DOASENSE READER

USER MANUAL

Last revised: 08-2024, WI 7.5-14-EN-Rev03

IVD CE

Contents

List of abbreviations

BCR – Barcode reader
CRE – Creatinine
DCU – DOASENSE Control Urines
DOAC – Direct oral anticoagulant
FXA – Factor Xa inhibitor
LCD – Liquid-crystal display
LED – Light-emitting diode
LIS – Laboratory Information System
NEG – Negative
NORM – Normal
PC – Personal computer
POS – Positive
QC – Quality control
REF – Reference
RTC – Real-time clock
THR – Thrombin inhibitor
USB – Universal Serial Bus

Note: For further instrument-specific abbreviations, see chapter 1.4

1. Introduction

This manual contains the operation and maintenance instructions for the DOASENSE Reader.

1.1 Intended use

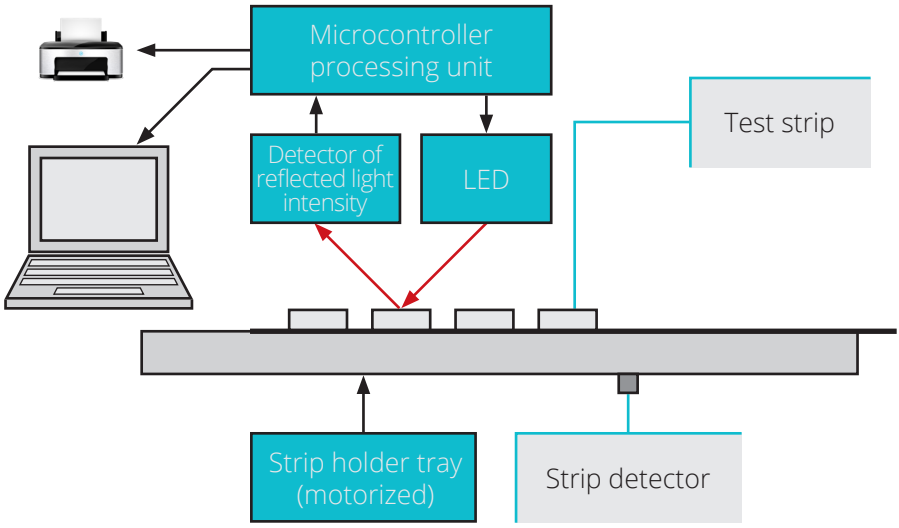
The intended use of the DOASENSE Reader is the qualitative determination of direct oral factor Xa inhibitors, direct oral thrombin inhibitors, and creatinine in patient's urine by photometric evaluatin of the diagnostic test strip DOAC Dipstick. The DOASENSE Reader reads out specific colours on the DOAC Dipstick pads, which are specifically designed to measure the above-mentioned parameters. The DOASENSE Reader is an in vitro diagnostic medical device intended for professional use only.

Only use DOAC Dipstick test strips within their expiration date!

1.2 Measurement principle

Figure 1 shows the theoretical working principle of the DOASENSE Reader. The instrument uses LEDs with specific wavelengths as light sources to illuminate the respective test surfaces (e.g. the test strip pad). The reflected light is detected by a photodiode. The measured level of reflected light is transformed into the analyte's concentration on the respective test pad.
The DOAC Dipstick is immersed into the urine sample and then placed onto the strip holder tray. The built-in strip detector recognizes the inserted strip and starts timing the incubation. After 10 minutes, the strip holder tray is pulled into the DOASENSE Reader under the measuring head and the intensity of reflected light is measured. The microcontroller processing unit converts the reflected light intensity into an analytical value. The corresponding qualitative result is presented on the display and printed by the built-in thermal printer. Data is displayed as negative ("neg") or positive ("pos") for factor Xa inhibitor and thrombin inhibitor, and as "normal" or "low" for creatinine. After measurement is completed, the tray is ejected and the user can dispose of the measured strip. The instrument is then ready for the next measurement.

Figure 1: The principle of measurement by the DOASENSE Reader
The DOASENSE Reader has a strip holder tray, which moves the DOAC Dipstick by a motor into the inner part of the instrument. The strip detector senses the presence of a test strip on the strip holder tray.
LED light of defined wavelengths is reflected by the pads of the DOAC Dipstick onto a detector.
Based on the intensity of the reflected light, a microprocessor unit generates the test results, which are shown on the display and printed by the built-in printer.



1.3 User interfaces

1.3.1 Overview of the instrument

Figure 2: Description of the front part of the instrument
The front part of the instrument contains the strip holder tray onto which the DOAC Dipstick is placed. It also includes a display, where the results of the test pad evaluation are visualized, and a printer inside the upper part of the instrument for printing the results. The printer paper roll is placed under a lid that can be opened manually by pushing the paper release button.

1.3.2 Connectors

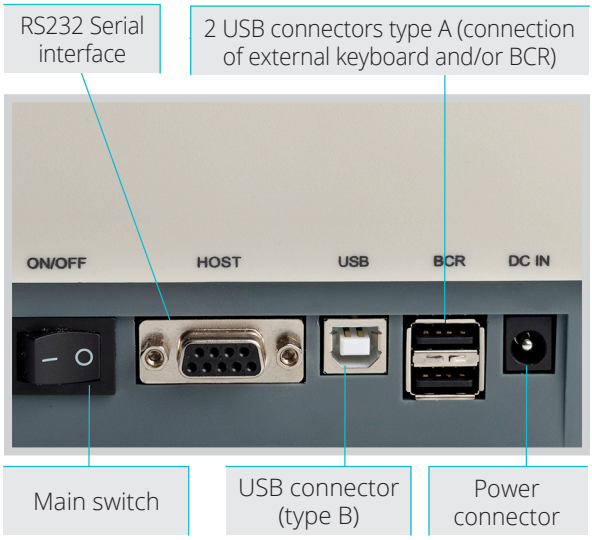


Figure 3: Description of the rear part of the instrument
From left to right:
The on/off switch, an RS232 interface as well as a USB type B connector for sending data to external devices (e. g. to a Laboratory Information System), two USB type A connectors to connect the instrument with an external keyboard or BCR, and the electric power connector.

1.4 Display icons and abbreviations

ID - Patient identification code (digits or text, max. 15 characters)
Seq.No. - Sequence number of the measurement
Sample - Urine specimen to be measured
REM - Remission value
BCR - Barcode reader
Host - Interface for sending data to an external computer device (e.g. a Laboratory Information System (LIS). Note: To connect the instrument to an existing LIS system please contact your LIS provider for technical support.)
Smart Mode - Special incubation timing method for multiple test strips

Icons


low battery 0 %


battery 25 %


battery 50 %


battery 75 %


battery 100 %


external keyboard or BCR connected

external PC USB connected


USB pendrive connected


incompatible USB pendrive connected


USB pendrive connected, OK


connected to external power source

1.5 Labels and precautions

The DOASENSE Reader should only be operated with a power supply unit of type GTM96180-1811-2.0, in order not to endanger the user by electric shock. In addition to the approved power supply, only connect USB 2.0 standard keyboards or barcode readers, or standard RS232 compatible PC devices to the DOASENSE Reader.

To ensure safe functioning of the instrument, only use the included power supply unit. If the cable breaks, immediately stop using the instrument and replace the power supply unit.
Never open the DOASENSE Reader's case.

Contact to urine is inevitable when using this instrument, and materials contaminated with human urine can be infectious. Therefore, always follow Good Laboratory Practice and safety guidelines when using this instrument. Wear protective gloves and a lab coat and be cautious when handling urine samples. Wearing protective gloves is also recommended during service and maintenance.

Used test strips must be treated as hazardous waste and disposed of according to national biohazard and safety guidelines or regulations.

Biohazard – Urine samples are potentially infectious materials.

If the DOASENSE Reader is not used according to the handling instructions specified in this User Manual, the protection provided by the equipment may be impaired!

1.6 Other information

1. Inappropriate use may terminate any warranty claim from the user to DOASENSE.
2. The DOASENSE Reader may only be used by a trained professional.
3. Do not dispose of the instrument as household waste! Recycle in accordance with national legislation.

2. Installation

2.1 Unpacking

When opening the package, make sure not to damage the content. Take out the instrument and all other parts carefully. After unpacking, check the instrument and all accessories for visible damage and check that your package contains all the parts listed below. Figure 4 shows the complete package content. If a part is damaged or missing, please contact your distributor.

Figure 4: Accessories of the DOASENSE Reader

The DOASENSE Reader package contains the following (see figure 4):
- DOASENSE Reader
- Power supply unit with four plug adapters
- Serial interface cable
- 1 roll of thermal printer paper (contact your distributor for re-order information)
- Tube with control strips
- User manual (i.e. this manual, not shown in the figure)
- Plastic incubation pad for use with Smart Mode

2.2 Setting up the instrument

The equipment must be installed and used by trained personnel only. The DOASENSE Reader must be used only in an indoor environment setting.

Please follow the steps below:

- Select a suitable location for installation of the DOASENSE Reader that is horizontal, stable, dry, clean, well ventilated and near a power outlet. Ensure that disconnection of the power supply unit and of accessory cables can be easily performed in the selected location.
- The instrument should be placed at least 25 cm from walls or other objects (in every direction).

To ensure correct functioning and reliable results, the instrument should not be exposed to direct sunlight, intensive artificial light, vibrations, or extreme temperatures.

Do not place the instrument close to a window, centrifuge, or heated surface.

The operating temperature is between +15 and +35 °C. The optimal temperature range for the instrument is between +20 to +25 °C. For optimal performance, the humidity should be between 20 and 80 %.

- Select a suitable power outlet according to the input requirements printed on the provided power supply unit. The power outlet must be easily reachable so the plug can be removed in case of emergency. Connect the power supply unit and optional interfaces following the steps below.

Only the power supply unit provided with the instrument should be used. The DOASENSE Reader should only be operated with a power supply unit of type GTM96180-1811-2.0.

- The DOASENSE Reader can also be operated with batteries. The battery compartment is located at the bottom of the instrument. Six 1.5 V type AA batteries should be used.
  When inserting the batteries, please pay attention to the polarity, which is indicated in the compartment.

Check that the master switch on the rear side is turned off!

- Optional: Connect the serial cable and the keyboard or BCR to the reader (use type A USB connectors).
- Connect the output plug of the power supply unit to the DOASENSE Reader.
- Connect the power supply unit to the power outlet.

Inserting the printer paper: Refer to figure 5.

- Open the printer cover by pressing the release button.
- Place the paper roll into its holder and pull it out approx. 10 cm forwards.
- Hold the paper with one hand while closing the cover with the other.
- Close the cover by pressing in the middle or on both sides of the cover until it snaps into place.

Never apply asymmetric pressure to the cover!

Figure 5: Placement of thermal paper into the DOASENSE Reader

The DOASENSE Reader is now ready to be turned on; switch on the instrument at the main switch.

After the power is switched on, the display lights up and the DOASENSE Reader carries out a self-test. During this test the optics and the built-in calibration pad are tested.

After the self-test is successfully completed, the instrument prints out an OK message.

The DOASENSE Reader is now ready to perform measurements.

The DOASENSE Reader display has a touch-sensitive screen. The touchscreen will guide the user through all operations. The screen will display messages, instructions, and options. Choose options by touching the appropriate button on the screen.

3. Routine operation overview

3.1 User account and login

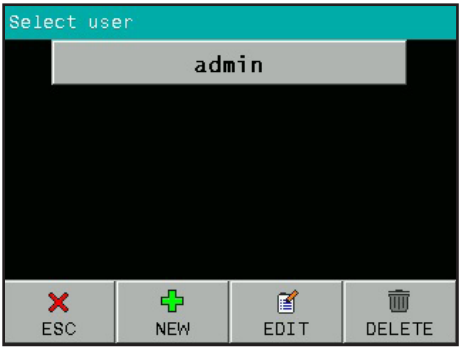
Depending on the requirements of the clinical laboratory, up to four user accounts can be added to the predefined fixed admin account. This allows the responsibility for urine sample evaluation to be assigned to other employees.

After turning on the DOASENSE Reader and after the self-test is finished, the following screen is displayed:

It is possible to perform measurements as admin (login password is 1234) or to create admin accounts for other users.

Pressing OK immediately starts the anonymous measuring mode (i.e. performing measurements not as a specific user).

Press ADMIN, and after the password 1234 is entered, the following screen is displayed:



Press the NEW button if you want to create a new user account. Enter the user name and user password.

It is possible to create four user accounts:

It is also possible to edit the existing user accounts by pressing the EDIT button, or to delete a selected user account by pressing the DELETE button.

User account names are an integral part of the measured results (urine samples and control measurements). Therefore, it is possible to identify who carried out each measurement.

If anonymous measurements are made, without a defined user login, the printed results will not contain any operator information.

3.2 Ready-to-Measure status

The DOASENSE Reader is ready to perform measurements after the user has logged in to a user account or the anonymous account. The user has the following options:

1) Putting the test strip on the tray and starting measurements.
2) Entering the information about the patient and the sample, or changing the settings if needed.

Once the DOASENSE Reader is in Ready-to-Measure status, the following screen is displayed:

The user can select different functions from the toolbar at the bottom of the screen:

- Press PATIENT to enter patient information:
  - o Seq.No
  - o ID

- Press SAMPLE to enter sample information:
  - o Select a sample colour from the predefined list
  - o Select a sample clarity from the predefined list
  - o Insert a comment

- Enter the system menu by pressing the MENU icon.

- Put the instrument into Standby mode by pressing the HOME button (the instrument will automatically go into Standby mode after a defined period of inactivity).

3.3 Measurement

The DOASENSE Reader automatically starts measuring when a DOAC Dipstick is placed on the strip holder tray.

Perform the following steps to carry out a measurement:

- Optional: enter a new Seq.No or ID if necessary.
- Optional: if you want to define the appearance of a sample, before performing a measurment manually select a colour or clarity from the predefined menu using the respective buttons or an external BCR (see chapter 3.5). Note: The colour and clarity parameters are for documentation purposes only and are not used by the DOASENSE Reader for assessing whether the DOAC Dipstick can be evaluated. This assessment has to be performed by the user, as described below.
- Immerse the DOAC Dipstick into the urine sample according to the DOAC Dipstick instructions.
- Remove excessive urine from the test strip by following the DOAC Dipstick instructions.

Assess the urine colour on the urine colour pad (pad 2), which does not contain reagents, following the instructions of use for the DOAC Dipstick. This colour has to be identified with the naked eye by the person who performed the test. If the urine colour pad shows an abnormal colour, the test strip must not be inserted into the DOASENSE Reader.

Note: Unlike the other pads on the DOAC Dipstick, pad 2 does not have to be incubated before the urine colour is determined – the result can be read by the naked eye as soon as the test strip has been placed into urine. In this respect this instruction for assessing the urine colour pad (pad 2) differs from the incubation and evaluation instructions in the DOAC Dipstick instructions for use.

- Insert the DOAC Dipstick into the strip holder tray of the DOASENSE Reader (Figure 6).

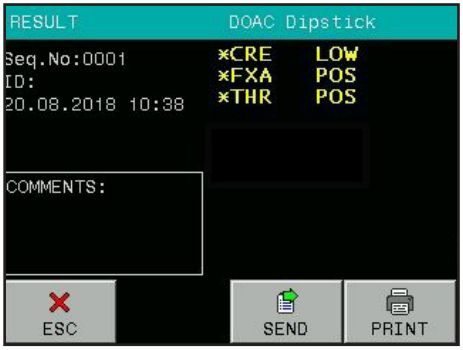
Perform the above-mentioned steps quickly because the incubation starts timing as soon as the strip is placed on the strip holder tray.

Figure 6:
Placement of the test strip onto the strip holder tray of the DOASENSE Reader

The DOASENSE Reader has a built-in strip detector at the end of the insert area, under the tray. If the strip is placed correctly, this detector will recognize it and the incubation countdown will start.

A progress bar displays the status and progress of the incubation:

- After 10 minutes the reader pulls the tray into the instrument, measures the strip, and displays the result.



The result is shown on the LCD display. Positive or non-normal parameters are marked with * and are displayed in yellow on the screen. Press the PRINT or SEND key to print or resend the results at any time. Touching the screen within the comment box allows a comment to be added to the result. If automatic printing is chosen, the results will be printed automatically.

IMPORTANT: Pad 2 of the DOAC Dipstick is not evaluated by the DOASENSE Reader! This pad is evaluated visually by the user. If the colour of pad 2 is visually evaluated as "abnormal" then the test strip must not be analysed by the DOASENSE Reader.

If a comment on this measurement already exists, the new comment will overwrite the existing comment! The comment and all results are stored in the memory of the DOASENSE Reader. Placing a new strip onto the strip holder tray will start the next measurement procedure. Pushing the ESC button sends the program back to the Ready-to-Measure status.

- After the strip is measured, the DOASENSE Reader ejects the strip holder tray. Remove the strip and disposed of it manually. Used test strips must be treated as hazardous waste according to national biohazard and safety guidelines or regulations (see also the DOAC Dipstick instructions for use).

The instrument automatically increases the Seq.No after every measurement.

Interpretation of DOASENSE Reader results:

Display/Print: "*FXA POS" (positive): direct oral factor Xa inhibitor is present in the urine.
Display/Print: "FXA NEG" (negative): direct oral factor Xa inhibitor is not present in the urine.

Display/Print: "*THR POS" (positive): direct oral thrombin inhibitor is present in the urine.
Display/Print: "THR NEG" (negative): direct oral thrombin inhibitor is not present in the urine.

Display/Print: "*CRE LOW" (low): creatinine in the urine is low, indicating renal insufficiency; therefore, the results of pad 3 and pad 4 may be false negatives.
Display/Print: "CRE NORM" (normal): creatinine in the urine is normal. Pad 3 and pad 4 can be evaluated.

If the result is "positive" for both DOACs (factor Xa inhibitor and thrombin inhibitor), then the test is probably invalid because it is unlikely that a person is treated with both types of DOAC.

The urine colour pad (pad 2) is not evaluated by the DOASENSE Reader; pad 2 must be evaluated visually before the DOAC Dipstick is placed on the strip holder tray of the DOASENSE Reader, and must be re-evaluated visually after the incubation of the DOAC Dipstick in the DOASENSE Reader (see section 3.3).

3.4 Patient identification

- Seq.No - working with sequence numbers
- Patient ID - working with identification numbers

Sequence number (Seq.No)

To enter a new sequence number, touch the PATIENT button and then select the SEQ.NO button.

Use the numeric keypad to enter a number between 1 and 9999. Confirm with OK.

Patient ID

When the ID button is selected, a similar screen appears. Enter an ID (maximum 15 characters/digits). This ID can also be entered using an external keypad or BCR.

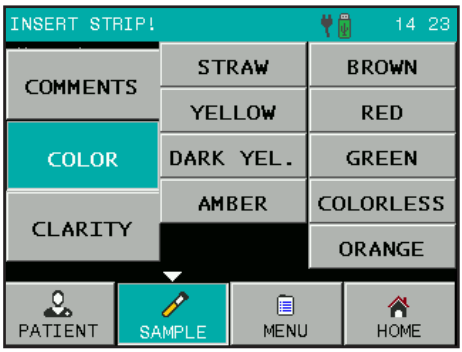
3.5 Colour and clarity

It is possible to define the colour and clarity of the urine sample before placing the test strip onto the strip holder tray. Colours and clarities are predefined and can be modified by the user in the Customization menu (see chapter 4.7).

The colour and clarity parameters are for documentation purposes only and are not used by the DOASENSE Reader for assessing whether the DOAC Dipstick can be evaluated. This assessment has to be performed by the user, as described in the chapter „Measurement".

There are nine different colours and four different clarities available.

The different possibilities will be listed after the SAMPLE, COLOR, or CLARITY buttons are pressed:



Pressing the relevant button will select the corresponding information. It will appear on the display and will be added to the next measured sample. To delete previously selected information, go into the selection menu and press the COLOR or CLARITY button again. The program then clears the previously set value.

Colour and clarity can also be described using an external BCR.

The following special barcodes are used for prompt and comfortable input of colour and clarity. The colour and clarity information is entered automatically after the barcode has been read. It is recommended to make a laminated copy of these bar codes for routine laboratory use.

Barcodes – Colour

COLOUR	BAR CODE
STRAW COLOURED	9019
YELLOW	9029
DARK YELLOW	9039
AMBER	9049
BROWN	9059
RED	9069
GREEN	9079
COLORLESS	9089
ORANGE	9099

Barcodes – Clarity

CLARITY	BAR CODE
CLEAR	9 1 1 9
CLOUDY	9 1 2 9
TURBID	9 1 3 9
DARK	9 1 4 9

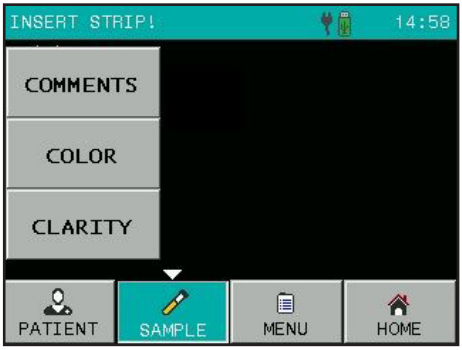
3.6 Comments

It is possible to add comments (39 characters long) to the measurements in three different ways:

- Before the measurement
- After the measurement, when the result is displayed on the screen
- When the result is selected from the memory

To add a comment before a measurement starts, use the COMMENT button:

This picture shows an example screen where all measurement-related parameters have been set:



3.7 Cleaning

Remove the strip holder tray from the DOASENSE Reader only when the instrument is switched off!

To keep the instrument clean and to avoid cross-contamination, the strip holder tray must be cleaned regularly. Please ensure that the test strip is free of excess urine before placing it onto the strip holder tray. Wipe any residues of urine off the tray with absorbent material before measurement. The strip holder tray must be cleaned at the end of every working day (see Figures 7 and 8) using potable water.

To clean with disinfectants, use an **alcohol disinfectant (with a maximum 85 % alcohol content) such as ethanol or isopropanol solution.**

Never use acetone cleaning petrol or other aggressive solvents for cleaning!

The strip holder tray can be removed from the DOASENSE Reader by pulling it out manually for easy cleaning.

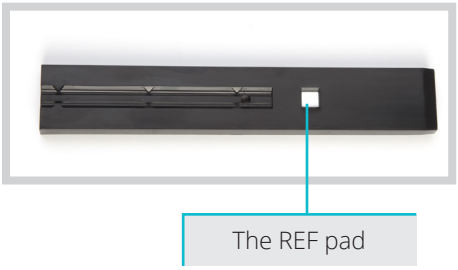
Pay attention not to damage, scratch, or rub the white REF plastic pad on the strip holder tray when removing it!

The REF pad can also be cleaned and wiped with soft materials.

The instrument case and the touchscreen can also be wiped with the above-mentioned cleaning or disinfectant agents.

Figure 7: Cleaning the strip holder tray

Figure 8: Cleaning the REF pad on the strip holder tray



WASTE DISPOSAL:

Used test strips and cleaning material should be treated as potentially infectious and should be disposed of in accordance with local and national regulations related to safe handling of such materials.

4. Menu structure

The DOASENSE Reader has a clear, well-organized menu structure. The LCD display guides the user through the menu. The menu functions are represented by buttons or list controls.

Pressing the touchscreen activates the desired function. The pressed buttons are highlighted blue.

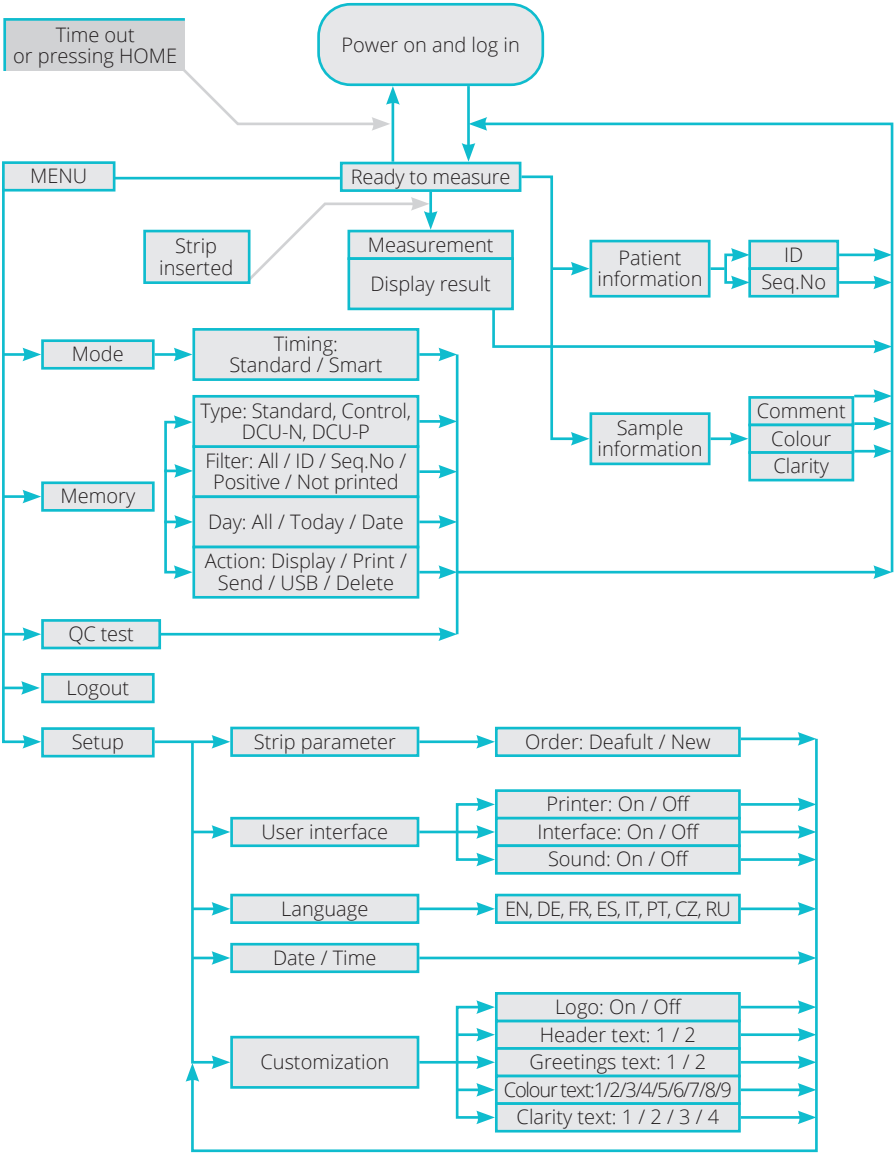
If no button is pressed for a few minutes, the DOASENSE Reader goes into Standby mode.

In Standby mode, the reader pulls in the strip holder tray and the buttons disappear from the screen, and the current time is displayed instead.

To leave Standby mode and activate the Ready-to-Measure status, simply touch the screen.

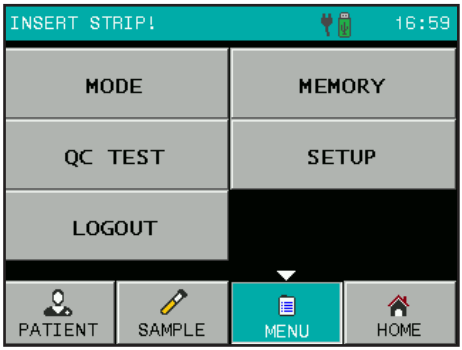
4.1 Menu overview

Figure 9: Menu flowchart



4.2 Main menu

After pressing the MENU button in Ready-to-Measure status, the following main functions are available:



- Mode
  The instrument can work in two timing modes:
  - Standard Mode - Smart Mode
  In **Standard Mode** the DOAC Dipstick is placed onto the strip holder tray and the incubation timing is started. After 10 minutes, the DOASENSE Reader measures the colour of the strip and reports the result.
  In **Smart Mode** the DOAC Dipstick is incubated outside the DOASENSE Reader and up to four strips can be incubated in parallel, shortly after one another. The details are described in chapter 4.2.1.
- Logging out
  Touch LOGOUT on the screen to log yourself out.
- Memory function
  The DOASENSE Reader can retain the last 400 urine sample results, 100 grey control strip measurements, and 100 DOASENSE Control Urine measurements. The stored results and related information (date, time, comment, colour, etc.) can be selected, displayed, printed, or sent to the computer at any time.
- QC test
  - Proper function of the instrument's measuring capability can be tested using the grey control strip and the DOASENSE Control Urines.
  - The instrument measures the grey control strip and compares the result with predefined values.
  - The test result is displayed and also printed for QC purposes.
  - Results from the DOASENSE Control Urines are automatically compared with target values that are listed in the instructions for use of the DOASENSE Control Urines.

  See section 4.2.3 for a detailed description.
- Setup
  The working parameters of the DOASENSE Reader can be set here.

4.2.1 Timing modes

The DOASENSE Reader has two different incubation timing modes: Standard Mode and Smart Mode.

Standard Mode

This is a linear workflow as described in the routine measurement chapter. When working in this mode, only one strip can be measured every 10 minutes because of the sequential process and 10 minute incubation time of the DOAC Dipstick.

Smart Mode

In this mode, a higher throughput of DOAC Dipstick measurements can be achieved in the DOASENSE Reader. Throughput is increased by incubating the test strips in parallel outside of the DOASENSE Reader. Place the dipped test strips outside of the DOASENSE Reader and when the respective incubation time elapses, insert the individual test strip into the DOASENSE Reader to be measured. In Smart Mode, use the incubation pad with four marked incubation areas, and the reader displays four software timers that correspond to the incubation areas on the incubation pad.

General workflow in Smart Mode:

- Dip the first test strip into the urine sample and remove excess urine according to the instructions for use. Then place the strip on the strip holder tray. The instrument detects the strip and starts timing the incubation.

The first strip remains on the strip holder tray for the whole incubation time.

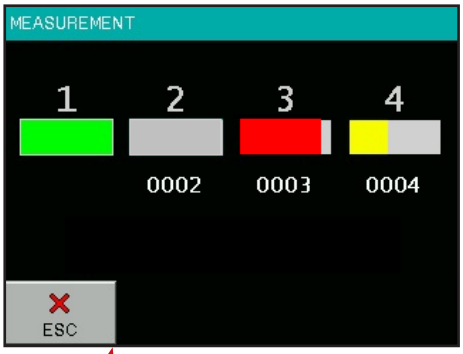
- After 150 seconds, the second timer turns green on the screen and is ready to use. Whenever a timer is green, it is possible to dip another strip into a urine sample.
- After removing excess urine, place the second dipped strip onto the part of the incubation pad with the corresponding number and start the timer by pressing the displayed timer bar. The green progress bar turns yellow and starts timing the incubation for this strip.
- Repeat the process with additional test strips you would like to measure.
- After 10 minutes, the first strip is pulled into the DOASENSE Reader and evaluated. After the evaluation, the DOASENSE Reader ejects the strip holder tray and the first strip can be removed and disposed of. The DOASENSE Reader shows a message to explain this.
- When the incubation time of the second strip is almost complete, the DOASENSE Reader beeps and the progress bar changes from yellow to red. The DOASENSE Reader will prompt the user to insert the second strip. Place the second strip on the tray and wait for the evaluation.
- Repeat the process with additional test strips you would like to measure.
- When the respective incubation time of the additionals strips is almost complete, the DOASENSE Reader beeps and the progress bar changes from yellow to red. Text messages on the screen indicate when the respective test strip should be inserted or removed.
- After removal, each measured strip should be disposed of properly.

The following pictures help to understand the Smart Mode procedure.

Figure 10-A shows that incubation timer 1 is available to receive a new test strip. The incubation has finished on timer 2 and the respective strip has been measured. The incubation is still ongoing for test strips assigned to timers 3 and 4 (the test strips are numbered Seq.No 0003 and 0004 as shown). Figure 10-B shows the strips for timers 3 and 4 incubating in the areas marked “3” and “4” on the incubation pad.

Figure 10-A: Display using Smart Mode (upper figure)

Figure 10-B: Setup for Smart Mode measurements (lower figure)



Always keep the incubation pad clean to prevent cross-contamination among samples.

4.2.2 Memory

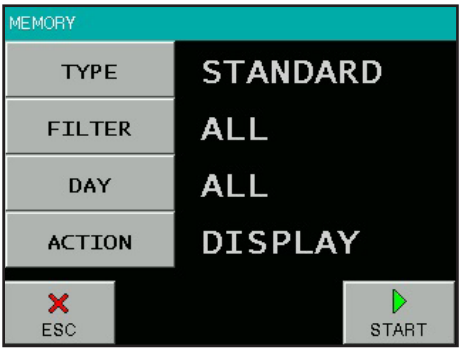
The reader has a non-volatile internal memory, which automatically stores the last 400 urine sample results, 100 grey control strip measurements, and 100 DOASENSE Control Urine measurements.

The oldest result will be overwritten by a new measurement without any warning. When the current measurement is finished, the DOASENSE Reader stores the result along with the following parameters:

- Test strip result
- Seq.No
- ID
- Date and time
- Colour
- Clarity
- Comment

Search in the memory by touching MENU and then MEMORY.

The Memory screen allows you to perform different actions on selected information stored in the memory:



With the TYPE, FILTER, and DAY buttons you set the selection parameters. The START button activates the selected action.

The desired measurement can be selected as follows:

- Select the TYPE criterion:
  - o Standard - results of urine samples
  - o Control - results of grey control strips
  - o DCU-N - results of normal (negative) control urines
  - o DCU-P - results of pathological (positive) control urines

- Select the FILTER criterion:
  - o All - all stored results
  - o ID - enter the desired ID
  - o Seq.No - enter the desired Seq.No
  - o Positive - where at least one value was positive
  - o Not printed - results that were not printed yet
  - o Error - failed measurements

- Select the DAY of the measurement:
  - o All - regardless of the date
  - o Today - selects only the results measured today
  - o Specific date - selects only the results measured on the entered date

  (The program offers only those days for which there are results in the memory)

- Choose an ACTION (what will happen with the selected results):
  - o Display - the selected results will be displayed
  - o Print - the selected results will be printed
  - o Send - the selected results will be sent to HOST, RS232, and USB
  - o USB - the selected results will be sent to USB pendrive
  - o Delete - the selected results will be deleted

When all three above-mentioned parameters (Filter, Day, and Action) have been defined, activate the process by pressing the START button.

Note:
USB port is a standard cable connection interface for personal computers and consumer electronic devices. USB ports allow USB devices to be connected to each other and transfer digital data.
Before transferring data, connect the respective type of USB device (cable for connecting to PC, or pendrive to store the data externally) and then select the action. Results will be transferred automatically.

Selecting “Display” will display the selected results as follows:

The last result in the list will be displayed first.
Use arrow buttons to move forward or backward in the list.
The respective displayed result can be printed and new comments can be added.

4.2.3 QC check

The QC test menu allows you to test the proper functionality of the DOASENSE Reader.

4.2.3.1 Grey control strips

The purpose of this test measurement is to verify that the optical measuring capability of the instrument works properly. Perform this test according to local requirements, or at least once a week, or when you receive ambiguous results during normal use. The grey control strips for testing the instrument are provided in the DOASENSE Reader package.

Carefully clean the strip holder tray before using the grey control strips for the QC test. This prevents degradation of the grey control strips.

Place the grey control strip on the strip holder tray with its wide end pointing forwards so that this wide end is pulled into the DOASENSE Reader first.

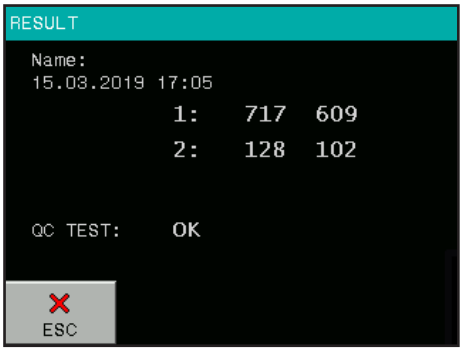
Follow the steps below:

- Select the QC TEST button in the MENU section
- Press “Check strip”
- Press the 13-digit number button and enter the calibration code for the batch of the control strips (found on the control strip tube) or use the BCR. Confirm with OK.

- Place one of the grey control strips on the strip holder tray
- The DOASENSE Reader starts the measurement
- Wait until the measurement is completed

After the measurement, the DOASENSE Reader compares the obtained remission values with the predefined ranges stored in the instrument in every greyscale and wavelength. After this evaluation, the instrument displays and prints out the results. If the measured values comply with the predefined values, the results of the QC test are OK.

Typical screen display after QC test:



If a new tube of grey control strips is used, the respective calibration code needs to be entered accordingly (by BCR or manually).

Retain the print-out for QC documentation. If the test fails, a test error is reported and the wrong result is displayed in red. If this happens, repeat the test with another control strip. If an error is reported again, contact your service representative.

Keep the grey control strips in the tube, do not touch the strip surfaces by hand, and handle them with care The control strips are reusable. All important information can be found on the label of the tube containing the grey control strips. Do not use expired grey control strips!

4.2.3.2 DOASENSE Control Urines

The DOASENSE Control Urines are external quality assurance materials for use with the DOAC Dipstick and the DOASENSE Reader. Contact your distributor for further details about the DOASENSE Control Urines. With these quality assurance materials, the user can test the functionality and quality of the DOAC Dipstick and DOASENSE Reader. The DOASENSE Control Urines are only intended for use with the DOAC Dipstick and the DOASENSE Reader and are for professional use only. Values measured with the DOASENSE Reader are automatically compared with target values. Do not use expired DOASENSE Control Urines!

Test performance:

- Choose the QC TEST option found in the MENU section.
- Remove two DOAC Dipsticks from the tube.
- Press the DCU-N button.
- Dip the first test strip into the DOASENSE Control Urine labelled as negative control (DCU-N), remove excess urine and place the strip on the strip holder tray.
- After the negative control is evaluated, press the DCU- P button.
- Dip the second strip into the DOASENSE Control Urine labelled as positive control (DCU-P), remove excess urine and place the strip on the strip holder tray.
- Wait for evaluation.

After the evaluation is complete, the results are automatically compared with predefined target values in the DOASENSE Reader's memory. If the result agrees with the target values, the result is displayed in white and marked as "QC test: OK". Unsatisfactory results are marked in red and printed with two exclamation marks and marked as "QC test: ERROR".

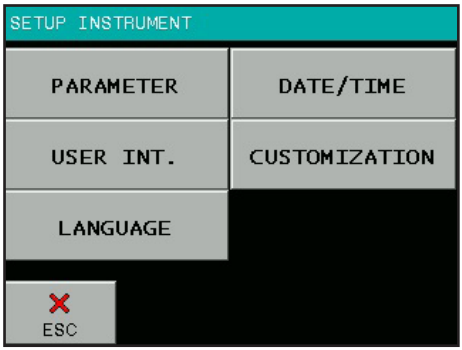
If this happens, check the expiration date of all materials you have used and repeat the measurement with new test strips/new vials of DOASENSE Control Urines. If the error message persists, contact your service representative.

Retain the print-out for QC documentation purposes.

4.2.4 Setup

The DOASENSE Reader allows you to change settings to suit your workplace requirements.

The available settings are displayed in the following format:



The working parameters are organized as follows:

- PARAMETER – strip- and measurement-related parameters can be set here:
  Printing order of the evaluated parameters

- USER INTERFACE – turns the following user interfaces on/off:
  PRINTER
  SOUND
  (Note: Turning off the sound also deactivates notification sounds, used e.g. in Smart Mode!)
  ID MODE

- LANGUAGE – select the official language of the country of distribution from the list of available languages

- DATE /TIME – set the date, time and date format

- CUSTOMIZATION – customizes the header text and logo, and defines colour and clarity texts

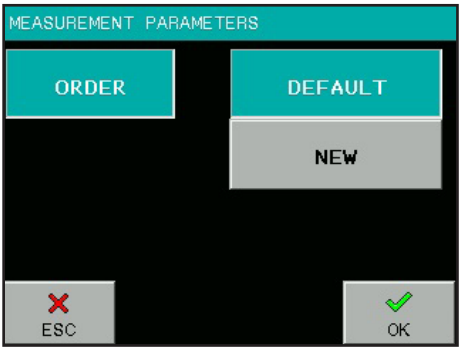
4.3 Parameter settings

This menu item has the following submenu:

- Printing order

4.3.1 Printing order

The user can choose in which order the individual parameters will be printed:



Pressing the DEFAULT button means the printing order corresponds to the order of parameters as listed on the DOAC Dipstick tube. (Please note that the DOASENSE Reader does not evaluate or display the DOAC Dipstick pad for assessing urine colour, so this parameter is not listed in the order.)

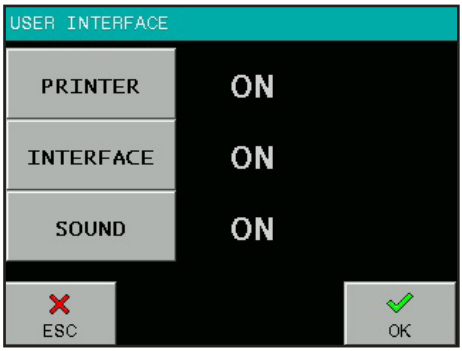
This order can be changed according to the user's preference by pressing NEW. The program then offers all parameters, which should be selected one after the other in the desired order.

4.4 User interface

In the USER INTERFACE menu item, the built-in interfaces can be set to ON or OFF. These interfaces are:

- Printer
- Serial interface
- Sound

The factory setting for all interfaces is: ON.



Printer ON/OFF determines whether the results will be printed automatically after measurement or not. If this feature is switched off, the instrument will measure the strip and store the result, but will not print it. The result can be printed at any time from the memory, or when the respective result is displayed.

Interface ON/OFF determines whether the results will be sent to HOST automatically after measurement or not. If this feature is switched off, the instrument will measure the strip and store the result in the memory, but it will not send it. The result can be sent at any time from the memory, or when the respective result is displayed.

Sound ON/OFF turns the button feedback beep and the sound notifications on or off.

4.5 Language settings

In the LANGUAGE menu, you can select the language of the instrument. Pressing the corresponding button makes the selection. The button showing the currently selected language is highlighted. Press the OK button to adopt the selection.

Select the official language of the country of distribution from the list of available languages.

4.6 Date/time settings

The time and the date as well as the date format can be set here.

Select the DATE/TIME button in the SETUP menu and the following display will appear:

To change the date or time values, press the corresponding button. A numeric keypad will appear and the desired value can be entered. When date and time are correct, press the FORM button to adjust the date format.

The following formats can be selected:

Year – Month – Day YYYY-MM-DD
Day – Month – Year DD-MM-YYYY
Month – Day – Year MM-DD-YYYY

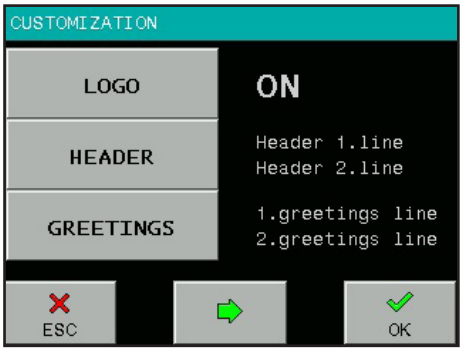
Pressing the OK button adopts the current time and date settings. The real-time clock in the DOASENSE Reader is powered by a built-in lithium battery. This battery is independent from the removable batteries.

4.7 Customization menu

The CUSTOMIZATION menu allows you to enter user-defined texts into the DOASENSE Reader. The text lines can be entered with an on-screen alphanumeric keypad or with a connected external keyboard.

Possible user-defined texts include:

- Two result header lines, which appear on every result print-out, max. 24 characters
- Two greeting lines, which are printed after the self-test, max. 24 characters
- Four texts for describing urine clarity, each max. 10 characters
- Nine texts for describing urine colour, each max. 10 characters



In addition to the adjustable texts, the LOGO ON/OFF switch is accessible from this menu item.
If LOGO is set to ON, the DOASENSE logo will be printed with every result print-out.

To move from page to page, press the ◄► buttons.

4.8 Powering by batteries

The DOASENSE Reader can be operated with batteries. The battery compartment is located at the bottom of the instrument. Six 1.5 V type AA batteries should be used. When inserting the batteries, please pay attention to the polarity, which is indicated in the battery compartment.

Figure 11: The battery compartment on the bottom of the DOASENSE Reader

When batteries (type LR6) are used, 200 measurements with printing or 240 measurements without printing can be made with one set of batteries. The instrument displays a BAT icon on the LCD that gives information about the battery status.

To prolong battery life, consider the following:

- Turn off the automatic printing feature and print the result only when necessary.
- If the measurement series has been completed, switch off the instrument

The Standby mode also consumes energy!

The instrument beeps as a warning in Standby mode when battery power is being used.

If the power supply unit is used, the instrument will receive its energy from the power supply unit and no battery power is consumed.

5. Service information

Only use the instrument as instructed to analyse the DOAC Dipsticks. Please do not open the instrument or make any other unauthorized modifications. The DOASENSE Reader is a highly sensitive and accurate optical measuring instrument. All optical components and the reference pad (REF PAD) are adjusted with special tools during the manufacturing process.
Unauthorized modifications or opening the instrument in an inappropriate way can result in maladjustments of the optical measurement head, or similar damage, which can compromise the accuracy of the results.

5.1 Trouble-shooting

In case of any error, please refer to the following table. It suggests possible error causes together with corrective actions.

Error description	Possible cause	Corrective action
The reader cannot be switched on. The display remains dark.	Power supply is not connected or wrong type.	Check the power supply and the connections.
Self test failed.	Strip holder tray is missing or the REF PAD dirty or movement of the tray obstructed.	Check the strip holder tray, it must be clean and easy to move also by hand.
The reader doesn't print, or the printout is not visible.	Paper cover is not closed. Wrong paper is loaded (not thermal paper). Paper is inserted with wrong side up.	Check the printer visually, for any damage or jam. Insert the right type of paper correctly. Close the printer cover.
The reader does not recognize the inserted strip.	The strip holder tray is in wrong position.	Check if the hole of the tray is exactly above the strip detector.
Host communication failed.	Serial cable is not attached or wrong. Interface mode is turned OFF, or parameter doesn't match with HOST settings.	Check the cable! Check that interface mode is ON and parameters are correct.
Reader displays Measurement Error.	Strip is placed wrong. Wrong strip is used. Dry or not fully moistened strip is used.	Repeat the measurement with correct strip.
Reader displays Dry strip.	Dry strip was used.	Dip diagnostic strip into a sample of urine and repeat the measurement.
Reader displays Mechanical error.	Strip holder tray is missing or it is in wrong position.	Turn off the reader and insert/remove and insert the strip holder tray.
Reader displays Ref PAD Error.	Reference pad is dirty or mechanically damaged.	Turn off the reader and clean strip holder tray including reference pad according to section 3.7; in case of mechanical damage contact your service engineer.
Reader displays Wrong strip.	The reader does not recognize the test strip because of: misplaced strip, insertion of different type of test strip (not a DOAC Dipstick), insertion of test strip upside down.	Repeat the measurement with a correct test strip (DOAC Dipstick) and ensure that the test strip is inserted correctly.

5.2 Service information

In case of error, consult the troubleshooting guide first. If the error persists, please contact your distributor for customer service.

Never open the DOASENSE Reader's case.

5.3 Safety information

The DOASENSE Reader complies with the EMC directive 2014/30/EU and low voltage directive 2014/35/EU.
The DOASENSE Reader complies with the European requirements of the IVDR (EU) 2017/746 Regulation on in vitro diagnostic medical devices.

To dispose of batteries in the EU, the 2006/66/EC directive of the European Parliament applies. Because they contain pollutants, batteries must not be disposed of as household waste. They must be given to collection points designed for that purpose.

Disposal of the DOASENSE Reader:
In order to comply with the EU directive 2012/19/EU (WEEE) we take our devices back and dispose of them free of charge. Disposal via public collection systems is prohibited. We either re-use them or give them to a recycling company that disposes of them in line with law. For disposal, please contact your local distribution partner.
For countries outside the EU, batteries and devices should be disposed of in accordance with your local waste disposal regulations.

5.4 Producer

The legal manufacturer of the DOASENSE Reader for use with the DOAC Dipstick is:

DOASENSE GmbH
Waldhofer Str. 102
69123 Heidelberg
Germany
Tel.: +49 6221 825 9785
Fax: +49 6221 825 9786
E-mail: info@doasense.de
www.doasense.de

5.5 Guarantee conditions

The warranty period is 12 months. The original commercial invoice must be presented in case of a claim during the warranty period. The warranty is not valid in cases of improper handling. The warranty is limited to repairs of defective parts or, at our sole discretion, replacement with a new and defect-free instrument.

Any warranty claims made or alleged do not influence the total warranty period of 12 (twelve) months. Further claims are excluded, especially claims for compensation for direct or indirect damages.

Please refer to our current Terms and Conditions for the Sale of Goods, which can be found at www.doasense.de/agb.html.

5.6 Compatible consumables

- DOAC Dipstick –
  Container with 12 test strips:
  DOASENSE order reference number 0001
- DOASENSE Control Urines –
  Pack with artificial control urines (1x negative & 1x positive):
  DOASENSE order reference number 0003
- Replacement Control Strips for DOASENSE Reader –
  Container with three control strips:
  DOASENSE order reference number 0004
- Thermal printer paper:
  Use standard thermal printer paper rolls of dimension 57 mm wide, 25 m long; for example „Soennecken 4012"

6. Technical parameters

The following table summarizes the main technical parameters of the DOASENSE Reader:

General	Dimension	230×127×110 mm
	Weight	0.9 kg without batteries
	Power source	External power supply: GTM96180-1811-2.0 9V DC 2.0A 100-240V / 50-60 Hz
	Pollution degree	2
	Transient overvoltage category	II
	Mains supply voltage fluctuations	up to +/- 10 %
	Power consumption max / standby	18W / 2W
	Battery	6×1.5 V AA
	Battery life type LRG	200 measurements with printing or 240 without printing
Measurement	Method	Reflection photometry
	Throughput	Up to 24 test strips per hour
	Wavelength	380 and 535 nm
	AD resolution	10 bit
User Interface	Printer	58 mm graphical thermal printer, 24 char/line
	LCD	320×240 colour TFT
Memory	Capacity	400 results of urines samples 100 results of grey strips 100 results of control urines
	RTC	Lithium battery kept real time clock
Interfaces	Host interface	RS232 serial interface, USB connector (1x USB B)
	BCR / keyboard and PC	USB connector (2x USB A, 1x USB B)
Recommended operating environment	Temperature	15–35 °C Optimal range 20–25 °C
	Humidity	20–80 %
	Place	Indoor use only Clean, dry and well ventilated location Horizontal surface No shock or vibration No direct sunlight At least 25 cm away from walls or other objects
	Altitude	Up to 2000 m above sea level
Storing / transport	Temperature	-20–60 °C
	Humidity	20–90 %

Performance characteristics:

The analysis of the DOAC Dipstick colours by the DOASENSE Reader gives the results "negative" and "positive" for DOACs and "normal" and "low" for creatinine. The threshold of the reader's measurement is calculated based on the cut-off value between negative and positive.

The DOASENSE Reader cut-off values for apixaban, edoxaban and rivaroxaban concentrations in the urine sample are < 100 ng/ml ("FXA negative") and > 275 ng/ml ("FXA positive"). The DOASENSE Reader cut-off values for dabigatran are < 75 ng/ml for "THR negative" and > 300 ng/ml for "THR positive". The evaluation of the DOAC Dipstick colours by the DOASENSE Reader in the ranges between the cut-off values can either be "negative" or "positive" (data on file).

A normal CRE result indicates that the concentration of creatinine in the urine sample is above 0.25 g/l. A low CRE result indicates that the concentration of creatinine in the urine sample is below 0.25 g/l.

Limitations

As test results are qualitative, no quantitative interpretation of the results can be performed.

The results must always be interpreted by a physician in connection with the clinical context of the patient. No treatment decisions should be made solely based on the outcome of a DOAC Dipstick analysis performed by the DOASENSE Reader.

A "low" creatinine test result may give false negative results of DOACs in urine and DOAC concentrations in plasma/blood may be high or elevated.

Persons with colour vision deficiency or colour blindness must not perform the DOAC Dipstick test or use the DOASENSE Reader.

Expected values and reference ranges

Creatinine: reference range: 0.25–3.0 g/l (2.2–26.5 mmol/l) (Ref.: Needleman).

DOACs: normal values are below 5 ng/ml (LC-MS/MS method). Patients under DOAC treatment typically display values above 200 ng/ml (Ref.: Schreiner).

Please also refer to the Instructions for Use of the DOAC Dipstick product for further details.

7. Serial interface protocol

The DOASENSE Reader has an RS232 interface to a HOST computer. If the communication is enabled (Interface: ON) the reader sends the result immediately after the measurement. Stored measurements can also be sent at any time from the memory.

The hardware parameters of the RS232 port are:

Baud rate: 19 200 Bd
Bit length: 8
Parity: No
Stop bit: 1

The interface has a DB9 mother type connector with the following PIN connection:

PIN number	Connected
2	TxD
3	RxD
5	GND
1, 4, 6, 7, 8, 9	- not connected

If a USB host is connected, the DOASENSE Reader sends the data through the USB port as well. The format of the data stream is identical to the serial (RS232) protocol. The communication is unidirectional (DOASENSE Reader -> HOST) and in ASCII text form. The reader sends one result in one package.

Please refer to

www.doasense.de/ifu

or contact your local DOASENSE representative for details on the data format used by the DOASENSE Reader.

USB drivers for external devices can be obtained for example at this website:
http://www.ftdichip.com/Drivers/VCP.htm

8. Short instructions

1. Check carefully that the instrument is complete and not damaged.
2. Connect the instrument to the power supply unit and plug the power supply unit into a power outlet.
3. Switch on the instrument at the main switch.
4. Wait until the instrument has performed the self-test.
5. Set the mode of results (direct printing after analysis, printing after measurement of all samples, sending to the external network, etc.).
6. Before placing the test strip on the strip holder tray of the DOASENSE Reader, visually assess the urine colour pad to determine whether the result is “normal” (the colour manifests immediately).
7. Start the measurement in the mode Seq.No or ID.
8. Complete the measurements of urine samples; follow all recommendations during the operation, which are included in the DOAC Dipstick instructions for use.
9. Clean the instrument when your daily measurements are completed.
10. Leave the instrument in Standby mode or switch it off at the main switch.

9. Symbols

CE	CE Mark – Instrument complies with European requirements of the IVDR (EU) 2017/746 Regulation
IVD	In vitro diagnostic medical device
	Classified collection of electrical and electronic equipment
	Manufacturer and date of manufacture
	Attention
REF	Catalogue number
	Consult instructions for use
SN	Serial number
	Indicates that caution is necessary when operating the instrument, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences.
	Indicates that there are potential biological risks associated with the medical device.

10. Literature

Schreiner R et al. Res Pract Thromb Haemost 2017; 1(Suppl.1): PB 491.

Harenberg J et al. Semin Thromb Hemost. 2019;45:275-84..

Harenberg J et al. Clin Chem Lab Med 2016; 54: 275-83.

Du S et al. Clin Chem Lab Med 2015; 53: 1237-47.

Harenberg J et al. Semin Thromb Hemost 2015; 41: 228-36.

Favaloro EJ et al. Semin Thromb Hemost 2015; 41: 208-27.

Harenberg J et al. Thromb J 2013 Aug 1; 11(1): 15.

Needleman SB et al. J Forensic Sci 1992; 37: 1125-33.

11. Index

DOASENSE GmbH

Waldhofer Str. 102
69123 Heidelberg
Germany
Tel.: +49 6221 825 9785
Fax: +49 6221 825 9786
E-mail: info@doasense.de
www.doasense.de

IVD CE