iHealth®

Smart Pulse Oximeter
Oxymètre de pouls sans fil
Ossimetro wireless per il rilevamento del battito
Pulsioxímetro inalámbrico
Funkgesteuertes Pulsoximeter
Oxímetro de Pulso Wireless
Draadloze Pulse-Oxymeter
Ασύρματο Οξύμετρο Παλμού

OPERATION MANUAL
Manuel de presentation
Manuale dell'utente
Manual de Introducción
Bedienungsanleitung
Manual de Funcionamento
Gebruikshandleiding
Εγχειρίδιο Λειτουργίας

EN

iHealth

MODEL PO3M
Smart Pulse Oximeter
OPERATION MANUAL

TABLE OF CONTENT

SYMBOLS

The symbols below associate with your PO3M

Symbols	Definition of Symbol
	Symbol for"THE OPERATION MANUAL MUST BE READ"
	Symbol for "WARNING"
	Symbol for "TYPE BF APPLIED PARTS"(Silica gel pad)
	Symbol for "no alarm for SpO2"
	Symbol for "ENVIRONMENT PROTECTION-Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority of retailer for recycling advice".
	Symbol for "Manufacturer"
	Symbol for "Country of manufacture"and "Date of manufacture"
	Symbol for "EUROPEAN REPRESENTATIVE"
	Symbol for "SERIAL NUMBER"
IP22	IP code of the device: this device's grade of against ingress of solid foreign objects -- ≥12.5mm diameter (and the against access to hazardous parts with finger); the grade of waterproof is dripping (15° tilted).
CE 0197	Symbol for "COMPILIES WITH MDD93/42/EEC REQUIREMENTS"

INTENDED USE

The PO3M Smart Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.
The smart pulse oximeter is intended to measure blood oxygen saturation and pulse rate of adults above 16 years old in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc.).
The Smart Pulse oximeter is not intended for continuous monitoring.

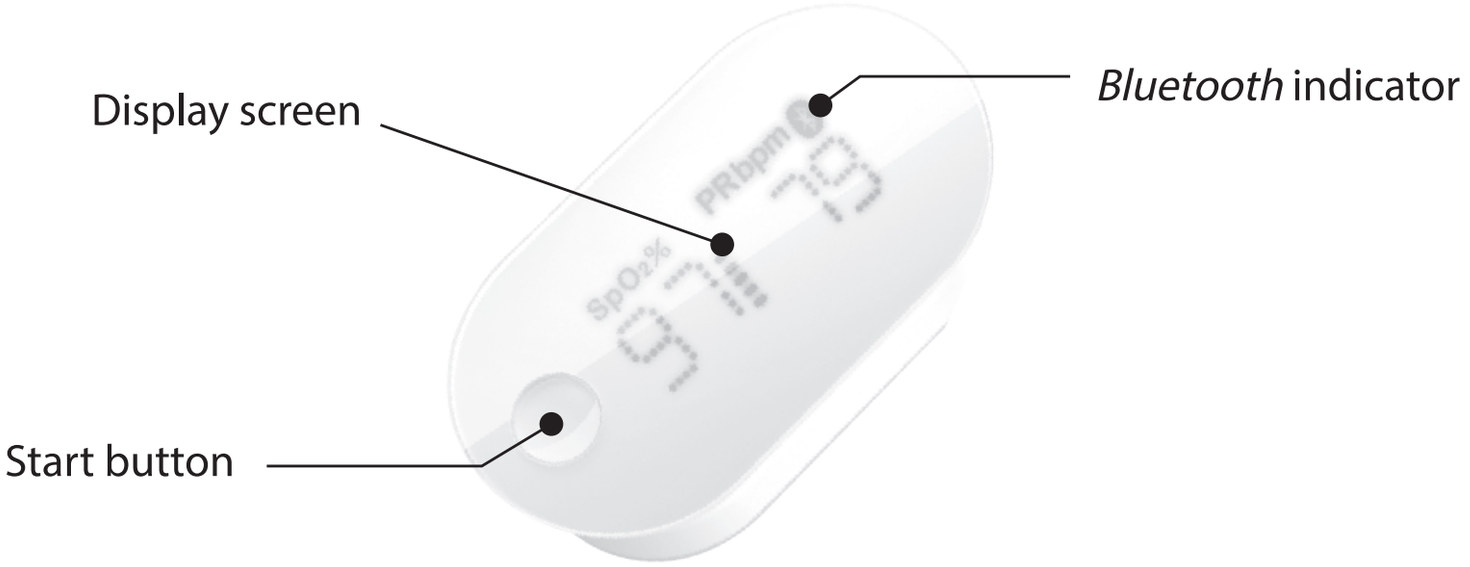
Compatibility

The Smart Pulse Oximeter PO3M works with both iOS and Android devices.
For a complete list of compatible devices, visit our support on page on www.ihealthlabs.eu

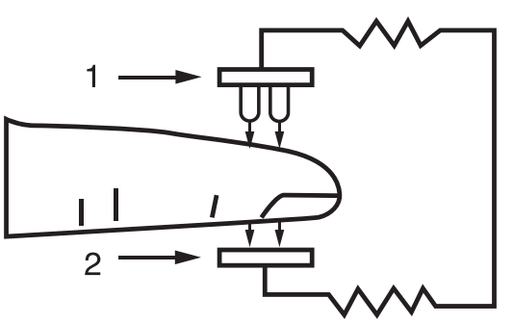
PACKAGE CONTENTS

One (1) Smart Pulse Oximeter PO3M
One (1) Lanyard
One (1) Operation Manual
One (1) Quick Start Guide
One (1) USB cable

PARTS AND DISPLAYS



DEVICE DESCRIPTION



PO3M pulse oximeter measures the amount of oxygen in your blood and the pulse rate. The oximeter works by shining two light beams into the small blood vessels or capillaries of the finger; the measured signal is then obtained by a photosensitive element and processed by the microprocessor. The oxygen saturation (SpO2) is measured as a percentage of full capacity.

Typically, a SpO2 reading between 94%-99% is considered normal. High altitudes and other factors may affect what is considered normal for a given individual. Concerns about your readings should be shared with your physician or healthcare professional.

IEC 60601-1Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 Medical electrical equipment -Part1: General requirements for basic safety and essential performance）
IEC 60601-1-2:2014/EN 60601-1-2:2015 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests)
IEC 60601-1-11:2015（Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment）
ISO 80601-2-61:2011 (Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use).
Hereby, [Andon Health CO.,LTD], declares that this [PO3M] is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. Directive 2014/53/EU declaration of conformity can be downloaded on the following link : https://www.ihealthlabs.eu/support/certifications

CONTRAINDICATIONS

The PO3M Smart Pulse Oximeter cannot be used on infant babies.

⚠ WARNINGS

1.This device is for use on adults only.
2.Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.
3.Do not use the device in a magnetic resonance (MR) environment.

⚠ Notice

1.Do not use the device as the only basis for making medical decisions. It is intended only to be used as additional information that you can give to your licensed health care professional.

2.The device might misinterpret excessive movement as good pulse strength. Limit finger movement as much as possible when using the device.

3.The device has no alarms of blood oxygen saturation and pulse rate, and it will not sound if the amount of oxygen in your blood is too low or your pulse rate is abnormal. If the measurement of SpO2 and pulse rate is not in the normal range, please contact your health care professional.

4.Do not place the device in liquid or clean it with agents containing ammonium chloride or products that are not listed in this Operation Manual.

5.Any of the following conditions may reduce the performance of the device:
a)Flickering or very bright light;
b)Excessive Movement;
c)Weak pulse quality (low perfusion);
d)Low hemoglobin;
e)Nail polish, and/or artificial nails;
f)Any tests recently performed on you that required an injection of intravascular dyes

6.The device may not work if you have poor circulation. Rub your finger to increase circulation, or place the device on another finger.

7.The device measures oxygen saturation of functional hemoglobin. High levels of dysfunctional hemoglobin (caused by sickle cell anemia, carbon monoxide, etc.) could affect the accuracy of the measurements.

8.Do not use the device in a combustible environment (oxygen enriched environ ment).

9.Do not use the device outside the specified operating temperature range, and do not store the device outside the specified storage temperature ranges

10.The materials used in the device conform to the biocompatibility and nontoxic regulations and present no hazard to the body.
11.Use in emergency vehicles with communication systems may affect accuracy of the measurements.
12.The packaging of the device is recyclable, and it must be collected and disposed according to the related regulation in the country or region where the package of the device or its accessories is opened.
13.Any material of the device that may cause pollution must be collected and disposed according to local rules and requirements.
14.Any single functional tester cannot be used to assess the accuracy of a pulse oximeter.
15.Do not stare at the lighting LED, as it may irritate your eyes.
16.The device is calibrated to display FUNCTIONAL OXYGEN SATURATION
17.Do not use the device for more than 30 minutes.
18.The wavelength range of pulse oximeter can be especially useful to clinicians
19.Because the pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter measurements can be expected to fall within ±Arms of the value measured by a oximeter.
20.The SpO2 accuracy was tested by comparing it to a Co-oximeter and the pulse rate accuracy was tested by comparing it to a function tester.
21.The device shall not be installed close to or stacked with other devices. When it is necessary to be close to or stacked with other devices, please observe if the device can operate normally under such setting first. For recommended measures of avoiding or reducing such interference, please refer to the section of "ELECTROMAGNETIC COMPATIBILITY INFORMATION".
22. This device requires a medical AC adapter with an output of DC 5.0V that complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 such as or IEC 60950 approved computer could be used for charging the equipment.

ASP5-05010002JU(input: 100-240V,50/60Hz,200mA;output: DC 5V,1.0A). Please note that the monitor jack size is USB mini B.The USB jack should be used for charging only.

⚠ This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

⚠ The patient is an intended operator.

⚠ Keep the device out of the reach of children/pets to avoid inhalation or swallowing of small parts.

⚠ If you are allergic to plastic/rubber, please don't use this device. Be careful to strangulation due to cables and hoses, particularly due to excessive length

Keep unit out of the reach of young children/pets.

⚠ Not servicing/maintenance while the me equipment is in use.

USING YOUR PULSE OXIMETER

Before Using Pulse Oximeter

The smart pulse oximeter may be used when the user is seated, standing or lying down. The user should not walk or run during measurements and should take care of not excessively moving the finger where the device is attached and the corresponding hand and arm.

It is recommended that the user should wash hands before use. Nail polish, especially dark shades, may affect the accuracy of the measurement and it is suggested that any polish be removed prior to monitoring.

The device is suitable for using on any finger excluding the thumb. It is preferred to use the index or middle finger.

Charge The Battery Before First Use

Link the Smart Pulse Oximeter to a USB port of a electrical power source, and press the "start" button. Then the battery indicator " ▭ " will blink, which means the battery charging is started. When the battery indicator " ▭ " stops blinking, it means the battery has been fully charged.

When charging/using, shall not touch charging USB por and the patient simultaneously.

Download App

Download the free "iHealth MyVitals" app from the Apple App Store or Google Play Store. Follow the on-screen instruction to register and set up your iHealth user account.

Access iHealth Cloud

Upon setting up your app user account, you will also have access to a free, secure iHealth Cloud account by using your app email and password.
Go to www.ihealthlabs.com, then click on "Sign In".

Turn *Bluetooth* "On"

Your iHealth Smart Pulse Oximeter uses *Bluetooth 4.0* Low Energy (BLE) technology. Enable *Bluetooth* on your mobile device and launch the app to initiate the connection. The *Bluetooth* icon will light up and stop flashing when a successful connection is established. The date and time of the Pulse Oximeter will be synced with your mobile device upon a successful connection.

TESTING INSTRUCTIONS

1. Open the clamp of the Pulse Oximeter, then place your middle, ring or index finger of your left hand into the rubber opening of the oximeter with nail side down and display side up, as pictured.

2. On the front panel, press the "Start" button once to turn the oximeter on.
3. Keep your hand still for the reading.
4. After a few seconds, your SpO2 reading will appear on the oximeter display screen and the app if the app is turned on.

5. If the signal strength is too low, switch to another finger and perform the test again.

USING WITHOUT SMART DEVICE

After it has been used for the first time, the date and time of the Pulse Oximeter PO3M will be synchronized with your device. It can also be used without being connected to an smart device. In this case, the measurement data is stored in the memory and can be uploaded to the app when the connection is re-established. The Pulse Oximeter PO3M can store up to 100 measurements. When the memory is full, any new measurement overwrites the oldest ones.

CARE AND MAINTENANCE

1. Clean the device once per week or more frequently if handled by multiple users.
2. Wipe the device with a soft cloth dampened with rubbing alcohol to avoid cross infection. Do not pour the alcohol directly on or into the device. Dry with a soft cloth, or allow to air dry.
3. Avoid dropping this device on a hard surface.
4. Do not immerse the device in water or other liquid, as this will result in damage to the device.
5. If this device is stored below 0 ℃, please acclimate the device to room temperature before use.
6. Do not try to disassemble this device.
7. The PO3M is a precision electronic instrument and must be repaired/serviced by an accredited iHealth service center.
8. Incorrect replacement of battery by inadequately trained personnel could result in an unacceptable risk (e.g., excessive temperatures, fire or explosion). The battery can maintain the performance characteristics for a minimum of 300 charge cycles.if the battery cannot charge the power normally or the Pulse Oximeter cannot use normally, please connect with the authorized maintenance personel.

9. No component can be maintained by user in the device. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied.

10. The patient simulator « Index 2 », made by the Fluke company, can be used to verify operation of the oximeter.

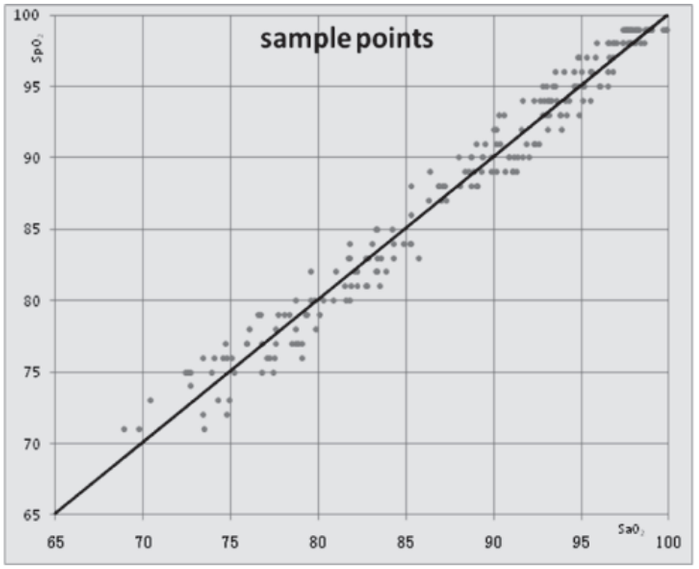
11. The expected service life of the PO3M is about 5 years.

SPECIFICATIONS

1. Model: PO3M
2. Classification: Internally powered, type BF (applied part: silica gel pad)
3. Enclosure degree of ingress protection: IP 22
4. Display System: LED
5. Power Source: battery 3.7V ⎓ Lithium-ion 390 mAh
6. Peak wavelength: 660nm/880nm;
7. Maximum optical output power: 1mW;
8. SpO2 Measuring Range: 70-99%
9. Average Root Mean Square (ARMS) of SpO2 Accuracy: 80%～99%: ±2%, 70%～79%: ±3% ,<70%: no definition.
10.

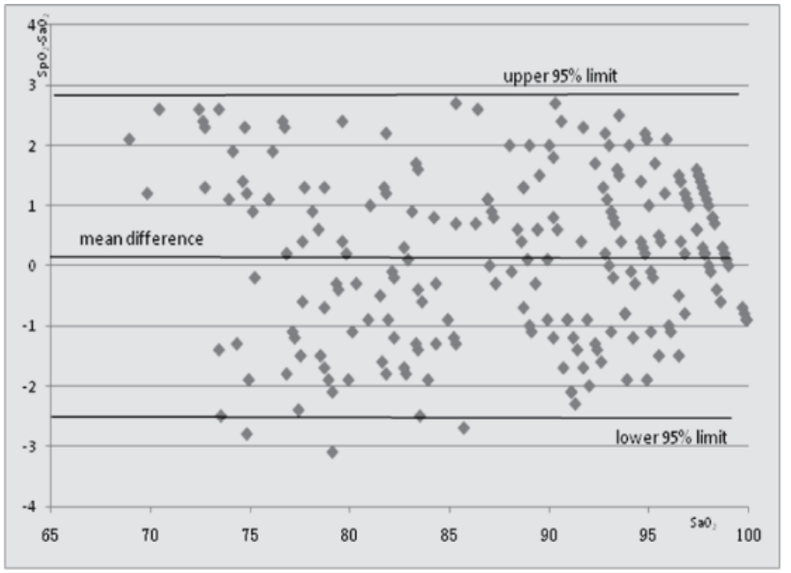
Range	Arms
90%~100%	1.2215
80%~89%	1.3282
70%~79%	1.7277

The figure below shows the graphical plot of all SaO2 versus SpO2 with linear regression fit for all the sample data in the clinical protocol.



Scatter plot of SaO2 versus SpO2 with linear regression fit

The figure below shows the graphical plot of SaO2 versus error (SpO2 – SaO2) with upper 95% and lower 95% limits of agreement:



Scatter plot of difference between methods against the SaO2

11.Pulse Rate Measuring Range: 30/min-250/min

12.Pulse Rate Accuracy: 30/min ~ 99/min: ±2, 100/min ~ 250/min: ±2%.

13.Data update period: 15s

14.Automatic Shut-off: After 8 seconds of no indication on the sensors

15.Operation Environment: 5℃-40℃; Humidity <80%; Atmospheric pressure: 700hPa-1060hPa

16. Storage and Transport Environment: -20℃-55℃; Humidity < 95%; Atmospheric pressure: 700hPa-1060hPa

TROUBLESHOOTING

Problem	Possible Cause	Solution
SpO2 or pulse rate shows no value, or the number fluctuates.	1.Finger may not be inserted correctly. 2.Finger or hand may be moving. 3.The device may be damaged	1.Remove finger and re-insert, as directed. 2.Try to keep perfectly still and test again. 3.Please contact the iHealth Customer Service.
The device does not turn on.	1.The battery may be low. 2.The device might be damaged.	1.Charge the battery and try again. 2.Please contact the iHealth Customer Service.
"E1" is displayed on the screen	The sensor is damaged	Please contact the iHealth Customer Service.
Low Battery indicator is ▭ blinking.	The battery is low.	Charge the battery and try again.
The app cannot find the Smart Pulse Oximeter PO3M.	The *Bluetooth* does not work	Re-establish the *Bluetooth* connection. If still not successful, restart your smart device.

IMPORTANT INFORMATION REQUIRED BY THE FCC

This device complies with Part 15 of the FCC Rules. Its operation is subject to the following two conditions:

(1) This device may not cause harmful interference.

(2) This device must accept any interference received, including interference that may cause undesired operation.

Note: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment of and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

IMPORTANT INFORMATION REQUIRED BY THE INDUSTRY CANADA

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by

Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Manufacturer Information

ANDON HEALTH CO., LTD.
No. 3 Jinping Street, YaAn Road, Nankai District, Tianjin 300190, China.
Tel:+86-22-87611660

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131, USA.
Toll Free: 1-855-816-7705
www.iHealthlabs.com support@ihealthlabs.com

EC REP iHealthLabs Europe SAS www.ihealthlabs.eu
36 Rue de Ponthieu, 75008, Paris, France
Customer service: support@ihealthlabs.eu

CE 0197

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product is applicable to the equipment and system requirements for the purpose of receiving radio frequency energy for the purpose of the work, Bluetooth receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, Bluetooth modulation types:GFSK , effective radiated power: < 20dBm

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home healthcare environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 – Input A.C. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles