EN

Please read these instructions carefully before using this product.

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nexkin DSPT

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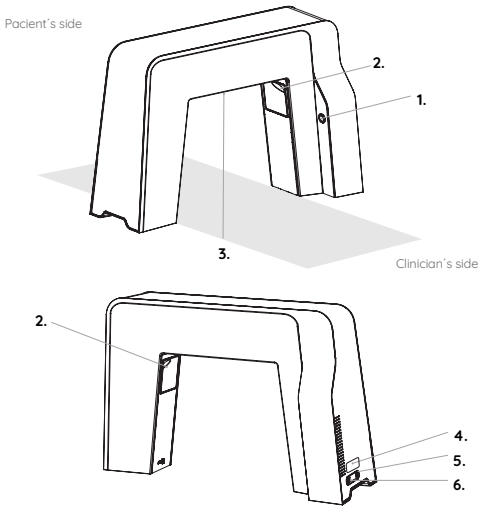
Package includes the following items::

- Device Nexkin DSPT
- Medical power supply Class I
- 1.2m Power cord, class H05VV-F and core section 0.75m²
- Instructions for use of the device.

It does not include the Tablet to interact with the Graphical User Interface (GUI).

The technical and design contents of this manual are subject to change without notice to improve quality. The current version of this instruction manual can be found at **www.nexkinmedical.com/downloads**

Figure 1.



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

1. INTENDED USE

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

2. DESCRIPTION OF THE PRODUCT

It automates and digitizes the skin prick test reading and provides test 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 in children, teenagers, adults and the elderly regardless of race and sex.

3. INSTRUCTIONS FOR USE

3.1 CONNECTING THE DEVICE

1. Place the device in a way that allows the correct distance between patient and device.
2. Connect one end of the power supply to the device and the other 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 PAIR TABLET TO DEVICE

1. On the tablet, go to Settings > Wi-Fi (iOS) or Settings > Connections > Wi-Fi (Android).
2. Turn Wi-Fi on.
3. Tap the Wi-Fi network name (SSID) which appears on the device label. If the Wi-Fi network does not appear, make sure Nexkin DSPT is turned on and the tablet is near it.

4. Enter the network password (WIFI KEY), which appears on the device label. Then tap Join. If you cannot tap Join, the password you've entered is incorrect.

3.4 USE OF THE DEVICE

1. Switch on the device.
2. Check that the Wi-Fi connection to the device has been established.
3. From the Tablet, start the graphical interface (app) to interact with the device.
4. Configure and/or verify the test to be performed.
5. Follow the steps indicated in the graphical interface (app).

For more information about the graphic interface, please refer to the information available in the app. If in case of any doubt, please contact the manufacturer.

3.5 GUIDELINES FOR CORRECT READING

Figure 2.

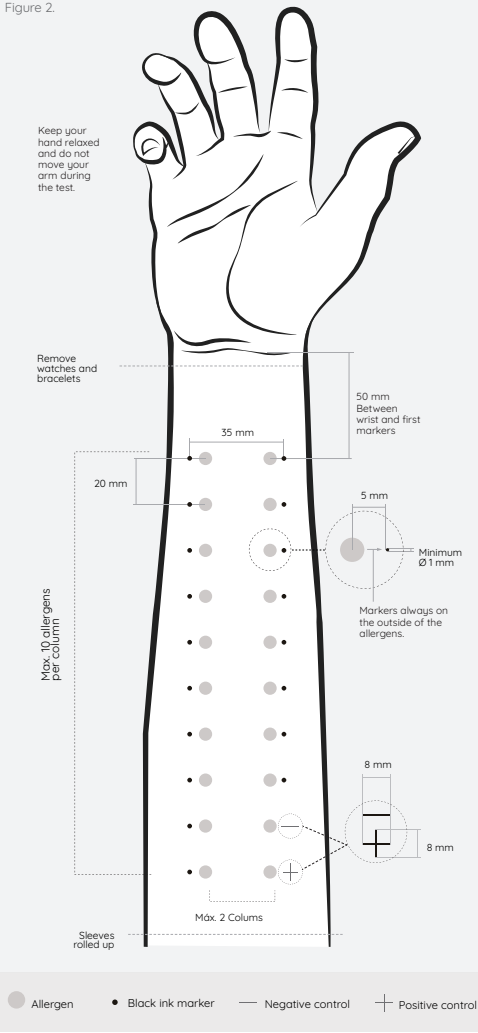
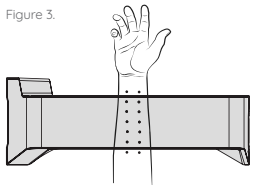
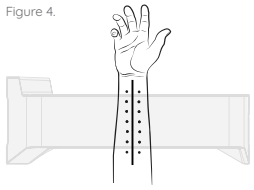


Figure 3.



1. The arm must be well aligned and perpendicular to the device.
2. The light beam must be centred between the allergens/markers as shown in Figure 4.
3. Do not move the device during reading.

Figure 4.



3.6 DEVICE SHUTDOWN

In the menu of the graphical interface (app), select "Switch off device".

4. CLEANING AND DISINFECTION

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

Do not immerse any part of the device or cables in liquid. Do not moisten to the point where liquid flows.

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

To clean the outer housing of the device, a damp cloth with water can be used. Cleaning wipes may also be used.

It is recommended not to touch with bare hands the upper window from which the laser is emitted and the side windows where the cameras are located.

5. SAFETY WARNINGS AND PRECAUTIONS

- This device is not intended for diagnostic or treatment use of any kind and is not a substitute for the reasonable judgement of a healthcare professional.
- Contact the manufacturer in case of unexpected problems or situations inherent to the operation.
- Any serious incident that has occurred to the user and/or patient in relation to the product should be reported to the manufacturer and to the Competent Authority of the Member State (for Europe) or relevant health authority (for other countries) in which the user and/or patient is established.
- This device uses a Class 2 laser, according to IEC 60825-1. This laser is safe for those who have a normal flicker reflex since the reflex limits accidental exposure and thus preventing ocular damage. However, it is recommended to avoid direct eye contact and not stare at the light for a long time.
- Do not expose the device to rain or moisture.
- If the device is not to be used for an extended period of time, it is recommended that it be unplugged from the mains.
- Do not position the device in such a way that makes unplugging difficult.
- For proper operation, do not enable any other Wi-Fi connection on the tablet not described in this document.
- Do not share the Wi-Fi network identifier (SSID) or Wi-Fi network password with anyone.
- This device uses an external CLASS I electrical power source that is not resistant to liquid penetration. This device has no applied parts.
- Ensure that the power cable does not impede the free movement of people.

6. CONTRAINDICATIONS

To ensure that the device fulfils its intended use, the contraindications of the prick test must be considered. The test must be carried out on healthy skin, in patients who do not have the following conditions: scars, tattoos covering all or a large part of the forearm, active urticaria, severe atopic dermatitis, intense dermographism, treatment with drugs that interfere with the skin test.

7. EXPLANATION OF SYMBOLS

- Manufacturer
- Caution
- Read the instructions carefully before using this device
- WEEE (Waste Electrical & Electronic Equipment)
- SN Serial number
- CE conformity mark
- MD Medical Device
- UDI Unique Device Identification
- Fragile, handle with care
- Keep dry
- Temperature limit
- Humidity limit
- Laser beam
- "ON/OFF" (Power button)
- # Model number

8. MAINTENANCE AND TROUBLESHOOTING

The device does not require any routine or preventative maintenance.

The device has alerts in its graphical interface (app) to notify of detected problems. Follow the instructions provided and if not resolved, contact the manufacturer.

In case of malfunction of the device (including the graphical interface), discontinue use, perform test readings according to the usual manual method and contact the manufacturer.

All modifications, repairs and checks must only be carried out by the manufacturer.

Do not disassemble or attempt to repair the device.

If the protective lenses of the optical components of the device are scratched or significantly damaged, contact the manufacturer.

9. DISPOSAL OF THE DEVICE

Applicable in countries with separate collection systems.

The product and its electronic accessories should not be disposed of with other household waste at the end of their working life.

For information on recycling of this product please contact your local authorities, waste collection service or the manufacturer.

10. WARRANTY

The warranty period of this equipment is 12 months from the date of purchase. Within the warranty period, any defect in the device attributable to both materials and workmanship will be remedied by either repairing, replacing parts, or providing a new device, at the manufacturer's discretion.

The guarantee does not cover breakdowns due to improper use, breakage due to shocks and inadequate electrical connections.

The guarantee will lose its coverage in the event of repairs being carried out by unauthorized persons.

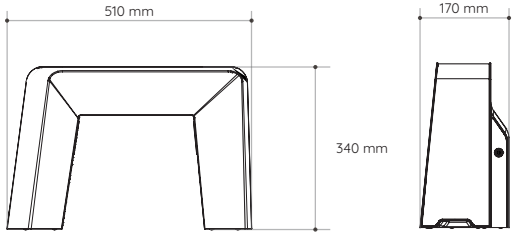
In case of failure of the device, both within and outside the warranty period, contact the manufacturer

11. LIMITATION OF LIABILITY

Innoprick, S.L. disclaims all liability in the event of an accident due to improper use of the equipment, or failure to follow the instructions for use and maintenance.

In no event shall either Innoprick S.L. or the customer be liable to the other for any incidental, indirect, special or consequential damages (including without limitation lost profits or lost business opportunity) that the other party may incur by reason of its having entered into or relied on a purchase or lease agreement, or arising out of the performance or breach of such an agreement, even if the party against whom a claim is made was advised or knew of the possibility of such damages. The foregoing limitation shall apply regardless of the form of the claim in which such liability may be asserted, including breach of contract, tort (including negligence) or otherwise.

12. TECHNICAL SPECIFICATIONS



Size	510 x 170 x 340 mm (length x width x height)
Weight	7,2 Kg
Liquid penetration	IPX0
Low power laser	Class 2, according to IEC 60825-1: 2014 Continuous wave laser Wavelength: 405nm Power: 15 mW Beam divergence angle: 60º

Power supply	Type: Medical power supply 12 V DC 60 W Class I Input: 100 - 240 V / 50 - 60 Hz Medical safety approved (2x MOPP) according to ANSI/AAMI ES 60601-1 and IEC/EN60601-1.
Connections	RJ45 connector (Ethernet)
Wifi	Standards: IEEE 802.11bgn Operating frequency: IEEE 802.11 bgn ISM Band, 2.400GHz ~ 2.4835GHz, Modulation: 802.11b: DSSS (DBPSK, DQPSK, CCK) 802.11a/g: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) Effective Radiated Power: 12.2 dBW / 16.6 W
Transportation and storage Conditions	Temperature: -20ºC to 50ºC (-4ºF to 122ºF) Humidity: 20% to 80% relative humidity, non-condensing. Atmospheric pressure: 700hPA to 1060hPA
Use environment conditions	Temperature: 5ºC to 40ºC (41°F to 104°F) Humidity: 20% to 80% relative humidity, non-condensing. Atmospheric pressure: 700hPA to 1060hPA
GUI	To use the graphical interface app (GUI), a commercial tablet must be used with the following technical specifications: • 9.7-inch or larger screen • Resolution 2048 x 1536 or above. • Wi-Fi connectivity (802.11a/b/g/n/ac), dual band (2.4 and 5 GHz) • Minimum 2 GB RAM. • Minimum 32 GB of storage. • Chip A10 Fusion or better performance. • Operating system iOS 12, Android 9 or latest versions.
Measurements	Measuring trueness: Repeatability: area ≥ 25mm2: ± 6% area ≥25mm2: ± 2% area < 25mm2: ± 8% area < 25mm2: ± 3% (According to ISO 5725 standard)
Applicable regulations and standards	REGULATION (EU) 2017/745 on medical devices. This device complies with the following standards: ISO 14971:2019 ISO 13485:2016 IEC 62304:2006/A1:2015 IEC 60825-1: 2014 IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014/A1:2021 IEC 60601-1-6:2010/A1:2013

13. ELECTROMAGNETIC COMPATIBILITY

This device is designed for use in professional medical environments.

The device is in compliance with standards relating to electromagnetic compatibility, not causing electromagnetic disturbances, and complying with immunity standards.

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

- The device should not be located close to other electrical devices or stacked with other devices.
- The use of accessories, transducers, or cables not specified or provided by the manufacturer may adversely affect EMC performance.
- This device should only be connected to a protective grounded power distribution network to avoid risk of electric shock.
- Portable RF communications equipment (including antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including any cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

This equipment does not have an essential performance.

If these electromagnetic disturbances persist, contact the manufacturer.

NOTE: The emission characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment, this device may not provide adequate protection to RF communication services. The user may need to take mitigation measures, such as relocating or reorienting the equipment.

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product must ensure that it is used in such an environment.

The following tables are included for your reference:

RECOMMENDED DISTANCES TO PORTABLE OR MOBILE RF COMMUNICATIONS DEVICES

The equipment is intended for using in an electromagnetic environment in which RF radiations are controlled. User can help prevent electromagnetic interference by maintaining a minimum distance between portable or mobile RF communications devices (transmitters) and the equipment as recommended below, according to the maximum output power of the communications devices.

Maximum power output of the transmitter (W)	Distance according to the frequency of the transmitter (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 output power not listed above, the recommended distance d in meters (m) can be determined using the equation applicable to the transmitter frequency, where P is the maximum power output in watts (W) according to the manufacturer of the transmitter.

NOTE 1: At the frequencies of 80 MHz and 800 MHz, the distance is applied for the highest frequency range.

NOTE 2: These guidelines cannot be applied in all situations. Electromagnetic propagation is affected by absorption and reflection

To maintain basic safety with respect to electromagnetic disturbances during the expected life of the equipment, all indications contained in this manual must be followed.

IMMUNITY LEVELS (PROFESSIONAL HEALTHCARE ENVIRONMENT)

IMMUNITY TEST	BASIC EMC STANDARD OR TEST METHOD	IMMUNITY TEST LEVELS
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table.
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m - 50 Hz or 60 Hz
Electrical fast transients / bursts	IEC 61000-4-4	±2 kV - 100 kHz repetition rate
Surges line to ground line to line	IEC 61000-4-5	±0,5, ±1, ±2 kV ±0,5, ±1 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V (0.15MHz - 80MHz) 6 V (in bands ISM between 0,15 MHz and 80 MHz) 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_t for 0,5 cycles en 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_t for one cycle and 70% U_t for 25/30 cycles Unique phase at 0º
Voltage interruptions	IEC 61000-4-11	0% U_t for 250/300 cycles
NOTE: U_t: rated voltage(s)		

IMMUNITY LEVELS TO RF WIRELESS COMMUNICATIONS EQUIPMENT

The customer and/or user should help keep a minimum distance between RF wireless communications equipment and our device as recommended below.

TEST FREQUENCY (MHz)	BAND (MHz)	SERVICE	MODULATION	MAXIMUM POWER (W)	DISTANCE (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

EMISSION LIMITS Class A Group 1 according to standard UNE-EN 60601-1-2:2015 + A1:2021