**EN**

Read these instructions carefully before using this product.

14.06.2023 IFU001, v7

nexkin DSPT

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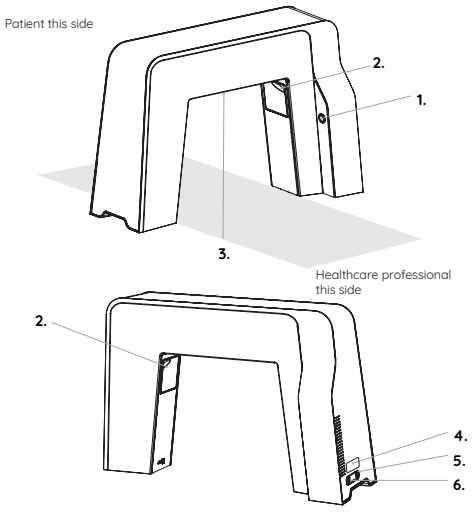
The package includes the following items:

- Nexkin DSPT device
- Class I medical power supply
- Power supply cable
- Device instructions for use

It does not include the tablet required to use the graphical user interface (GUI).

The technical and design contents of this manual are subject to change without prior warning in order to improve their quality. The latest version of this instruction manual can be found at: **www.nexkinmedical.com/downloads**

Figure 1.




1. On/Off button.
2. Side window.
3. Upper window.
4. Product label.
5. Power supply socket.
6. RJ45 port (Ethernet)

## 1. INTENDED USE

Nexkin DSPT is a medical device to aid in wheal detection and measurement in the reading of skin allergy tests.

## 2. PRODUCT DESCRIPTION

Automates and digitalises skin allergy test readings, providing the results in digital format.

The device must only be used by qualified health professionals in a medical consultation office (professional healthcare facility environment and normal ambient conditions).

The device can be used on children, adolescents, adults and the elderly, regardless of sex or race.

## 3. INSTRUCTIONS

### 3.1 CONNECTING THE DEVICE

1. Position the device in a way that allows the correct distance between the patient and the device..
2. Connect the power supply to the device and then to the mains.

### 3.2 DOWNLOAD AND INSTALL THE GRAPHICAL INTERFACE

Download and install the Nexkin app.

Nexkin App available on:

GET IT ON Google Play

Download on the App Store

### 3.3 LINK THE TABLET TO THE DEVICE

1. On the tablet go to Settings > Wi-Fi (iOS) or Settings > Connections > Wi-Fi (Android).
2. Enable Wi-Fi.
3. Select the name of the Wi-Fi network (SSID) that appears on the device label. If the Wi-Fi network does not appear, check that the Nexkin DSPT is switched on and the tablet is nearby.


4. Enter the network password (WIFI KEY) shown on the device label. Press "OK".

   If you are unable to press "OK", the password you have entered is incorrect.

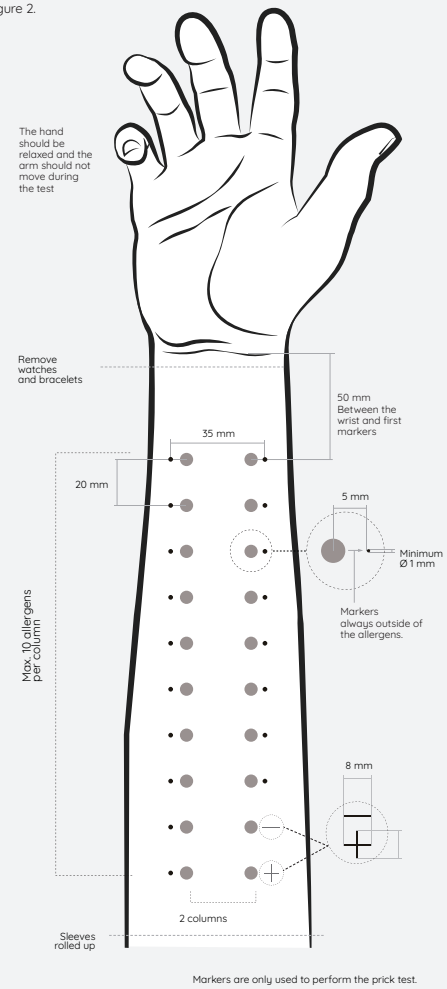
### 3.4 HOW TO USE THE DEVICE

1. Switch on the device.
2. Check that the device is connected to the Wi-Fi.
3. On the tablet, start the graphical interface (app) to interact with the device.
4. Configure and/or confirm the test to be carried out. You can choose from a prick test or intradermal test.
5. Follow the steps shown on the graphical interface (app).

For more information on the graphical interface, see the app. In case of doubt, contact the manufacturer.

### 3.5 HOW TO OBTAIN A CORRECT READING

Figure 2.




Markers are only used to perform the prick test.

Allergen · Marker with black ink — Negative control + Positive control

1. The arm must be nice and straight and at a right angle to the device.
2. The light beam must be focused between the allergens as shown in Figure 4.
3. Do not move the device when taking the reading.

Figure 3.

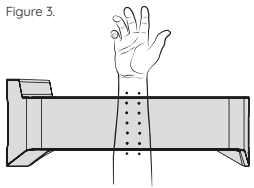
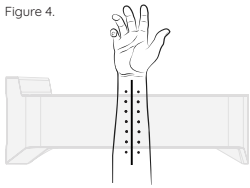


Figure 4.



### 3.6 TURNING OFF THE DEVICE

In the graphical interface menu (app), select 'Turn off device'.

## 4. CLEANING AND DISINFECTION

Before cleaning the device, ensure that it is disconnected from the mains.

Do not submerge the device or cables in liquid or wet it to the extent that liquid is visible on the surface.

Do not use any abrasive products to clean the medical device.

Use a cloth dampened with water to clean the outer casing of the device. You can also use cleaning wipes.

You should not touch the upper window from which the laser is emitted or the side windows where the cameras are with your bare hands.

## 5. WARNINGS AND SAFETY PRECAUTIONS

- This device is not intended for diagnostic use or treatment of any kind and is not a substitute for sound medical judgement.

  Contact the manufacturer in the event of any problems or unexpected events when operating the device.

  Any serious incident that has occurred to the user and/or the patient in relation to the device must be reported to the manufacturer and to the Competent Authority of the Member State (for Europe) or the relevant authority (for other countries) where the user and/or the patient are established.

  This device uses a Class 2 laser, in accordance with standard IEC 60825-1. This laser is safe for those with a normal blink reflex as said reflex limits accidental exposure and prevents eye damage. However, direct eye contact must be avoided and the light must not be looked at for prolonged periods.

  Do not expose the device to rain or moisture.

  If the device is not going to be used for a prolonged period, it should be disconnected from the mains.

  Do not place the device that make it difficult to operate the disconnection device (plug).

  To ensure that it works correctly, do not enable any other Wi-Fi connection on the tablet that is not specified in this document.

  Do not share the Wi-Fi network identifier (SSID) or the Wi-Fi password with anybody.

  This device uses an external CLASS I power supply that is not impermeable to liquids. This device does not have applied parts.

  Ensure that the power supply cable does not restrict the free movement of persons in the room.

## 6. CONTRAINDICATIONS

To guarantee that the device correctly complies with the intended purpose, you must take into account the contraindications of skin allergy tests. They must be performed on healthy skin and on patients who do not have the following: scars; medium-sized or large tattoos covering all or most of the forearm; active urticaria; severe atopic dermatitis; or intense dermographism; or patients undergoing treatment with medicinal products that may interfere with the skin test.

## 7. EXPLANATION OF SYMBOLS

- Manufacturer
- Caution
- Read the instructions carefully before using this device.
- Not for general waste (waste electrical and electronic equipment)
- SN Serial number
- CE mark
- MD Medical device
- UDI Unique Device Identifier
- Fragile. Handle with care
- Keep dry
- Storage temperature range
- Storage humidity range
- Laser radiation
- "ON/OFF" (power)
- # Model number
- Rx Only Prescription device (USA only)

## 8. MAINTENANCE AND TROUBLESHOOTING

The device does not require routine or preventive maintenance.

The device provides alerts in the graphical interface (app) to warn about any problems detected. Follow the instructions provided and if the problem is not solved, contact the manufacturer.

In the event of misuse of the device (including the graphical interface), stop using it, perform the test readings with the usual manual method and contact the manufacturer.

Any modifications, repairs or checks must only be carried out by the manufacturer.

Do not disassemble or attempt to repair the device.

If the protective glass over the optical components on the device becomes scratched or badly damaged, contact the manufacturer.

## 9. DISPOSING OF THE DEVICE

Applicable in countries with selective waste collection systems.

The product and its electronic accessories must not be disposed of with other domestic waste at the end of its service life.

For information on how to recycle this product, contact your local authorities, the waste collection service or the manufacturer.

## 10. GUARANTEE

This device has a 12-month guarantee from the date of purchase. Within the guarantee period, any material or manufacturing defect in the device will be corrected either through repair, replacement of parts or provision of a new device, according to the manufacturer's criteria.

The guarantee does not cover damage caused by misuse, breakage due to knocks, failure to follow the instructions for use or unsuitable electrical connections.

The guarantee will become invalid if any repairs or modifications are carried out by unauthorised persons.

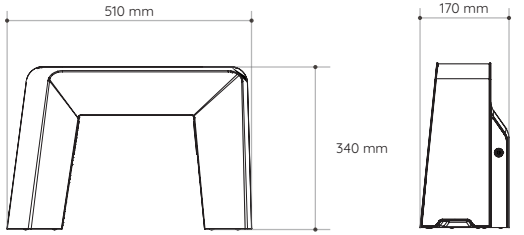
In the event of device failure, both within and beyond the guarantee period, contact the manufacturer.

## 11. LIMITATION OF LIABILITY

Innoprick, S.L. waives all liability in the event of accidents due to misuse of the device or failure to follow the instructions for use and maintenance.

Under no circumstances shall Innoprick, S.L. or the customer be liable to the other party for any indirect, special, consequential or incidental damages (including the loss of profits or loss of business opportunities) that the other party may incur due to signing the purchasing or rental agreement, or which may arise from compliance with or failure to comply with said agreement, even if the party against whom the claim is brought was warned or was aware of the possibility of such damages. The above limitation shall apply regardless of the type of claim.

## 12. TECHNICAL SPECIFICATIONS




| | |
|---|---|
| **Size** | 510 x 170 x 340 mm (length x width x height) |
| **Weight** | 7.2 kg |
| **IP rating** | IPX0 |
| **Low-power laser** | Class 2, pursuant to standard IEC 60825-1: 2014<br>Continuous-wave laser<br>Wavelength: 405 nm<br>Output: 15 mW<br>Beam divergence: 60° |

| | |
|---|---|
| **Power supply** | Type: medical power supply<br>12 V DC<br>60 W<br>Class I<br>Input: 100–240 V/50–60 Hz<br>Medical safety approved (2 x MOPP) pursuant to ANSI/AAMI ES 60601-1 and IEC/EN60601-1.<br>The power supply cable must have the following characteristics or higher: type H05VV-F and 0.75 $m^2$ core section |
| **Connections** | RJ45 (Ethernet) connector used for data exchange with the hospital system and for maintenance work by the manufacturer. |
| **Wi-Fi** | Standard IEEE 802.11bgn<br>Operating frequency: IEEE band 802.11 bgn ISM, 2.400 GHz ~ 2.4835 GHz,<br>Modulation: 802.11b: DSSS (DBPSK, DQPSK, CCK)<br>802.11a/g: OFDM (BPSK, QPSK, 16-QAM, 64-QAM)<br>802.11n:<br>Effective radiated power: 12.2 dBW/16.6 W |
| **Transport and storage conditions** | Temperature: -20°C to 50°C (-4°F to 122°F)<br>Humidity: 20% to 80% relative humidity, no condensation.<br>Atmospheric pressure: 700 hPA to 1060 hPA |
| **Ambient conditions for use:** | Temperature: 5°C to 40°C (41°F to 104°F)<br>Humidity: 20% to 80% relative humidity, no condensation.<br>Atmospheric pressure: 700 hPA to 1060 hPA |
| **GUI** | To use the graphical interface (GUI) and see the results, a commercial tablet must be used with the following technical specifications:<br>• 9.7 inches or larger<br>• Resolution: 2048 x 1536 or higher<br>• Wi-Fi connection (802.11 a/b/g/n/ac), dual band (2.4 and 5 GHz)<br>• Minimum 2 GB RAM<br>• Minimum 32 GB of storage<br>• Chip A10 Fusion or higher<br>• Operating system: iOS 12, Android 9 or latest |
| **Measurements** | Measurement accuracy:<br>Area ≥ 25 $mm^2$: ± 6%<br>Area < 25 $mm^2$: ± 8%<br>Repeatability:<br>Area ≥ 25 $mm^2$: ± 2%<br>Area < 25 $mm^2$: ± 3%<br>(pursuant to standard ISO 5725) |
| **Applicable regulations and standards** | REGULATION (EU) 2017/745 on medical devices.<br>ISO 14971:2019<br>ISO 13485:2016<br>IEC 62304:2006/A1:2015<br>IEC 60825-1: 2014<br>IEC 60601-1-6:2010+A1:2013+A2:2020<br>IEC 60601-1:2005+A1:2012+A2:2020<br>IEC 60601-1-2:2014+A1:2020 |

## 13. ELECTROMAGNETIC COMPATIBILITY

This device is designed for use in professional medical settings.

The device complies with electromagnetic compatibility standards. It does not cause electromagnetic interference and complies with immunity standards.

To prevent adverse effects on the patient and operator, the device requires the following special precautions with regard to electromagnetic compatibility (EMC):

The device must not be placed near to other electrical devices or in a pile with other devices.

The use of accessories, transducers or cables not specified or provided by the manufacturer may negatively affect electromagnetic compatibility.

To prevent the risk of electric shock, this device must only be connected to an earthed power supply.

Portable RF communication devices (including aerials) must be used at least 30 cm (12 inches) away from any part of the device, including the cables specified by the manufacturer. Otherwise, this device's performance may be impaired.

In the event of electromagnetic interference, the user must switch off the device (without touching or moving the device).

If the electromagnetic interference persists, contact the manufacturer.

The device needs to capture a minimum of clinically usable quality images to achieve its essential performance.

This implies that both the laser and the cameras are working properly. In case the essential performance degrades, the user will receive a warning message in the GUI, the test will be invalid, and the reading will have to be repeated.

PLEASE NOTE: the characteristics of the emissions of this device make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If used in a residential setting, this device may not provide suitable protection to radiofrequency communication services. The user may need to take mitigating measures, such as changing the direction or location of the device.

The product is designed for use in the electromagnetic environment specified in the following table. The customer or user of the product must ensure that it is used in said environment.

The following tables are included for your reference:

| RECOMMENDED DISTANCES FROM PORTABLE AND MOBILE RF COMMUNICATION DEVICES | | | |
|---|---|---|---|
| The device is designed to be used in an electromagnetic environment in which radiated RF interference is controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output of the communication equipment. | | | |
| **Maximum nominal output of the transmitter (W)** | **Separation distance according to the transmitter frequency (m)** | | |
| | **150 kHz to 80 MHz** $d$=1.17 $\sqrt{P}$ | **80 MHz to 800 MHz** $d$ = 1.17 $\sqrt{P}$ | **800 MHz to 2.5 GHz** $d$ = 2.33 $\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.74 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |
| For transmitters with a maximum nominal output not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the transmitter frequency, where p is the maximum nominal output of the transmitter in watts (W) according to the transmitter manufacturer. | | | |
| NOTE 1: at 80 MHz and 800 MHz, the separation distance for the maximum frequency range is applied. | | | |
| NOTE 2: these guidelines cannot be applied to all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people. | | | |

To maintain basic safety in terms of electromagnetic interference throughout the expected service life of the device, all of the instructions in the manual must be followed.

| IMMUNITY LEVELS (PROFESSIONAL HEALTHCARE SETTING) | | |
|---|---|---|
| **IMMUNITY TEST** | **BASIC EMC STANDARD OR TEST METHOD** | **IMMUNITY TEST LEVELS** |
| Electrostatic discharge | IEC 61000-4-2 | ± 8 kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| Radiated RF field | IEC 61000-4-3 | 3 V/m<br>80 MHz–2.7 GHz<br>80% AM in 1 kHz |
| Proximity fields from wireless transmitters | | See the RF wireless communication device table. |
| Output frequency magnetic field | IEC 61000-4-8 | 30 A/m–50 Hz or 60 Hz |
| Electrical fast transient pulses/bursts | IEC 61000-4-4 | ±2 kV–100 kHz repetition frequency |
| Overload<br>AC network, line to earth<br>AC network, line to line | IEC 61000-4-5 | ±0.5, ±1, ±2 kV<br>±0.5, ±1 kV |
| Conducted interference caused by RF fields | IEC 61000-4-6 | 3 V (0.15 MHz–80 MHz)<br>6 V (in ISM bands from 0.15 MHz to 80 MHz) |
| Voltage drops | IEC 61000-4-11 | 0% $U_T$ for 0.5 cycles<br>at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ for 1 cycle and 70% $U_T$ for 25/30 cycles<br>single phase at 0° |
| Voltage interruptions | | 0% $U_T$ for 250/300 cycles |
| $U_T$: nominal voltage(s) | | |

| LEVELS OF IMMUNITY TO RF WIRELESS COMMUNICATION EQUIPMENT | | | | | | |
|---|---|---|---|---|---|---|
| The customer and/or user must help to maintain a minimum distance between RF wireless communication devices and our device, as recommended below. | | | | | | |
| **TEST FREQUENCY (MHz)** | **BAND (MHz)** | **SERVICE** | **MODULATION** | **MAXIMUM OUTPUT (W)** | **DISTANCE (m)** | **IMMUNITY TEST LEVELS (V/m)** |
| 385 | | TETRA 400 | 18 Hz pulse modulation | 1.8 | 0.3 | 27 |
| 450 | 430–470 | GMRS 460FRS 460 | FM ± 5 kHz deviation<br>1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704–787 | LTE band 13, 17 | 217 Hz pulse modulation | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800–960 | GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5 | 18Hz pulse modulation | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700–1990 | GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS | 217Hz pulse modulation | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400–2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7 | 217Hz pulse modulation | 2 | 0.3 | 28 |
| 5240 | 5100–5800 | WLAN 802.11<br>a/n | 217Hz pulse modulation | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

**EMISSION LIMITS** Class A group 1 pursuant to standard UNE-EN 60601-1-2:2015 + A1:2021.