





HEALTHSENS NEPHROPOC®

POCT FOR THE EARLY DIAGNOSIS AND MONITORING OF RENAL DISEASE.

Enzymatic creatinine biosensor that measures the creatinine concentration and estimates the glomerular filtration rate in a single drop of peripheral blood, fundamental parameters for the early diagnosis and monitoring of kidney disease.

USER MANUAL

INSTRUCTIONS FOR USE

IMPORTANT

Dear **Healthsens Nephropoc**® Owner: Thank you for choosing **Healthsens Nephropoc**® as your blood creatinine monitoring system. Please read this manual carefully before using the device for the first time as it contains important information regarding its correct usage. The user manual has all the instructions needed to analyze blood creatinine levels and effectively use the **Healthsens Nephropoc**® device. The creatinine analyzers **Healthsens Nephropoc**® have been designed

to aid you and your healthcare professionals in the monitoring of your blood creatinine levels. If you have any questions regarding the **Healthsens Nephropoc**® system, the test strips, analysis results or these instructions, immediately contact our **Customer Service at the telephone number +34 985 232 428** (available Monday to Friday from 9:00 to 18:00, UTC+1).

SYMBOLS AND ICONS OF THE DEVICE



Battery low



Battery empty



Precautions and warnings: refer to the user manual and the documentation included with your system to consult the safety information.



Direct current (DC)



Refer to user manual



Manufacturer



Lot number



Serial number



Temperature storage limits



In vitro diagnostic product



Do not reuse



Sterilized by irradiation



Do not dispose of with general waste



Expiration date



Contains enough material for <n> analysis



Biohazard

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IMPORTANT SAFETY INSTRUCTIONS

Read this before using your **Healthsens Nephropoc**[®] device. These basic safety precautions should always be taken:

- The reader, test strips, lancets and lancing device of **Healthsens Nephropoc**[®] are to be used exclusively by one patient. Do not share with anyone, not even relatives. Do not allow different patients to use the same system.
- Strict supervision is required when the device is to be used by, or in close vicinity, to children or people with disability or invalidity.
- Use the device only for its intended purpose, described in this manual.
- Do not use test strips that were not supplied by the manufacturer.
- Do not use the device if it is not working correctly or has sustained damage.
- Before using any product to verify your blood creatinine levels, read carefully the instructions and perform the test.
- Store the vial with the test strips out of the reach of children, as the cover of the vial and the test strips could pose a choking hazard.
- Never chew or swallow a test strip. If this occurs, go to a medical center immediately.
- Every single component of this Kit can be considered of a high risk and capable of transmitting contagious diseases, even when cleaned and disinfected.
- The purpose of these devices is to be used for the self-monitoring of the patient. They must never be used by more than one patient as this could cause the transmission of contagious diseases such as Hepatitis or HIV.

IMPORTANT HEALTH-RELATED INFORMATION

Interferences in the creatinine measurement

Blood creatinine measurement with the reader device **Healthsens Nephropoc**[®] is not affected by creatinine most common interferences.

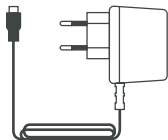
Analysis results

The reader device **Healthsens Nephropoc**[®] provides creatinine results between 0.9 mg/dL and 15 mg/dL. Normal blood creatinine values in adults are lower than 1.2 mg/dL.

HEALTHSENS NEPHROPOC® CONTENT



Reader device
Healthsens Nephropoc®



Battery charger
Healthsens Nephropoc®



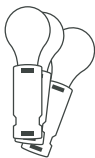
Case for the
Healthsens Nephropoc®



Creatinine test strips
Healthsens Creatinine Strip®
Healthsens Nephropoc®



Lancing device
Healthsens Nephropoc®



Sterile lancets for the lancing device
Healthsens Nephropoc®

*The test strips are sold separately. To obtain test strips please contact the Personal Hotline or ask your pharmacist or healthcare professional.

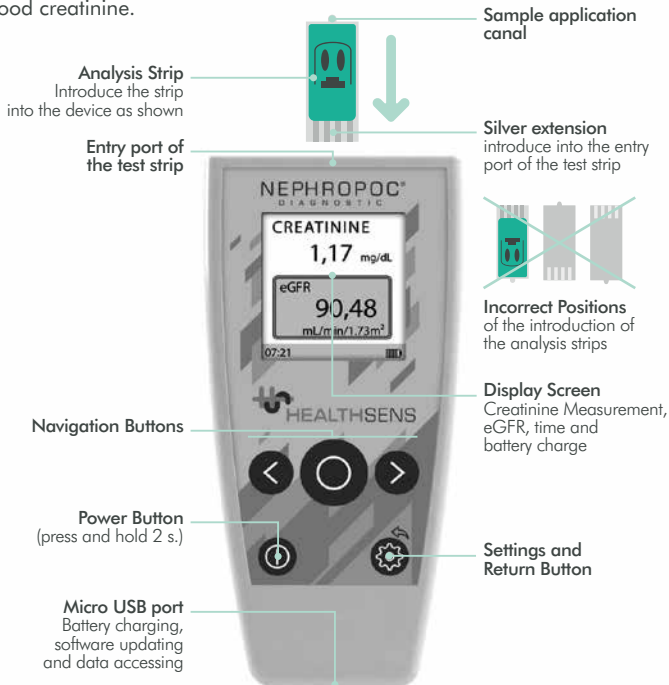
NOTE To use the lancing device, please refer to its specific instructions manual.




WARNING Keep the reader and analysis material out of the reach of children. The small parts, such as the test strips, lancets and lancet protectors could pose a choking hazard if they are ingested. **DO NOT** ingest or swallow these components.

SYSTEM CONFIGURATION

System functionalities of the Healthsens Nephropoc® device for the determination of blood creatinine.



Turning the device on





Press and hold the (picture of the on/off button)  button for two seconds. In the display screen, the message “Waiting for the drop” will appear.



SYSTEM PREPARATION

Before using the device for the first time, you must introduce your demographic information (weight, age, gender and race) and the lot serial number of the test strip you were about to use. Make sure the predetermined time, date and language are correct so that all the analysis results are accompanied by their appropriate date and time.

Configuring user profile

To configure the User Profile you must press the settings button . In the menu that appears, press  or  to hover over USER PROFILE (should be highlighted in green) and press the middle button  to enter the selected option.

Step 1 Set WEIGHT

To set the **Weight**, you must navigate the menu pressing the ◀ or ▶ buttons to hover over the Weight option (should be highlighted in green) and press the middle button ○ to enter the selected choice. Change the weight value with the button ◀ to lower the value or ▶ to raise the value. Press the middle button ○ to enter the selected choice.



Step 2 Set AGE

To set the **Age**, you must navigate the menu pressing the ◀ or ▶ buttons to hover over the Age option (should be highlighted in green) and press the middle button ○ to enter the selected choice. Change the age value with the button ◀ to lower the value or ▶ to raise the value. Press the middle button ○ to enter the selected choice.



Step 3 Set GENDER

In the option **Gend** you have the option to select male or female. In case the predetermined gender is correct you do not have to change anything. To change the Gender you must navigate the menu pressing the ◀ or ▶ buttons to hover over the Gender option (should be highlighted in green) and press the middle button to enter the selected choice. Change the gender value with the ◀ or ▶ buttons. Press the middle button to enter the selected choice.



Step 4 Set RACE





In the option **Race** you have the option to select afroamerican (afroam) or other. In case the predetermined race is correct you do not have to change anything. To change the Race you must navigate the menu pressing the ◀ or ▶ buttons to hover over the Race option (should be highlighted in green) and press the middle button to enter the selected choice. Change the race value with the ◀ or ▶ buttons. Press the middle button to enter the selected choice. To return to the Settings menu press the ⚙ button once. If you wish to return to the main screen press ⚙ once more.









Configuring TEST STRIP s/n

TEST STRIP refers to the reactive creatinine test strip of the **Healthsens Nephropoc®**.

Depending on the production lot, two A and B parameters, that correspond exclusively to that particular lot, will have to be introduced into the system so that the creatinine concentration results are correct.

To set the **TEST STRIP** S/N values press the settings button . In the menu press  or  to hover over **TEST STRIP** S/N (should be highlighted in green) and press the middle button  to enter the selected choice.

Two series of numbers will appear on the screen, separated by a slash /. The first series consists of four digits that correspond to the A parameter, and the second series of four digits, preceded by a negative (-) or positive (+) sign, correspond to the B parameter. Look in the test strip vial for the A and B parameters that correspond to that lot.













To select the correct values you will have to navigate the menu pressing the  or  buttons to hover over the digit you wish to change (should be highlighted in green) and press the middle button  to enter the selected choice. Change the value with the  button to lower the value or  to raise the value (the digit you are changing would be highlighted in blue). Press the middle button  to enter the selected choice.

Repeat the procedure until all the digits are the same as the A and B parameters printed on the test strips vial, do not forget to introduce the positive or negative sign of the B parameter.

To return to the Settings menu press the  button once. If you wish to return to the main screen press the  button once more.










Configuring language

To configure the **LANGUAGE** you must press the settings  button. In the menu, press  or  to hover over Configuration (should be highlighted in green) and press the middle button  to enter the selected choice. Inside this menu press  or to  hover over Language (should be highlighted in green) and press the middle button  to enter the selected choice. To select the correct language press  or  and  to enter. To return to the Settings menu press the  button once. If you wish to return to the main screen press  once more.



Configuring eGFR



The Healthsens Nephropoc[®] enables the calculation of the estimated glomerular filtration rate (eGFR) according to four different formulas: CDK-EPI, MDRD-4 IDMS, HS (Healthsens) and Cockcroft-Gault.

To visualize the eGFR that you wish you must first press the settings button . In the menu, press  or  to hover over Configuration (should be highlighted green) and press the middle button . Inside this menu, press  or  to hover over eGFR (should be highlighted green) and press the middle button  to enter the selected choice.



To choose the **eGFR** you wish to view, press









To return to the Settings menu press the  button once. If you wish to return to the initial screen press  once more.

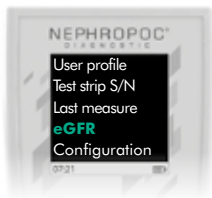
NOTE by default the selected eGFR is the HS option.

View different eGFR

If you wish to view an **eGFR** different to the currently selected option, you can do so once the blood creatinine determination has finished.

To view the rest of the **eGFR** values, you must press the settings button . In the menu, press  or  to select **eGFR** (should be highlighted in green) and press the middle button  to enter the selected choice. Inside this menu the values of **eGFR** calculated with four different methods will appear.

To return to the Settings menu, press the  button once. If you wish to return to the initial screen press the  button once more.



START OF THE TEST

The reactive test strip **Healthsens Creatinine Strip**[®] consists of an electrode with a mix of chemical reagents. The creatinine of the blood sample mixes with these special reagents contained in the test strip, and a small electric current is produced. The intensity of this current is directly proportional to the amount of creatinine contained in the blood sample.

The **Healthsens Nephropoc**[®] reader calculates the estimated glomerular filtration rate (eGFR) by the means of four different equations that use the creatinine value obtained and the demographic information of the patient as input values. The eGFR value of the currently selected option appears on the screen, next to the creatinine concentration.

TEST PROCEDURE

The items that you need are: the Healthsens Nephropoc(R) reader device, the **Healthsens Creatinine Strip**[®] reactive test strips for creatinine, the user manual, the lancing device, and a new and sterile lancet.

NOTE Please refer to your User Manual and the instructions of the lancing device to obtain detailed information on its use.

Step 1 Turn on the device

Once the device is on, adjust the required parameters (User profile, Test strip S/N,...) if necessary, and return to the initial screen. When the message “Waiting for the drop” is displayed, the device is ready to carry out the creatinine determination.



Step 2 Insert the test strip

Take a test strip from the test strip vial and cover the vial afterwards immediately. Wait for 10 minutes for the test strip to warm up to room temperature and insert it into the test strip entry port, silver extension first and facing upwards. Push the strip into the device until it does not go any further. Make sure the lot code number introduced into the device is the same as the one on the vial of the test strip.



ATTENTION The test strip must ALWAYS be picked up by its sides. If the test strip is picked up incorrectly the determination of blood creatinine could not be correct.

Step 3 Apply the sample

When the screen displays “Waiting for the drop”, place the blood drop closer to the device and make contact between the drop and the sample application canal located in the outer border of the test strip. With the inside of the finger pointing upwards, keep the blood drop in contact with the canal until the strip’s cell is full. The reader will begin the measurement automatically.

If the reader begins measuring before the strip’s cell is full, do not add more blood to the strip; dispose of the strip and start again. If the strip’s cell did not fill up, the result could be inaccurate. If you had any problem filling up the strip, get in contact with **Healthsens’ Customer Service** at the telephone number +34 985 232 428.

Step 4 Precise results

The results of the creatinine and eGFR analysis will appear on the screen in 40 seconds.



ANALYSIS RESULTS

The Healthsens Nephropoc® reader device delivers creatinine results between 0.90 mg/dL and 15 mg/dL. If the creatinine result is lower than 0.90 mg/dL the screen will display ≤ 0.90 mg/dL.

The normal blood creatinine values for healthy adults are under 1.2 mg/dL. If your creatinine levels were high, a warning message “Please see your Doctor” would appear on the screen.



NOTE If the creatinine value is different from your usual values repeat the test.

UNEXPECTED CREATININE RESULTS








If your creatinine result is outside the range of your usual values, go through this list to check if any of these problems might have occurred. If your creatinine concentration results are still unusual please see your doctor.

Possible error sources	Actions
Have you followed the instructions?	Refer to the Test procedure chapter and repeat the creatinine measurement. Contact Healthsens Customer Service at the telephone number +34 985 232 428.
Have you introduced correctly the A and B parameters that correspond to the test strip lot you are currently using?	Confirm the A and B parameters printed on the test strip vial are correctly introduced into the Healthsens Nephropoc[®] device (TEST STRIP S/N). If this is not the case, enter the correct values and repeat the creatinine measurement with a new test strip.
Were the test strips expired?	Dispose of the test strips past their expiry date. Repeat the measurement with a non-expired strip.
Was the test strip vial always hermetically sealed?	Substitute the test strips if you think the vial has been opened for a while. Repeat the creatinine measurement.

Possible error sources	Actions
Has the test strip been used immediately after extracting it from the vial?	Repeat the measurement with a new test strip.
Have the test strips been stored at a temperature of 4° C in a dry place?	Repeat the measurement with an appropriately stored test strip.
Has the test strip warmed up a few minutes prior to its use?	Repeat the measurement with a warmed up test strip.
Are you not sure yet of what caused the error?	Contact Healthsens Customer Service at the telephone number +34 985 232 428 .

CONSULT PREVIOUS RESULTS

The device keeps a register of the 56 most recent results, which include the blood creatinine, the eGFR, and the time and date the measurement was performed.

To view previous results, press the settings button . In the menu, press  or  to select Last measurement (should be highlighted in green) and press the middle button  to enter selected choice. Inside this menu, press  or ; or  to navigate the various pages.

Each page will display up to 8 results, with a total of 7 different pages. The most recent measurement will be the top second register of page 7.

When the device registers 56 results, adding another result will delete the oldest register.

CARE AND MAINTENANCE

Storage of the device

Store the reader, the charger and the lancing device in the case. Keep it in a dry and fresh place between 15°C and 40°C. Do not refrigerate. Store the items away from direct heat and sunlight.

The vial with the **Healthsens Nephropoc**[®] test strips must remain hermetically sealed when not in use. The strips must only be stored in the original vial. To avoid damaging them, do not transfer them anywhere else.

The reactive test strips must be stored in refrigeration at 4°C once open to maintain them in optimal conditions during a maximum period of up to 6 months.

Use the test strip 10 minutes after taking it out of the vial.

Do not use the test strips of any vial that has been damaged or left open.

Do not use the test strips after their expiry date (printed on their container).

Avoid dust, food products or liquids from entering the test strip.

Do not bend, cut or alter in any way the **Healthsens Nephropoc**[®] test strips.

The **Healthsens Nephropoc**[®] test strips must only be used once. Never reuse a test strip in which you have previously applied blood.

The test strips must be disposed of in biological waste containers.

Cleaning and disinfection

Cleaning and disinfection are two different procedures, both of which are to be performed. Cleaning is part of the usual care and maintenance routine, and must be done prior to disinfection. However, cleaning does not eliminate all germs. Disinfection is the only way to reduce your exposure to diseases. To read the information on cleaning, go to page 25, for information on disinfection go to page 26.

Cleaning the reader device and the charger

The reader device must be cleaned whenever it appears dirty. Use a towel dipped in detergent mixed with water or alcohol (70%).

- DO NOT use alcohol or any other cleaning solution.
- DO NOT allow liquids, dirt, dust or blood penetrate the test strip entry port nor the micro USB port.
- DO NOT spray cleaning products onto the reader device nor submerge it in liquid.

Hold the reader with the strip entry port pointing downwards and use a soft cloth dipped in water and soft detergent to clean the exterior of the device. Make sure to drain excess liquid before doing so.

Dry everything with another clean and soft cloth.

Disinfection of the reader

You must periodically clean the reader. Clean it before disinfecting. For disinfection you can use domestic bleach (with a minimum 5.5% content of sodium hypochlorite)*. Prepare the disinfection solution by mixing 1 part of domestic bleach with 9 parts of water.

*Follow the manufacturer's instructions on the use and storage of the bleach.

Hold the reader device with the test strip entry port pointing downwards. Use a soft cloth dipped in the previous solution to clean the exterior of the reader and lancing device until the surfaces are moist. Make sure to drain excess liquid before cleaning the reader.

Next, cover the surface you are disinfecting for a minute with the bleach-dipped cloth. Immediately after pass a dry, clean and soft cloth over the device, and allow it to dry.

Wash your hands with soap and water after handling the reader. If you detect signs of deterioration, contact the **Customer Service: +34 985 232 428**.



ATTENTION Do not dismantle or manipulate the inside of the device. In the event of a device failure, the repair must be done by an authorized technical service center.

BATTERY OF THE DEVICE

The Healthsens Nephropoc® device is powered by a “X” battery.



WARNING Do not manipulate the battery. They can explode and/or cause burns if installed incorrectly, recharged, placed in water, fire or high temperatures.



IMPORTANT Solely use the official charger of the Healthsens Nephropoc®. The use of non-approved adaptors or cables could cause performance issues, faults or damages that are not covered by the guarantee.

Battery indicator

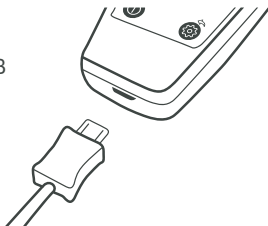
In the creatinine measurement screen you can see the battery icon.



If the battery is low or the reader does not turn on, charge the battery.

Charging the battery

Connect the USB cable to the micro USB port of the Healthsens Nephropoc® device, and the plug to a power outlet.



Warning screens

The Healthsens Nephropoc® device can display the following warnings on the screen.

Warning screens	Actions
Battery Low	Battery Low. Change the battery or connect the charger.
Temperature Error	Temperature Error. The device only works when the ambient temperature is between 15°C to 40°C.
Strip Removed	Strip Removed. The test strip was removed before completing the test. The analysis is cancelled.
Short Sample	Insufficient Sample. Not enough sample volume was deposited into the test strip. Repeat the measurement with a new test strip.

SPECIFICATIONS

Performance characteristics

The operating range of the **Healthsens Nephropoc**[®] is between 0.9 to 15 mg/dL of creatinine.

Precision

The precision data was obtained by testing the **Healthsens Nephropoc**[®] with certified creatinine standard solutions and venous blood samples. Tables 1 and 2 present the results typically obtained with a test strip lot.

Table 1 Precision Laboratory standards

Creatinine levels	Number of samples	CV (%)
Low (0,78 mg/dl)	10	7,1
Medium (1,19 mg/dl)	10	7,6
High (4,57 mg/dl)	10	6,9

Table 2 Precision Blood samples

Creatinine levels	Number of samples	CV (%)
0,9	10	12,0
1,16	10	12,6
1,5	10	11,1
2,02	10	8,6
4,6	10	7,4
7,88	10	5,3

The precision results indicate that, when blood samples are measured, the maximum expected variability is 12.6%.

Lot reproducibility

The precision of two different test strip lots was evaluated measuring certified creatinine standard solutions.

Table 3 Lot reproducibility

Test strip lot	Creatinine levels	Number of samples	CV (%)
TCR-20190619	Low (0,78 mg/dl)	10	10,4
	Medium (1,19 mg/dl)	10	10,0
	High (4,57 mg/dl)	10	9,1
TCR-20190530	Low (0,78 mg/dl)	10	11,5
	Medium (1,19 mg/dl)	10	10,4
	High (4,57 mg/dl)	10	17,8

TECHNICAL SPECIFICATIONS

Size	95 (L) x 48 (W) x 20 (H) mm.
Weight	58,67 grams
Analysis methodology	Enzymatic
Power	+5VDC/4W
Display screen	LCD
Memory	56 test results including date and time
Operating conditions	15°C-40°C and between 20%-80% of relative humidity (without condensation)
Storage conditions	15°C-40°C and less than 85% of relative humidity
Measurement units	creatinine in mg/dL and eGFR in mL/min./1.73m ²
Measurement range	0.9 mg/dL - 15 mg/dL
Sample	Recently extracted capillary blood
Sample volume	11,50 uL

GUARANTEE

Healthsens guarantees that the **Healthsens Nephropoc**[®] device will be devoid of material and fabrication defects for a period of three years after the initial purchasing date. The guarantee is only valid for the original buyer and is non-transferable.

ELECTRICAL AND SAFETY RULES

This device conforms to the international CISPR 11: Class B standard (only irradiation). The energy emissions are low and unlikely to cause interferences in nearby electrical equipment. The immunity of the device has been proven by the Level 3 electrostatic discharges procedures as specified in the IEC 61326 System of Conformity. In addition, the immunity of the device against radiofrequency interferences has been proven in the interval from 80 MHz to 2.5 GHz, and at 3 V/m, as specified in the IEC 61326-1 or 61326-2.

The device complies with the requirements of immunity to electrical interferences at the frequencies and test levels specified in the international standard ISO 15197.

The use of this device near electric or electronic equipment emitting electromagnetic radiation could affect the correct functioning of the device. Avoiding the use of the device in the presence of sources of electromagnetic radiation is recommended.

Amongst the most common sources of electromagnetic radiation are mobile phones, walkie talkies and garage door remotes.

DO NOT use the device where aerosols are being applied or where oxygen is being administered.

OUR COMMITMENT TO YOU

Our goal is to provide high-quality healthcare products and an efficient service commitment to our clients. If you are not completely satisfied with this product, or if you have any question regarding the use of any of our products, please contact our **Customer Service line at +34 985 232 428** (from Monday to Friday, 9:00 to 18:00 UTC+1). If you cannot contact our service, or require urgent medical attention, please contact your healthcare professional for assessment.

CONTACT INFORMATION



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