

Công ty TNHH Trung Nhân

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

HƯỚNG DẪN SỬ DỤNG
MÁY PHÂN TÍCH SINH HÓA
MODEL: NEPHSTAR, NEPHSTAR PLUS

Người đại diện hợp pháp của cơ sở
Ký tên (Ghi họ tên đầy đủ, chức danh)

GIÁM ĐỐC



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Nephstar™

Instruction Manual



Goldsite Diagnostic Inc.

NS001

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1. Caution

1). The **NEPHSTAR** contains no components that can be replaced by the user except for the fuses.

Do not tamper with the warranty seals on both side of the instrument.

Refer to the Trouble-Shooting guide (Section 10) if the NEPHSTAR does not function correctly. If it is still impossible to trace the fault, contact the supplier.

2). Reagents of different catalogue number can not be mixed used.

3). Avoid spillage of liquids over the case.

4). This product should be only used by trained persons. Adherence to the given procedure is recommended. Standard laboratory practice should be followed to ensure safety while handling potentially infectious agents.

5). Power supply voltage operation range is $220 \pm 10\%$.

6). The temperature of working condition should be 15 -30 . Relative humidity is less than 85%,altitude is less than 3500m

7). The storage temperature should be -5~40; relative humidity should be less than 85%,altitude should be less than 3500m.

8). The precision of the assays performed will be depended upon the use of well maintained, calibrated pipettes.

9). Goldsite Diagnostics NEPHSTAR cuvettes are designed for single use only. Re-use will lead to false results. The used cuvette should be regarded has the potential of

infectivity, please dispose it according to standard laboratory instruction to ensure safety.

10). If this NEPHSTAR is not used in accordance with the operating conditions and instructions, electric protection system may be impaired.

11). Do not put NEPHSTAR in places where the power supply is hard to cut off if any dangerousness existed

2. Intended Use

For *in vitro* diagnostic use.

Nephstar is an endpoint nephelometer that uses the measurement of light scattered by antibody/antigen reaction to determine protein concentrations.

The light source is a diode laser that emits at 670nm. The focused light passes through a cuvette containing the reaction mixture, where antibody/antigen complexes cause light to be scattered. This scatter is proportional to the amount of antibody/antigen complexes that have formed, and is detected by a photodiode.

For each assay, a scatter reading is taken at the beginning of the antibody /antigen reaction (blank or 1 reading), followed by a second scatter reading at a fixed time. The analyte concentration is calculated using the difference between these two readings.

NEPHSTAR is intended for use in determine specific protein concentrations in body fluids using the principle of nephelometry.

3. The Main Parameters

Working mode: continuous working

Service life:5 years

Measurement Method: Fix-time nephelometry

Light Source: Diode laser (670nm class)

Ambient Operating Temperature: 15-30

Input: pre-programmed magnetic card and 16 key membrane keypad.

Output: 24 x 24 LCD screen

Thermal printer:

Thermal paper roll: width---- 56 ± 0.5 mm

thickness----53 - 60g/m

Characters:

(ANK character set): 12 x 24 dot, 1.25(width) x 3.00(height) mm

(International Chinese character): 24 x 24 dot, 4.00(width) x 5.00(height) mm

Dimensions:

Width: 270mm

Depth: 288mm

Height: 130mm

Weight: 2.9kg

Power supply: 220V \pm 10% AC 50Hz \pm 1Hz 45VA

Cuvette: only for NEPHSTAR use cuvette

Waterproof level: IPX0

All the print paper, cuvette and reagents are provided by the suppliers.

4. Outward Picture of NEPHSTAR Analyzer

Fig 1 Upper View



Printer - thermal

LCD display - matrix LCD display. Displays results and instructions for the user.

NUMLOCK Guiding light-The guiding light lights when press NUMLOCK key

Input keyboard - for the input of number and character

Dust prevention cover

Cuvette

Cuvetter chamber - for positioning of the reaction cuvette during assay.

Swipe Card Reader - for the input of curve parameters into the NEPHSTAR

Fig 2 Rear View



RS232 interface – for connection to the NEPHSTAR using the plug cap or serial wire and the transferring of the assay results data from NEPHSTAR to computer

Power On/Off switch

Fuse – 250V 4A

Power Supply Cable Jack

Printer

5. Installation

EQUIPMENT SUPPLIED AS BELLOW:

1 x NEPHSTAR
Fuses: 5 x 1A
1 x Operating Manual
1 x Electronic Pipette (optional)
1 x Pipette Charging Stand (optional)
1 x Forceps

Read these instructions carefully before use.

When unpacking the NEPHSTAR check that all of the components listed are included and check visually for damage caused during the shipment. Report any damage immediately to the supplier.

The NEPHSTAR should be used in a clean environment as dust contamination can lead to false results.

Stand the NEPHSTAR on a solid, level surface avoiding direct sunlight, dust contamination and heat sources.

Before connecting the NEPHSTAR to a power supply make sure that the voltage is as below range: a.c.220V \pm 10%.

Connect the NEPHSTAT to the power supply and switch on, using the power on/off switch.

The NEPHSTAR has been designed for use in a laboratory temperature range of 15-30 . Accuracy of results cannot be guaranteed when used outside this range.

Electronic pipette and relative reagents (optional)

They all have passed CE standard. For more details please refer to the instructions for both of them.

Stand the pipette charging stand on a solid, level surface and fix the electronic pipette on it. Before first use, the electronic pipette should be charged at least for 12 hours.





Refer to the use instruction of electronic pipette, see appendix: Using the Electronic Pipette

Note:1. Each instrument has a CD attached to instruct the installation



2. For the computer, the data transferring assistant, it is not supplied by the supplier. It only can be used under bellow requirement:
 - a. The computer must meet requirements of local law.
 - b. The Computer and Nephstar can not be powered by the same multi-socket.

6. Set Up



This mode is used when first installing the NEPHSTAR and allows the operator to configure the following parameters: Date format; Date; Time; Audible alarm; User's name.

- 1). Switch NEPHSTAR on.
- 2). Press 
- 3). Press 
- 4). Set up date format, date and time by instruction. Press numeric keys to recompose,  to confirm and  to skip the set up.
- 5) Audible alarm: If the audible alarm is switched on, the operator message will be accompanied by a beeping alarm during the operation or after it when there are mistakes in wrong key-press.
- 6). Setting up user's name: The user can set up his name, or press ENTER if you want to skip it.

Input number by pressing numeric keys.

Input character by pressing  first, then characters are available when  lights.

Hold the character key and different characters can be switched; release it when the needed character is appeared.

During the whole set up, press  if there is any input error, and press , it will come back to step 2)

7. Magnetic Card Mode




This mode employs reagents that have been optimized for use on the NEPHSTAR. Users do not need to do the calibration curve; related parameters are stored in the magnetic card supplied with the reagents pack.

Parameters are loaded by passing the swipe card through the swipe card reader, in a straight line from the front of the instruments to the rear.

The card must be passed with the magnetic strip at the bottom and facing left.

Loaded parameters are stored in the memory for future use so that if the same lot or reagents is used again, the parameters do not need to be re-entered. If a different lot of reagent is used, the previous parameters are overwritten when new details are entered from the swipe card.

The default mode is magnetic card mode when NEPHSTAR is switch on.

- 1). Switch NEPHSTAR on
- 2). Enter Chemistry number. Press the appropriate numeric key(s) for the assay required, as shown on the swipe card and press  if confirmed. If you are running a new assay, you will be asked to swipe the magnetic calibration card.
- 3). The assay name and lot of reagent are displayed. Check carefully; press  if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.
- 4). Sample ID. The default number is 1. Press number keys to enter the sample ID; or press  accept currently displayed sample ID.

5). Sample Dilution: The default sample dilution comes from the magnetic card. Press number keys to enter dilution number or press **ENTER** to accept the default sample dilution.

6). Place cuvette in chamber. Place the cuvette containing a stirring bar and sample. If the sample needs dilute, diluents sample use using NEPHSTAR Sample Diluents supplied in NEPHSTAR Accessory pack according to the dilution scheme in 5)

Note: When putting sample into the cuvette, ensuring sample is pipetted only onto the bottom of cuvette but not onto the side of it, otherwise NEPHSTAR will sense the addition of reagents and the assay will begin.

7). Add reagent. Add reaction buffer and antiserum simultaneously into the cuvette using the electronic pipette.

Blank measurement and sample measurement are automatically processed and time is counted down. The results will be displayed and printed automatically when time is up.









Press **PRINT** if more printed reports are needed.

Note: NEPHSTAR has already calculated the sample dilution, the results is the actual concentration of the sample.

8). On completion of the assay remove the cuvette; press **ENTER** to perform the next assay. Sample ID will increase sequentially. For alternation of the dilution press **BACK** once, and for alternation of sample ID, press **BACK** twice by tip in the right number. During the whole assay, press **BACK**, it will come back to the formal step, press **ESC**, the assay will begin again.

8. User Prepared Chemistry (UPC) Mode

UPC mode is designed to allow the user to develop “in-house” assays. User needs to configure reagents, define laboratory parameters and do the calibration curve by him. Results are produced as scatter units.

- 1). Switch power on.
- 2). Press  .
- 3). Press  .
- 4). Enter self-defined chemistry number, press  to confirm.
- 5). Enter blank time. Enter a blank read time. Minimum 3 seconds and maximum 999 seconds.
Press  to confirm.
- 6). Enter read time. Enter an assay read time. Minimum 3 seconds and maximum 999 seconds.
Press  to confirm
- 7). Enter reagents additions: Enter the number of reagent additions required. Minimum 1, Maximum 9. Press  to confirm
- 8). Enter sample ID
- 9). Place cuvette in chamber. Place a cuvette containing the first reagents and a stirring bar, into the cuvette chamber.
- 10). Add reagent. For reagent addition assays the operator is prompted to make further reagent additions. Each addition should be confirmed by pressing  . NEPHSTAR will sense the addition of the final volume and begin to assay automatically.
(Note: the final reagent volume should no less than 400ul)
- 11). On completion of the assay screen will display the initial date before reaction and the coefficient variations during the reaction.
- 12). To continue to assay samples, press  to repeat the next assay. Sample ID will increase sequentially.

9. Operator Messages

Message	Possible Cause(s)	Suggested Action
Invalid card	1. Calibration card swiped incorrectly	Swipe card again
	2. Calibration card is for a different assay to that selected	Check chemistry number on card matches selected assay
Wrong version Contact supplier	1. Calibration card is wrong or impaired	Contact your local NEPHSTAR supplier for change
	2. Calibration card swiped incorrectly	Swipe card again
Blank too high	Sample is too turbid for an accurate determination to be made	Check sample is not lipaemic, turbid, icteric or haemolytic
Reagent expired	Reagent lot has passed its recommended use-by date	Repeat the assay with new reagent
Result < xxxx	Result obtained is below the pre-programmed assay range	Repeat the assay using a more dilute sample
Sample concentration is too high, it needs a high diluent	The assay result is higher than pre-setting assay rang	Repeat the assay using a more dilute sample

10. Trouble Shooting

PROBLEM	POSSIBLE CAUSE(S)	SUGGESTED ACTION
Blank LCD display	1. Power supply not switch on	Ensure both power supply and NEPHSTAR are switched on
	2. Fuse(s) blown in NEPHSTAR	Check fuses. Replace if either or both are non-functional
No “Add reagent” message when cuvette placed in chamber	Cuvette is not pushed far enough into cuvette chamber to be detected	Push cuvette firmly down into chamber
Blanking starts before reagent added	Sample on the side of cuvette	Remove cuvette and wait for blanking to finish. Enter new ID, turn cuvette around and replace in chamber. Place cuvette in chamber slowly
NEPHSTAR fails to blank when reagent added	Addition not recognized by instrument	Discard cuvette and repeat assay
Swipe card details not loaded	1. Swipe card used wrong way up	Swipe the card again
	Card being swiped at wrong time	Check card is being swiped only when requested to
	Dust, particles or moisture on magnetic strip	Wipe card with dry cloth and swipe again
Printer not functioning	1. Printer run out of paper	Place a new roll of paper in the printer
	2 . The printer remainder does not cover appropriately	Check the printer cover is being cover appropriately
Numbers can't be input	Number keys are locked	Press 

11. Quality Control

It is recommended that appropriate serum/sample controls should be assayed with each batch of samples. Results should only be accepted if the control results are within the stated values.

12. Maintenance

REMOVE ANY MINOR SPILLAGES OR STAINING.

The equipment should be disconnected from the power supply and carefully wiped with a damp cloth. Avoid spilling fluids into the cuvette chamber. Always allow the equipment to dry out before use.

CHANGING THE PRINTER PAPER.

A red line on the paper indicates when the roll needs changing.

1. Remove the remainder of the roll by pressing the paper feed button.
2. Lift the cover and place the new roll into the roll compartment with the free end at the bottom.
3. Feed the end of the roll into the print head (between the metal plate and the black plastic print head) and press the paper feed button continuously until the paper is drawn in and appears out of the slot on the print head.
4. Close the lid, feeding the paper through the slot in the lid.

CHANGING THE FUSES

If the NEPHSTAR fails to operate, please check or change fuses. Disconnect the NEPHSTAR from the power supply then unscrew the fuses holder until it is released. Insert the appropriate fuse into the cap, making sure to replace the fuse with one of the same rating.

13. Warranty

Goldsite Diagnostics warrants the NEPHSTAR against defects in material and workmanship. Defects that occur within three years following the date of delivery will be corrected free of charge, provided that the defect occurred under normal and proper use. This warranty excludes damage resulting from shipping, misuse, carelessness, neglects and repairs or alternations made by anyone other than an authorized Goldsite Diagnostics representative and **the warranty is invalidated if the seals on the case have been tampered with.** The Goldsite Diagnostics' liability under this warranty is limited to the repair of defects or the replacement of the product, and is covered by the term of this warrant.

Appendix: Using the electronic pipette

The electronic pipette is requisite for conducting most of the assays. The pipette is used for sample dilution and especially for simultaneous addition of reaction buffer and antiserum of respective assays. When NEPHSTAR operates, the dilution mode 'dd' of the pipette is mostly used.

With dilution mode 'dd' two different solutions separated by an air gap are aspirated and then dispensed together with automatic blow-out. The purpose of the air gap is to avoid contamination when aspirating the second volume but it will not prevent the two liquids from mixing in the tip. In NEPHSTAR assays, the two solutions can be either sample and sample diluent or reaction buffer and antiserum.

The speed of aspiration and dispense of solutions in tip can be changed between '1' and '5' ('1' slow and '5' fast).

In NEPHSTAR assays, aspiration speed should be set at '1' and dispense speed at '3'.

Program the electronic pipette

- 1) Switch the pipette on and the alphabet 'E' will be showed on the display.
- 2) Press the START button twice.
- 3) Press **M** until 'dd' is showed on the display.
- 4) Press **E** to confirm the mode selection.
- 5) Press **▲** or **▼** to set the volume of the first reagent.
- 6) Press **E** to confirm.
- 7) Press **▲** or **▼** to set the volume of the second reagent.
- 8) Press **E** to confirm.

Set the pipetting speeds

- 1) Press **S ▶** to display the current aspiration speed.
- 2) Press **▲** or **▼** until desired aspiration speed is displayed.
- 3) Press **E** to confirm speed selection. Display shows the current dispense speed.
- 4) Press **▲** or **▼** until desired dispense speed is displayed.
- 5) Press **E** to confirm speed selection.

Note: The speed may not be changed in the middle of the aspiration or dispensing cycles.











Note: The default speed is '3' for all speed settings.

Using the pipette with the 'dd' mode

- 1) Using a 1ml pipette tip, position the tip to aspirate volume 1 and then press the START button.
- 2) With the tip in the air press the START button again to aspirate an air gap.
- 3) Position the tip to aspirate volume 2 and press the START button.
- 4) Finally, position the tip over the dilution tube or cuvette and press the START button to dispense all the solutions.

Recommendations

- 1) Hold the pipette vertically when aspirating the liquid and place the tip only a few millimeters into the fluid.
- 2) After aspirating the air gap, it is recommended to wipe off the liquid on the external surface of the tip with a tissue. Do not wipe the tip at any other time.
- 3) Always pipette against the inside wall of the receiving vessel and remove the tip by drawing it up against the inside wall.
- 4) Always position the tip above liquid surface when dispensing.

	Caution, consult accompanying documents. Please read the instructions carefully before operating the product.
SN	Manufacture's serial number
	Authorized representative in the European community
	Date of manufacture
	Manufacture
	In Vitro diagnostic medical device.
	Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive) after over the valid term within 5 years, the machine should be treated on local law or regulation requirement. To avoid hurt users and pollute environment.
	The equipment bears CE mark CE indicating its conformity with the provision of Council Directive 98/79/EC concerning medical devices, and fulfills the essential requirement of Annex I of this directive.
	FRAGILE Contents of the transport package are fragile therefore it shall be handled with care.
	THIS WAY UP Indicates correct upright position of the transport package.
	KEEP AWAY FROM RAIN Transport package shall be kept away from rain.



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