



Igloo Reader Pro Instructions for Use

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Introduction

Thank you for purchasing Igloo Reader Pro, an Dx365 product.

At Dx365, our mission is to make personal health diagnostics and testing simpler and more affordable.

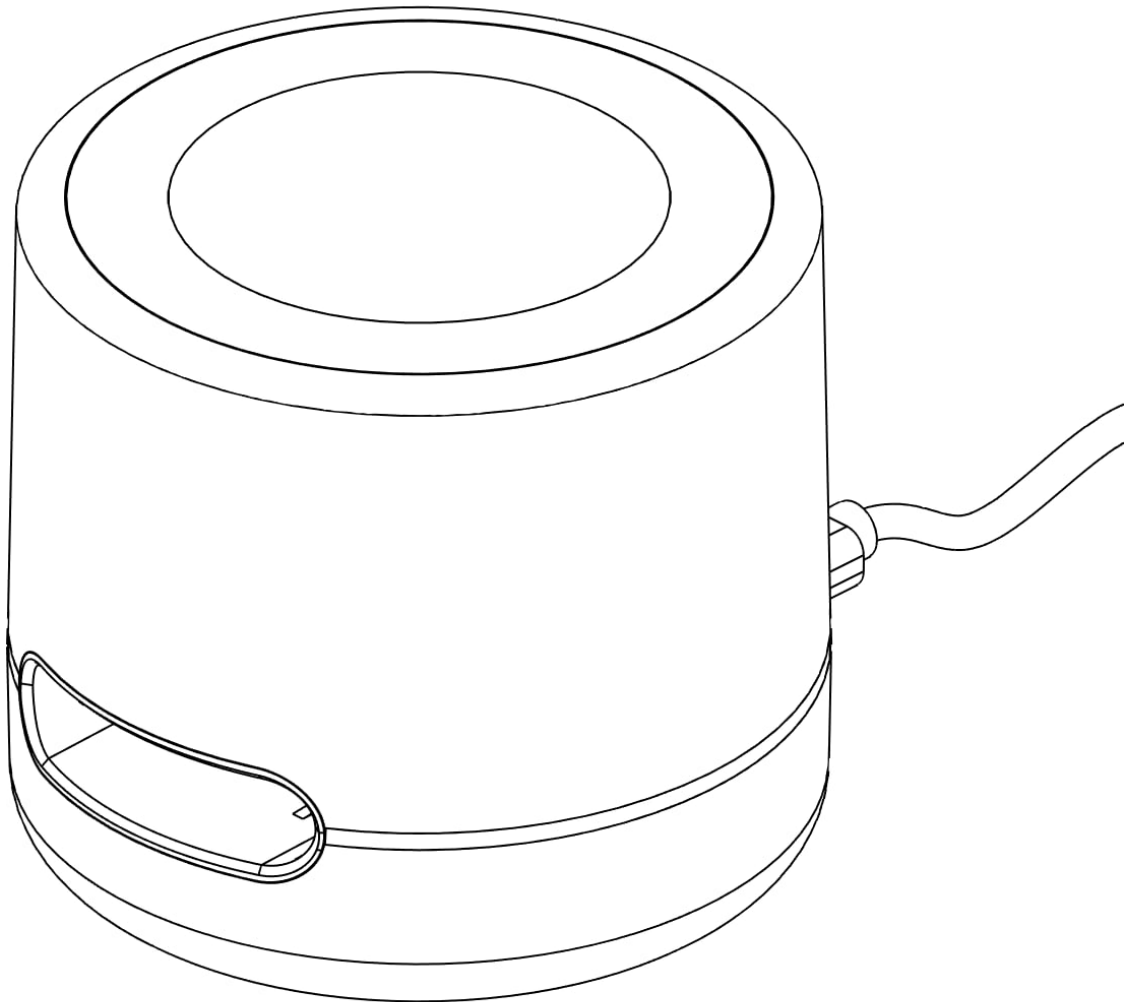
Dx365 Igloo Reader Pro (reader) is portable electronic IVD medical device for professional use intended for reading, processing and analysing qualitative, quantitative and semi-quantitative in-vitro lateral flow immunochromatographic and colorimetric tests. Device can be powered by a 2000 mAh Li-Ion battery or an USB-C cable. The USB-C cable can be used for charging the device. Device enclosed in a plastic case with an LED indicator ring, a touch display on the top and a reset button on the bottom. The slot on the device's case supports various types of adapters for test cassettes from different manufacturers. Device transmits data via the included USB and BLE interfaces.

While in use, the device might come into contact with potentially infectious materials such as biological fluids. It is thus recommended to regularly clean the device with a disinfectant solution such as Mikrozid® AF Liquid, Aerodesin®2000 or similar.

Dx365 Studio is desktop application for LFA manufacturers.

Dx365 Cloud is Server setup (software and database) which serves data exchange between other components through the Internet.

Please read the below instructions carefully before using your reader.



Intended Use

Dx365 Igloo Reader Pro is intended for optically measuring any partners lateral flow assay automatically and displays the results in a qualitative, semi-quantitative or quantitative depending on the partner lateral flow assay that is used. Dx365 Igloo Reader Pro is for professional use it is intended to be used as an aid to the diagnosis of the applicable partner lateral flow assay.



It is intended to be used by developers, manufacturers, test distributors or potentially in pharmaceutical industry: medical doctors, nurses, medical laboratory assistant/technician, pharmacist

The clinical indications for using Dx365 Igloo Reader Pro are limited by the limitations of each respective individual qualitative, quantitative or semi-quantitative in-vitro lateral flow immunochromatographic or colorimetric test.

The device can be used with various commercially available lateral flow tests and customized cassette adapters.

Customized adapters are not included in the delivery but Dx365 may recommend their preferred shape and manufacturing method.

You must calibrate the device to each test batch or test type before using it for test reading. For using test metadata needs an Data Matrix or Barcode placed on the top of the test cassette with registrated (test unique identifier) in the Dx365 Cloud.

The full test specific metadata can be stored to the Igloo Reader Pro by using Dx365 Studio application via internet or special training cartridge with QR code. The training cartridge is not included in the delivery.

Symbols Used in this Manual

	Caution
	Safety warning
	Consult User Manual
	Manufacturer
	In-Vitro Diagnostics



	Date of manufacture
IP20	Degree of enclosure protection (IP Code)
	Non ionizing electromagnetic radiation
	Catalog number
	Protection class of electronic equipment
	European Conformity mark
	Do not use if the packaging is damaged
	Do not dispose with general waste. Please refer to the country-specific rules and regulations.

Safety Information

Please follow the mandatory safety information supplied with Dx365 Igloo Reader Pro.

Please read this chapter carefully before using the device.

Safety Instructions

When used properly, the device cannot adversely affect the life and health of patients.



Measurement results obtained using the device should always be analyzed by professionals.



Results obtained using rapid tests should only be interpreted by professionals in conjunction with other diagnostic procedures and clinical data to eliminate any false positive or false negative results.



In case of any non-professional use, always check the test results with a physician.

Cautions



The device is equipped with a Li-ion battery. Do not heat it above the set temperature or expose it to direct sunlight.



The risk of electric shock is minimized but cannot be eliminated. Observe necessary precautions when using electronic devices.



When used properly, the device cannot be a source of infection. However, contamination due to the biological material being tested is possible. Always wear gloves and observe the specific laboratory precautions.



Always follow the instructions in the in-vitro test's manual and this user manual.



Use the device for its intended purpose only.

General Precautions



Be aware that liquids can cause irreparable damage to Dx365 Igloo Reader Pro.



Do not clean reader with excess liquid and do not spray disinfectants directly onto or into it. Considering these limitations, the device can only be cleaned with a disinfectant solution (e.g. Mikrozid® AF Liquid, Aerodesin® 2000 or similar) applied to a cloth.



Do not expose the device to strong electromagnetic radiation. This may cause data to be lost.



Protect the device from dust as it can damage some of its parts and affect test results.



Do not heat the device above the set temperature and do not freeze.



Use the device with the supplied cable and with a recommended charger only. Using chargers that are not recommended may cause the device to malfunction.



Do not disassemble the device, otherwise the warranty will be automatically voided.



Do not insert non-intended tools or any other objects into the device slot, as they may cause the device to malfunction.



The device is not shockproof. Be careful as the device case is smooth enough for it to slip out.



The device is intended for use outside of the human body. Do not insert body parts into the device.



The device is resistant to movement but the manufacturer does not recommend shaking the device.



All in-vitro test measurements need to be done on a horizontal surface. Do not move or rotate the device during the measurement as this may cause its contamination or incorrect measurement results.



Preparing a test cassette without following the instructions may lead to incorrect test results.



Always check that you are using the appropriate cassette adapter with a specific test cassette.



In case of absence of calibration test information on reader be sure to insert the training cartridge with adapter into the DX365 Igloo Reader Pro prior effecting the measurement



A test cassette from a test batch that the device is not calibrated with may negatively affect the measurement result accuracy.

Prerequisites

You need no special training or special skills other than reading and adhering to this manual.

Configuring the Igloo Reader Pro Firmware



Carefully read the End-User License Agreement (EULA) shown at first application startup. You may not use the product without accepting the End-User License Agreement.

You should set date and time in a reader settings. This is important for storing test results and usage logs.



If you have any problems with the reader firmware, upgrade it to the latest version. If the problem persists, contact support and do not use the device until you receive further instructions.

Step-by-Step Instructions

The steps to start working with the device are the same regardless of the delivery package.

Before You Begin

Prepare a work area for your Dx365 Igloo Reader Pro.

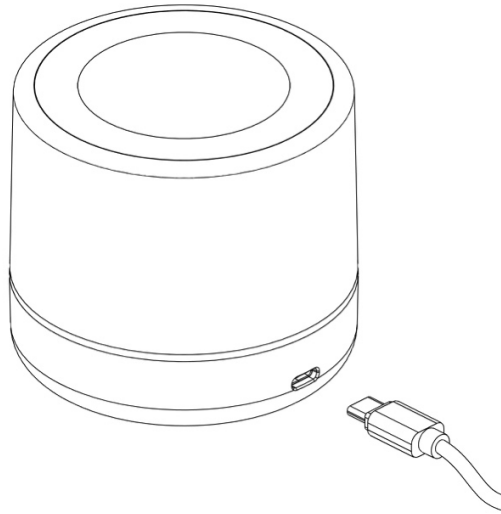
Place reader on a flat surface away from any liquids as they could damage the device.



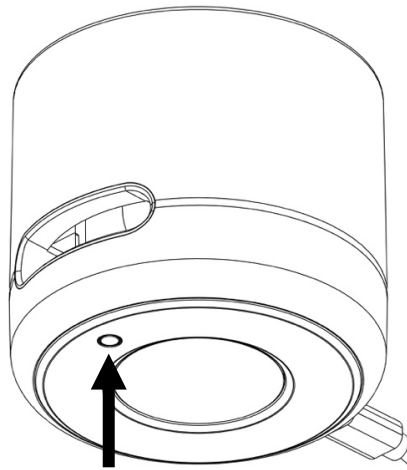
The work area should have enough free space to be able to easily insert and eject the test cassette adapter (cartridge).

To turn on your reader for further startups, either:

1. Connecting it via USB-C cable to your charger or computer.



2. Pressing the button on bottom side of the reader.



3. The screen will turn on and after loading you will see a main menu of the reader.

You can now start working with your reader.



If the self-test during the reader turn on was unsuccessful, the device indicator will flare in red.

In this case, refer to chapter **Troubleshooting** below or contact support. Do not use the device until the problem is cleared.

Measurement



Use gloves.

1. Switch on your reader.
2. Press "New measurement" and fill in the parameters: Patient ID, and optionally age and sex.
4. Choose one of the options: "Timer" switcher i.e. measurement within Dx365 Igloo Reader Pro using internal timer.



Device reads the incubation time and other important test information from the Data matrix or barcode placed on the test cassette. Prior to the measurement, make sure the Data matrix or barcode is located on the test cassette.

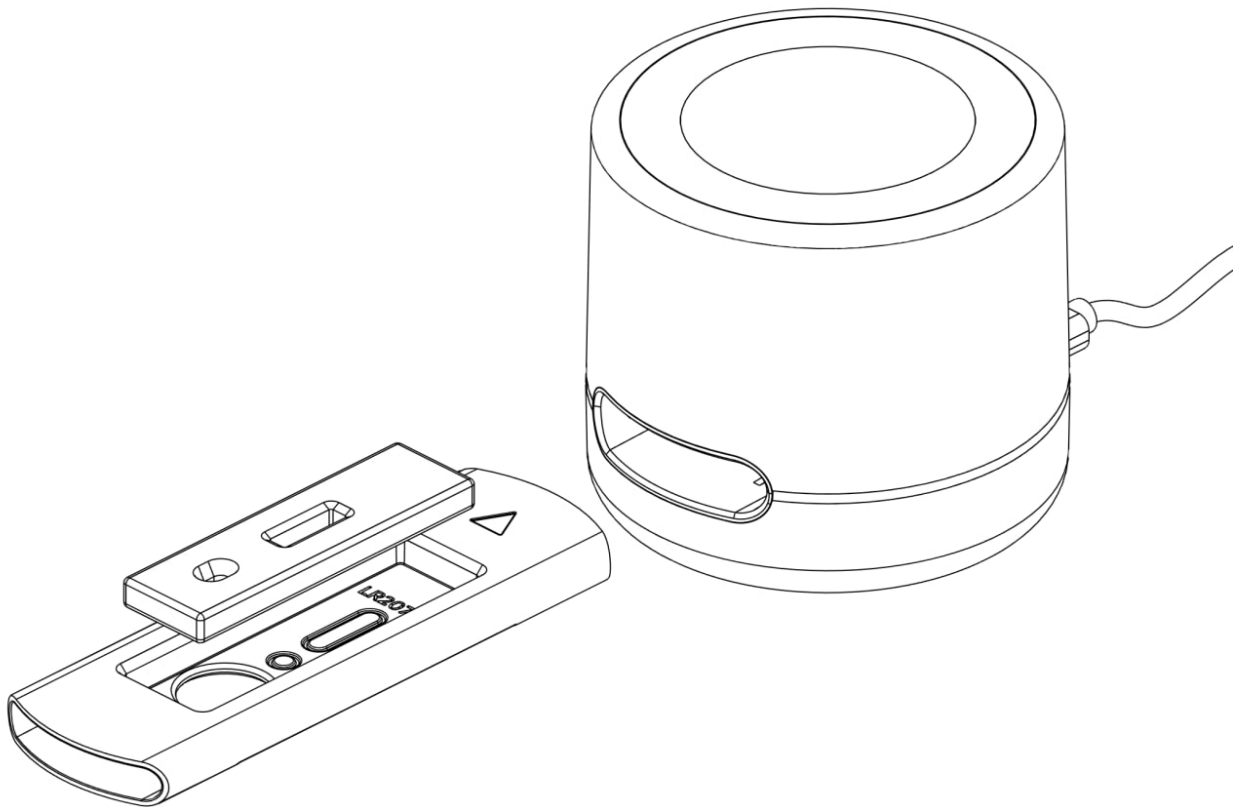
4. The device indicator will "breathe" fast. The device will prompt you to insert an adapter with the test cassette into the device.

5. Prepare the test cassette following its instructions for use.



Incorrect preparation of the test cassette can lead to incorrect test results.

6. Place the test cassette into the cassette adapter with test strips facing up and insert them together into the device slot according to the adapter direction. **The sample well on the test cassette must be facing the outside of the device.**



The device is intended for use with various cassette adapters, but the test cassette must be suitable for the test cassette adapter.



In case barcode is not identified by the device using - use QR code placed on metadata cartridge, placing it first into the adaptor and inserting into the device.

6. Dx365 Care starts the measurement, with the device indicator rotating and the application showing the measurement progress. If you have inserted the cassette adapter with the test cassette into the device before launching the application, eject the adapter and insert it again.



The measurement process always starts with the countdown of the incubation time. Note that this process cannot be undone or paused once started.



Do not eject the cassette adapter until the reading is complete. If you eject the adapter for more than 10 seconds, the incubation time will be reset and the application



will ask to start the measurement again. In this case inserting of the same test may lead to incorrect measurement results.



If the user wants to conduct a measurement without the timer, they need to turn off the timer switcher. The device will then start measurement without a timer immediately after the cartridge is inserted. In this case, the user needs to manually measure the incubation time.

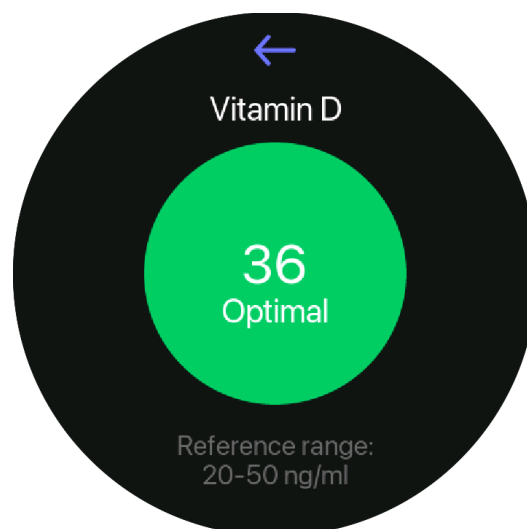


Do not disconnect the USB-C cable until the reading is complete as this may terminate the measurement or lead to incorrect results.



Do not move the device during the measurement as this may cause the cassette adapter to get ejected without your noticing it or lead to incorrect measurement results .

7. Upon successful measurement, the device indicator will stop rotating and start to breathe while Dx365 Care retrieves the result from reader. Once done, the application will and show the result on the screen.



8. If the test result is invalid or cannot be obtained from device, the application will show an appropriate message. In this case, use another test cassette to perform the test from the beginning.

9. Eject the cassette adapter and remove the used test cassette.



Remember that the test results can be false positive or false negative for a variety of reasons. Make sure to always have professionals double-check the results obtained using the approved comparable diagnosis technique.



The manufacturer does not recommend starting a measurement if the battery level is below 9 %, as the device might run out of charge before the procedure is completed. Nevertheless, the application will be warning about a critical battery level.



A test cassette can only be used once.



Remember that the biological fluids introduced into the test cassette are classified as infectious biological waste.



Always follow the instructions for the correct disposal of used test cassettes.



Some lateral flow test manufacturers do not recommend evaluating test results after a certain time has passed, always follow IFU of the test.

The device is reusable. To continue measurements, save or export the test result using the application menu. To make another test, follow the instructions above.

Device Indicator Legend

Color	Mode	Meaning	Cases
White	Fast breath	Reader needs your attention or action (also check notifications in the application)	Insert or eject the cassette adapter Measurement completed successfully Measurement error
White	Fast rotation	Device is busy	Measurement in progress Reader is self-testing its internal components Firmware update in progress



White	Slow rotation	Some background process	Battery is charging, nothing else is happening
White	Slow breath	Reader is ready, nothing else is happening	Battery is from 10% to 100%
White	Flare	Connection established	Device is connected and ready to work with Dx365 Care
Yellow	Flare	Battery is low, please charge	Device is 'slowly breathing' and each 3rd breath is flaring yellow: battery is from 1% to 10%
Red	Flare	Device can't make measurements	Battery is below 9%, please reconnect cable and try again Self-test returned an error
Blank		Device is resting	Device is turned off or in Sleep mode

Cleaning, Turning off and Storing Your Dx365 Igloo Reader Pro

In case the device has been contaminated, clean it with a disinfectant solution, such as Mikrozid® AF Liquid, Aerodesin® 2000 or similar applied to a cloth.

To avoid biological contamination, follow the cleaning recommendations after each use.

After 10 minutes of inactivity, the device indicator becomes less bright. After 15 minutes Dx365 Igloo Reader Pro automatically goes into standby mode.

#	Issue	Causes and recommendations
1	The device does not turn on.	Check the USB-C cable connection to your computer. Check the type of the cable used. Charge the device. Use the reset button (see #6).



#	Issue	Causes and recommendations
2	The application can't connect to the device.	Check the type of the cable used. Restart the application. Check BLE configuration. Use the reset button to reload the device (see #6).
3	The measurement does not start.	The adapter wasn't inserted into the device correctly or sufficiently – check the cassette adapter. Check the Data Matrix barcode on the top of the cassette or review the Dx Care notification. Check availability of the internet for download metadata or use training cartridge with QR.
4	No measurement result was obtained.	The adapter ejected before the measurement was complete, repeat the procedure with new test. The battery is insufficiently charged, connect the device via USB-C cable, results will be taken from the device if the measurement was finished.
5	Self-test error.	Contact support.
6	Device not responsive.	Use the reset button located on the rubber at the bottom of the device. Press the button, release and then push again within 5 seconds to reset reader to its factory firmware and settings.
7	Device behaves incorrectly.	Push twice the reset button, located under the rubber at the bottom of the device.
8	Device doesn't charge	Contact support.
9	The device does not turn off.	Disconnect the USB-C cable. Don't press the touch button and don't connect to the device from within the application. After 15 minutes, the device will go into standby mode.



If you touch the device before this time has passed, the indicator will start breathing slowly and the device will wait for a new interaction.

Another way to turn off the device is to press the off button on the main screen. The device will show you the screen where you can approve the turning off, with a long push on the off button.



Always store the device out of the reach of unrelated people or children.

The manufacturer recommends storing the device in a closed medical cabinet or desk.

Troubleshooting

*Please note, that Reader with a set of lateral flow tests, is a single unit that is certified, produced, distributed and supported by its Legal Manufacturer**.*

*You can normally find Legal Manufacturer** name and contact information on kit packaging, additional sticker on reader bottom or via your distributor.*

Technical Specifications

The device is equipped with a Li-ion battery. Every device is shipped with a USB-C cable. The device User Manual is provided in an electronic form.

Cassette adapters are not included*. The availability of the adapter in the delivery package depends on the type of delivery.

Dx365 reserves the right to change the specifications at any time.

Technical Data

Device type	Dx365 Igloo Reader Pro
SN	See type plate on the back of device
Test principle	The test is done by measuring of the different colored lines (test and control) on a test strip. The test lines are evaluated either qualitatively by checking whether the test band occurs at all or quantitatively / semi-quantitatively by calculating the color intensity according to the peak height or the surface area under the peak curve. Both methods can be used to determine the analyte concentration.



Measuring time	Several seconds excluding incubation time
Storage capacity:	Data store in the Dx365 Care application
Power supply	Rechargeable Li-ion Battery Voltage 3.7 V Rated capacity 2000 mA
Accuracy	Inter-reader CV 2 % Intra-reader CV 3 %
Recommended charger (not included)	Type FW8002MUSB/05 Input 100-240V/50-60Hz/160-80 mA Output 5V/1400 mA
Environment	Working 5 – 40°C, 20% to 80% RH (non-condensing) Storage 0 - 45°C, 20% to 80% RH (non-condensing) Transportation - 10 - 60°C, 20% to 80% RH (non-condensing)
Input power	5V, 1400 mA
Weight	Approx. 270g
Dimensions	Height: 91 mm Width: 87,5 mm Depth: 87,5 mm
Connection	USB-C cable
Wi-Fi & Bluetooth Module	802.11 b/g/n, 2.4 GHz, powered up 100 mW
Degree of protection:	IP20
Issue date	
Expiration date	
Warranty	One year

Scope of Delivery

1. Dx365 Igloo Reader Pro
2. USB-A to USB-C cable



Regulatory Information

Dx365 Igloo Reader Pro is CE marked in compliance with the essential requirements of the following European Commission (EC) Directives:

In Vitro Diagnostic Medical Devices Directive 98/79/EC

Restriction of Hazardous Substances Directive 2011/65/EU

Radio Equipment Directive Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at <https://support.dx365.world/legal>.

The disposal of Dx365 Igloo Reader Pro must be carried out in accordance with Regulation 2002/96/EC.

Customer Support and Service Information

Dx365 Igloo Reader Pro is maintenance free.

The Dx365 Igloo Reader Pro is designed with a self-test function every time it is turned on. The camera sensor automatically calibrates at regular intervals throughout its life cycle.

Warranty period is limited to one year. The manufacturer guarantees the correct operation of the device in compliance with its operating instructions and recommendations.

If a defect is found in the device, it must be returned for repair or replacement.

The manufacturer does not assume warranty obligations in the following cases:

- ☐ if Reader was used for purposes other than its intended purpose;
- ☐ in case of violation of the rules and operating conditions;
- ☐ if Reader has traces of unqualified repair attempts;
- ☐ if the defect has arisen due to natural wear of the cable supplied;
- ☐ if the defect is caused by a change in the design or circuit of reader not provided by manufacturer;



- if the number of battery recharge cycles will exceed 500 during the first year, then warranty expires since the moment of this event.
- if the defect is caused by moisture, high or low temperatures, corrosion, oxidation, ingress of foreign objects, substances, insects, liquids inside the device.

The warranty does not cover the following defects of Dx365 Igloo Reader Pro:

- mechanical damage that occurred after the device was handed over to the consumer;
- malfunctions due to ignoring system requirements for work with Reader.

If you will keep the device clean and handle it carefully without damaging its internal parts, the device provides long-term and accurate measurements.

Reader lifetime is limited and depends on the number of measurements or battery recharges made.

Reader is anticipated to provide the expected performance for up to 500 battery charging cycles. However, in order to optimize this number, the device should not be stored continuously without being used for extended periods of time.

If stored for a long time, the reader should be fully charged, fully discharged and fully charged again at least once every 90 days. Otherwise, the functionality of the battery is not guaranteed. However, even in this scenario, no safety risks are anticipated.

The expiration of the warranty does not prohibit the use of reader, the manufacturer is not responsible for the results obtained after the device expiration.

More information is available at <https://support.dx365.world/>

For additional information and support please contact support@dx365.world

Device is powered by a Li-Ion 2000 mAh battery, please follow the internal regulations of your country for the proper disposal of the device.

If returning the device to the manufacturer, make sure to disinfect it first according to this manual.

The name and address of the device and software manufacturer:

Dx365 GmbH

Hedwig-Porschütz-Straße 14, 10557, Berlin



***The name and address of the Legal Manufacturer:*

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