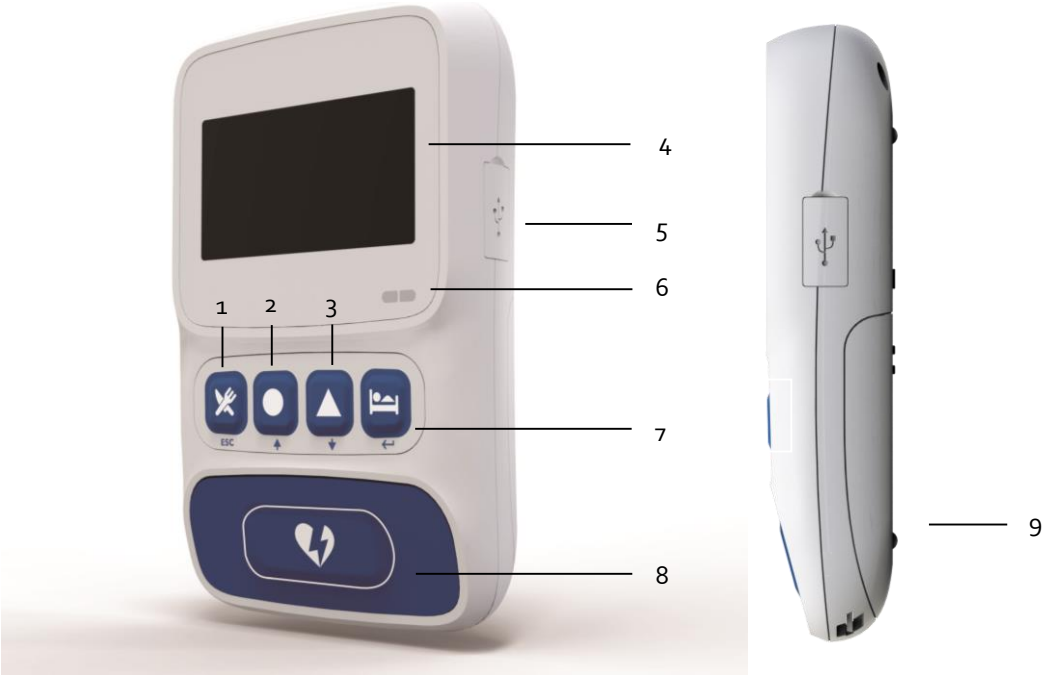


1	Operation handle
2	Duct
3	Releasing device（hard connection）
4	pH capsule
5	Releasing device（soft connection）
6	Capsule breaker
7	Vacuum air outlet
8	Buckle1
9	Buckle2
10	Buckle 3

The releasing device consists of hard connection and soft connection. The pH capsule is placed on the releasing device, it is to be putted into the esophagus via duct and attached to the esophageal wall by moving the three buckles at the operation handle.

3. Data Recoder

The data recorder, illustrated as follows, is to be carried by the patient. It is fed by 3 triple-A batteries and consists of a LCD and is mainly for receiving, processing and storing esophageal pH value transmitted by pH capsule in a real time manner and importing data via USB cable to data analysis workstation for analysis and diagnosis.



#	Marking	Description
1		**A multi-functional key** • **BACK key** Serves as the BACK key during calibration with recorder • **Meal Event Key** If the patient eat or drink during monitoring, press this key to start Meal event. Press this key again to end Meal event • Press  +  at the same time to set system Language warning tone, backlight duration , and view information • Press  +  at the same time to enter the pH calibration program

#	Marking	Description
2		**A multi-functional key** • **User-defined Event keys** User-defined Event keys serve as extra event record such as **cough or wheeze or laryngospasm or belching or chest pain**. For example, the patient belches during monitoring, press this key to start belching event and it will return to the normal event automatically in 10 seconds • **ADD key** Serves as the ADD key during calibration with recorder. • Press  +  at the same time to stop the pH study.
3		**A multi-functional key** • **User-defined Event keys** User-defined Event keys serve as extra event record such as **cough or wheeze or laryngospasm or belching or chest pain**. For example, the patient coughs during monitoring, press this key to start cough event and it will return to the normal event automatically in 10 seconds • **SUBTRACT key** Serves as the SUBTRACT key during calibration with recorder.
4		**LCD** Displays parameter and event information during calibration and event setting for the capsule
5		**USB Port** Communicate with Computer
6		**Indicator light** • **Power indicator: on the right side** • **Signal Indicator: on the left side** Received the capsule signal, the signal indicator light is blue, 3s/ flashing; Lost capsule signal, the signal indicator light is red, 3s/ flashing After calibration (waiting for the record), the signal indicator light is yellow. At the end of the study, the signal indicator light is green.
7		**A multi-functional key** • **ENTER key** Serves as the ENTER key during calibration with recorder. • **Supine Event Key** If the patient is supine during monitoring, press this key to start Supine event. Press this key again to end Supine event
8		**Heart burn** If the patient suffers from heart burn during monitoring, press this key to start Symptom event. It will return to the normal event automatically in 10 seconds

#	Marking	Description
9		**Battery Packs** Three AAA batteries

Caution

- Heart burn **or** User-defined Event:

  Press key when it happens

  ✓ The event indicator light on the right corner is on:

   or  or  .

  ✓ It will return to the upright event automatically in 10 seconds while the event indicator light on the right corner is off:

   or  or 

- Meal **or** Supine：

  ✓ Press the event key when begin --- The event indicator light on the right corner is flashes every 3 seconds

   or 

  ✓ Press the event button again when end --- The event indicator light on the right corner is off:

   or 

4. Data Analysis Workstation

Data analysis workstation consists of computer, printer and data analysis software. Hardware requirements are described below:

- 4G or above DDR memory
- 160 GB or above hard disk
- USB 2.0 port or above
- 14" or above display
- Color printer

Caution

Please ensure that your hardware at least meets the configuration requirement before installation of data analysis software.

Software features and functions

Features

- Name: pH Capsule Data Analysis Software.
- Version: V2.3 or above.
- Language: simplified Chinese/English.
- Output format: WORD /PDF.

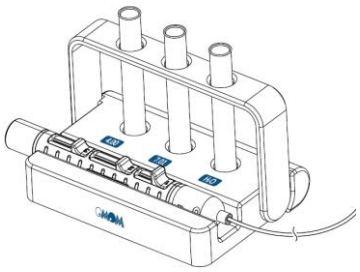
Functions

- pH calibration
- Display real time value
- Display pH curves at all stages, phased stages and for a period of time
- Zoom in and out curves
- Save curves
- DeMeester score and reflux exponential statistic
- SI and SAP statistic
- Edit status of records
- Define the patient's statues' color
- Import and export patient database
- Save all data of a patient in a folder under specified path
- Generate report supporting user-defined and print modes, as well as WORD and PDF format.

5. Other Accessories

Calibration stand

It consists of base, a tube rack and 3 tubes of 20ml. Place the conveyor and buffer solution during calibration, illustrated as follows:



Buffer solution

Buffer solutions of pH 4.00(or pH1.07) and pH7.01 respectively for calibrating pH capsule sensor.

Caution

Buffer solution must be medical calibration solution which is suitable for antimony electrode. Users can choose pH4.00 buffer solution instead of pH1.07. Make the selection according to the hint given by the software or the recorder. Otherwise, The system defaults for pH4.00.

Battery

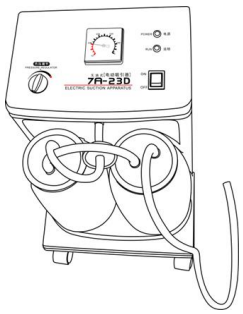
Three dry triple-A batteries are required for the power source of the data recorder.

USB cable

It is used to connect the data recorder and the data analysis workstation for data transmission.

Vacuum Extractor

With the suction pipe connecting the vacuum air outlet at the front end of the conveyor handle, the vacuum extractor enables pH capsule to attach to the esophageal wall for gripping and fixing depending on vacuum suction. Its appearance and structure are as shown in follow. The limit of vacuum suction is ≥0.08MPa(600mmHg).



Attention

Accessories are not components of the pH Capsule System but are necessary for system operation.

Product Features

- The capsule is disposable, free from cross-infection.
- The pH capsule is best to be fixed 5cm above the LES to provide more ac-curate monitoring result.
- It requires no indwelling catheter during the monitoring period, so it doesn't affect the patient's appearance and it is comfortable to wear.
- It allows the patient to maintain regular diet during the monitoring period. The result can reflect the actual symptoms of the patient.

Indications and Contraindications

1. Indications

- Patients have classic symptoms of acid reflux or heartburn and are considered as GERD patients;
- Patients suffer from unexplained chronic pharyngitis, hoarseness, trachitis or asthma and are considered as patients having extraesophageal symptoms of GERD;
- Patients who are considered as GERD patients and are positive in PPI therapeutic test.

2. Contraindications

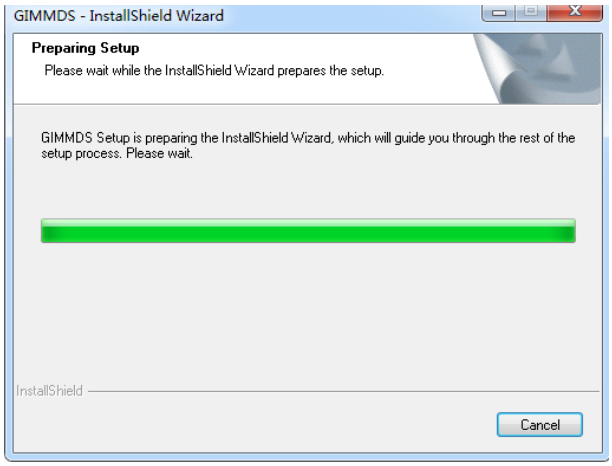
- Patients who are confirmed (or suspected) to suffer from upper esophageal or nasopharyngeal obstruction;
- Patients who are confirmed (or suspected) to suffer from esophageal varices according to gastroscopy, clinical radiology or other examination;
- Patients who are confirmed to suffer from esophageal mucosa erosion according to gastroscopy or other examination;
- Patients who are confirmed (or suspected) to suffer from congenital digestive tract malformation, gastrointestinal obstruction, and perforation, stricture or fistula of digestive tract according to clinical radiology or other examination;
- Patients who had bleeding tendency or gastrointestinal bleeding in the recent 6 months or have taken anticoagulant drugs for a long period of time;
- Patients who suffer from heart disease and are not stable;
- Patients implanted with pacemaker or other medical device;
- Patients who had history of allergy to polymer material.

Chapter 2: Software Installation

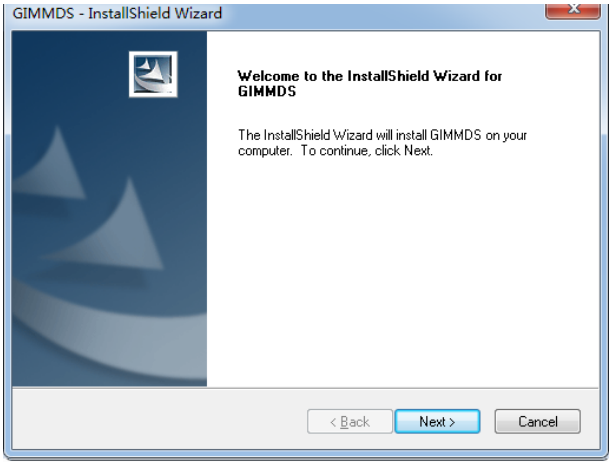
The computer must run Windows7 operating system or higher. The installation of the data recorder driver and the data analysis software are described below based on Windows 7 operating system. Installation in other operating systems may be completed according to the practical situation

Data Analysis Software

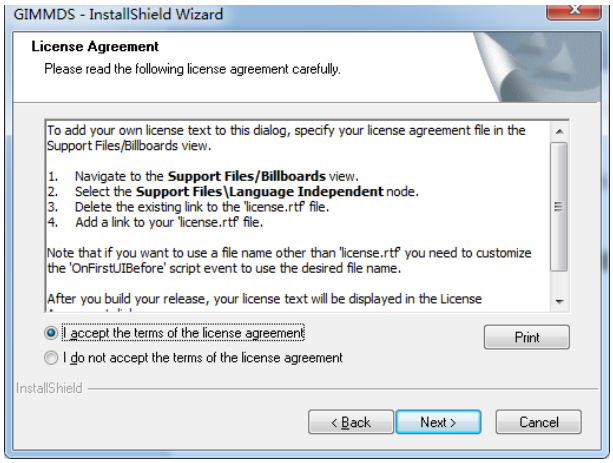
Run the installation CD of the data analysis software. Install the software as following: Prepare to installation



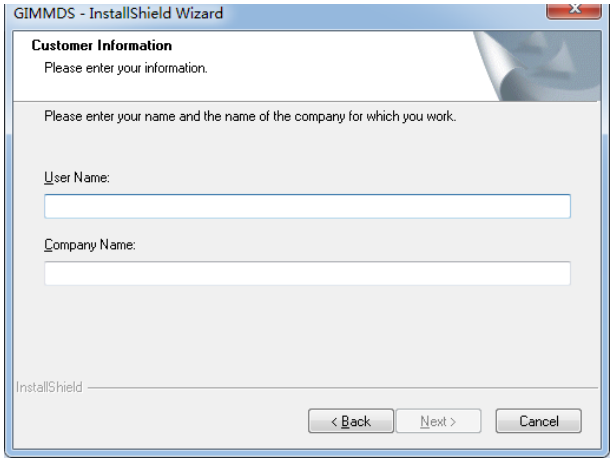
Click "Next" to continue.



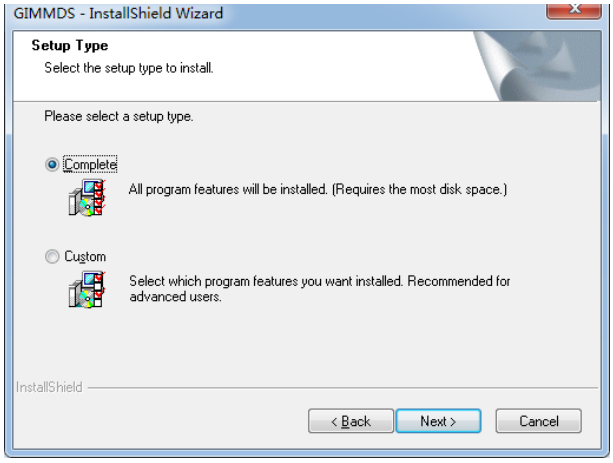
Select "I accept …" and click "Next" to continue.



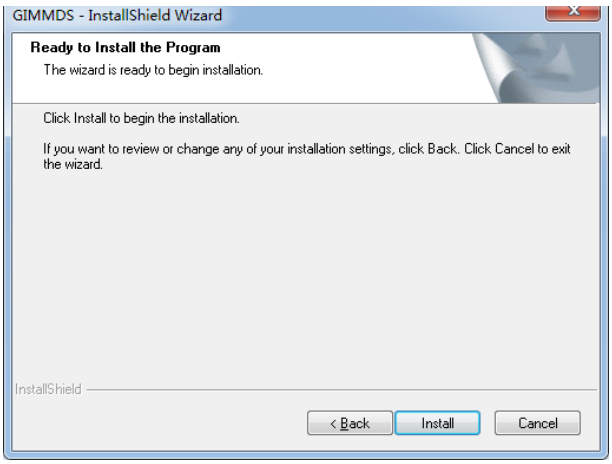
Enter information and click "Next" to continue.



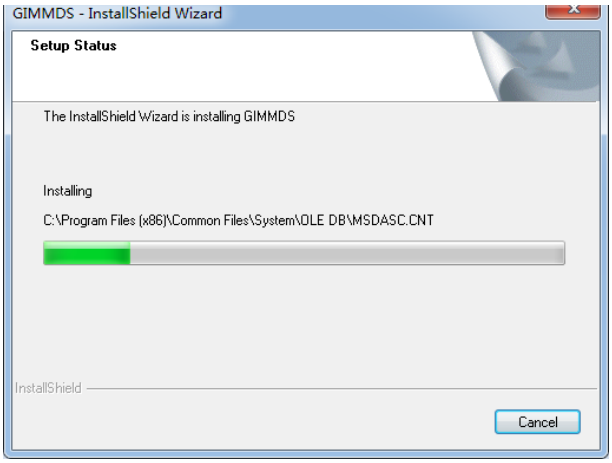
Choose "Complete" and click "Next" to continue.



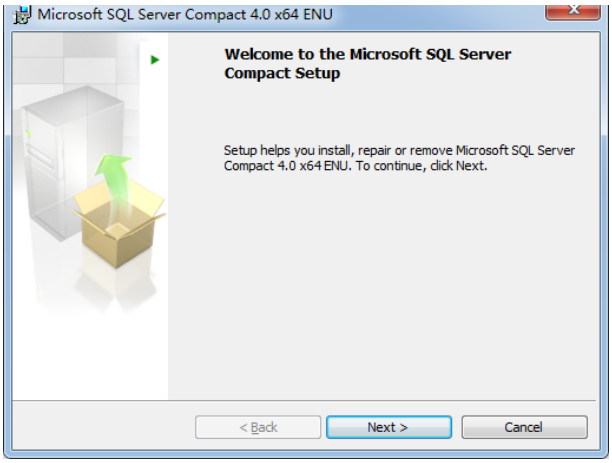
Click "Install" to continue.



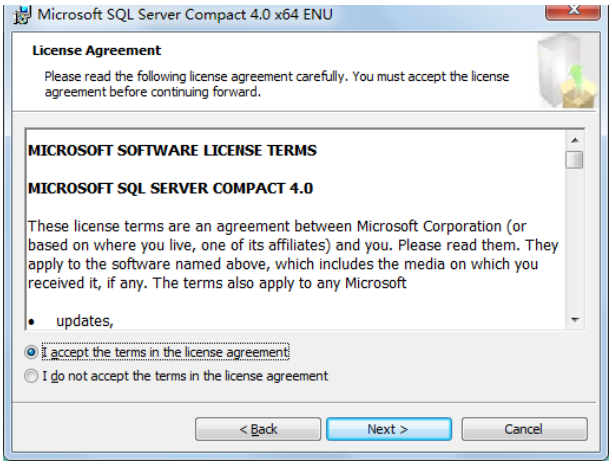
Installing…



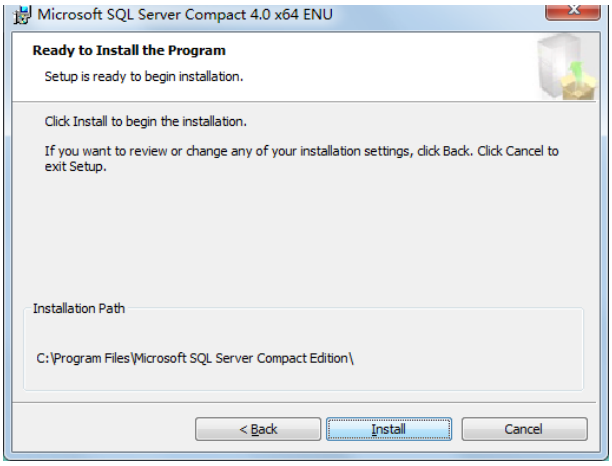
Click "Next" to install, repair or remove Microsoft SQL Server Compact 4.0x64 ENU



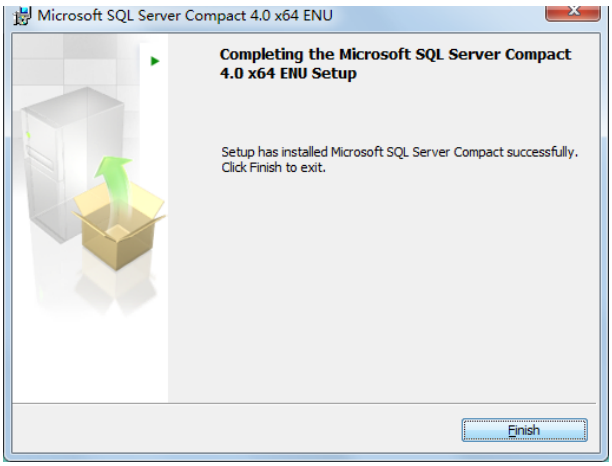
Select "I accept…" and click "Next"



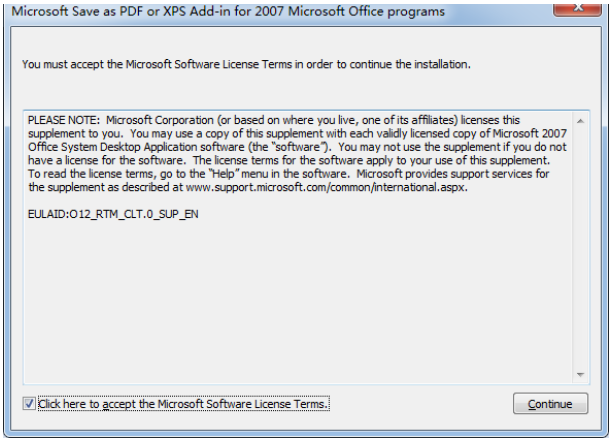
Click "Install"



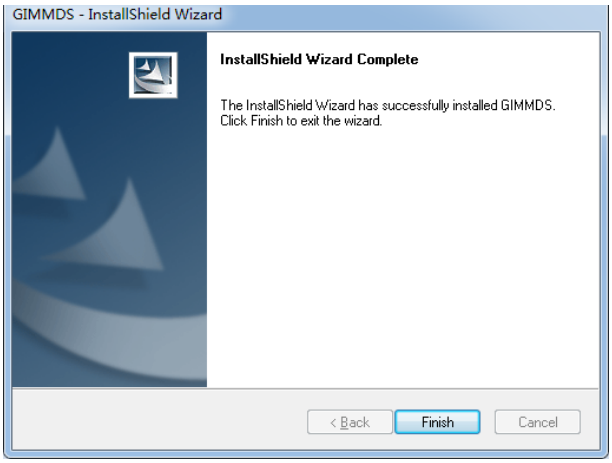
Click "Finish"



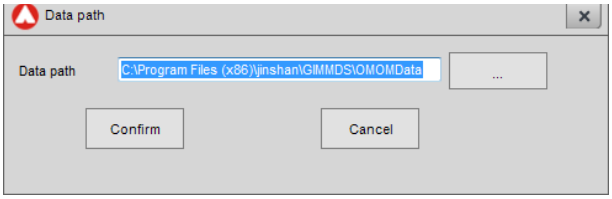
Select "Click here…" and click "Continue"



Click "Finish", then the installation procedure is finished.



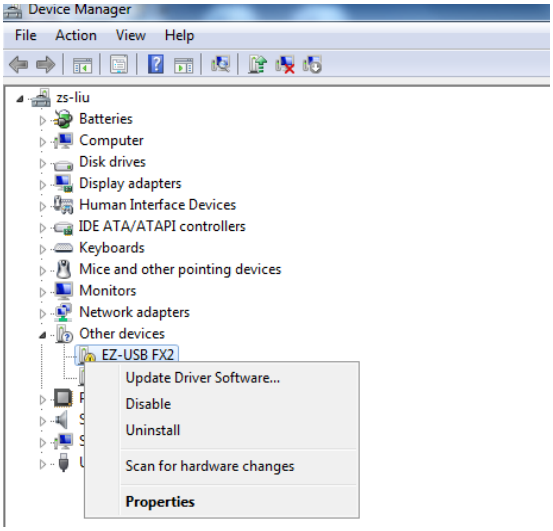
Choose "Date path", and click "Confirm" to enter the OMOM IpHDS interface.



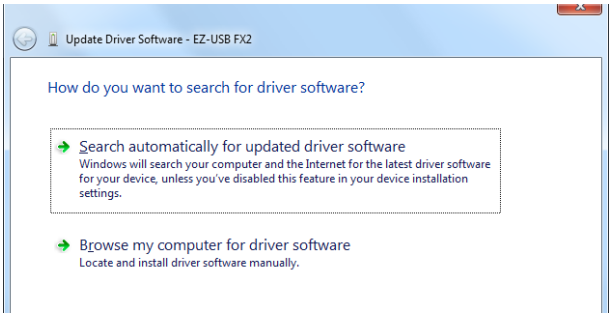
Data Recorder Driver

Connect the data recorder to the computer and power it on, install the driver as following:

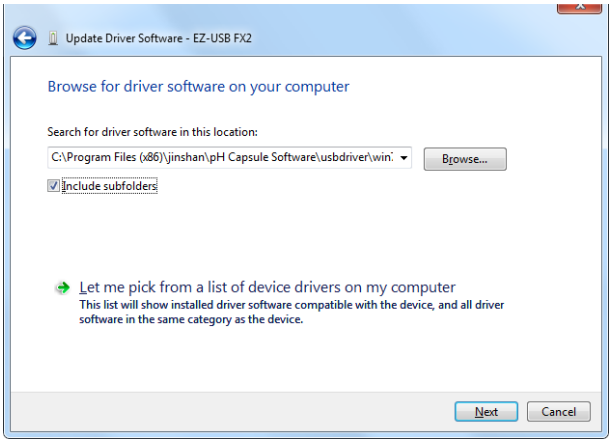
Choose "*Computer/Cystem properties/Device manager/Other devices*" and right click "*EZ-USB FX2*" (Different PC, USB's name may display different), Choose "Update Driver Software".



Select "Browse..."to continue.



Select "Browse" to search the path of driver, Select "Include..." ,then click "Next" to continue.



Attention

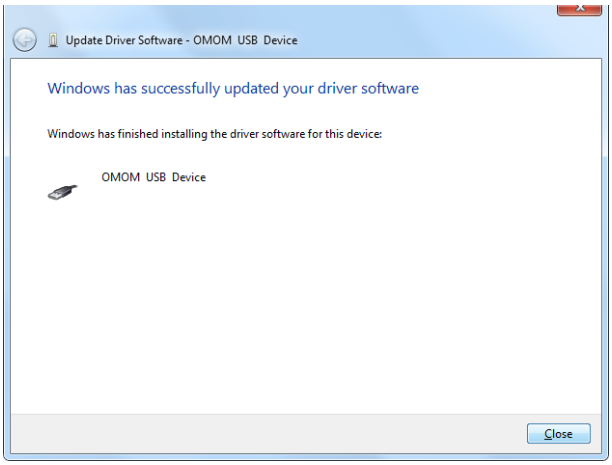
The default driver is installed in:

Program Files\jinshan\OMOM IPHDS\drivers\JSPH3\win7 (for win 7operation system)

or Program Files\jinshan\OMOM IPHDS\drivers\JSPH3\ win10 (for win 8 and win10 operation system)

Click “Install” to continue.

Click “Close” to close the window



Attention

Driver installation is available to the current USB port only and installations with other USB ports may be completed by repeating the installation procedure prescribed under this section.

Chapter 3: Monitoring Procedure

This chapter describes step-by-step how to perform pH monitoring with the pH Capsule Monitoring System. The procedure can be as follows:

Attention

- Before monitoring process, the user should prepare sterile gloves, one AA battery, medical tape, lubricant (or liquid paraffin), medical buffer solutions and distilled water.
- The pH calibration can also be operated by the recorder (see Appendix B for details).
- If examination is made against 2 or above patients simultaneously, distance between patients has to be more than 100m. Otherwise, interfere of radio communication between the data recorder and the pH capsule will occur.

Patient Screening

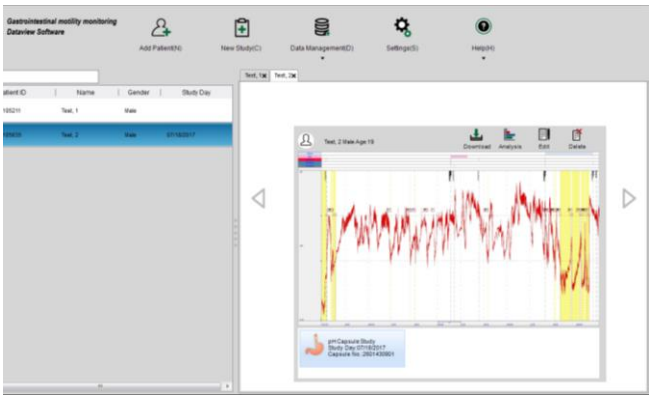
Doctors screen patients to make sure if the patients are suitable to undergo pH Capsule Monitoring System or not. Doctors should introduce the checking instructions to patients. Start fasting before 12 hours of Start monitoring, fasting water before 6 hours of Start monitoring.

Please see the indications and the contraindications in Chapter 1.

Device Preparation

1. Turn on the software

Double click the software icon  to enter the OMOM IPHDS interface.



2. Recorder preparation

- Install a new battery
- Use the USB cable to connect the recorder to the computer and turn it on

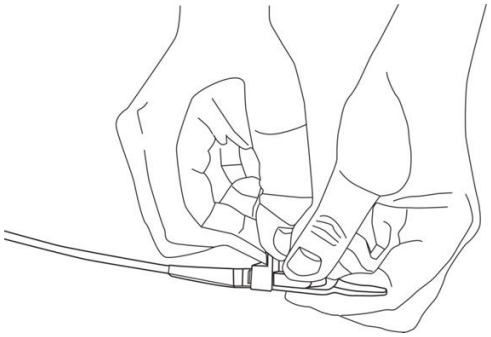
Caution

- The data recorder alerts and will stop working at low battery level. Please check the battery level frequently, and replace them immediately when running low.
- The data recorder requires three triple-A batteries for power supply. Replace batteries before the examination to maintain sufficient power level.
- Used batteries shall be disposed according to local laws and regulations.
- Take the batteries out from the data recorder and store them separately after examination.

3. pH capsule preparation

- Place the calibration stand and tubes
- Fill the tubes with corresponding buffer solutions and distilled water
- Take the pH capsule and conveyor out of the packing bag, and remove the electricity breaker,

  illustrated as follows：



- Pre-soaking :Dip the pH capsule into Buffer Solution pH 4.00 or pH 1.07 at least 4min

Warning

PH capsule shall be used immediately after unpacking and pH capsule which is not used immediately after unpacking shall be disinfected before reuse.

Caution

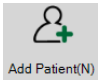
- Please hold the capsule with the releasing device while taking the capsule off, in order to prevent the capsule falls off from the device.
- The LED indicator of the capsule shall flash once in every 3 seconds.
- Do not touch the sensor while taking off the capsule.
- Do not start two pH capsules in a short distance, otherwise capsules will interfere with each other and fail to receive data.

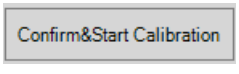
Attention

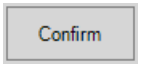
Align the breaker with the vacuum absorption hole to lock the capsule. It indicates that the capsule is switched off when the LED indicator stops flashing.

System Preparation

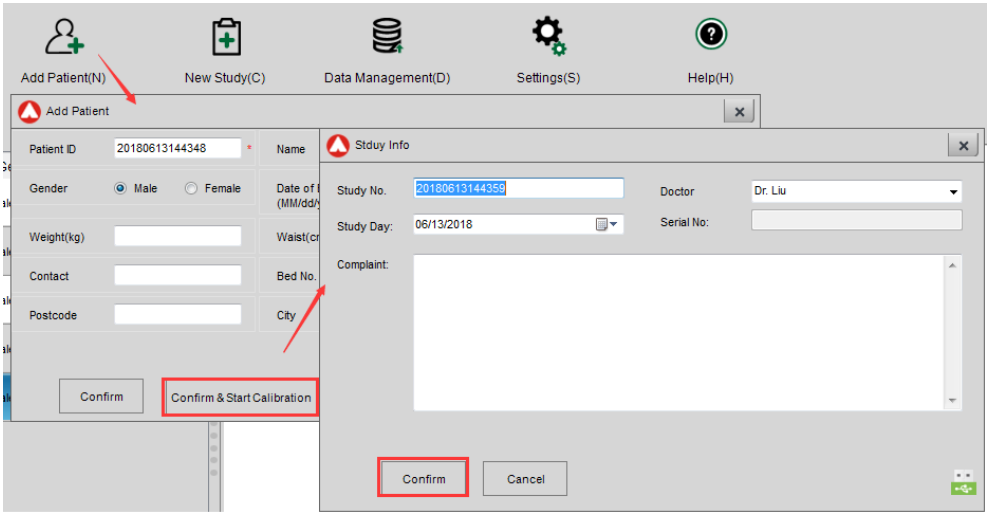
1. Add patient and patient information

Click 

to enter the **Add Patient interface**. Fill in patient's basic information, items marked with"*" are required information. The patient ID cannot be replicate with the existing patient ID. Patient's age cannot be above 201 years old. Click 

to enter the Study Infor **Interface** and fill in study information, then Click 

to enter the pH capsule calibration interface. Illustrated as follows：



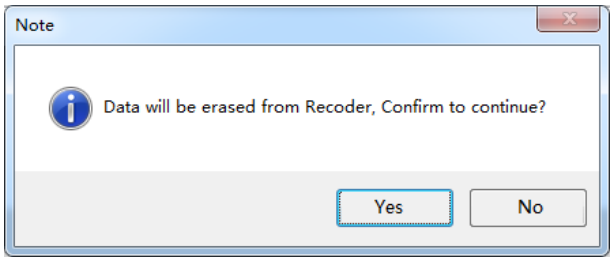
Caution

If recorder did not connect with computer, you can see  icon at study infor interface and calibration interface.

2. pH calibration

Caution

- It's necessary to calibrate the pH capsules before monitoring; otherwise, the system can't work as normal.
- The pH capsule should be cleaned by distilled water after pH calibration.
- The pH calibration can also be calibrated using a data recorder. See Appendix B / Calibration with Recorder for details.
- Make sure download the pH data, before presoak. The study data in the recorder will be completely cleared and cannot be restored during the presoak.



Warning

Please wear sterile gloves to avoid contamination during calibration. To avoid contamination, the pH capsule can only contact calibrating solution, distilled water and sterile gauze.

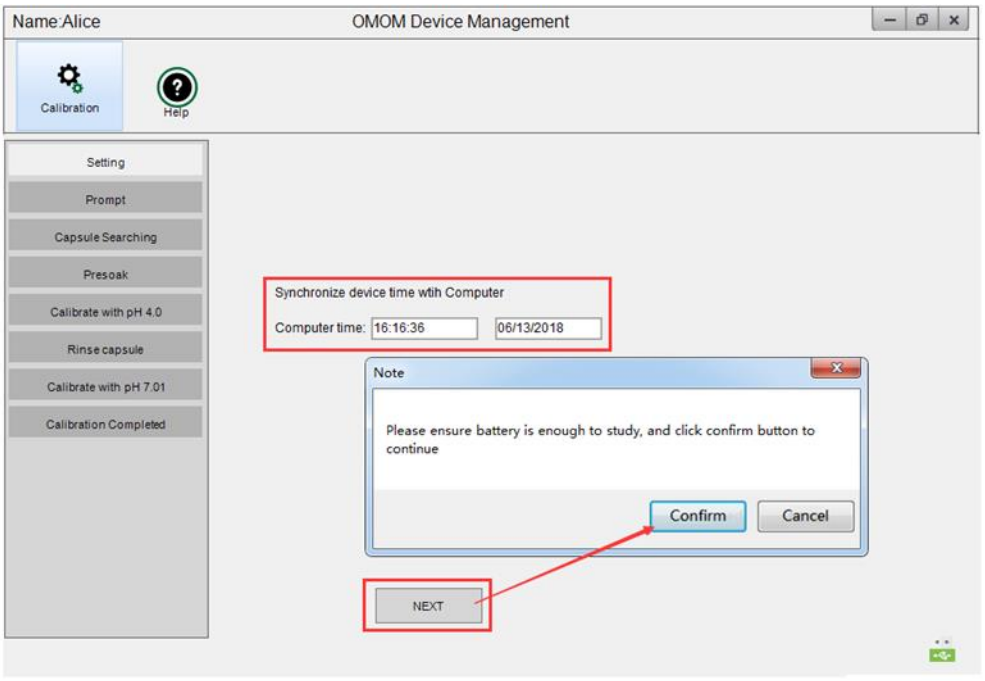
Attention

- Please use standard buffer solutions otherwise the accuracy of the pH value measured may be affected.
- The system will calibrate any buffer solution again automatically if pH capsule fails to pass the calibration or error occurs in the buffer solution.

Step 1: Information settings

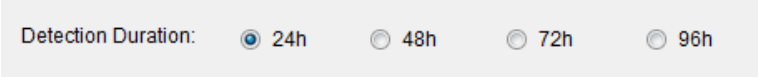
1) Recorder time and computer time synchronization

Confirm the computer time, click "Next", again confirm that the recorder battery is full, click "confirm" to enter the next operation.



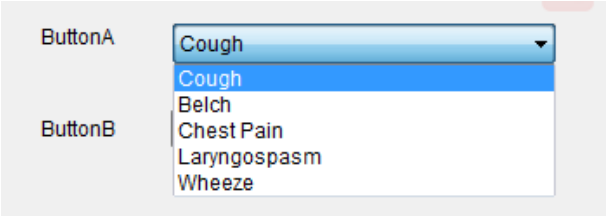
2) Choose the detection duration

There are four detection durations, such as 24h, 48h, 72h and 96h. The user selects the detection duration according to the clinical needs. Click "Next" to enter the next operation.



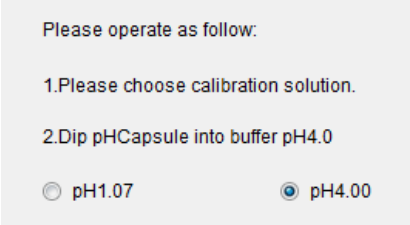
3) Set the status of recorder button A and button B

Click the drop-down button to select the state of the recorder button A and button B. There are various states of cough, belching, chest pain, throat and wheezing; click "Next" to proceed to the next step.



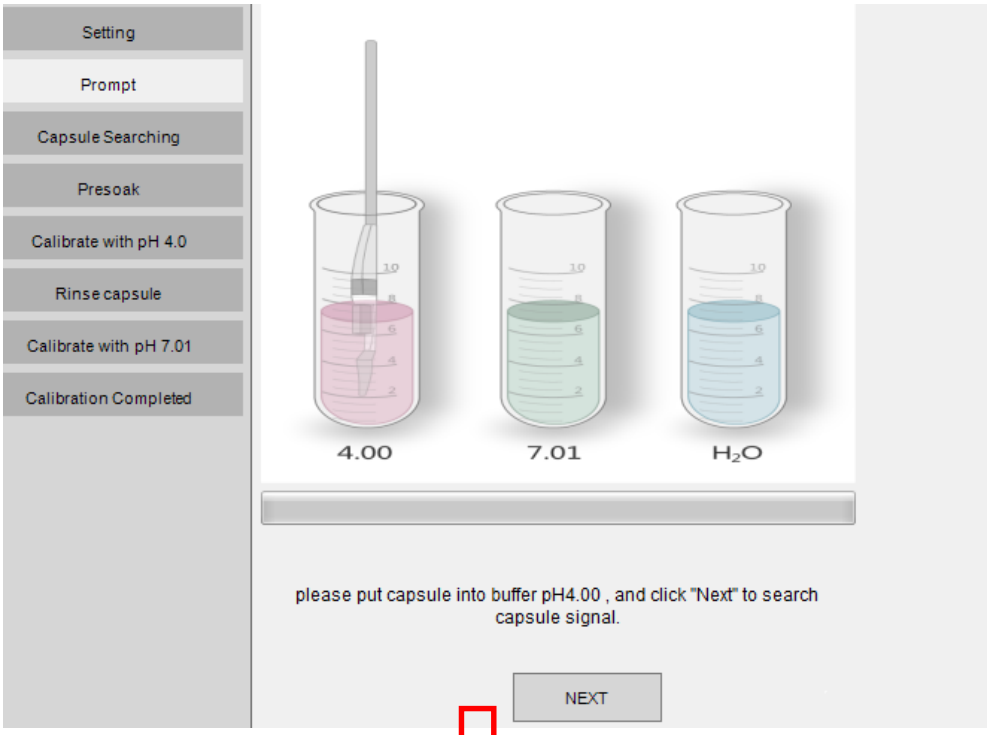
4) Confirm calibration type

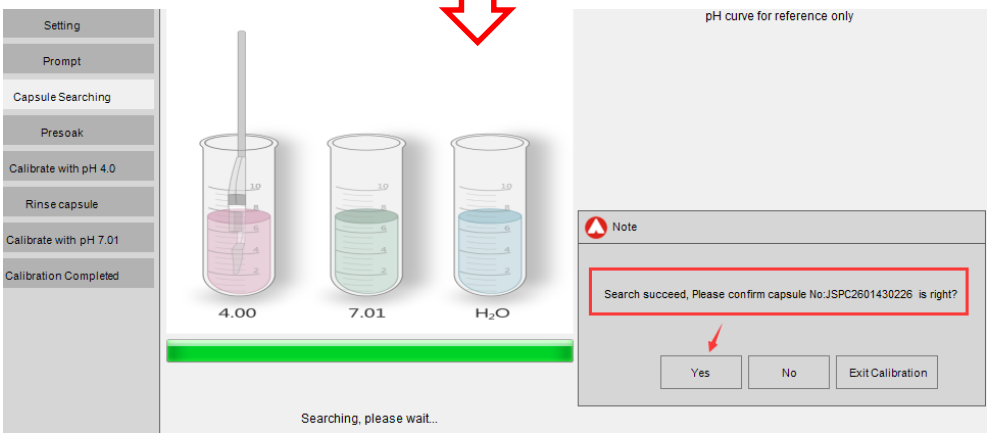
The calibration type consists of pH1.07/pH 7.01 and pH4.00/pH 7.01, the default is pH4.00/pH 7.01, this manual will take pH4.00/pH 7.01 calibration as sample. Click "Next" to proceed to the next step.



Step 2： Information prompt and search capsule

Place the pH capsule in a solution of pH 4.00, and click "Next" to start searching for the pH capsule signal; after the search is completed, a prompt window will pop up. Please confirm that the serial number of the pH capsule is correct (with the pH capsule packaging serial number Check)


Setting
Prompt
Capsule Searching
Presoak
Calibrate with pH 4.0
Rinse capsule
Calibrate with pH 7.01
Calibration Completed
4.00
7.01
H2O
please put capsule into buffer pH4.00 , and click "Next" to search capsule signal.
NEXT


Setting
Prompt
Capsule Searching
Presoak
Calibrate with pH 4.0
Rinse capsule
Calibrate with pH 7.01
Calibration Completed
4.00
7.01
H2O
Searching, please wait...
pH curve for reference only
Note
Search succeed, Please confirm capsule No:JSPC2601430226 is right?
Yes
No
Exit Calibration

Step 3: Presoak

Put the pH capsule into the tube with pH4.0 solution and click "Next", then start presoaking it at least 4 minutes.

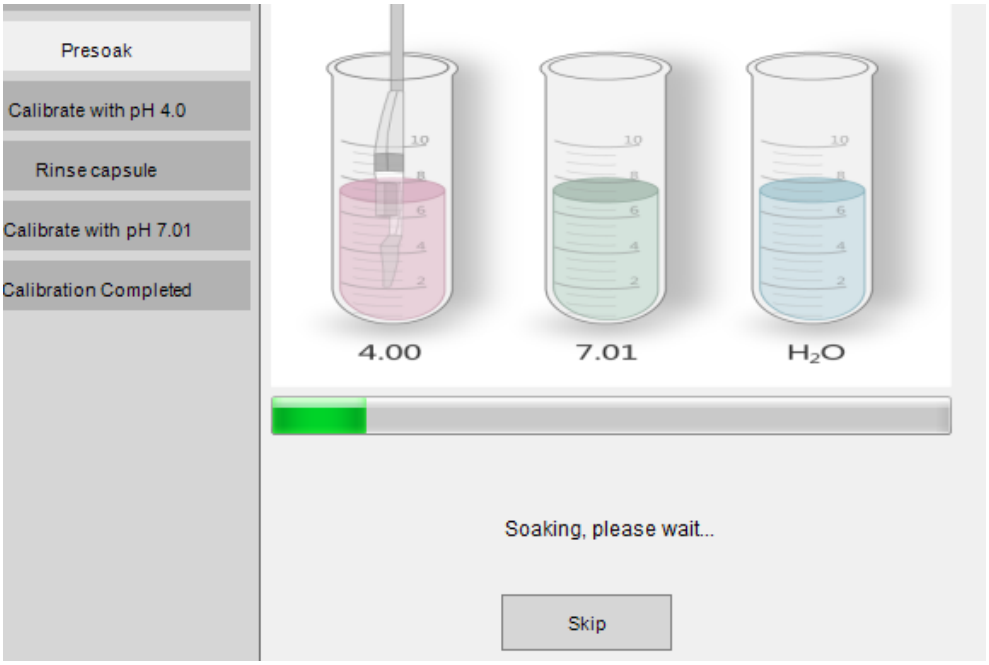
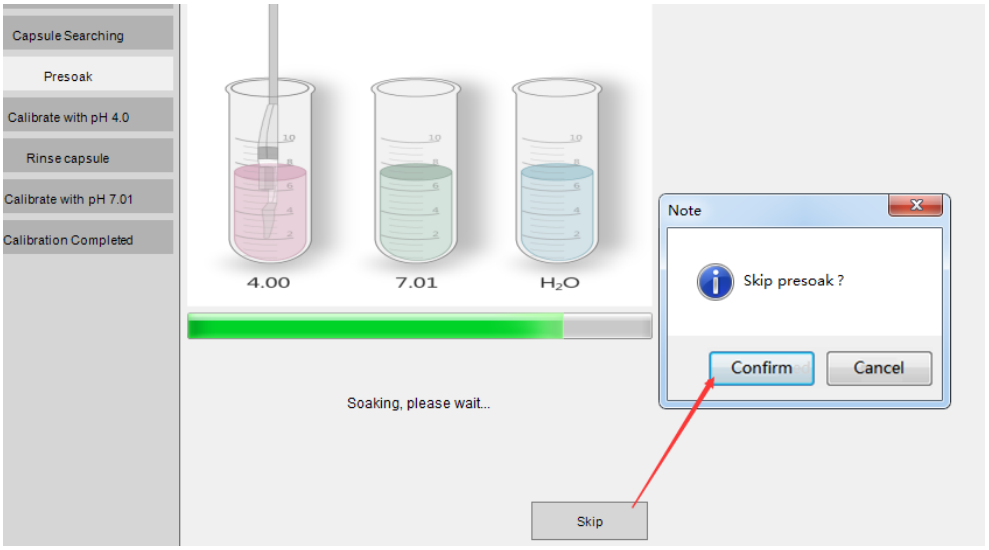


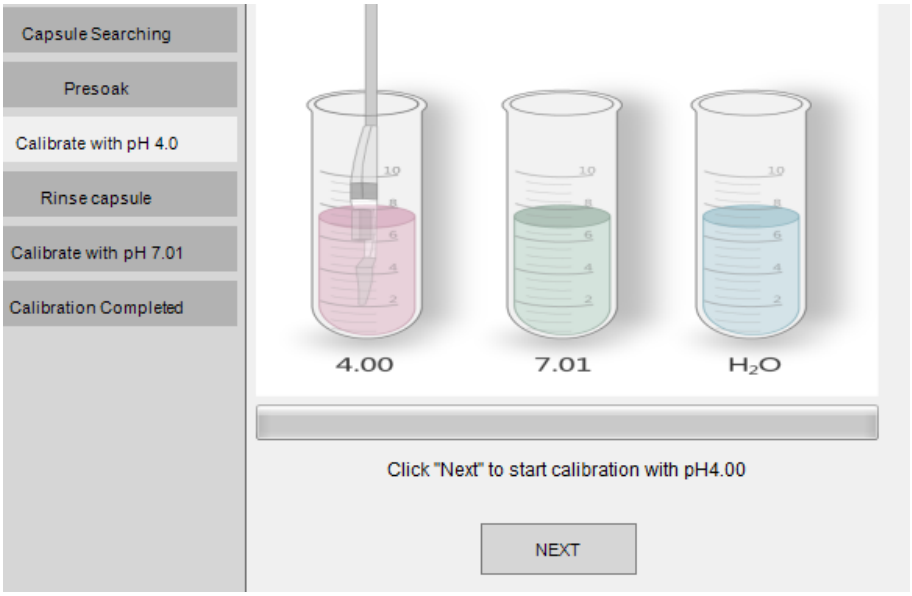
Figure 3. 1

- If the pH capsule has been presoaked for 4 min before starting the procedure, the "Step3: presoak" can be skipped. Click "Skip", the Notification will display, click "Confirm" to continue.

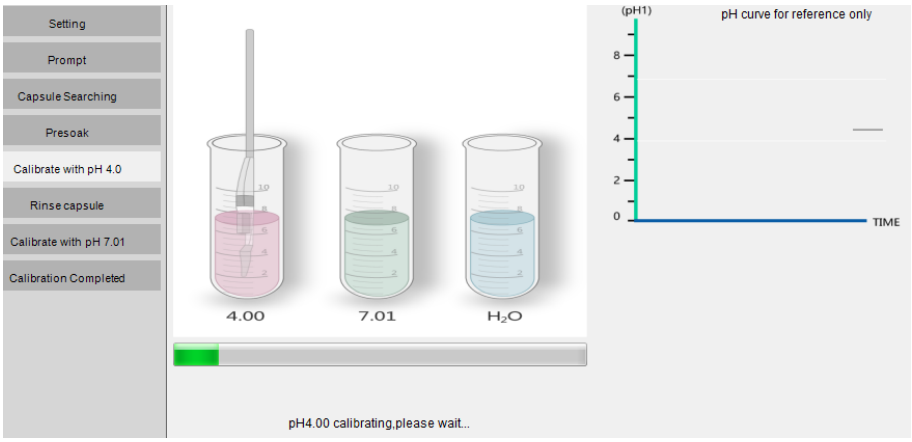


Step 4: pH 4.00 calibration

After finishing presoaking, click "Next" to start the pH 4.00 calibration

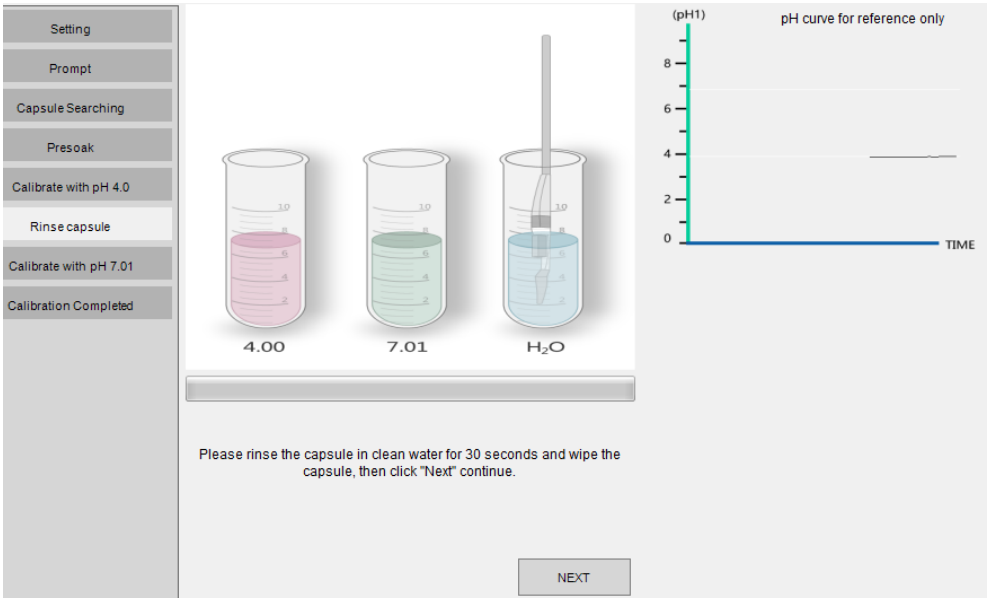


- Calibrating in pH 4.0, please wait…



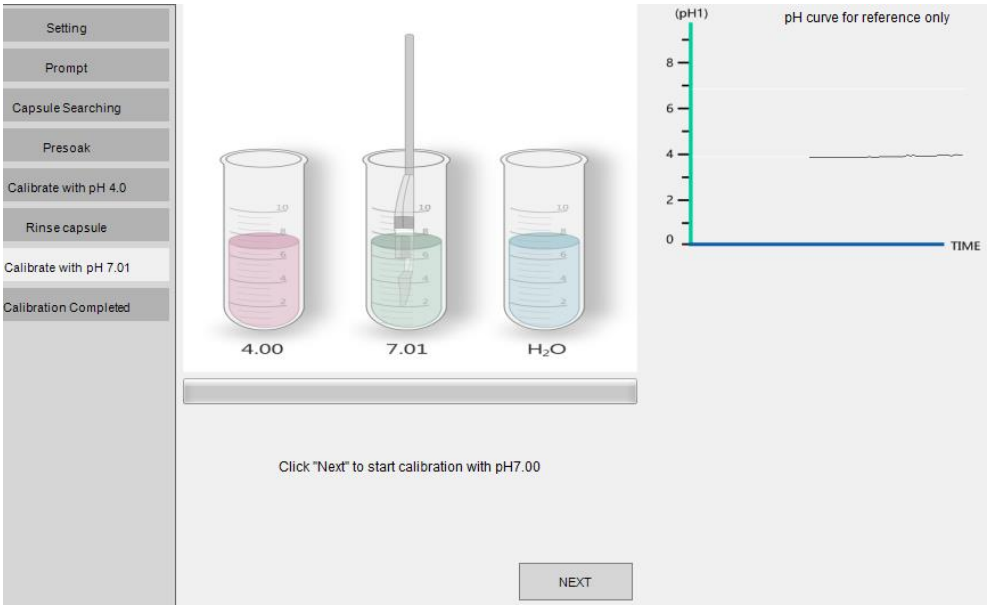
Step 5: Rinse pH capsule

Put the pH capsule into the distilled water and wash it, then click "Next".

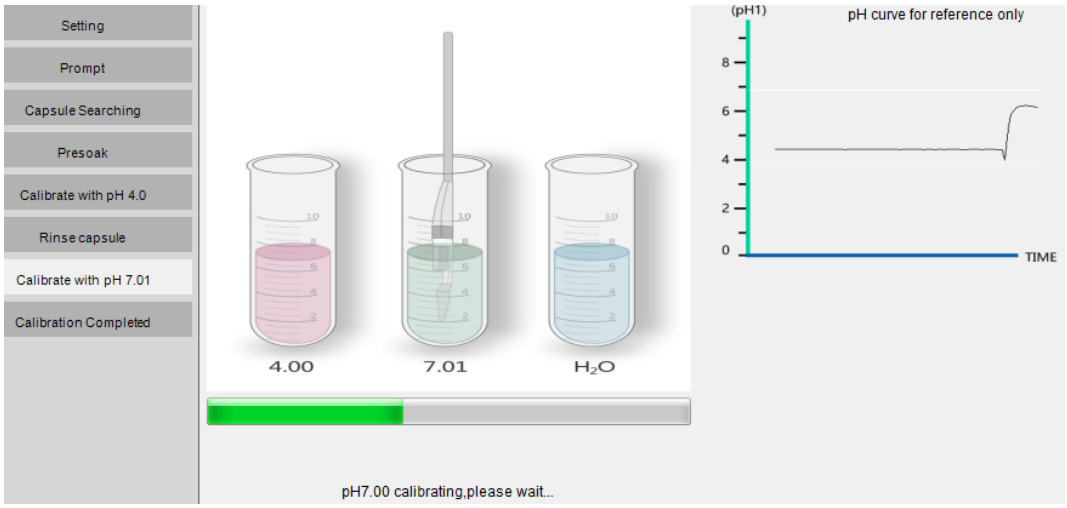


Step 6: pH 7.01 calibration

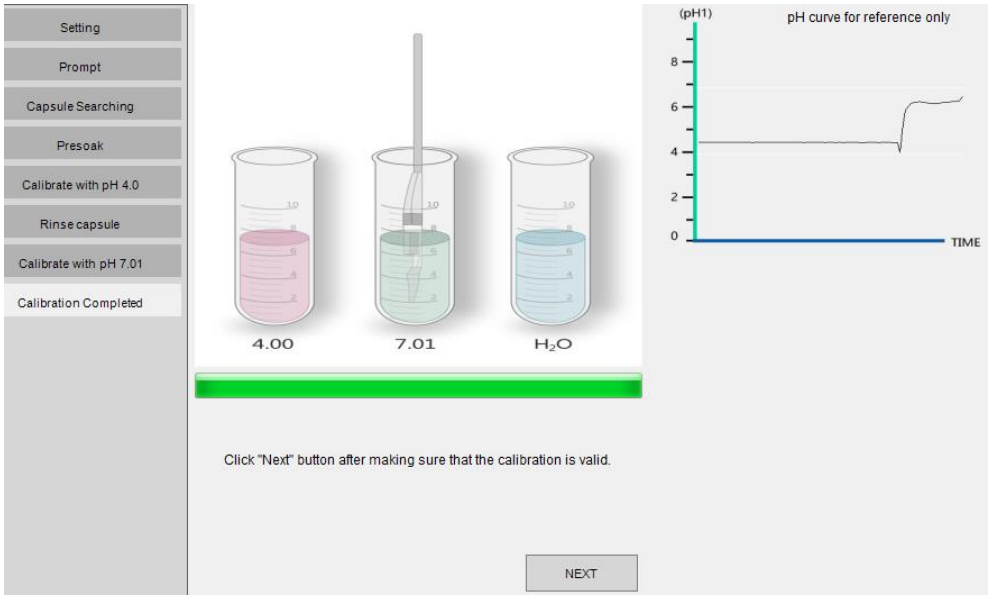
Take out the pH capsule and wipe it with a sterile gauze, then put the pH capsule into the tube with pH 7.01 solution. Click "Next" to start the pH 7.01 calibration.



- Calibrating in pH 7.01, please wait…



- Click "next" to complete calibration

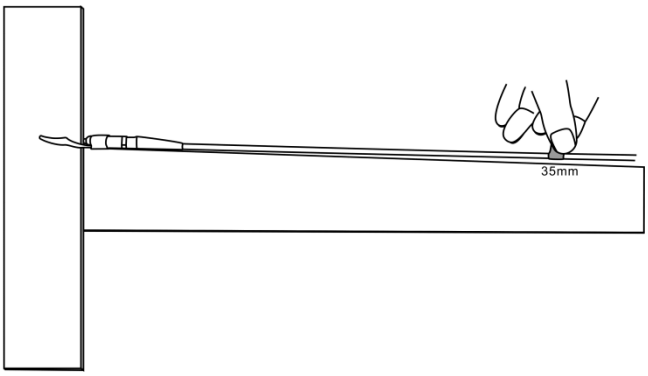


3. Gripping and fixing ph capsule

Attention

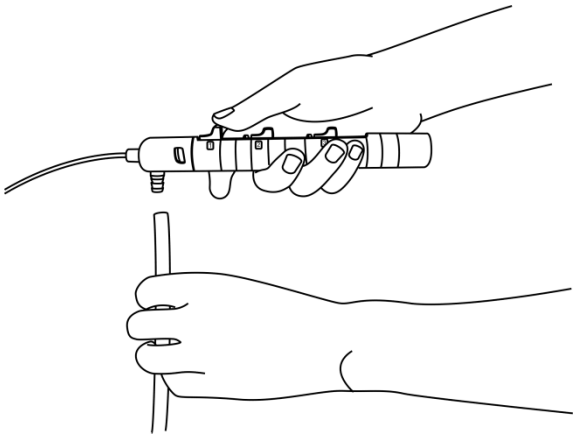
Make sure the gripper in the pressure suction hole is open; otherwise the capsule cannot be used anymore.

a. Measure the length between 5cm above the dentate line to incisor of the patient with gastroscope or esophageal manometry. Find the corresponding scale at the conveyor tube and mark the scale with adhesive tape; thus the inert length of the conveyor tube into the esophagus is determined, illustrated as follows.

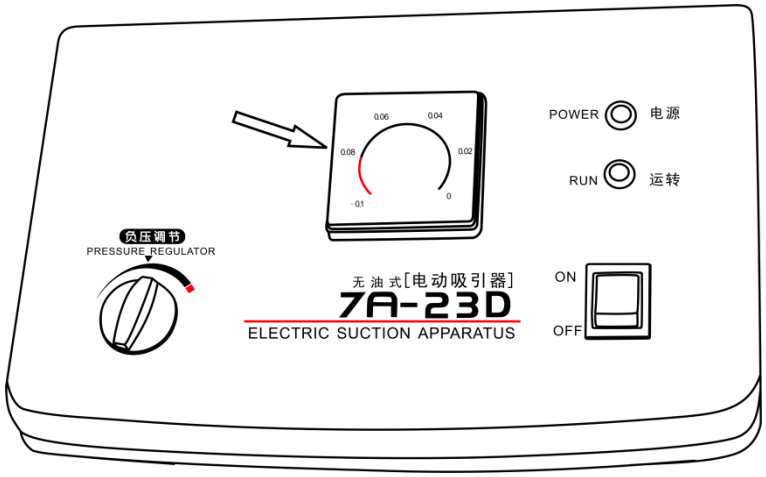


b. Apply some lubricant at the front end of the guiding head and put the conveyor slowly from oral cavity to the patient's esophagus until the mark at tube reaches the patient's incisor, illustrated as follows.

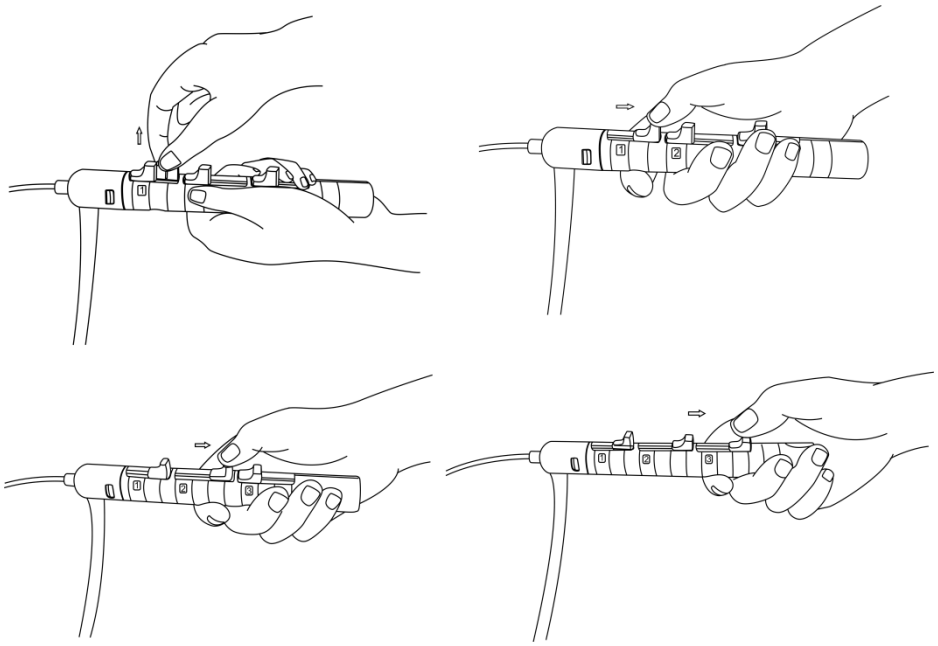
c. Connect the air inlet tube of the vacuum extractor to the vacuum air outlet at the front end of conveyor handle , illustrated as follows.



d. Switch on the vacuum extractor, adjust the Pressure Regulator knob, reach the pressure of 0.08MPa(600mmHg) and maintain for 5-10s, illustrated as follows.



e. Remove the retainer beside the buckle 1 of operation handle, and move buckle 1, buckle 2 and buckle 3 one by one in the direction shown by the arrow;, all buckles must be moved to the end, illustrated as follows.

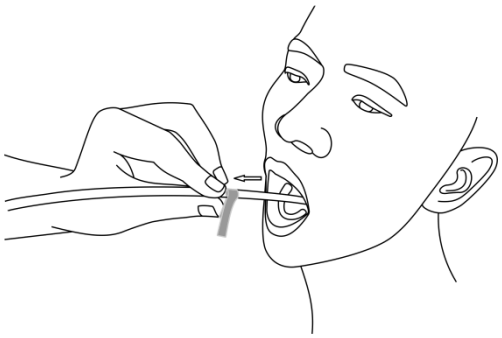


Caution

Those buckles must be moved to the end in strict accordance with the order of a, b and c otherwise the capsule is unlikely to be fixed properly.

a. Switch off the vacuum extractor and remove the air inlet tube from the handle.

b. Pull out the conveyor slowly. At this point, the pH capsule is fixed to the esophageal wall.



Warning

- The capsule will cause a micro-trauma to the esophageal wall during the fixing process. Doctors shall carry out operations in strict accordance with this manual in order to avoid other traumas.
- The handle and the duct of the conveyor are disposable supplies and cannot be reused.

Caution

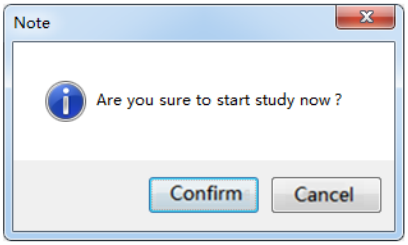
- Do not use the pH capsule if the sterilization bag is damaged before unpacking. Before capsule replacement, the previous capsule must be putted back in its package properly and switched off.
- The capsule must be calibrated before use. If the calibration needs to use solutions with different pH value, the capsule must be cleaned with water in advance.
- The vacuum extractor shall be maintained at 0.08MPa during the capsule fixing period. High pressure may be harmful. Such pressure shall be maintained at least for 5-10s. Otherwise, pH capsule could not be fixed.
- During the examination after the capsule is fixed, the patient should not practice strenuous exercise and shall take liquid or semi-liquid food instead of dry, hard and raw fiber foods.
- During the operation, the capsule shall be kept far away from magnetic field and other environments which may cause signal transmission interference.

Caution

The built in battery of the pH capsule will be left in the capsule after use;, it may cause environmental disruption, and must be disposed according to local laws and regulations.

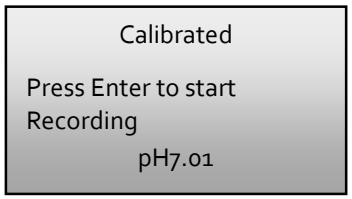
Starting monitoring

Click "Confirm" on work station, then start record data.



Caution

If the recorder is disconnected from the PC , Click on recorder to start record the data.



Notice in the Process of Monitoring

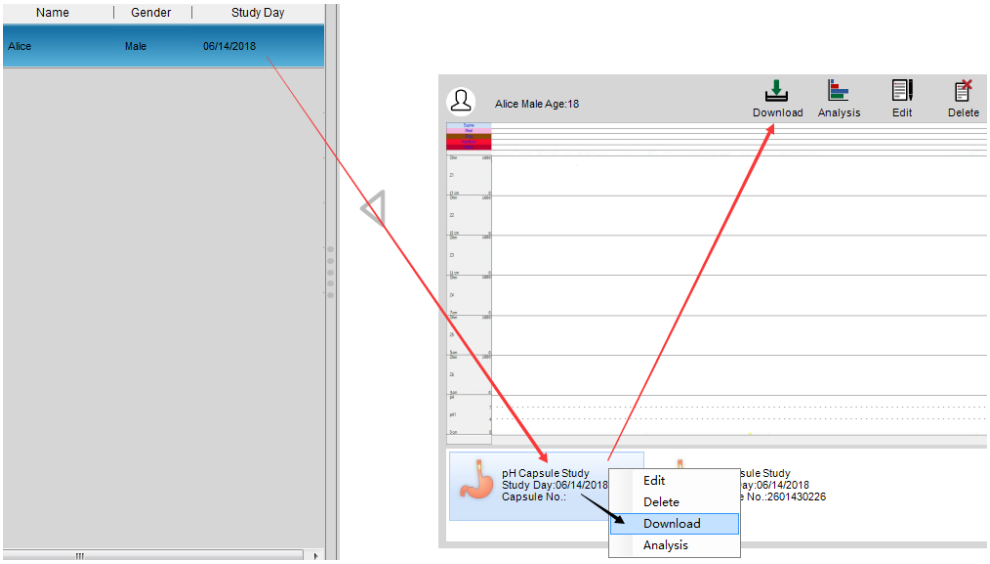
The monitoring lasts 24 hours or 48 hours or 72 hours or 96 hours, provide the doctor's emergency contact information to the Patient and make sure patients fully understand the following messages:

- Do not take vigorous exercise or eat hard dry food.
- Stay away from MRI equipment and other environments with high magnetic field.
- Keep the data recorder away from water; avoid taking shower which may cause water inflows to the recorder.
- Pay attention to low battery alarm of the recorder (the recorder beeps and displays "low battery"). Replace the battery timely since the data recorder will turn off automatically in one hour.
- Timely press button for recording events during the monitoring as following:
  - ✓ Press button meal once at the begging of eating and press again as you finish eating.
  - ✓ Press button supine once when you lie down and press again when you get up.
  - ✓ Press button hiccup only once in 10 seconds when hiccup.
  - ✓ Press button heartburn only once in 10 seconds when heartburn.
  - ✓ Press button drug only once in 10 seconds when take drugs.
- Call your physician if any unknown event occurs.

- Turn back the hospital after the monitoring is finished.
- The patient should not put the data recorder 3m away from himself/herself during examination.
- The patient should use the Event Form to register events during the examination.
- Ask the patient to check whether the LED of the Data Recorder is blinking green one time three second. If it stops blinking, the patient should contract with his/her doctor.
- Patient should turn off the data recorder after 96 hours.

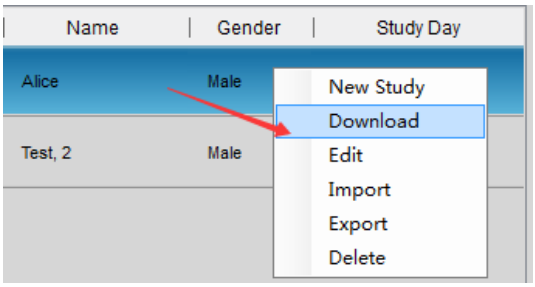
Data Downloading

After finishing monitoring, the data recorder should be switched on and connected with computer for downloading. Select a patient and monitoring item on the OMOM IPHDS interface and click download (or right-click, select Download) to download his/her data from the recorder.



User also can download data by follows:

- Select a patient and right-click, select Download to download his/her data from the recorder.

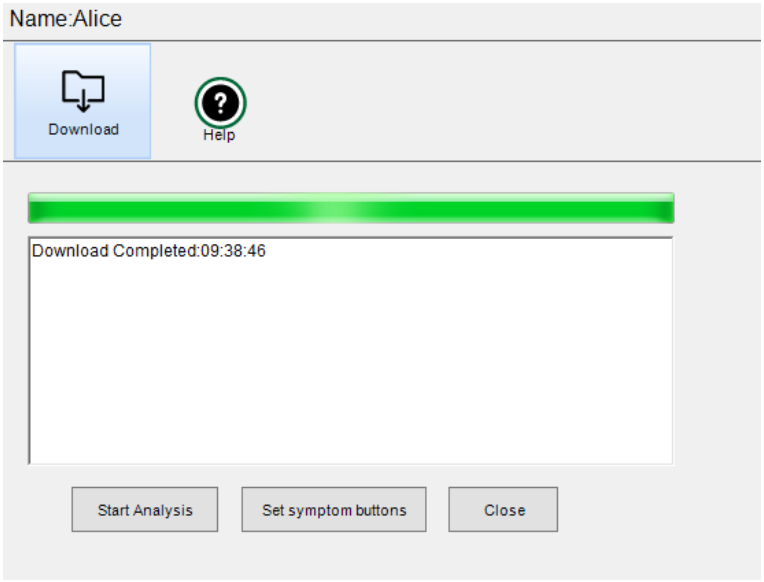


Attention

If calibrating the capsule through date recorder, new patient information should be added before clicking Confirm & Start Download, please see the details in Chapter 4.

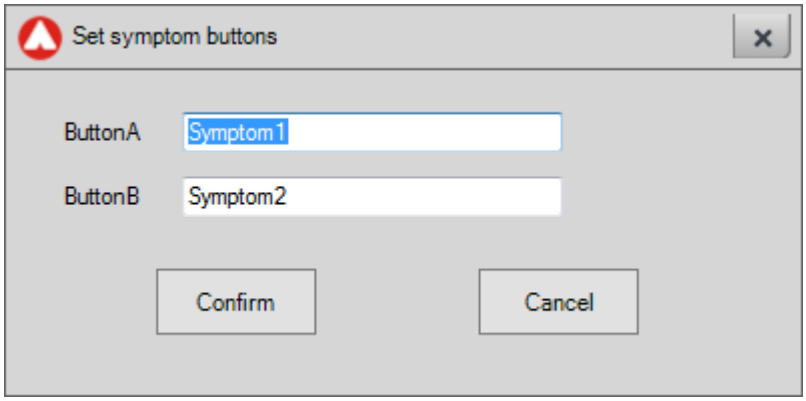
Data Analysis

Method 1: After finishing downloading, click Start Analysis to enter the data analysis interface (OMOM Data View Interface)



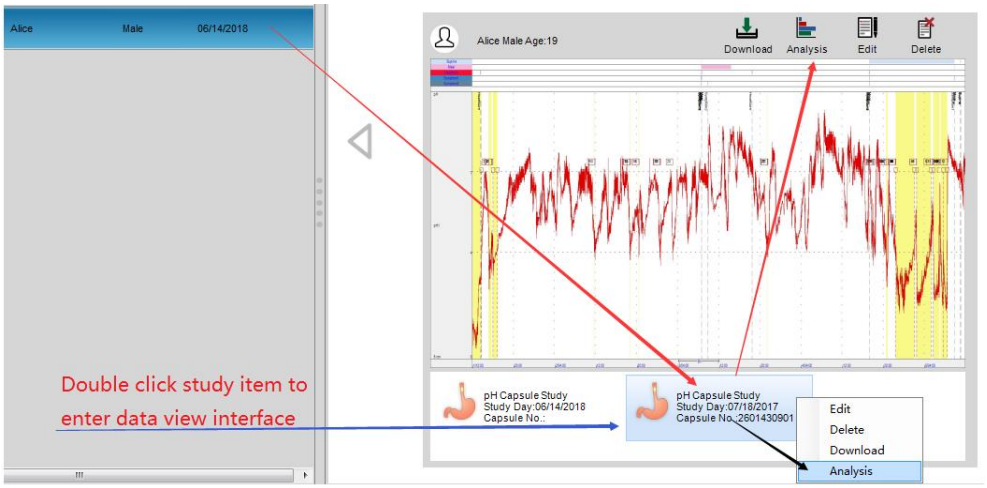
Attention

- If the patient use the symptom button A ， button B and record the Event Log Sheet during the process of monitoring , user need to set the corresponding event name.
- Click Set symptom button to set the name of Button A and Button B.

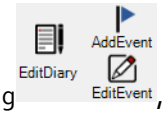


Method 2: Select a patient and monitoring item on the OMOM IPHDS interface and click 

(or right-click, select Analysis or double click study item) to enter the data analysis interface.



- The user can click 

and also can analyze manually by clicking 

, please see the details in Chapter 4.
- After analysis, click 

.

Print report

On the **OMOM Data View Interface,** click Report to enter the Print report interface.

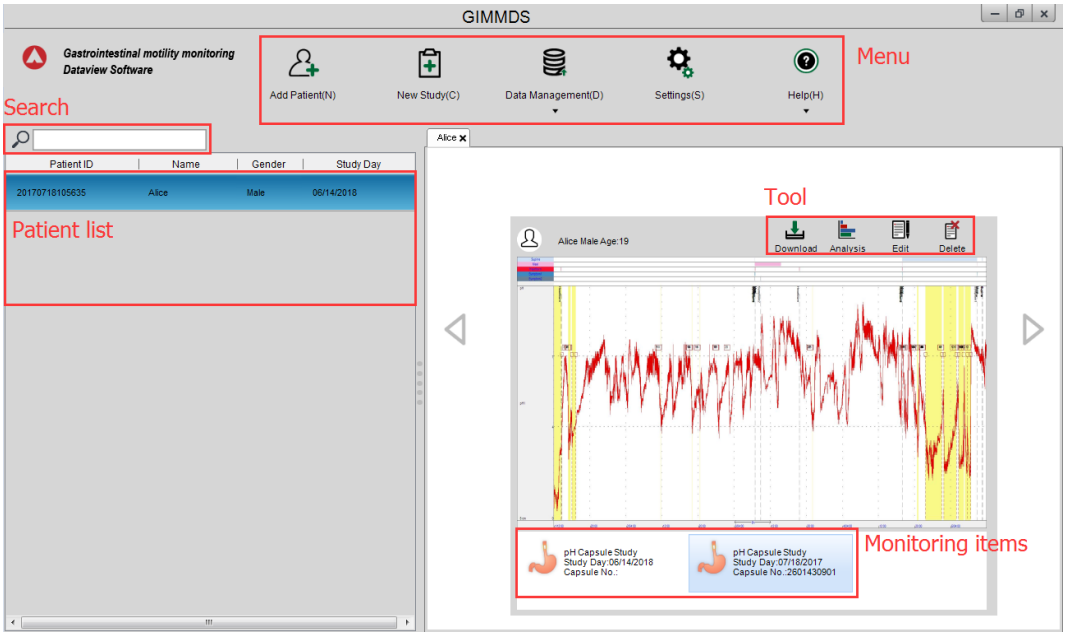
- Choose the items need printing.
- Preview: Clicking Preview can see the printing effect.
- Print: Click Print to print report.
- Save as word: Clicking Save as word can save the report word format.
- Save as PDF: Clicking Save as PDF can save the report PDF format.

Chapter 4: Operation of Data Analysis Software

This chapter mainly introduced the operation of the data analysis software and it will be presented according to the functions. It's not suitable for operations procedure instructions. About the clinical application, please process under the instruction of Chapter 3.

Patient Administration interface

Double click the software icon  to enter the OMOM IPHDS interface as below:



The main functions on the Patient Administration interface described as below:

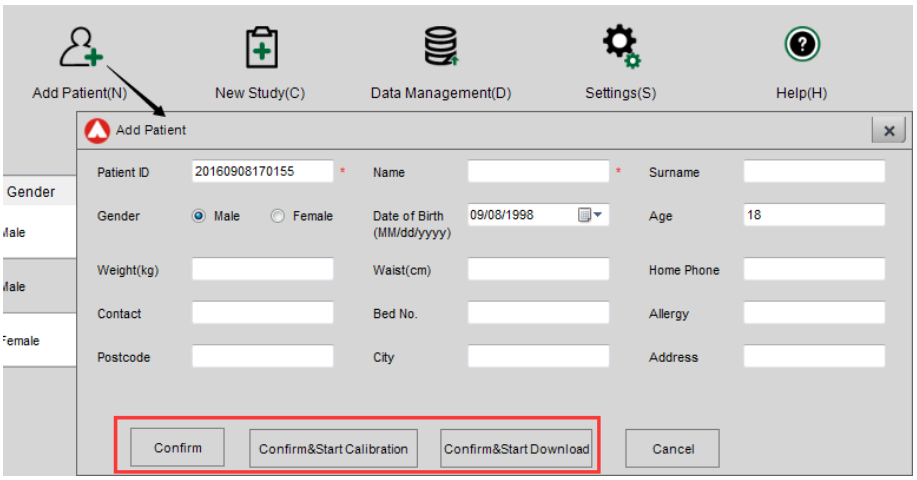
Items	Description
Menu	It shows these function buttons: Add Patient, New Study, Data Management, Settings, and Help.
Patient list	The patient list is presented according to patient ID, name, gender and study date
Tool	It shows these function buttons: Download, Analysts, Edit, Delete.
Search	Search according to keyword or category.
Monitoring	It shows the corresponding monitoring items which one patient can have multiple

Items	Description
list	monitoring items.

1. Patient Administration

Add Patient

- Click Add Patient to enter the Add Patient interface.
- Fill in patient's basic information, items marked with "*" are required information. The patient ID cannot be replicate with the existing patient ID. Patient's age cannot be above 201 years old.
- Click Confirm.



Attention

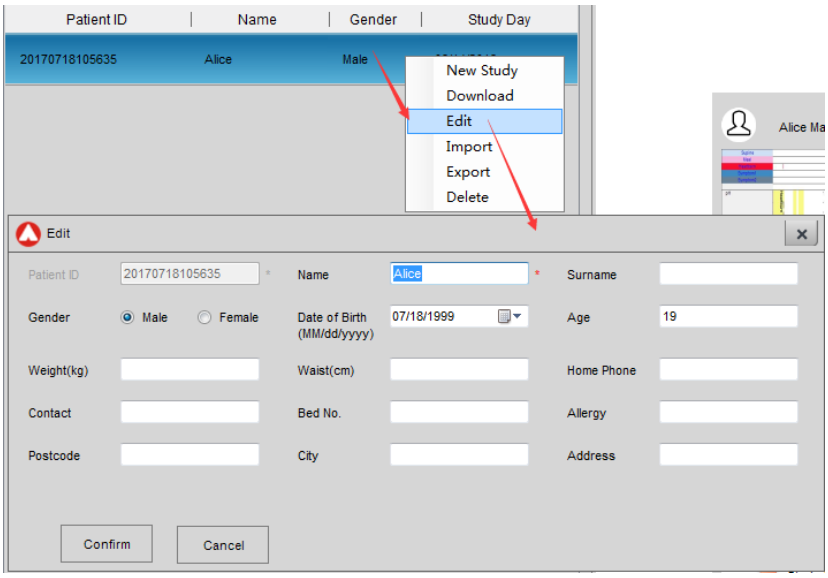
There are three confirmation methods here, please choose carefully:

- Click Confirm (Note: add a patient's basic information).
- Click Click & Start Calibration to enter the calibration procedure (Note: there are two calibration methods, one is calibrating the capsule by data recorder, the other is calibrating by the software. If choose the software to calibrate, please click this button).
- Click Confirm & Start Download (Note: If calibrating the capsule by the recorder, new patient information should be added before clicking this button).

Edit patient information

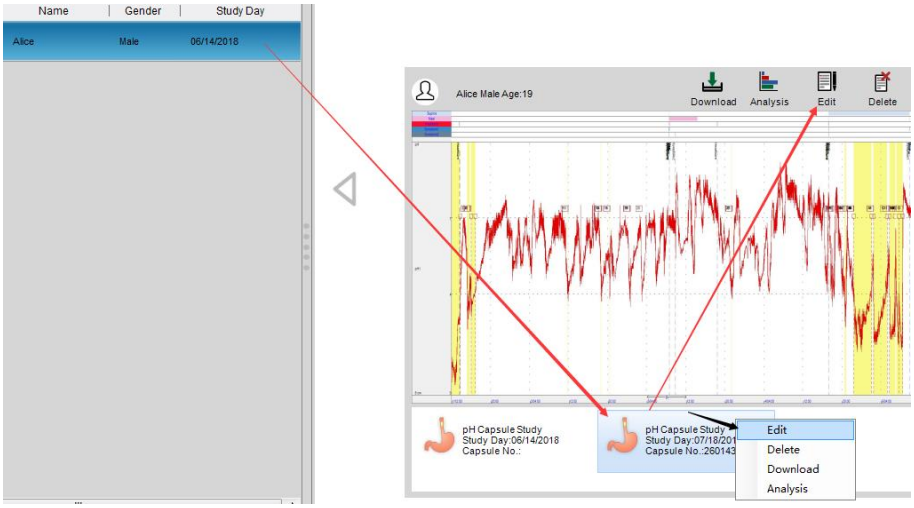
Basic information

- Choose the targeting patient and right click it to choose Edit, then the Edit interface will display.
- Choose the items needed editing (Except for the Patient ID), then modify the patient information.
- Click Confirm.

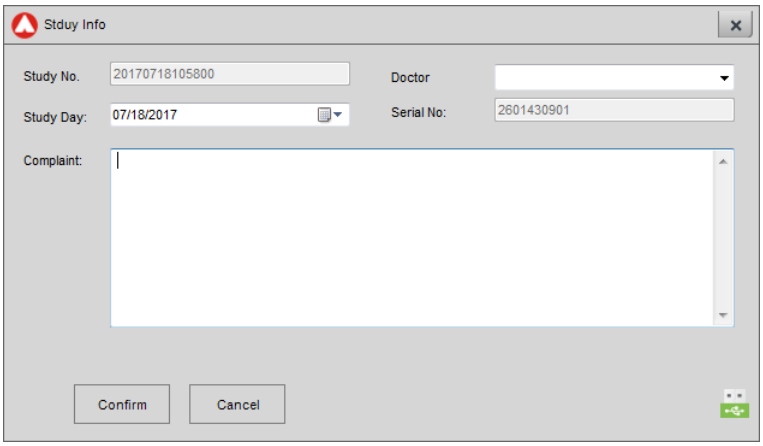


Study Information

- Choose the patient, then choose the patient item, after that, click Edit (or right-click the monitoring item and choose Edit) to enter the Study Infor interface,



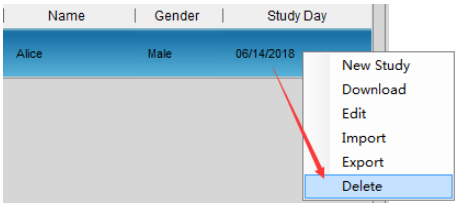
- All the information except for device SN can be edited.
- Click Confirm to save the edition.



Delete patient information.

Delete patient's basic information

- Choose the targeted patient, right click and choose Delete, the notification interface will display.

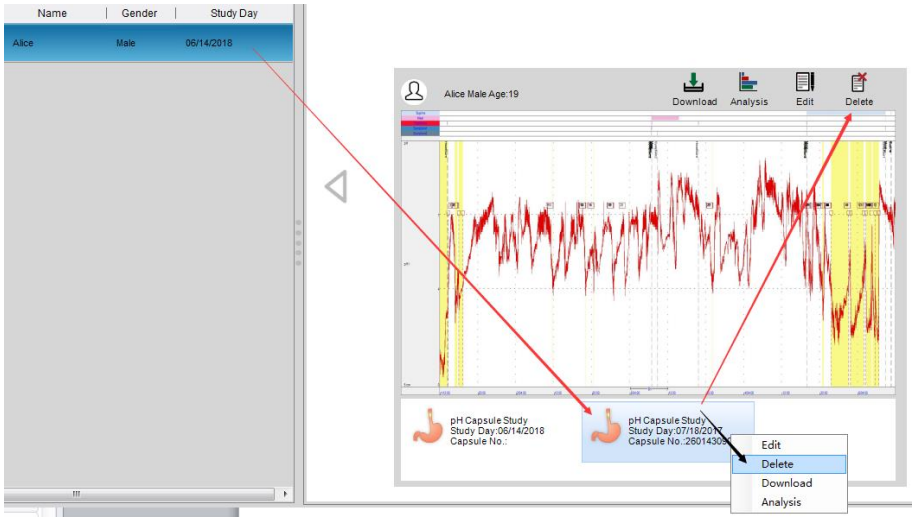


- Make sure you want delete this patient information before you "Confirm to delete patient", once you click OK, the patient's basic information will be deleted (The basic information in the patient list will be deleted, but the original data will be kept).

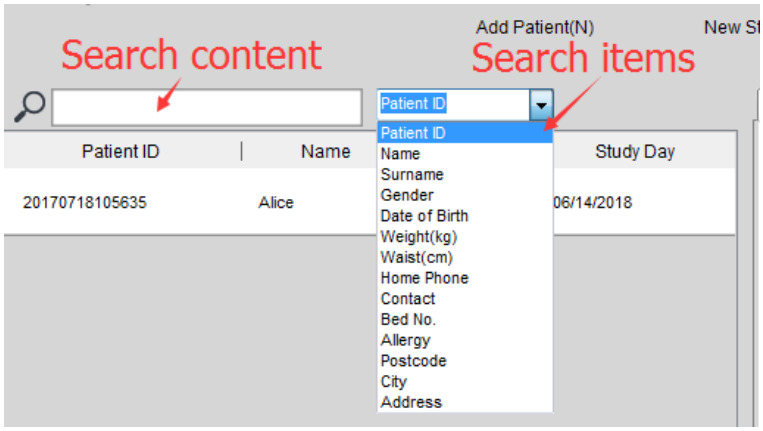
Delete patient's study information

- Choose the targeting patient, then choose the monitoring items, click 

or right click and choose Delete, the notification interference will display..
- Make sure you want delete this patient information before you "Confirm to delete patient", once you click OK, the patient's study information will be deleted (The study information in the patient list will be deleted, but the original data will be kept).



Search patient



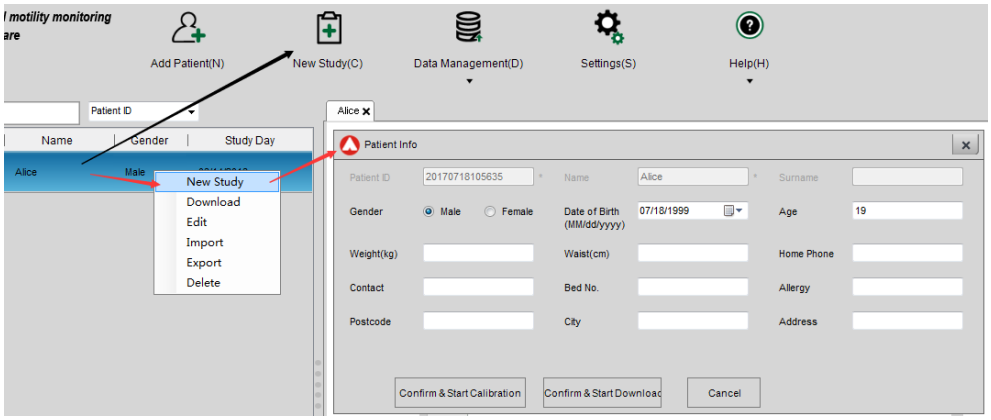
- Choose the searching items.
- Fill in the searching information according to the searching items.
- The searching information will appear in the patient list.

New study

Do a second monitoring for the existing patient.

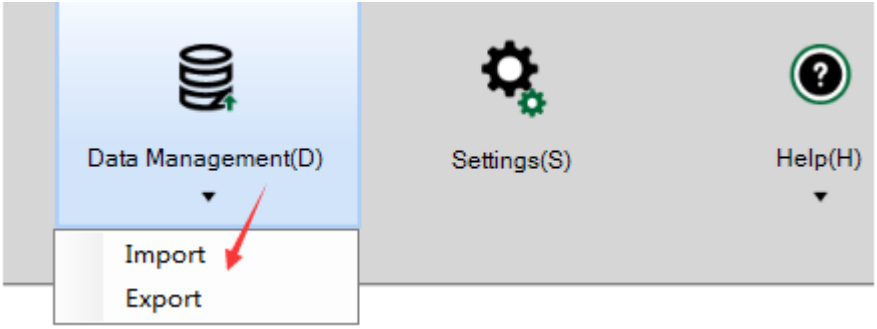
- Choose the targeting patient, click New Study or right click and choose New Study, the Patients Infor will display.
- Fill in patient's basic information, and click Confirm & Start Calibration, then the Study Infor interface will display
- Fill in "Study No., Doctor, Check Date, Complaints and Exam Item", Click Next to enter

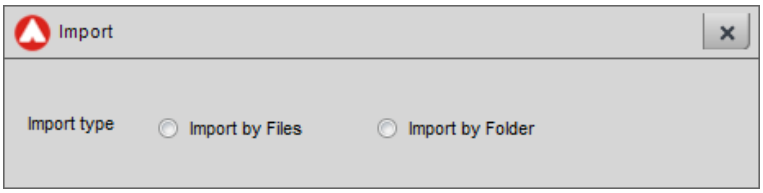
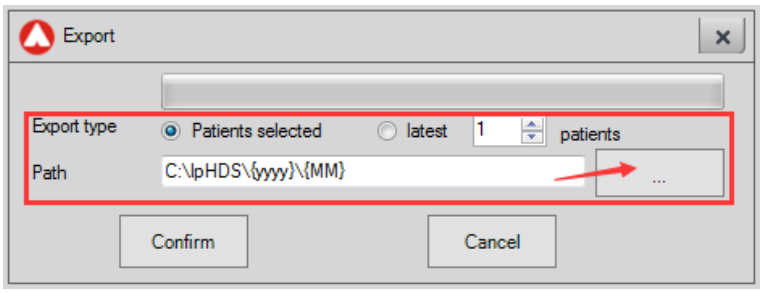
calibration interface, then calibrate the pH capsule according to the notifications.



2. Data Management

By click Data Management to Import and Export data.



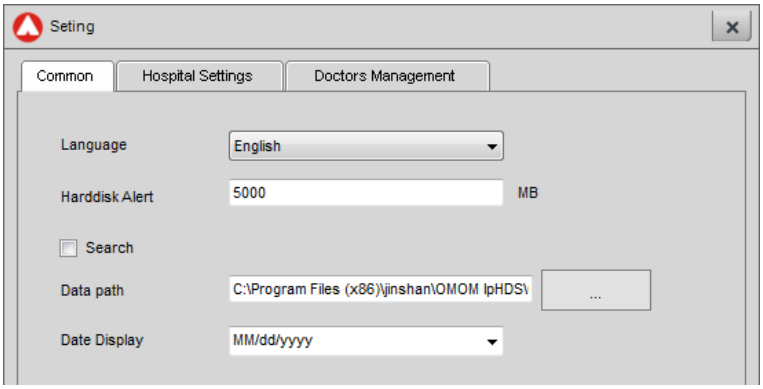
Option	Function
Import	Click Data Management \ Import, to choose **import type**. The importing data will be saved in the default data saving path 
Export	Select patient, and click Data Management \ Export, and choose Export Type and Path 

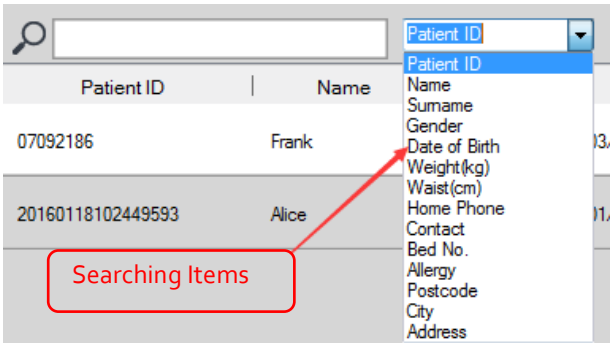
3. Settings

Click **Settings** to enter **Setting Interface**, change Common Settings, Hospital Settings and Doctors Management Settings.

Common Settings

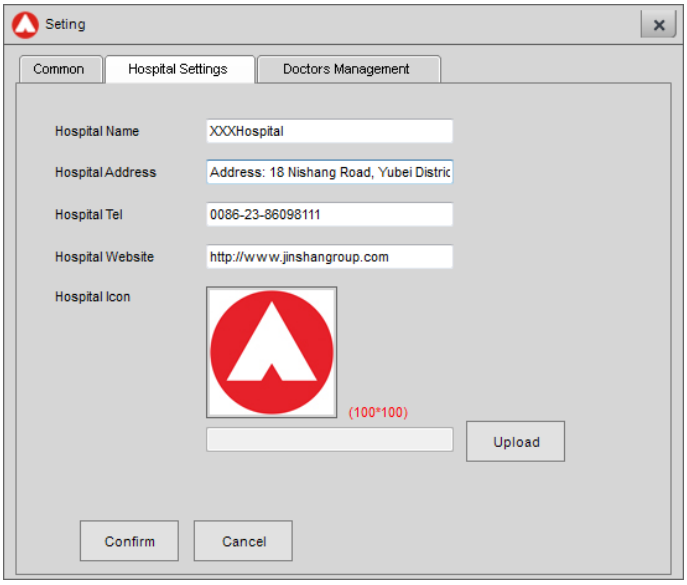
Click **Settings \ Common** to enter interface of Common Settings.



Option	Function
Language	Set the software language(Chinese or English)
Harddisk Alert	Set the Harddisk memory space When the memory space is small than the alerting space, the notification "Memory space is not enough, XXX MB left, please release more space for usage"
Search	Choose  and click Confirm, the menu bar will display searching items 
Saving path	Set the data saving path, the default saving path is C:\Program Files (x86)\jinshan\OMOM IpHDS\OMOMData) Click  to choose new saving path and click **Confirm** to set it
Date Display	Set date display on report and the data analysis workstation.

Hospital Settings

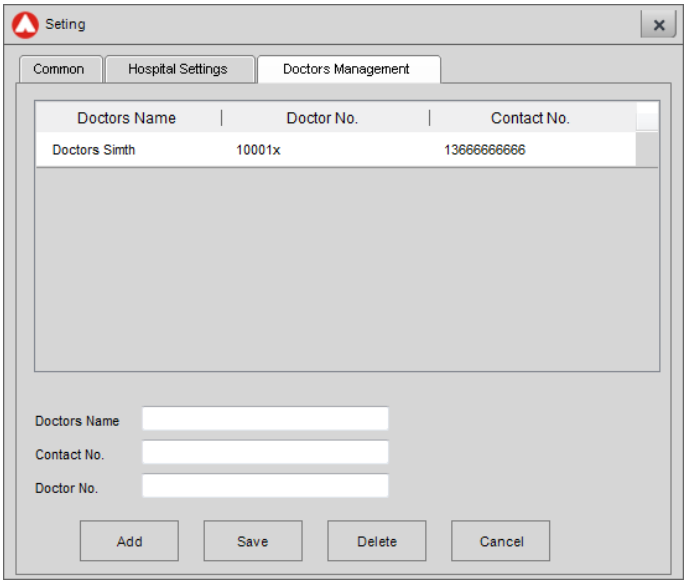
Click **Settings \ Hospital Settings** to enter interface of Hospital Settings.



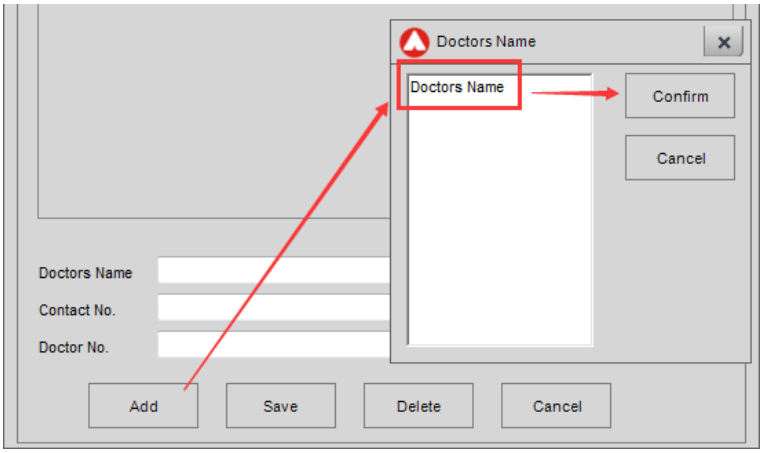
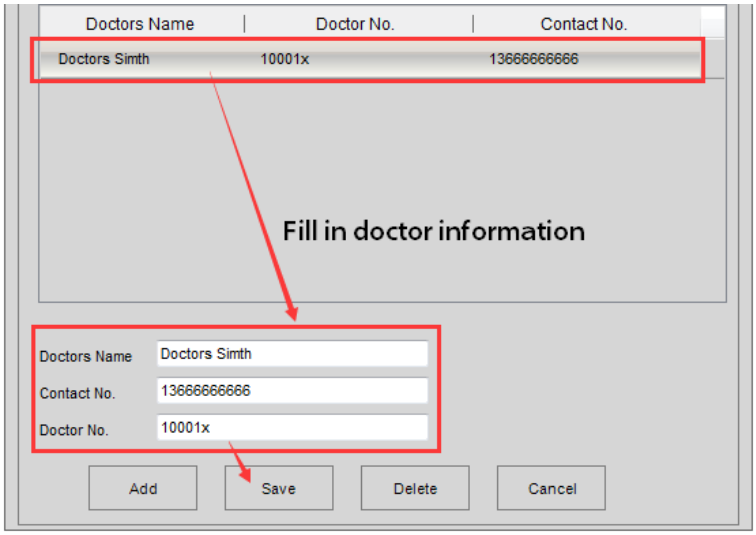
- Hospital name, hospital address, hospital tel, and hospital website can be filled, and hospital icon can be uploaded. The format of image should be JPG, and the pixel should be 100*100.
- Hospital information will show on report at page header.

Doctor management

Click **Settings \ Doctor Management** to enter interface of Doctor Management.



Option	Function

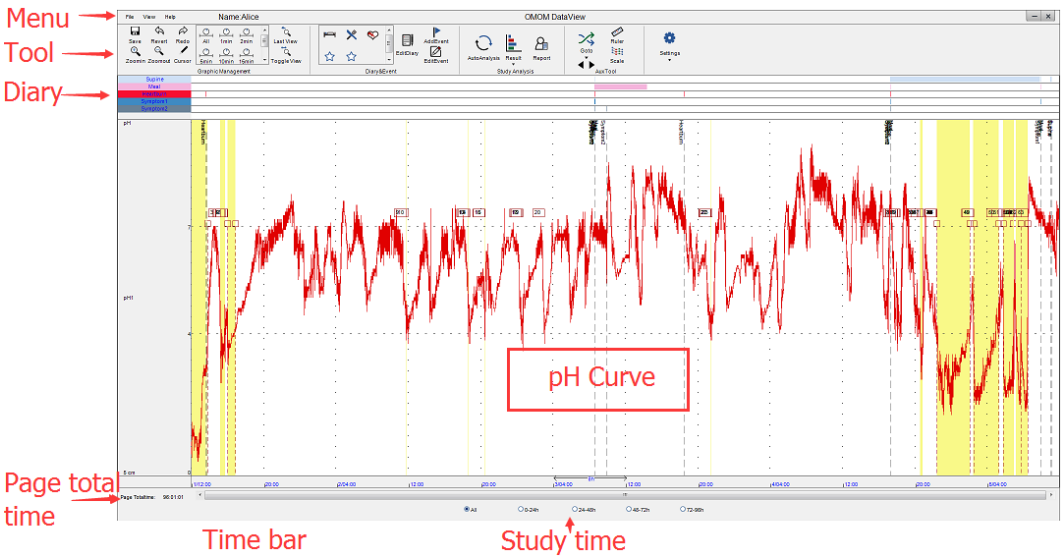
Option	Function
Add new doctor Add new doctor	Click Add to enter interface of doctors name, fill in doctors name and then click confirm 
Add or save doctor contact No. and doctor No.	Select doctor item to modify information Fill in doctor information (name, contact No. and doctor No.) and click **save** 
Delete doctor information	Select Doctor and click delete

4. Help

Name	Description
Help	The Help menu gives help information of the program
About	The About gives Program version, copyright and company information.

OMOM Data View Interface

Select the targeting patient, double click to enter **OMOM Data View Interface** (or select patient, to click analysis to enter OMOM Data View Interface).

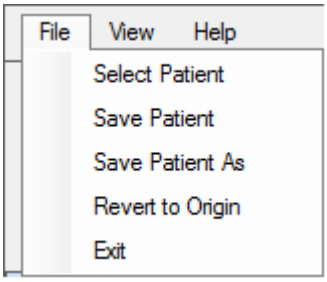


The main functions on the OMOM Data View Interface described as below:

Name	Description
Menu	It displays the file, view and help
Tool	It is consists of graphic management, diary & event, study analysis, aux tool and settings
Diary	It shows study status, such as belch, heartburn, drug, meal, supine, symptom 1 and symptom 2, and user can modify accordingly
pH curve	It shows pH curve
Page total time	It shows total time of default interface
Time bar	Pull, move Time bar to show different page
Screen display time	Quickly adjust the pH curve page display time, there are the following 5 options All 0-24h 24-48h 48-72h 72-96h

1. Patient Data management

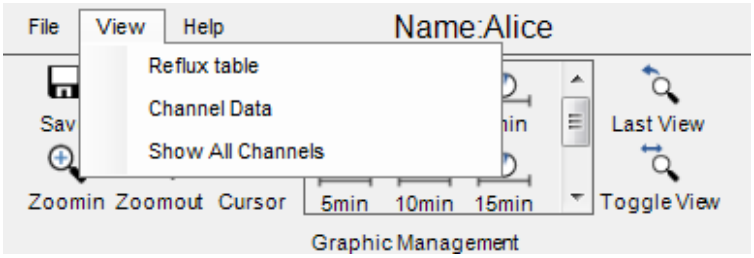
Open File on **OMOM Data View Interface,** its functions described as below:

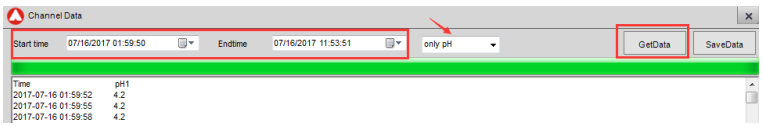


Option	Functions
Select Patient	Choose .PHD file to open a patient data
Save Patient	Save the edition of the patient's data
Save Patient As	Fill in document name, and set the saving path to save patient data
Revert to Origin	The edition will be deleted and the original data base status would be kept
Exit	Exit OMOM Data View Interface

2. View the reflux table and channels data information

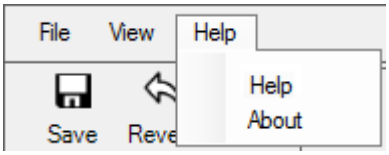
Open the View bar on the **OMOM Data View Interface,** its functions described as below:



Options	Functions
Reflux table	pH Reflux: to view the starting time, end time and duration of each pH reflux
Channel data	Choose Start Time, End Time, only pH, to have impedance value and pH value Duration should less than 12 hour and then click Get data Click Save data to save channel data 

3. Help

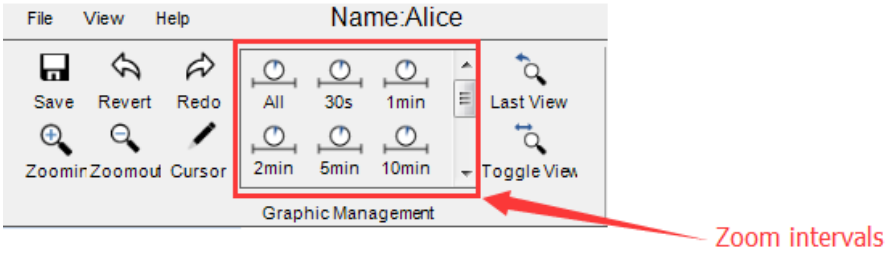
Click **Help** on **OMOM Data View Interface**, its functions described as below:



Option	Function
Help	The Help menu gives help information of the program
About	The About gives Program version, copyright and company information

4. Graphic management

The detailed functions of **Graphic management** on the **OMOM Data View Interface** shows as below:

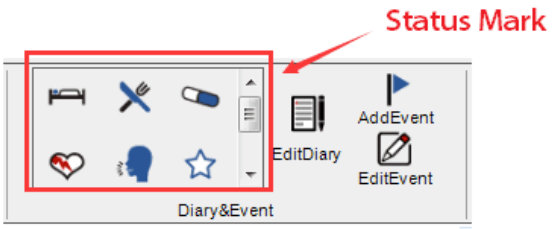


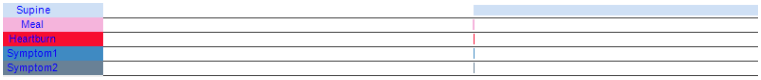
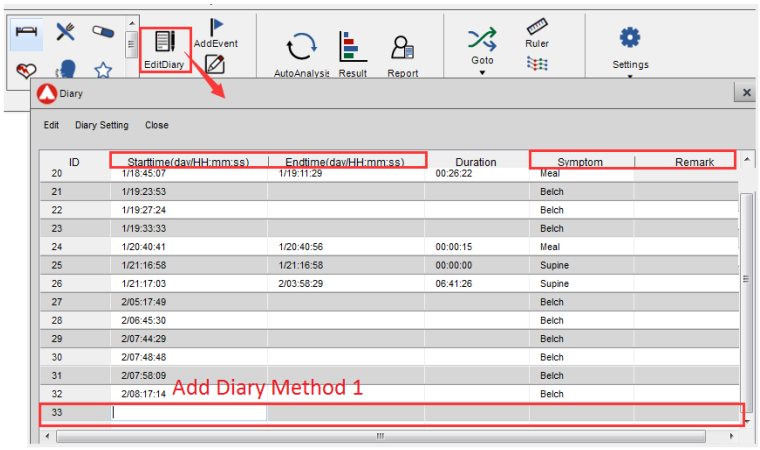
Option	Function
Save	Click **save** to save edited curve
Revert	Click **Revert** to revert last action of data edit
Redo	Click **Redo** to cancel last reverted action
Zoom in	Method 1: Click Zoom in to expand curve of pH curve; Method 2: Click and hold left button of mouse and pull on the right in any part of curve, to expand the curve
Zoom out	Method 1: Click Zoom out to lessen curve of pH curve; Method 2: Click and hold left button of mouse and pull on the left in any part of curve, to lessen the curve
Cursor	Click Cursor, cursor mode appear, red cursor line will show on the interface , choose cursor position and move by mouse The value of pH and impedance will show on left y-axis accordingly
Zoom intervals	Click intervals, choose different mode Different time mode can be choose, from 30s, 1 min, 2 min, 5 min, 15min,

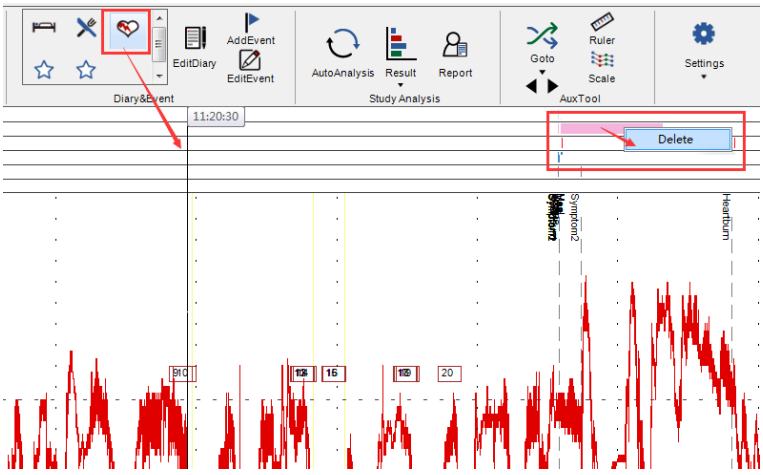
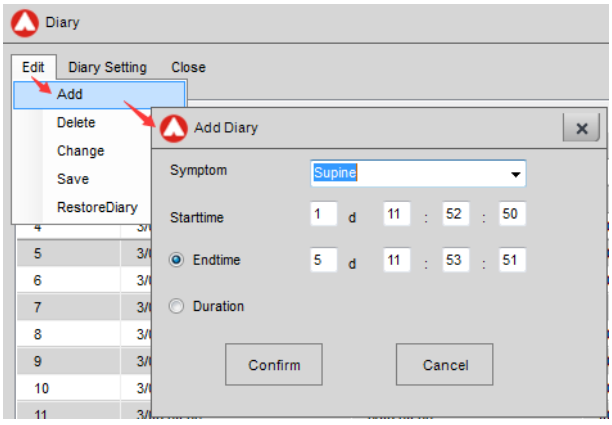
Option	Function
	30min, 4 hr. to all
Last View	Click last view, the interface will shows the last browse interface.
Toggle view	Click toggle view, the interface will switch to recently browse interface.

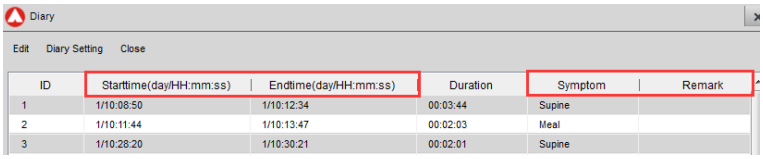
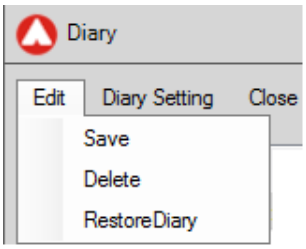
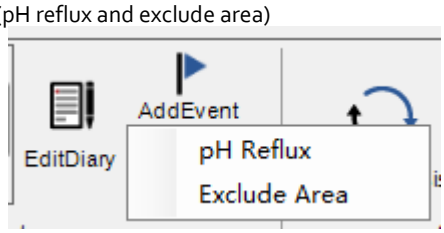
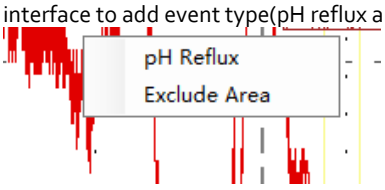
5. Diary & Event

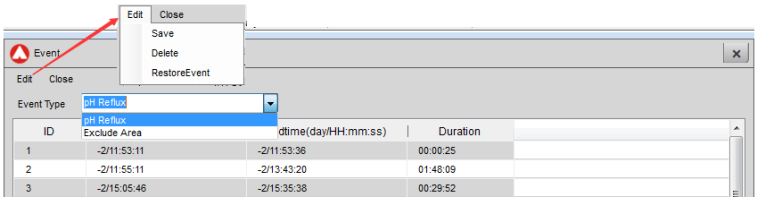
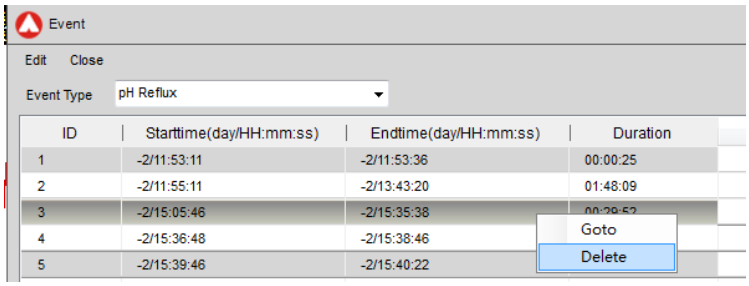
The functions of **Diary & Event** on the **OMOM Data View Interface** shows as below:



Option	Function
Status Mark	Add diary shortcut, see "Adding a diary " for details
Diary status bar	Show status during study, like hiccup, heartburn, drug, meal, supine, and user defined event 
Add Diary	Click "Diary Edit" to enter the "Diary" interface **Method 1:** Select the blank item by double click, fill in the diary data, like start time, end time, symptom and remark.  **Method 2:** Select the status mark, When black cursor appears, click left button on mouse one time to set the start of diary, and left click one more time to set the end of diary.

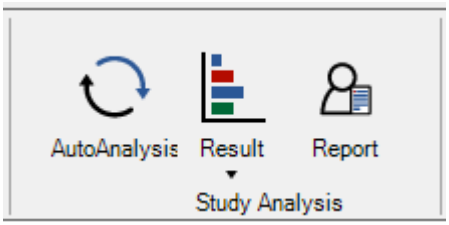
Option	Function
	 Note: Select the diary mark  , right-click, select delete to delete this diary. Note: When you add diary such as "supine, meal", you need to select the starting point and end point; when you add diary such as "heartburn, and belch", you only need to select the starting point. Method 3: Click Edit/Add to create a new diary. Select "Status" from the drop-down menu, enter the start time and end time (or duration), and click "Confirm". Note: When you add a "supine, meal", you need to enter the start time and end time (or duration); when you add other diary such as " heartburn, and belching", you only need to enter the starting time 
Edit Diary	Click Edit Diary, entering diary interface, and user can modify start Time, End Time, Symptom and Remark

Option	Function
	 • Modify: double click the modification item to fill in right data • Save: Click Edit \ Save • Delete: Select diary, click Edit Diary \ Edit \ Delete to delete selected message • Restore diary: Click Edit Diary \ Edit \ Restore Diary and the diary will recover to unedited condition  Diary setting: Click Edit Diary \Diary Setting, popup diary setting interface ; see settings, diary setting
Goto	choose one diary ,right-click, select Goto, the interface will switch to this diary
Add Event	**Method 1:** Click Add Event popup the pull-down menu, choose event type (pH reflux and exclude area)  **Method 2:** Right click any position on curve from pH curve, popup new interface to add event type(pH reflux and exclude area)  When black cursor appears, click left button on mouse one time to set the start of event, and left click one more time to set the end of event Note: You can fine-tune the start and end points of events gradually
Edit Event	Click Edit Event to popup interface of event edit

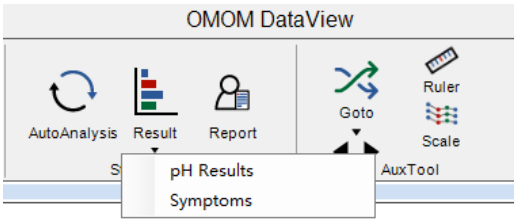
Option	Function
	 • Save: Click edit \ save • Delete: Method 1: Select event, and click Edit Event\Edit \ Delete selected event. Method 2: Select event, and right-click, select Delete to delete this reflux.  • Restore diary: Select diary, click Edit \ Restore Diary and the diary will recover to unedited condition • Event type: Click Event Type through pull-down menu, choose event type (pH Reflux and Exclude Area) to set event type • Edit: a. pH reflux, to edit and modify start time and end time b. Exclude area, to edit, and modify start and end time

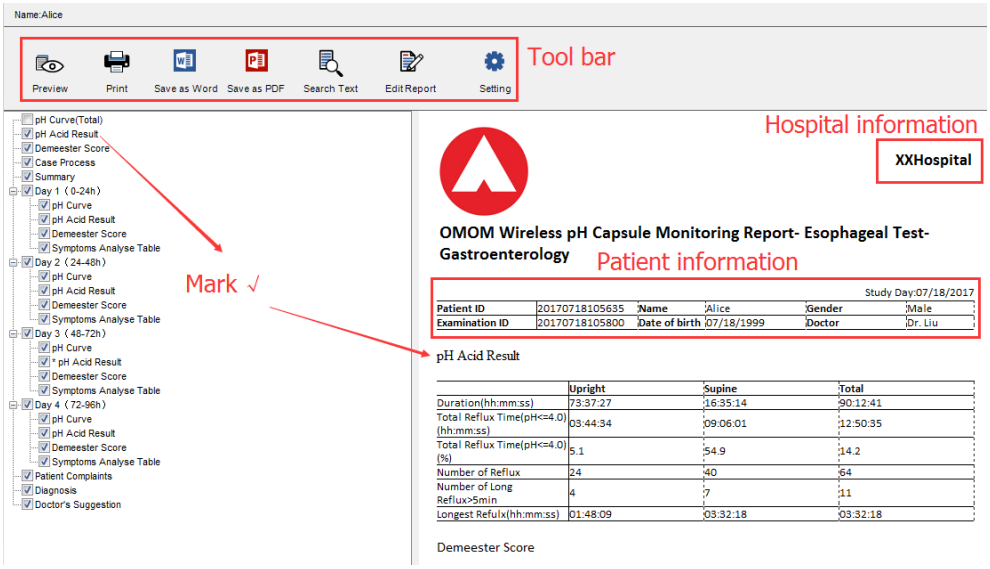
6. Study Analysis

Data analysis function on the **OMOM Data View Interface** shows as below:



Option	Function
AutoAnalysis	Click AutoAnalysis, the program will analyze the curve data automatically

Option	Function
	If user click AutoAnalysis again after data been edited, popup note that AutoAnalysis will cover the edited reflux, if continue, to click yes to restore the data to unedited condition
Result	Click Result, choose result type for result interface accordingly Result type: pH results and symptoms 
Report	Click report to enter report system, see figure 4.21 • Select print contents • Preview: click Preview to preview print contents • Print: click Print to print report • Save as Word: click Save as Word can save the report word form • Save as PDF: click Save as PDF can save the report PDF form Note:Does not support the software of Microsoft Office 2003 • Search Text: click Search Text, popup search interface , to fill in key words for searching • Edit report: click Edit Report to popup edit report interface , and to edit findings, conclusion, suggestions, memo, saving by click confirm



7. Aux Tool

Aux Tool function on the **OMOM Data View Interface** shows as below:

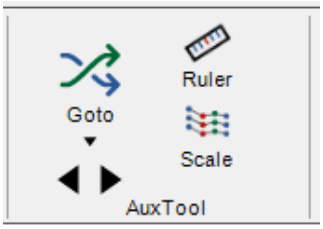
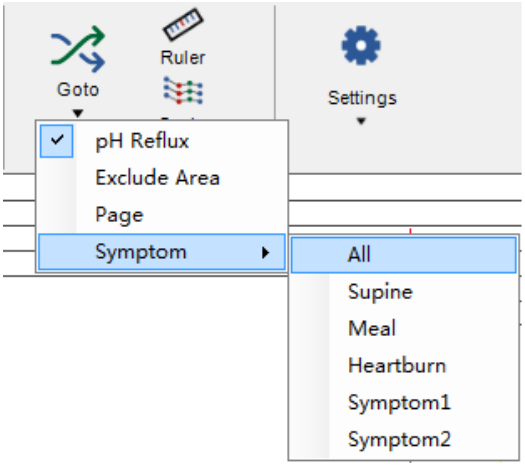
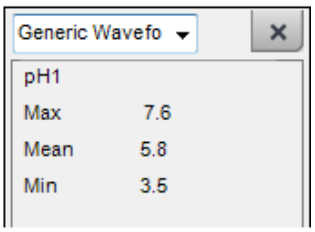
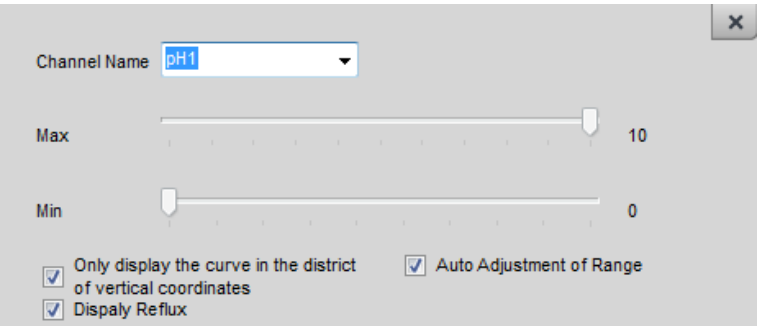


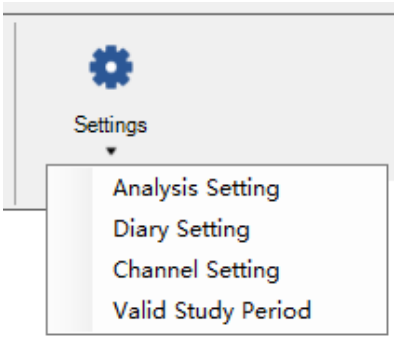
Figure4. 1 Aux tool

Option	Function
Goto	Click **Goto**, click reflux type from pull-down menu (pH Reflux, Exclude Area Page and symptom), for example, to select pH Reflux to review pH Reflux 
Goto reflux	Click ◀ or ▶ to view all the reflux one by one Click ◀ means view on the left, ▶ means view on the right; The shortcut key ← or → with same functions
Ruler	Click **Ruler**, choose selected area, the max, mean, min value of pH channel will show accordingly 
scale	Max: pull to set the maximum value in this channel Min: Pull to set the minimum value in this channel

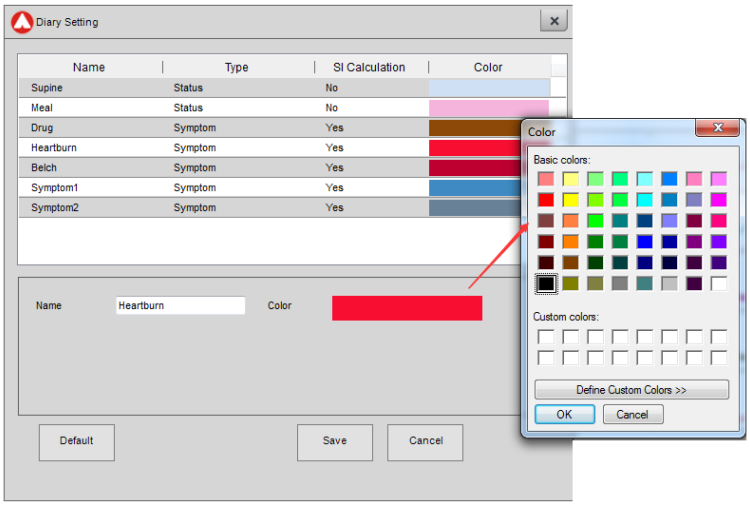
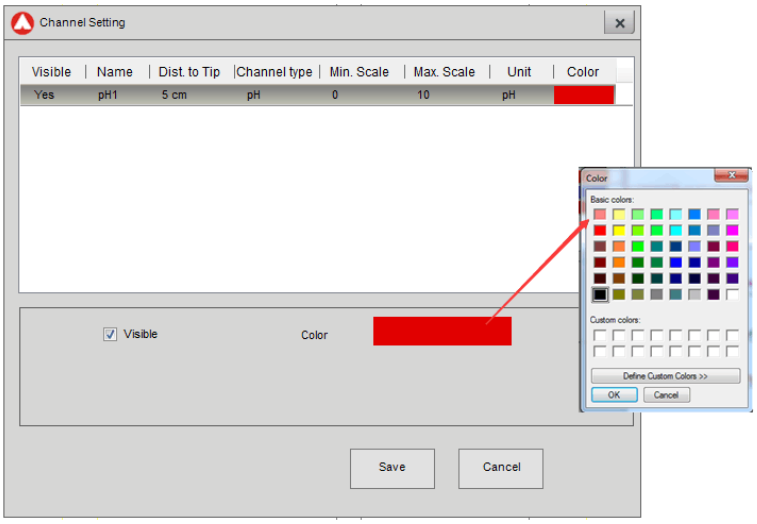
Option	Function
	Check box: • Only display the curve in the district of vertical coordinates • Auto adjustment of range (When selected, allchannel scale cannot be adjusted, and Max and Min value tool cannot be chose) • Display reflux (When selected, curve reflux will highlighted by yellow) 

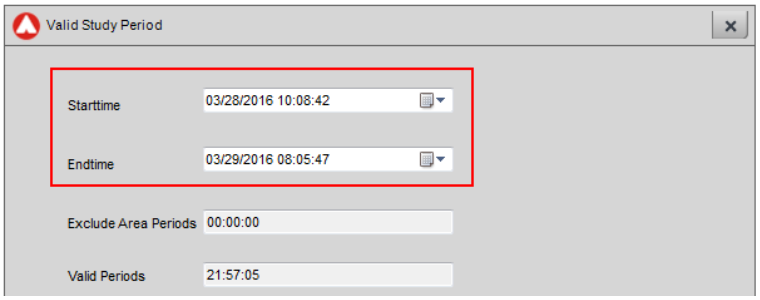
8. Settings

Settings function on **the OMOM Data View Interface** shows as below:



Option	Function
Analysis setting	Setup of pH offset: Set offset for pH 1.07,pH 4.0 and pH7.01 Setup of pH reflux: Set reflux Initial value, end value, Min. reflux duration, and long reflux duration Setup of Auto Analysis • exclude meal periods • include meal periods
Diary setting	The default status are,Supine, Meal, Drug, Heartburn, Belch, Symptom1 and Symptom2. select any status, like ***Heartburn***, find the modification items, for example, name or color to save • Default: Click default, to make diary the original status

Option	Function
	• Save: After modification, click **Save** Note: "supine and meal" status' name can 't be modified but can change the colur. 
Channel setting	Visibility and color of curve can be set. 
Valid study period	Start time and end time can be set according to clinical requirement.

Option	Function
	

Chapter 5: Trouble Shooting

Trouble shooting of pH Capsule

Faults	Causes &Solutions
Capsule indication light does not flash	Capsule over dated，change a capsule
Calibration failed	• False capsule serial number, reentering serial number • Calibration solution failure, renew solutions to restart calibration • Capsule over dated，change a capsule
Capsulefixation failed	• Capsule clamping arm closed, change a capsule • Fixing position failure, measure the fixing position according to the instructions • Low pressure, keep the pressure at 0.08MPa(600mmHg), and maintain for 10 seconds

Trouble shooting of Data recorder

Faults	Causes &Solutions
No response after power on the recorder	• Recorder failure, change a recorder • Batteries failure, check whether the batteries are correctly installed • Batteries used up, renew batteries
Recorder shuts down immediately after turning on	Batteries used up, renew battery
Recorder immediately cuts electricity supply	
Unstable signal receiving	• Interfered by other magnetic field, please keep distance from magnetic field • The distance between the capsule and the recorder is too far, keep them within 3 meters

Faults	Causes &Solutions
	• The capsule is already removed from the body through excretion, and the examination is over

Trouble shooting of Computer Interface

Fault	Causes &Solution
The computer and the recorder cannot communicate	• Recorder driver failure, uninstall and reinstall • USB Cable failure, change USB cable • Restart the computer
After connecting the recorder with the computer, it keeps pop up 'found new hardware' window	• Driver failure, re-install the recorder driver • USB port failure, change USB port • Restart the computer

Chapter 6: Maintenance

pH Capsule

- Store in a place free from radiation and pollution and controlled at 5 ℃ ~45 ℃ and 80%RH.
- Keep far away from magnetic field and maintain the outer package intake during storage.
- Keep out of reach of children.
- Use immediately after unpacking, if it is not used immediated after unpacking, it shall be disinfected before reuse.
- Do not use it when the validity of 14 months expires.

Data Recorder

- Store in a dry place free from pollution and controlled at 5 ℃~45 ℃and 80%RH.
- Ensure it is powered off before storage and take the batteries out if it will not be used for a long period of time.
- Do not put it near hot object or in fire and keep it far away from combustion source during operation or storage.
- Prevent water or other liquid from leaking in it during operation or storage.
- Sterilize the external surface regularly with 75% alcohol.

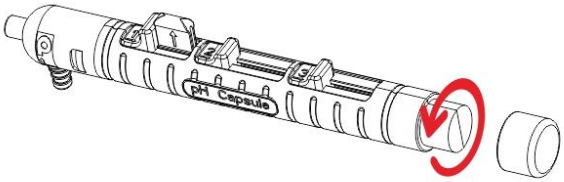
Data Analysis Workstation

- Protect against dust, dampness and electrostatic interference.
- Monitor system environment to be controlled at 0℃~50℃ and below 80% RH.
- Do not disassemble or repair the system without permission from relevant personnel and timely contact our after-sales engineer for help in case of system failure.
- Avoid squeezing, colliding or dropping of system parts.
- Computer hosting the data analysis software is supplied by 220 V AC power source by default. Please change setting in line with local AC voltage rating in countries other than China (refer to Computer Operation Manual for setting).
- Data analysis workstation is specially designed for the pH Capsule System. Do not use the software/hardware for purposes other than the intended ones otherwise free door-to-door service for computer failure will be invalidated.
- Refer to Computer Operation Manual for more information about protection measures.

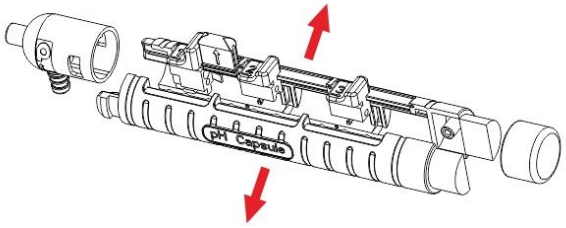
Appendix A: Handling procedure for the conveyor

Handling procedure for the conveyor cannot be taken out after the capsule fixation.

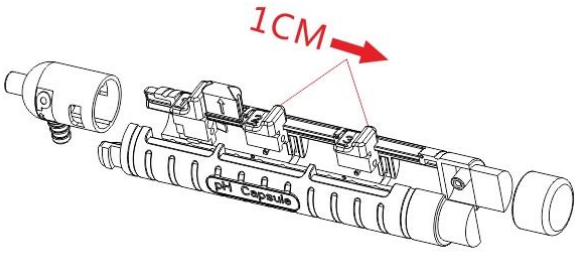
a. Disassemble the device by unscrewing the end handle , illustrated as follows:



b. Pull apart two half of the handle casing, illustrated as follows:



c. Withdraw the second and third buckle to the end with a minimum of t 1cm, illustrated as follows:



This will release the capsule and allow the removal of the catheter.

Appendix B: Recorder Functions

Alerts

The recorder buzzer beeps once with related message displayed on the screen for misoperation or abnormal situation, as shown in Table.

Screen backlight is on and displays…	**Description**
No capsule	Not receive capsule signal
Low Battery Voltage	Low Voltage Alarm
Overwritten	Built-in storage is overwritten
End of the study	Warning of end of the study
Buffer Solution Order Error	Buffer Solution Order Error
Recalibrate	No Calibration Data
Memory Self-Test Fails	Hardware self-test fails; exchange for a new recorder
Clock Chip Self-Test Fails	Reset the time of recorder

Calibration with Recorder

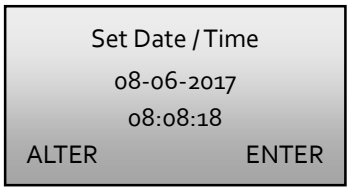
pH calibration can be completed with the recorder as follows.

1. Turn on Recorder

- Install a new battery.
- Press + at the same time, until the screen showing "please ensure the battery is enough to study!." Press to confirm and enter the next step
- The screen showing "Confirm to delate the last study and start a new study", press to confirm

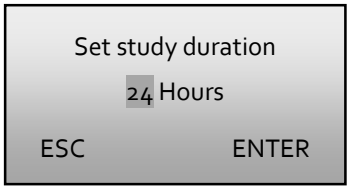
2. Set Date / Time

Press to date/time setting interface. Press to increase value, and press to decrease value, by pressing to entering next step.



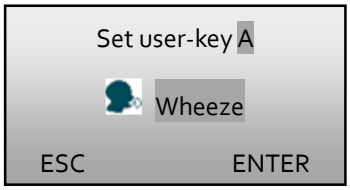
3. Set study duration

Study duration setting mode will follow date/time setting mode. Press or to select study duration(24h or 48hor 72hor96h), by pressing to entering next step.



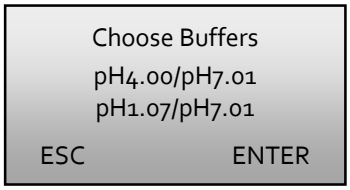
4. Set user-key A and B

User-key A and B setting mode will follow study duration setting mode. Press or to select status (cough **or** wheeze **or** laryngospasm **or** chest pain or belching), by pressing to entering next step.



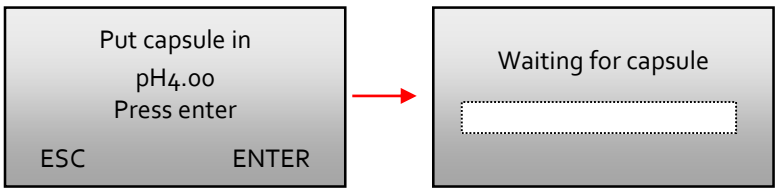
5. Choose Buffers

Entering interface of buffer solution choose (pH4.00/pH7.01 or pH1.07/pH7.01). Press to go back, and press or to choose and press for confirmation. **For example, we choose pH4.00/pH7.01.**



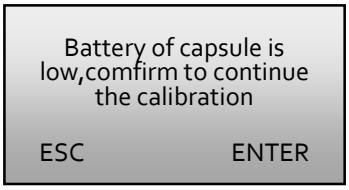
6. Presoak

The screen shows "Waiting for capsule", After about 1min, the screen shows the serial number of the capsule that has been found, checking whether SN is correct. If correct, press to start to soak, whereas, press to research.



Attention

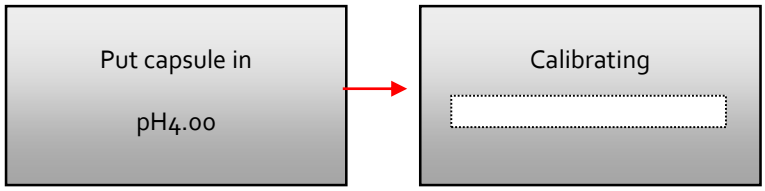
If the battery of capsule is low, the screen of recorder will display:



If the capsule already finished presoaking (4 min), press  to pass and the screen shows "Skip only if capsule was soaked in advance", press  to confirm and press  to go back.

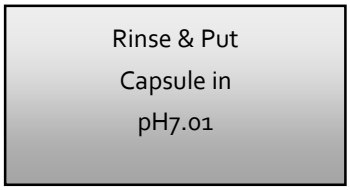
7. Calibrate with pH 4.0

After presoaking, the screen shows "Put capsule in pH4.00", to press  to confirm, and the screen shows "Calibrating , pH4.00" .



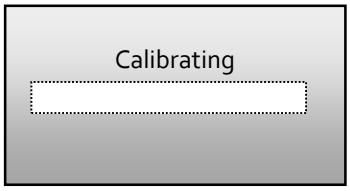
8. Rise pH capsule

After calibration with pH 4.0, the screen shows "Rinse & Put capsule in pH7.01", to rinse capsule in clean water and dry the pH capsule.



9. Calibration with pH 7.01

After capsule cleaned, put capsule into buffer solution pH 7.01, and press  to confirm, and the screen shows "Calibrating , pH7.01"

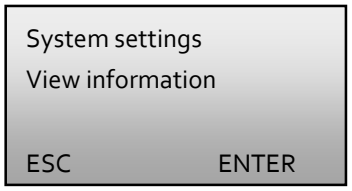


10. Start Recording

After calibration with buffer solution 7.01, the screen shows "Calibrated, Press Enter to start Recording".

Attention

a. Press  to set system Language ,warning tone, backlight duration and view information, the recorder displays as follow:



b. Press  or to choose System settings or View information.

- System settings：User can set the Language., warning tone, backlight duration
- View information：User can view the capsule's SN , the recording voltage and the capsule voltage

Appendix C: PARAMETERS

Main Parameters (pH Capsule)

- Dimension

  L: 26.5mm±1.0mm

  W: 6.0mm±0.4mm

  H: 5.5mm±0.4mm
- Weight: ≤2g
- Effective working time: ≥96 h
- Data acquisition frequency: 0.33Hz
- Effective communication distance: ≥12m (without obstruction in the air)
- pH measurement range: 1~9
- pH measurement accuracy

  Acidity: ±0.5

  Alkalinity: ±1

Main Technical Parameters (Conveyor)

- Weight: ≤100g
- Dimensions of duct

  Diameter: 3.2mm±0.6 mm

  Length: 770mm±20 mm
- Dimensions of releasing device

  Length of guiding head: 35mm±3 mm

  Length of hard connection: 31mm±3mm

  Length of soft connection: 31mm±3mm

Main Technical Parameters (Data Recorder)

- Dimension: 125mm*78.6mm*26.5mm
- Weight: ≤300g
- Working voltage: 4.5VDC
- Communication distance: ≤12m (No obstruction in the air)

- Working temperature: 5℃ ~ 40℃

Main Parameters (pH Calibration &Tube)

- Use/Store temperature buffer solution: 5℃ ~ 30℃.
- Accuracy buffer solution: ±0.05.
- Tube size: Φ18x140mm.
- Tube capacity: 20ml.

Appendix D: Electro Magnetic Compatibility

The pH Capsule System needs special precautions regarding to EMC (Electro Magnetic Compatibility) and it needs to be installed and put it into service according to the EMC information provided in this manual.

Table 1: Guidance and manufacturer's declaration -electromagnetic emissions

The model JSPH-3 is intended for use in the electromagnetic environment specified below. The customer or the user of the model JSPH-3 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR 11	Group 1	The model JSPH-3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model JSPH-3 is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2: Recommended separation distances between portable and mobile RF communications equipment and the model JSPH-3

The model JSPH-3 is intended to be used in the electromagnetical environment in which radiated RF disturbances is controlled. The customer or the user of the model JSPH-3 can prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the model JSPH-3 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter(W)	power 80MHz to of transmitter(m)		
	150kHz to 80MHz d=1.21/2	80MHzto800MHz d=1.2×P1/2	800MHz to 2,5GHz d=2.3×P1/2
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 rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer. NOTE l At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Table 3: Guidance & Declaration -electromagnetic immunity

The model JSPH-3 is intended for use in the electromagnetic environment specified below. The customer or the user of the model JSPH-3 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±1kV for Input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line to line ±2kV line to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model JSPH-3 requires continued operation during power mains interruptions, it is recommended that the model JSPH-3 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	Not applicable	Not applicable

NOTE UT is the a.c. mains voltage prior to application of the test level.

Table 4: Guidance & Declaration -electromagnetic immunity concerning Conducted RF & Radiated RF

The model JSPH-3 is intended for use in the electromagnetic environment specified below. The customer or the user of the model JSPH-3 should assure that it is used in such an environment.

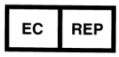
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF lEC 61000-4-6 Radiated RF lEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model JSPH-3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 3V d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. b Interference may occur In the vicinity of equipment marked with the following symbol:

NOTE I At 80 MHz end 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model JSPH-3 is used exceeds the applicable RF compliance level above, the model JSPH-3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model JSPH-3. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Appendix E: Labels

Signs in the Packaging and Product

	SINGLE USE ONLY		EXPIRATION DATE
	STERILIZED BY USING ETHYLENE OXIDE		BATCH CODE
IPX8	INGRESS PROTECTION		ECO-FRIENDLY AND RECYCLING
	CAUTION		TYPE BF APPLIED PART
	SERIAL NUMBER		FRAGILE
	KEEP DRY		CATALOGUE NUMBER
	DO NOT USE IF PACKAGE IS DAMAGED		THIS WAY UP
	MANUFACTURE		DATE OF MANUFACTURE
	CONSULT INSTRUCTIONS FOR USE		CE MARK
	STACKING LIMIT BY NUMBER		DO NOT ROLL
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

Chongqing Jinshan Science & Technology (Group) Co., Ltd.

Address	No.18, Nishang Road, LiangLu Industrial City, 401120 Yubei District, Chongqing, China.
Tel	0086-23-86098099
Website	http://english.jinshangroup.com
E-mail	international@jinshangroup.com
EC REP	Wellkang Ltd. Suite B, 29 Harley Street, London W1G 9QR, England, United Kindom