Diabetomics Insudex® Lateral Flow Reader

Instructions for Use

REF 2028

CE IVD

Contents

1. Introduction

Thank you for choosing the Diabetomics Insudex® Lateral Flow Reader. We are confident that this instrument will become an integral part of your laboratory.

Before using the Diabetomics Insudex® Lateral Flow Reader, it is essential that you read this user manual carefully. Following the instructions and safety information in this user manual will ensure safe operation and maintain the system in a safe condition.

1.1. Intended Use of the Diabetomics Insudex® Lateral Flow Reader

The Diabetomics Insudex® Lateral Flow Reader is intended for in vitro diagnostic (IVD) use in the detection and/or quantification of target analytes on lateral flow test strips.

The Diabetomics Insudex® Lateral Flow Reader is intended to be used only in combination with lateral flow (LF) tests indicated for use with the Diabetomics Insudex® Lateral Flow Reader, and only for applications that are described in the respective handbooks of our reader associates.

1.2. Target Population

The Diabetomics Insudex® Lateral Flow Reader is intended to be used by trained qualified professionals within a hospital setting or in an outpatient setting such as in a physician's office. The intended use does not include operation of the device in intensive care units or in operating theatres, unless all specific hygiene and patient safety requirements of these locations are followed by the user.

1.3. Product Classification

According to Directive 98/79/EC, Diabetomics Insudex® Lateral Flow Reader is classified outside of Annex II thus only a CE declaration of conformity is required.

1.4. Device Description

This device is a portable test reader that will yield qualitative and quantitative results for the lateral flow tests integrated in certain cassette models that are marketed by Diabetomics.

1.5. General Information

1.5.1. Scope of delivery

The delivery includes the following items:

1. Insudex® main unit (Cat.100032000).
2. Drawer (Cat.900013509).
3. External power supply unit (Cat.900020088).
4. Power cord (Cat.900020077, Cat.9000200078, Cat.9000200079, Cat.9000200081 or Cat.9000200082).

See Appendix A: Ordering Codes for more information.

1.5.2. Technical assistance

At Diabetomics we pride ourselves on the quality and availability of our technical support. Our Technical Service Department is staffed by experienced technicians with extensive practical and theoretical expertise in the use of Diabetomics products. If you have any questions or experience any difficulties regarding the Diabetomics Insudex® Lateral Flow Reader or Diabetomics products in general, do not hesitate to contact us.

Diabetomics customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other customers as well as to the researchers at Diabetomics. We therefore encourage you to contact us if you have any suggestions about product performance or new application and techniques.

For technical assistance, contact the Diabetomics Technical Service Department or local distributors.

1.5.3. Policy statement

It is the policy of Diabetomics to improve products as new techniques and components become available. Diabetomics reserves the right to change the specifications of products at any time.

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact Diabetomics Technical Service with any feedback.

1.5.4. Requirements for Diabetomics Insudex® Lateral Flow Reader users

Table 1 covers the general level of competence for the use and servicing of the Diabetomics Insudex® Lateral Flow Reader.

Task	Personnel	Training and experience
Routine use	Laboratory technicians or equivalent	Trained in techniques included in each cassette.
Servicing	Service Specialists only	Trained, certified, and authorized by Diabetomics

3. Safety Information

Before using the Diabetomics Insudex® Lateral Flow Reader, it is essential that you read this user manual carefully. Following the instructions and safety information in this user manual will ensure safe operation and maintain the system in a safe condition.

The following types of safety information appear throughout the Diabetomics Insudex® Lateral Flow Reader Instructions for Use.

WARNING	The term WARNING is used to inform you about situations that could result in **personal injury** to you or other persons. Details about these circumstances are given in a box like this one.

CAUTION	The term CAUTION is used to inform you about situations that could result in **damage to the instrument** or other equipment. Details about these circumstances are given in a box like this one.

The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

3.1. Proper Use

WARNING/ CAUTION	**Risk of personal injury and material damage** Improper use of the Diabetomics Insudex® Lateral Flow Reader instrument may cause personal injury or damage to the instrument. The instrument must only be operated by qualified personnel.

CAUTION	**Damage to the instrument** Avoid spilling water or chemicals onto the Diabetomics Insudex® Lateral Flow Reader instrument. Damage caused by water or chemical spillage will void your warranty.

In case of emergency, switch off the Diabetomics Insudex® Lateral Flow Reader with power button and unplug the power cord from the power outlet.

3.2. Electrical Safety

If operation of the Diabetomics Insudex® Lateral Flow Reader is interrupted in any way (e.g., due to interruption of the power supply or a mechanical error), first unplug the power cord from the power outlet, then switch off the instrument using the power button. Contact Diabetomics Technical Service after such an incident.

WARNING	**Rechargeable Batteries** The Diabetomics Insudex® Lateral Flow Reader has a battery pack inside that accomplishes the IEC 62133 standard: Secondary cells and batteries containing Alkaline or other Non-Acid Electrolytes – safety requirements for portable sealed secondary cells and for batteries made from them, for use in portable Applications - This WARNING is applicable to routine users as well as to technical service users. • Do not dismantle, open or shred batteries • Keep batteries out of the reach of children • Seek medical advice immediately if a battery has been swallowed • Do not expose batteries to heat or fire. Avoid storage in direct sunlight • Do not remove a battery from its original packaging. • Do not subject batteries to mechanical shock • In event of cell leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice. • Only use Batteries provided by Diabetomics. • After extended periods of storage, it may be necessary to charge and discharge the batteries several times to obtain maximum performance.

WARNING	**Electrical hazard** Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument unsafe. **This must be checked after service or maintenance.** Intentional interruption is prohibited. **Lethal voltages inside the instrument** This WARNING is applicable to routine users as well as to technical service users. • Risk of electrical shock and energy hazard. All failure should be examined by a qualified technician. Please do not remove the case of the AC adaptor by yourself! • Adaptors should be placed on a reliable surface. A drop or fall could cause damage.

	• Please do not place the AC adaptor in places with high moisture or near the water. • Please do not place the AC adaptor in places with high ambient temperature or near fire source. About the maximum ambient temperature, please refer to • Appendix B: Technical Data • . • Disconnect the AC adaptor from the AC power before cleaning. Do not use any liquid or aerosol cleaner. Only use a damp cloth to wipe it. • In case of replacement or a loosing of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed on the Appendix A: Ordering Codes In case of replacement, this must be ordered from Diabetomics.

To ensure satisfactory and safe operation of the Diabetomics Insudex® Lateral Flow Reader:

- The power cord of the external power supply must be connected to a line power outlet that has a protective conductor (earth/ground).
- No other external power supply neither power cords than the specified at “Appendix A: Ordering Codes” must be used. In case of replacement, this must be ordered from Diabetomics.
- The instrument must not be operated with the cover removed.
- If you suspect any instrument damage, contact Diabetomics Technical Services.

If the Diabetomics Insudex® Lateral Flow Reader becomes electrically unsafe, prevent other personnel from operating it, and contact Diabetomics Technical Service.

The instrument may be electrically unsafe if:

- The instrument or the external power supply appears to be damaged.
- The instrument has been stored under unfavorable conditions for a prolonged period.
- A different external power supply is used other than the one provided by Diabetomics.

WARNING	**Risk of electric shock** In case of replacement or lose of the external power supply or the power cord, these must be replaced only with the external power supply or power cords listed on the Appendix A: Ordering Codes and provided by Diabetomics.

3.3. Environment

Operating conditions

WARNING	**Explosive atmosphere** The Diabetomics Insudex® Lateral Flow Reader is not designed for use in an explosive atmosphere.
CAUTION	**Direct sunlight** Do not expose the Diabetomics Insudex® Lateral Flow Reader to direct sunlight or other powerful lights during operation.
CAUTION	**High humidity or liquids** Protect the Diabetomics Insudex® Lateral Flow Reader from high humidity and contact with liquids.
CAUTION	**Strong electromagnetic radiation** Do not expose the Diabetomics Insudex® Lateral Flow Reader to strong electromagnetic radiation.
CAUTION	**Strong ultrasonic radiation** Do not expose the Diabetomics Insudex® Lateral Flow Reader to strong ultrasonic radiation.

3.4. Biological Safety

Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS:

https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF

WARNING	**Samples containing infectious agents** Some samples used with the Diabetomics Insudex® Lateral Flow Reader may contain infectious agents. Handle such samples in accordance with the required safety regulations.

	Always read how to proceed in the cassette's instructions of use. The responsible person(s) (e.g., laboratory manager) must take the necessary precautions to ensure that the workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents, as defined in the applicable Safety Data Sheets (SDSs) or OSHA[1] ACGIH[2] or COSHH[3] documents. Venting of fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.
WARNING	**Samples containing infectious agents** Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, HHS: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF See: Section III—Principles of Biosafety Laboratory Practices and Technique The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards and must be trained and proficient in the practices and techniques required for handling such material safely. The director or person in charge of the laboratory is responsible for providing or arranging the appropriate training of personnel.
WARNING	**Samples containing infectious agents** To avoid hazards in case of cassette break use Primary Barriers and Personal Protective Equipment: Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, HHS: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF See: Section III—Principles of Biosafety Safety Equipment (Primary Barriers and Personal Protective Equipment). Safety equipment includes BSCs, enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials.

[1] OSHA: Occupational Safety and Health Administration (United States of America).
[2] ACGIH: American Conference of Government Industrial Hygienists (United States of America).
[3] COSHH: Control of Substances Hazardous to Health (United Kingdom).

3.5. Chemicals

WARNING	**Hazardous chemicals** Some chemicals used with the Diabetomics Insudex® Lateral Flow Reader may be hazardous. Always wear safety glasses, gloves, and a lab coat. The responsible person(s) (e.g., laboratory manager) must take the necessary precautions to ensure that the workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of toxic substances (chemical or biological), as defined in the applicable Safety Data Sheets (SDSs) or OSHA, ACGIH or COSHH documents. Venting of fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.

3.6. Maintenance Safety

CAUTION	**Damage to the instrument** Do not use spray bottles containing alcohol or disinfectant to clean the surface of the Diabetomics Insudex® Lateral Flow Reader instrument. Do not use products containing alcohol or other corrosive solvents to clean the Diabetomics Insudex® Lateral Flow Reader instrument.
WARNING	**Risk of electric shock** Do not open the panels on the instruments. **Risk of personal injury and material damage** Only perform maintenance that is specifically described in this Instructions for Use.

3.7. Waste Disposal

Used consumables, such as cassettes may contain hazardous chemicals or infectious agents. Such waste must be collected and disposed of properly in accordance with local safety regulations.

All packaging waste from cassettes must be collected and disposed of properly in accordance with local environment regulations.

For disposal of waste electrical and electronic equipment (WEEE) see Appendix D: Waste Electrical and Electronic Equipment (WEEE).

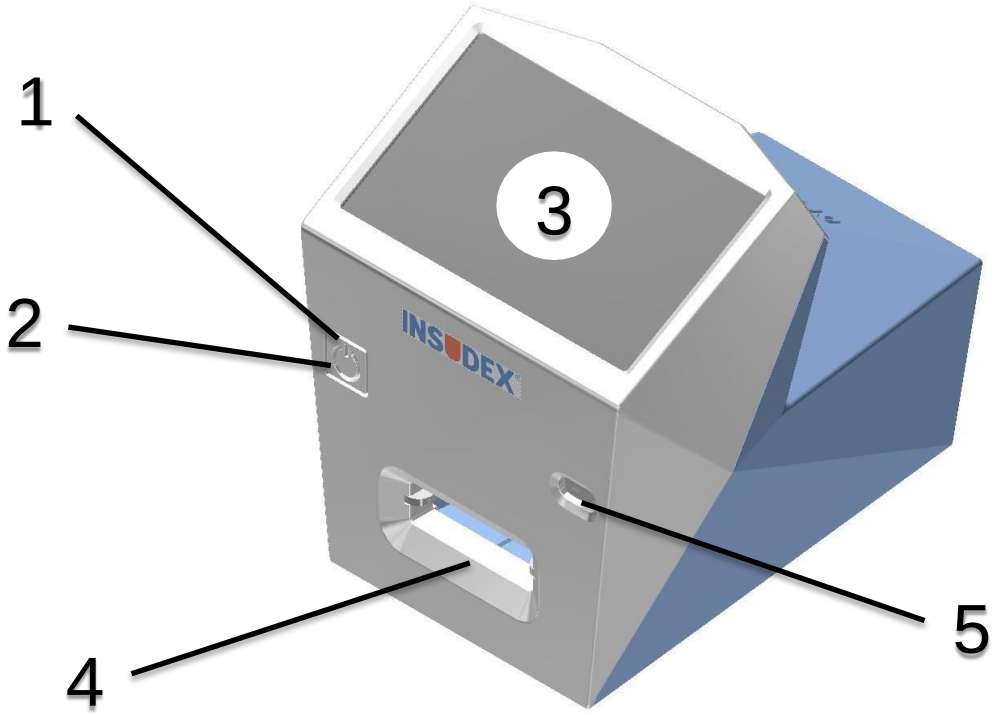
3.8. Symbols on the Diabetomics Insudex® Lateral Flow Reader Instrument

Symbol	Location	Description
	Type plate on the bottom of the instrument	Waste Electrical and Electronic Equipment (WEEE), see Appendix D: Waste Electrical and Electronic Equipment (WEEE).
	Type plate on the bottom of the instrument	CE Mark.
SN	Type plate on the bottom of the instrument	Serial Number.
	Type plate on the bottom of the instrument	Legal manufacturer.
	Type plate on the bottom of the instrument	Date of manufacture.
	Type plate on the bottom of the instrument	Consult instructions for use.
	Type plate on the bottom of the instrument	Consult caution information in the instructions for use.
IVD	Type plate on the bottom of the instrument	The device is an IVD product.

4. General Description

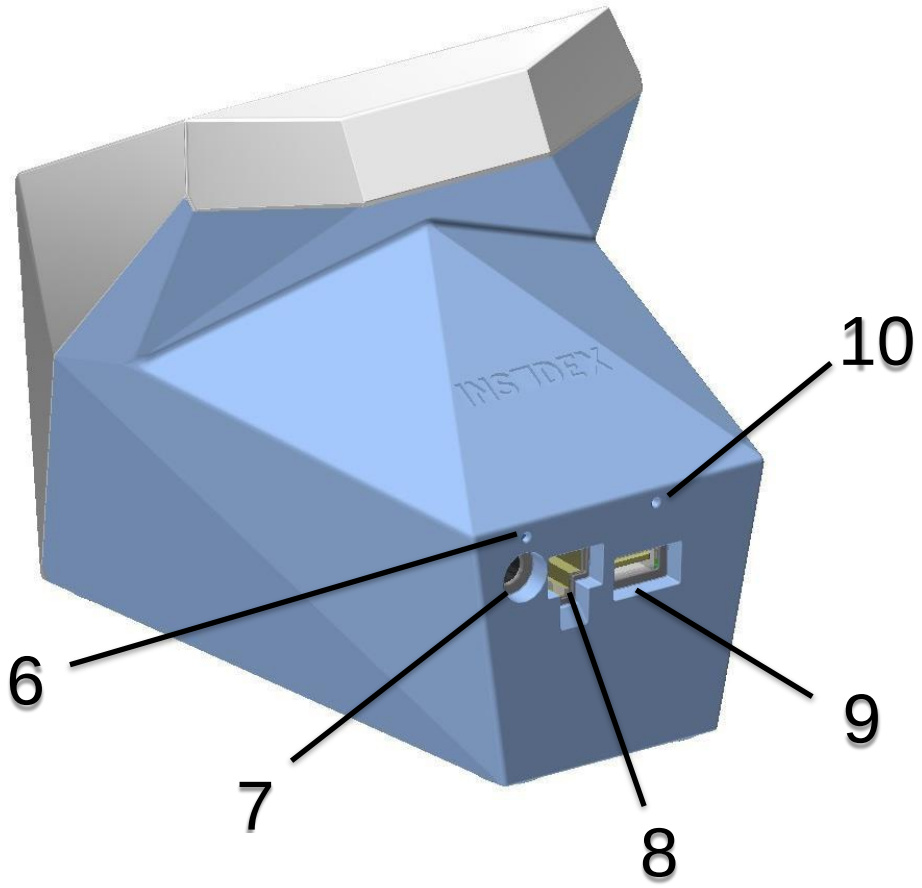
4.1. Instrument Overview

FRONT VIEW:



1. Power button
2. Device ON white LEDs
3. Touchscreen and display
4. Drawer insertion slot
5. Barcode reader

REAR VIEW:



6. Battery in charge red LED
7. External power supply socket
8. Ethernet socket
9. USB host port (only accessible for narrow USB memory sticks)
10. Software Wipe button hole

4.2. Accessories of the Instrument

3.2.1. Drawer

The drawer model must fit with the corresponding cassette model for a proper use of the instrument. See “Appendix A: Ordering Codes” to find available models.

3.2.2. External power supply

Connect the external power supply to mains, and the instrument to the external power supply to charge it. The red led above power supply socket should be lit when the power supply is properly connected.

WARNING	**Risk of electric shock** In case of replacement or loss of the external power supply, this must be replaced only with one of the power cords listed on the “Appendix A: Ordering Codes” delivered by Diabetomics.

3.2.3. Power cord

The instrument is equipped with a power cord with a plug suitable for the destination country. See “Appendix A: Ordering Codes” for details.

WARNING	**Risk of electric shock** In case of replacement or lose of the power cord, this must be replaced only with one of the power cords listed on the Appendix A: Ordering Codes” delivered by Diabetomics.

4. Installation

4.1. Unpack the Instrument

The packaging of the Diabetomics Insudex® Lateral Flow Reader can be stored for reuse.

4.2. Site Requirements

Place the Diabetomics Insudex® Lateral Flow Reader instrument on a stable surface, far away from powerful lights and near an earthed/grounded electrical outlet.

For a long period of use, kept the Diabetomics Insudex® Lateral Flow Reader instrument connected to power supply.

4.3. Power Cable Connection

The socket for connecting the power cable is on the back of the Diabetomics Insudex® Lateral Flow Reader instrument.

When the Diabetomics Insudex® Lateral Flow Reader is not in use for a long period of time, we recommend disconnecting the power cable.

4.4. Cassette Requirements

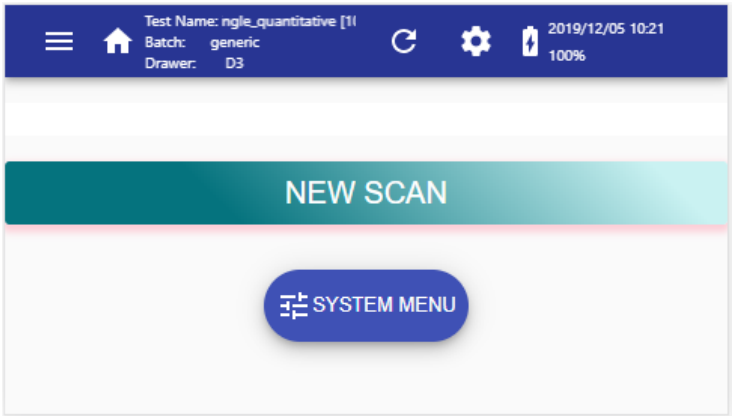
Before using the Diabetomics Insudex® Lateral Flow Reader instrument make sure that the cassette has not exceeded its expiration date.

WARNING	**Do not use expired cassettes** Review the expiration date of the cassette and do not use it if it is expired.

5. Operating Procedures

5.1. Main Screen Overview

The main screen displays current cassette configuration, date, time, battery status, new scan button and system menu button.



Main Window:

New Scan	Press this button to start the process to read and process a new cassette.
SYSTEM MENU	Press this button to enter to the system menu.

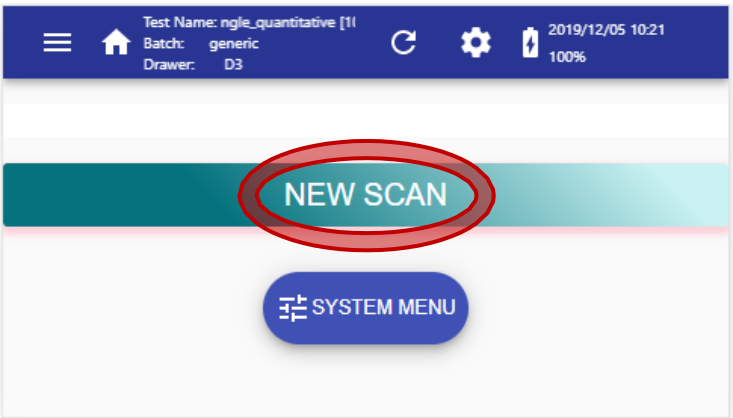
Main Toolbar:

	Shows the drop Side Menu.
	Return to Main Screen.
Test Name: QC016_dev2 Batch: 20190618 Drawer: D3	Cassette Configuration that is currently loaded in the reader.
	Loading icon. When a new page or image is loading, the icon spins.
	Shows the dropdown Tools Menu.
2019/07/05 13:32 98%	Date, time and battery status are shown here.

5.2. New Scan

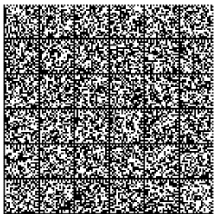
To perform a new scan, the next steps should be followed:

1- Push the 'NEW SCAN' button on the Main screen (see red circle) to enter to the scanning screen.



2- If the current Cassette Configuration, as shown in the top bar, corresponds to that of the cassette you are about to measure, skip this section. If it does not correspond, push on the 'CASSETTE CONFIG' button (see yellow circle) to load the new Cassette Configuration to be used in the next scan:

Take the Cassette Configuration barcode which is supplied along with the cassette box:

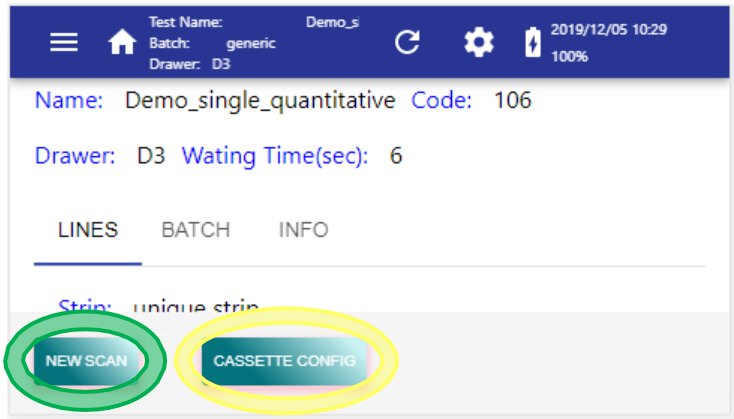


Place it in front of the instrument's barcode reader (5) at 5 cm of distance approximately. Push on 'ACTIVATE BARCODE READ' (see red circle). The barcode reader will start the scanning using a light that will disappear when the barcode has been read.

If the barcode is not read after 10 seconds, the device will return to the above window.

If the barcode is read but does not fit with which is expected, an error message will appear on the screen. Check the exposed barcode and touch the display outside the dialog box to skip the error message and return to above window.

In the new screen, the new Cassette Configuration data are shown. Drag up and down on the touchscreen and push the different tabs to see all data. Push on the 'NEW SCAN' button (see green circle) to return to the scanning screen. If the cassette configuration data is not correct, push on the 'CASSETTE CONFIG' button (see yellow circle) to scan another configuration.



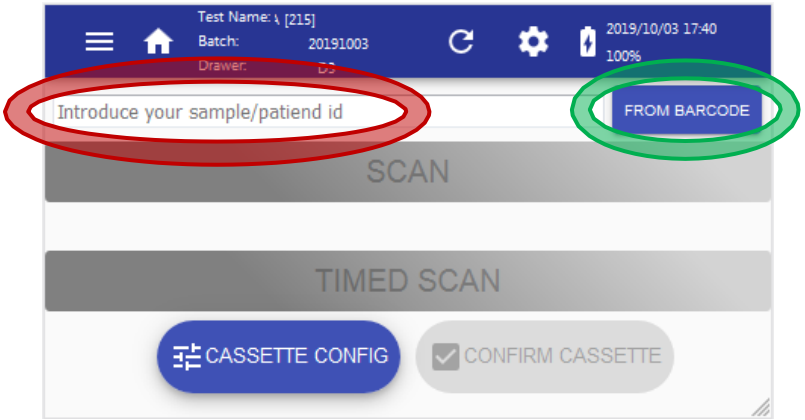
3- Back to scanning screen, push on the 'CONFIRM CASSETTE' button (see red circle) to confirm that current Cassette Configuration matches the cassette you are going to process. This step may be omitted depending on the options selected in the SYSTEM MENU.

Place the barcode printed on the pouch of the cassette in front of the barcode reader.

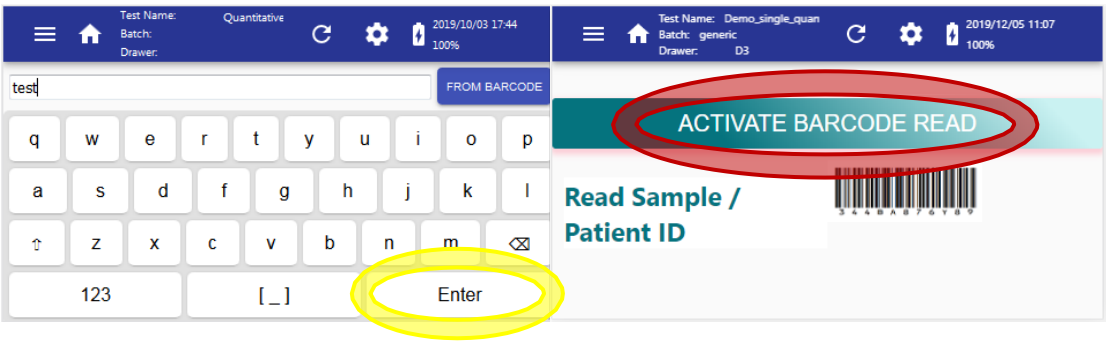
Push on 'ACTIVATE BARCODE READ' (see yellow circle). The barcode reader will start the scanning using a light that will disappear when the barcode has been read.

If the confirmed cassette does not correspond to the configuration currently loaded in the reader, an error message will be displayed. In such a case, use a cassette of the proper type, or load a new configuration corresponding to the current cassette.

4- After reading the cassette barcode, the instrument returns to the scanning screen. Push on the text 'Introduce your sample/patient id' (see red circle) to type the identification with a virtual keyboard or push on 'FROM BARCODE' button (see green circle) to scan the identification using the barcode reader of the device. This step may be compulsory or not depending on the options selected in the System Menu.

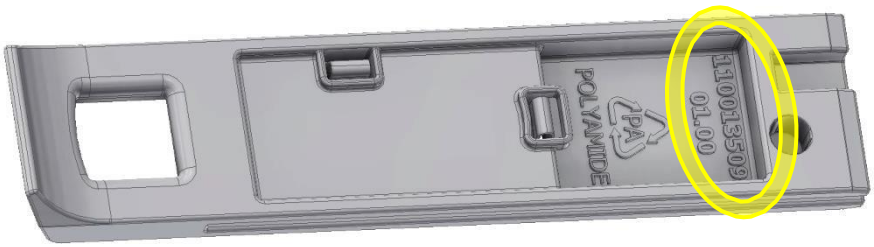


After typing an identification text on the virtual keyboard, push 'Enter' button (see yellow circle on left-side image) to proceed. To load the identification text from a barcode push on 'ACTIVATE BARCODE READ' button (see red circle on the right-side image) and place the barcode in front of the reader's light.

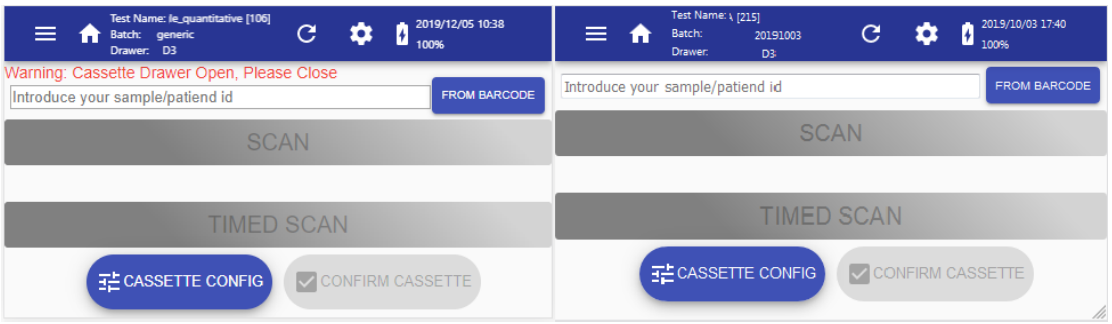


NOTE: Depending on the options of the System Configuration, if the reference you enter has already been used recently, a message will be displayed to warn the user to check whether it is an intentional re-scan of the same reference, or it is an error.

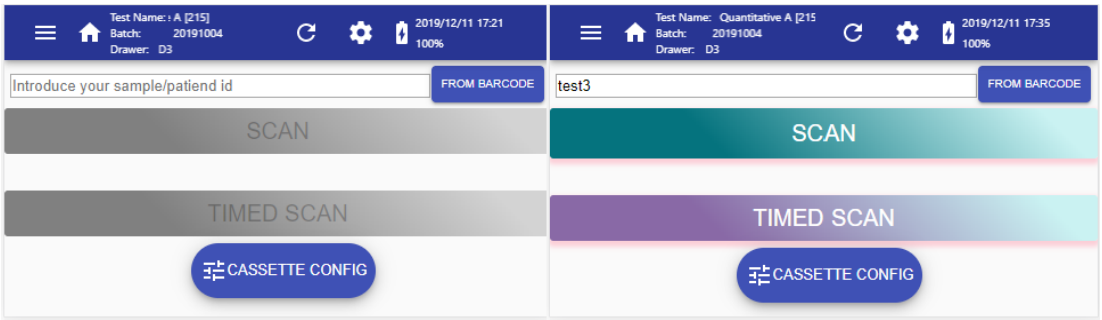
5- Insert the cassette into the corresponding drawer; ensuring that the code in the drawer bottom (see yellow circle) agrees with the drawer code displayed along with the cassette configuration at the top bar. Be sure that the cassette and the drawer surfaces are leveled; then push the drawer inside the reader.



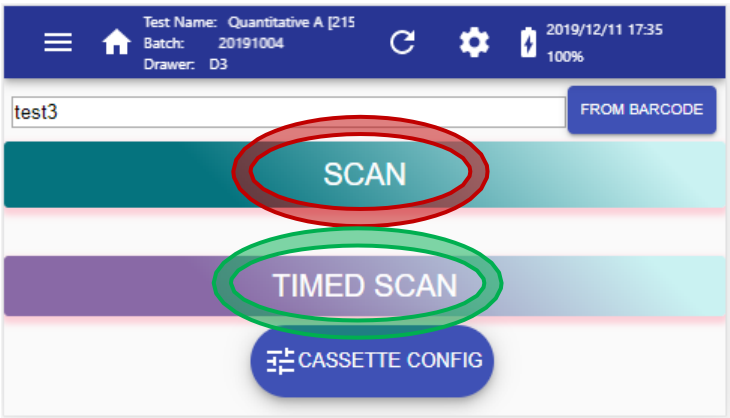
A warning appears on the screen to remember closing the drawer (see image on the left). When the drawer is inside the device, the warning is removed (see image on the right).



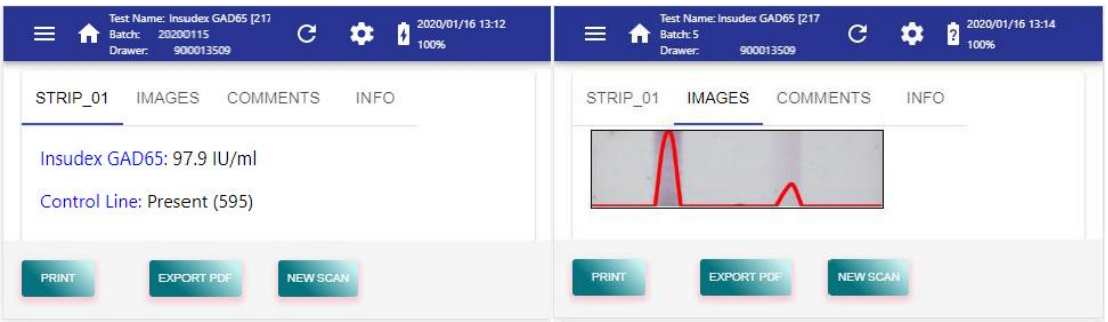
The scan buttons will remain in gray (see image on the left), until an ID is set and a drawer is placed inside the device (see image on the right).



6- If you have already waited the prescribed time after inoculating the sample into the cassette, push the 'SCAN' option (see red circle) to start the new scan immediately. Otherwise, if you have just inoculated the sample into the cassette, press the 'TIMED SCAN' option (see green circle); in this case the reader will automatically defer the scan until the prescribed waiting time had been elapsed.



7- The results of the scan will be displayed when the process ends. Drag up and down on the touchscreen, and press on the different tabs to see all data.



If a printer is connected and configured, press the 'PRINT' button in order to obtain a ticket/label containing the identification data and the summary results of the most recent scan. See section 5.3.2 to connect and configure a printer.

```
2020-01-16  13:09
ID: test3
Insudex GAD65 (217)
Lot: 20200115
Expiration: 2022-02-22
Reader: 100032000/00543

>strip_01
 Control: Present
  Result: 97.9 IU/mL
```

To export the results data into a PDF report file, connect a slim USB memory stick into the device's USB host port (previously formatted as described in section 5.3.1) and press the 'EXPORT PDF' button. Then you can transfer the PDF file into an external computer and from this print the report.

To process another cassette press on the 'NEW SCAN' button.

5.3. System Menu

In this menu diverse information is displayed and some settings can be changed:

5.3.1. SYSTEM

- Language: Select one language among those that are already installed in the reader.
- Air Plane Mode: Enable the air plane mode of the device, disabling WiFi connections.
- Inactivity Shutdown (min): Time in minutes since the last interaction with the reader, after which the system will power-down itself to save battery. Set to zero means disabled.
- Format USB: With this option, a slim USB memory stick can be properly formatted to be used to export CSV and PDF results, write logs, and to update the reader software.

- Export Logs to USB: Writes some internal files to a slim USB memory stick plugged into the USB host port, in order to send them to the technical service to aid for diagnose.
- Set Date/Time: Allows define the current date and time.
- Set Time Zone: Allows define the current time zone.

WARNING	The instrument is not ready to work with dates before manufacture's date.

5.3.2. PRINTER

Values of serial communication parameters are displayed and can be edited. Specifically: Baud rate, Parity, Data bits and Stop bits. Introduce those that correspond to your printer configuration.

The printer must have serial port and needs a USB adaptor or must be a USB printer emulating serial port.

If you want to use the printer Cat.90003069 (see 8.2 section), you should also order the USB adaptor Cat.90004203.

The default communication parameters of this printer are:

- Baud rate: 9600
- Parity: even
- Data bits : 8
- Stop bits : 1

5.3.3. INFO

Displays a list of information related to the reader. Specifically: Model, Serial Number, Ethernet IP, SSID, WiFi IP, WiFi Mode and DHCP mode.

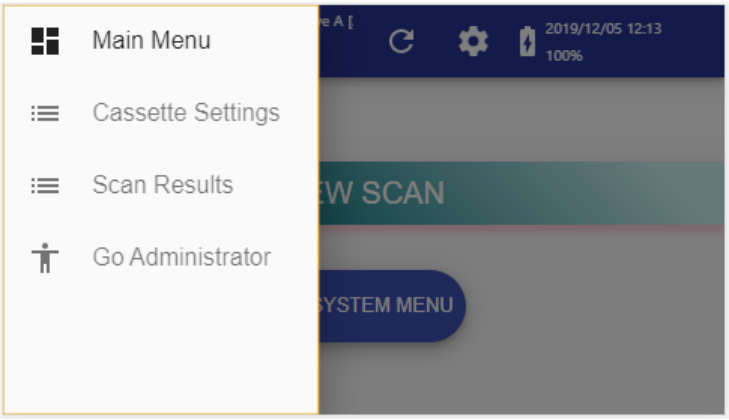
The information is automatically refreshed every 5 seconds (for example if the Ethernet cable is connected or disconnected).

5.3.4. VERSIONS

Displays a list of the versions of the software components of the reader. Specifically: Current SW Version, Hardware Version, Product Image Version, Wipe clean SW Version and Factory SW Version.

5.4. Side Menu

By pressing the menu symbol on the left of the top bar, a drop side menu will appear with following features:



5.4.1. Main Menu

The device returns to the main screen.

5.4.2. Cassette Settings

The current Cassette Configuration Settings is shown.

5.4.3. Scan Results

Access the list of stored scan results. The list is ordered with the most recent scan on top. Drag up and down on the touchscreen to displace the list.

For each scan in the list, the following information is displayed:

- Sample/Patient reference ID
- Date and hour of the scan
- Cassette type

In the upper-right corner there is a 'Export Results' button to export **all** results into a USB memory stick plugged into the USB host port of the reader (previously formatted as described in section 5.3.1). The results will be transferred as a CSV file, which can be later opened with a spreadsheet application in a computer. Optionally, the images corresponding to the exported results can be also exported.

To see the results of a particular scan result, press on it, and a screen with the summary of the results of the selected scan will be displayed. There it is possible to print a ticket, to export to a PDF file, or to delete this scan result.

About the exported file:

- File extension is .CSV
- Field separator/delimiter is character TAB, and numeric decimal separator is always character FULL STOP ".", regardless of the particular configuration of the computer where the exportation was done. This must be taken into account when importing the .CSV file into a spreadsheet application.
- The first row contains the headers/titles of the fields.
- For each cassette processing result, there are as many rows as lines (Control+Test) in all the strips of the cassette. For instance, one cassette with 2 strips, and each strip having 1 Control line and 2 Test lines, will have 6 rows of results.
- In the case of a strip where no Control line was found, then there will be no rows corresponding to Test lines (because they cannot be evaluated if Control line is missing).

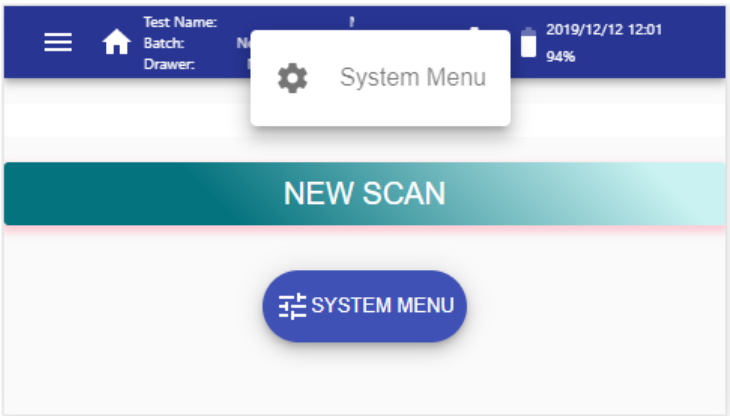
Parameters included in the results (for each processed line):

- Reference: Sample/patient id.
- uuid: Unique identifier of the scan (also included in the used image name).
- timeStamp: UTC time of the scan.
- comments: Comments added after the scan.
- cassette type: Name of Cassette Configuration Settings.
- cassette code: Code of Cassette Configuration Settings.
- batch ID: Batch id of cassette.
- due date: Expiring date of cassette batch.
- NormError: Processing parameter.
- lineError: Processing parameter.
- line warnings: Processing parameter.
- strip name: Name of the strip from a cassette.
- line name: Name of the line from a strip.
- result qualifier: Qualification result of the scan.
- quantifier index: System parameter.
- quantification: Quantification result of the scan (decimal separator ".").
- quantification units: Units of the quantification result.
- peak area: Measured intensity of the line (decimal separator ".").
- base line: Processing parameter.
- peak height: Processing parameter.
- peak position [mm]: Processing parameter.

- color channel: Cassette Configuration Settings parameter.
- bar width [mm]: Cassette Configuration Settings parameter.
- bar gap [mm]: Cassette Configuration Settings parameter.
- ppmm: Cassette Configuration Settings parameter.
- roi x [mm]: Cassette Configuration Settings parameter.
- roi y [mm]: Cassette Configuration Settings parameter.
- roi w [mm]: Cassette Configuration Settings parameter.
- roi h [mm]: Cassette Configuration Settings parameter.
- lower bound [mm]: Cassette Configuration Settings parameter.
- upper bound [mm]: Cassette Configuration Settings parameter.
- drawer intensity: Processing parameter.
- wb_factors: System parameter.
- applied thresholds: Cassette Configuration Settings parameter.
- quantification params: Cassette Configuration Settings parameter.
- fiducials: Processing parameter.

5.5. Tools Menu

By pressing the gear symbol on the center-right of the top bar a dropdown menu will appear, if Administrator Mode is enabled following features will appear:



5.5.1. System Menu

Explained in section 5.3.

5.6. Software Update

At the suggestion of Diabetomics, your reader may need to have its software updated. To execute the software update, perform the following steps:

- Make sure that the batteries are fully charged and that the reader is properly plugged to the mains supply.
- Format a USB memory stick in the system options menu of the reader (see section 5.3.1).
- Download the proper update package from Diabetomics website into a computer.
- Copy the downloaded update package from the computer to the memory stick.
- Switch-off the reader.
- Plug the memory stick into the USB port of the reader.
- Switch-on the reader.
- Follow the indications on the screen.

CAUTION	The software update procedure takes some time, during which the reader may seem unresponsive. Do not power-off the reader until the procedure is completed.

5.7. Software Wipe

WARNING: This is a last resort solution; run this procedure only if it has been requested by the Technical Support, and follow the instructions they could had given to you.

In case of a malfunctioning of the reader, the technical service might ask you to perform a Software Wipe. This operation restore the reader from software updates and leaves it in a stable condition. Results data will not be removed.

To execute the Software Wipe, perform the following steps:

- Power-off the reader.
- Insert a pin in the rear hole (10) and press the button inside (hold it pressed).
- Power-on the reader.
- Keep the button pressed until the message “sdcard ready” disappears.

CAUTION	The Software Wipe process takes some time, during which the reader may seem unresponsive. Do not power-off the reader until the procedure is completed.

5.8. Browser Generic Operations

Here some tips to browse this instrument:

- It is possible to move to previous windows by touching on the screen and dragging to the right. Then you can touch and drag to the left to return at the initial window.
- To remove an error message from the screen, touch the display outside the error window.
- To enter data through the virtual keyboard, only characters 0…9, a…z, A…Z, and SPACE are allowed.

6. Troubleshooting

Symptom	Probable cause	Recommended action
The unit cannot turn ON.	Battery discharged.	Plug the Power supply unit to recharge.
The unit switches-off spontaneously.	Too much time of inactivity elapsed (a message has been displayed for a while before switching-off).	Increase the inactivity time in the System Options menu.
The unit switches-off spontaneously.	Mains cord unplugged and battery getting too low (a message has been displayed for a while before switching-off).	Plug the mains supply and let the battery fully charge.
The unit cannot perform as expected.	Old version of SW.	Upgrade the SW.
The unit is not keeping the current date/time.	Internal button cell discharged.	Send the unit to Technical service for replacing the button cell.
The barcode reader light is on, but the barcode cannot be read.	The barcode is incorrectly placed in front of the barcode reader.	Move slightly the barcode forward-backward and tilting, until the barcode is read.
The barcode reader light is on, but the barcode cannot be read.	The barcode type is different than which is expected.	If you are loading the configuration, show the configuration barcode (a big one). If you are confirming the cassette, show the small barcode at the bottom of the cassette.
The barcode reader light is on, but the barcode cannot be read.	The barcode is damaged or the wrong type.	Replace the barcode with a correct one.
The unit cannot access the USB memory stick.	The USB stick is too wide, preventing its proper full insertion into the socket.	Use a narrow width USB memory stick.
The unit cannot access the USB memory stick.	The USB is not properly formatted.	Format the USB memory stick using the option in the System options.
The unit cannot access the USB memory stick.	The USB is not right connected.	Connect correctly the USB device.
The drawer is not detected.	Some obstacle prevents the drawer being completely inserted / The drawer is damaged.	Remove the obstacle / Replace the drawer.
When launching scan, the reader shows a message: No cassette in the drawer.	The user forgot to place the cassette in the drawer.	Place the cassette in the drawer
When launching scan, the reader shows a message: Normalization error: fiducial not found.	The drawer is not fully inserted inside the reader.	Push the drawer until the end stop is reached.
When launching scan, the reader shows a message: Normalization error: fiducial not found.	The white spots of the drawer are dirty or damaged.	Clean or replace the drawer.
When displaying results, the Control line says: Invalid and no results for the test lines are shown.	The control line is absent or too weak.	Inoculate correctly the cassette. Wait the prescribed time or use the Timed Scan feature.

If you contact the Technical Service for other malfunctions beyond those described above, they might ask you to send the log files. Use the ‘Export Logs to USB’ option of the System Menu (see section 5.3.1), and send the files by e-mail to the Technical Service.

7. Maintenance

7.1. Cleaning Procedure

To clean the Diabetomics Insudex® Lateral Flow Reader instrument use a lightly moistened cloth or an antistatic cloth.

CAUTION	**Damage to the instrument** Do not sprinkle inside the instrument neither close to the drawer slot.

8. Ordering Information and Technical Service

8.1 For technical assistance or to place an order, contact:

GLOBAL
Diabetomics, Inc.
Phone: +1 503-924-5110
Email: enquiry@diabetomics.com
Website: www.InsudexPOC.com

EC REP
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Diabetomics, Inc.
2345 NE Overlook Drive
Suite #140
Hillsboro, OR 97006, USA

9. Appendix A: Ordering Codes

9.1. Spare Parts

Product	Contents	Cat. #
Drawer Diabetomics Insudex®	1 unit	900013509
External power supply	1 unit	900020088
Power cord Schuko	1 unit	900020077
Power cord (USA / Japan)	1 unit	900020078
Power cord (UK)	1 unit	900020079
Power cord (Argentina)	1 unit	900020081
Power cord (China / Australia)	1 unit	900020082

9.2. Optional Accessories

Product	Contents	Cat. #
Printer (serial interface, 40 columns)	1 unit	90003069
Mini adapter USB to RS232	1 unit	90004203

10. Appendix B: Technical Data

Diabetomics reserves the right to change specifications at any time.

Specifications

Process time	from 15 seconds
Camera sensor	8 Mpixel
Touch screen	4,3''
Operating system	Linux
USB sockets	1 host port

Operating Conditions

Power range	12V +/-5%.
	(it is supplied with an external power supply unit that can be used in 100V-240V)
Frequency range	D.C.
	(it is supplied with an external power supply unit that can be used in 50Hz-60Hz)
Maximum power	40 W
Overvoltage category	II
Air temperature	15 ~ 30 ºC
Relative humidity	10 ~ 75 % (non-condensing)
Altitude	Up to 2000 meters (6500ft.)
Place of operation	For indoor use only
Pollution level	2

Transportation conditions

Air temperature	5ºC ~ 40ºC (41ºF ~ 104ºF) In manufacturer's packaging
Relative humidity	Maximum 75 % (non-condensing)

Storage conditions

Air temperature	5ºC ~ 40ºC (41ºF ~ 104ºF) In manufacturer's packaging
Relative humidity	Maximum 75 % (non-condensing)

Dimensions and Weight

Dimensions (WxHxD)	145 x 126.5 x 140 mm / 5.7 x 4.98 x 5.51 in
Weight	0.60 Kg / 1.32 lb

11. Appendix C: Warranty

The Diabetomics instrument has a 12-month warranty period.

The warranty is void when misuse of the equipment can be proved. Damage or manufacturing faults caused by impacts, chemical or corrosive products, liquids, damp, or other external factors, such as radiation, fire, or inadequate transport are not included.

In addition, the warranty will not apply if the equipment has been handled, repaired, or modified by not qualified or specifically designated personnel.

12. Appendix D: Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

13. Appendix E: RoHS Statement

The following information has been made available to comply with The Restriction of Hazardous Substances Directive, (RoHS2 & RoHS 3), short for Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Notes