


USER MANUAL

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I. INTRODUCTION



-  The complete user manual is available on a web space.
 To access other available languages, please scan the QR code at the end of this user manual > Chapter QR code. (p.17)

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1. Classification of device






- Complies with :  0459
- Date of first marking: 1998
- Usefull life: 10 years
- Class I type BF device
- Class I medical device with measuring function

This device complies with the restrictions imposed by section 15 of the FCC regulation. Its use meets the following conditions: (1) this device must not cause interference and (2) must accept interference from external sources, notably that are liable to cause malfunctions.

Those limits are set so as to ensure reasonable protection against interference in a residential environment. This device generates, uses and can emit radio frequency energy, which may interfere with radio communications if the device is not installed and used in strict conformity with manufacturer instructions. However, there is no guarantee that there will be no interference in certain conditions. You can confirm that this device is the source of interferences with radio or television reception by turning the device on and off.

In accordance with the requirements of FCC rules, any modification made to this equipment which is not expressly approved by the manufacturer would nullify the user's right to use this device.

2. Symbols

	Applied parts classified as Type BF in accordance with EN 60601-1 standard.
	Warning of possible HAZARD in the event of improper use (see user manual).
	Selective collection of this electrical and electronic equipment.
	Important: consult the documents supplied with the equipment.
	Manufacturer.

II. SAFETY CONSIDERATION



1. Precautions to be taken

- The device should not be exposed to direct sunlight or any strong light source. For best results the machine should be used with a constant degree of light.
- Do not place in a dusty atmosphere, or in conditions of high humidity.
- Protect the machine from all vibrations and sudden impacts.
- We advise you to manipulate this instrument with extreme care. Any fall could damage one of his components.
- No known contraindications.
- The device is not intended to be used in conjunction with oxygen rich environment.
- Never attempt to modify or disassemble this product yourself. It can result in malfunction or fire

	Temperature	Humidity	Atmospheric pressure
Use	[10°C ; 35°C]	[30% ; 90%]	[800hPa ; 1060hPa]
Storage	[-10°C ; 55°C]	[10% ; 95%]	[700hPa ; 1060hPa]

Disposal of the batteries and instrument

This device operates on 2 batteries of type LR06. Essilor draws you attention to the fact that commercially available batteries may contain heavy metals (mercury, cadmium or lead) which are harmful for the environment.

These batteries should not be rejected as ordinary waste, that is to say with household waste or ordinary industrial waste (DIB) for example. We recommend that you organize or have organized the collection, recovery or disposal of batteries. The same goes for the device.

2. Indications on electromagnetic compatibility

Portable and mobile radio frequency communication devices may interfere with the pupillometer.

The pupillometer is designed for use in the electromagnetic environment specified below. Customers and users of the pupillometer must ensure that it is used in this type of environment.

Electromagnetic emissions


Emission test	Compliance	Electromagnetic environment
Radio frequency emission. CISPR 11	Group 1	The Pupillometer uses RF energy only for its internal functions. Consequently, its RF emissions are very low and are not likely to generate interference in a nearby electronic device.
RF emissions CISPR 11	Class B	
Limits for harmonic current emissions IEC 61000-3-2	Not applicable	The pupillometer is suitable for use in all premises other than domestic premises and those directly connected to the low voltage power supply mains supplying buildings for domestic use.
Limitation of voltage changes, voltage fluctuations and flicker IEC 61000-3-3		

Electromagnetic immunity

Emission test	IEC 60601 test level	Compliance	Electromagnetic environment
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst immunity test IEC 61000-4-4	±2 kV for electricity supply lines ±1 kV for input / output lines	Not applicable	/
Surge immunity test IEC 61000-4-5	±1 kV between phases ±2 kV between phase and earth		/
Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11	0% U_T (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for 0.5 cycle) 0% U_T for 1 cycle 70% U_T phase with 0° for 25/30 cycles 0% U_T for 250/300 cycles		/
Power frequency magnetic field immunity test IEC 61000-4-8	30 A/m		Power frequency magnetic fields must exhibit the levels characteristic of a representative site located in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
RF interference generated IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.33 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a The field intensities of fixed transmitters, such as base stations for radiotelephones (cell/wireless/phones) and terrestrial mobile radios, amateur radio, AM and FM radiobroadcasting and TV broadcasting cannot be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, electromagnetic investigation on site must be considered. If the field intensity, measured at the point where the pupillometer is used, exceeds the applicable RF conformity level indicated above, observe the pupillometer to check that it is operating normally. If abnormal performance is observed, additional measures may be required, such as redirecting or repositioning the pupillometer.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communication equipment and the pupillometer

The pupillometer is designed for use in an electromagnetic environment with controlled radiated RF interference. The pupillometer customer or user can help prevent electromagnetic interference by keeping a minimum distance between the RF portable and mobile communication device (transmitters) and the pupillometer, as recommended below, depending on the maximum transmission power of the communication device.

Maximum output separation distance depending on the transmitter frequency (m) power rating of the transmitter in (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d= 1.2 \sqrt{P}$	80MHz to 800MHz $d= 1.2 \sqrt{P}$	800MHz to 2.5GHz $d= 2.3 \sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1		0.37	0.74
1		1.17	2.33
10		3.69	7.38
100		11,67	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

III. DESCRIPTION



1. Optical principle

Measuring the inter-pupillary distance

The patient (S) looks at the image of a target, with both eyes open, through a lens (B).

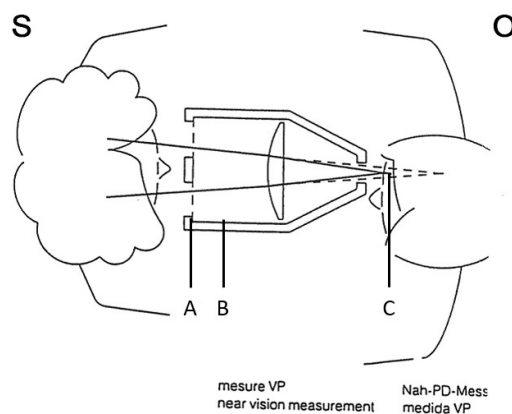
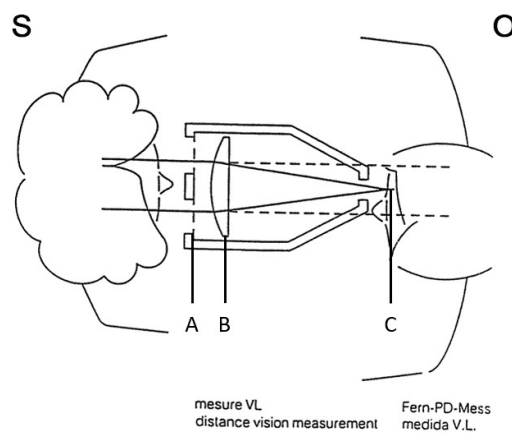
By moving the lens, the optician at O may change the patient's viewing distance from 35 cm to infinity. The target light is reflected on the outer surface of each cornea. These are the corneal reflections and they can be seen by the optician from point (C).

Parallax is not induced by this system.

This point is located on the patient's visual axis.

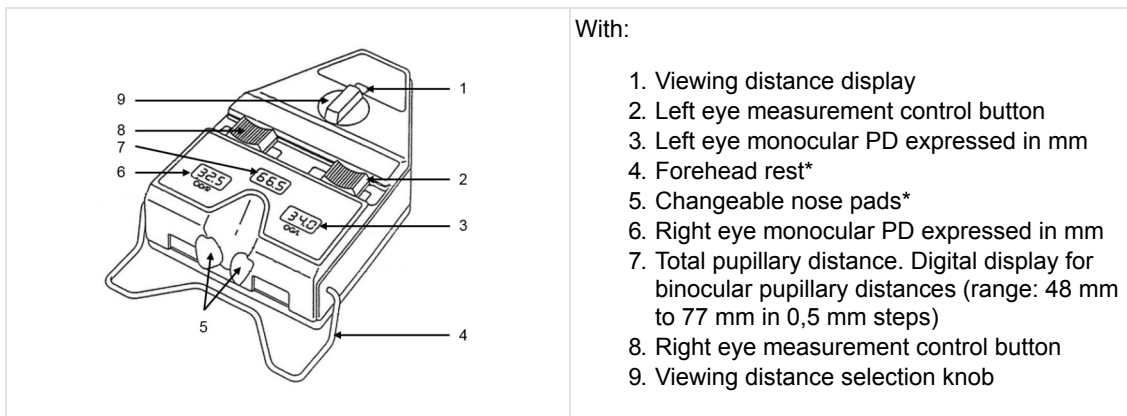
The optician is able to move a vertical graticule along the plane (A), taking one eye at a time, to align it with the corneal reflection.

The measurements for monocular distances and for the total distance will be automatically recorded on the instrument.



The values displayed by the product are expressed in mm. For any request from another unit such as the inch, please contact your sales representative.

2. Parts identification



With:

1. Viewing distance display
2. Left eye measurement control button
3. Left eye monocular PD expressed in mm
4. Forehead rest*
5. Changeable nose pads*
6. Right eye monocular PD expressed in mm
7. Total pupillary distance. Digital display for binocular pupillary distances (range: 48 mm to 77 mm in 0,5 mm steps)
8. Right eye measurement control button
9. Viewing distance selection knob



*

Applied parts.

The product is delivered with :

- an user manual
- 2 spare nose pads (1 left and 1 right)

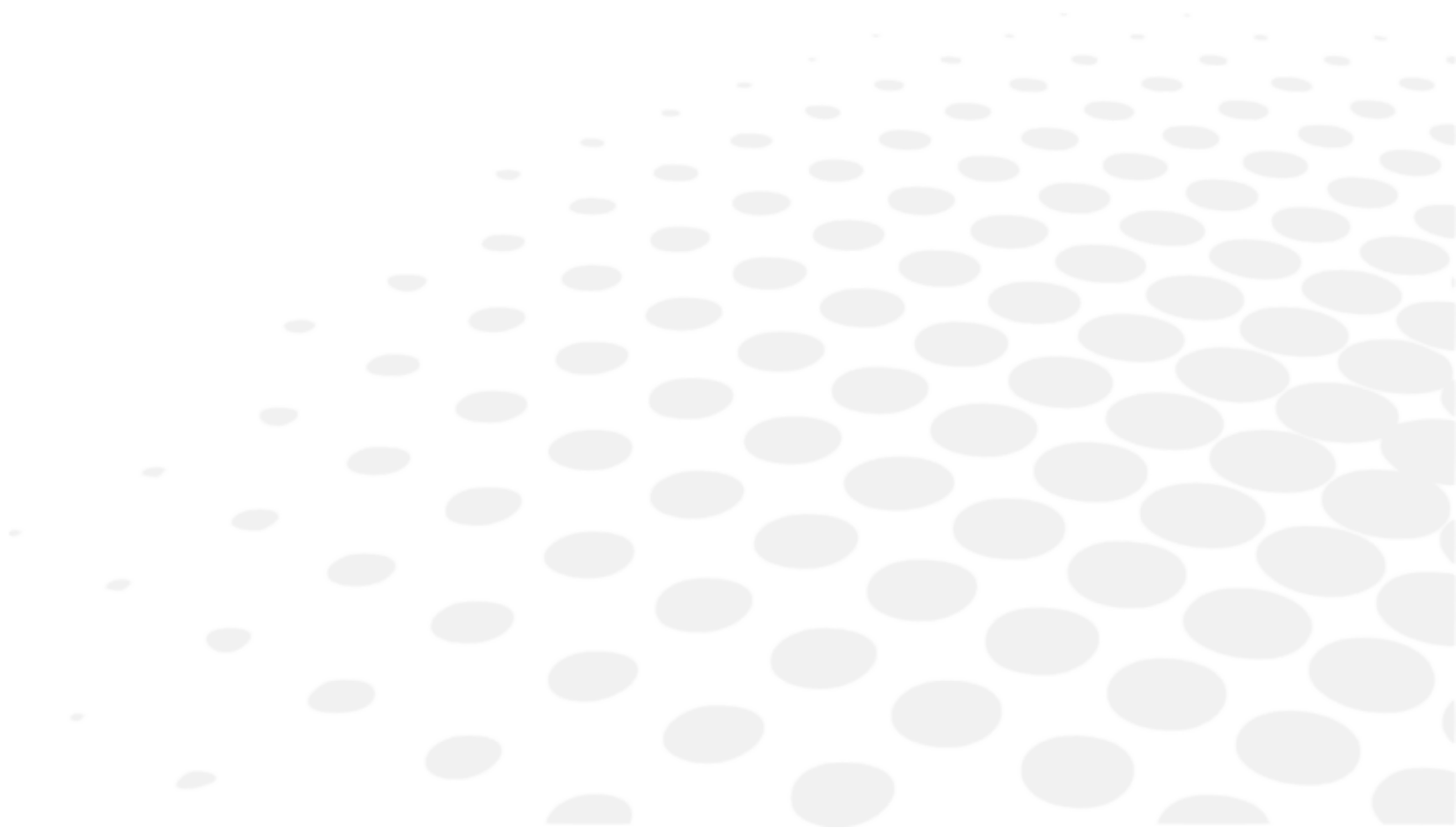


The digital display switches itself off if the pupillometer has not been used for more than 1 minute and a half.



When the pupillometer displays 77 mm of pupillary binocular distance, we recommend that you verify the measurement by another operating procedure. Indeed, the real measurement can be slightly different from 77 mm.

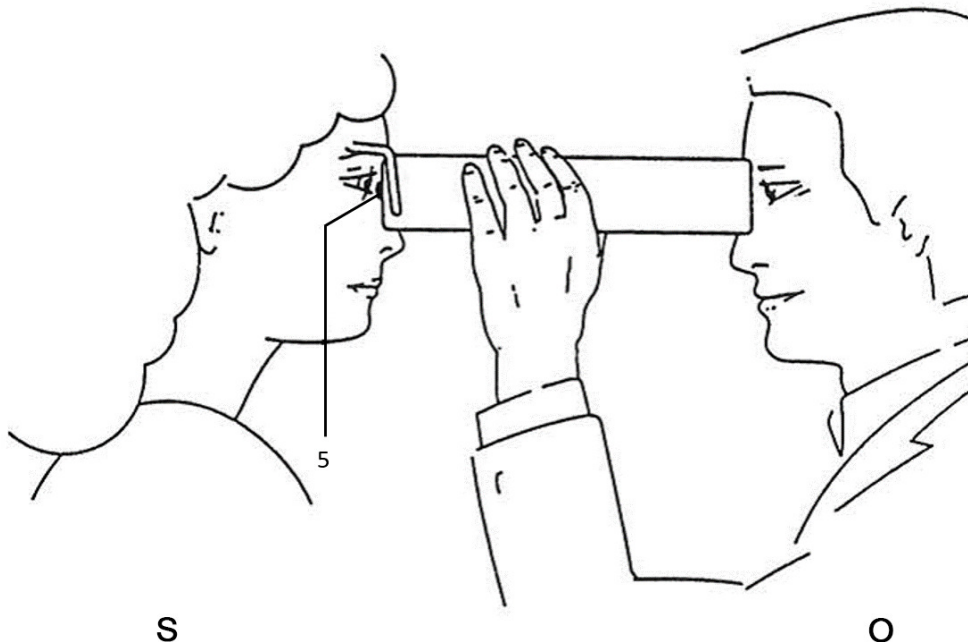
IV. Use



The working distance at which the measurements should be taken are selected by the optician.

Hold the device in both hands and rest it against the patient's nose and forehead. Ask him to focus on the illuminated target and align the mobile graticules with the corneal reflection.

In this position the device is automatically on. It switches itself off when it is turned upside down with the measurement scales above.



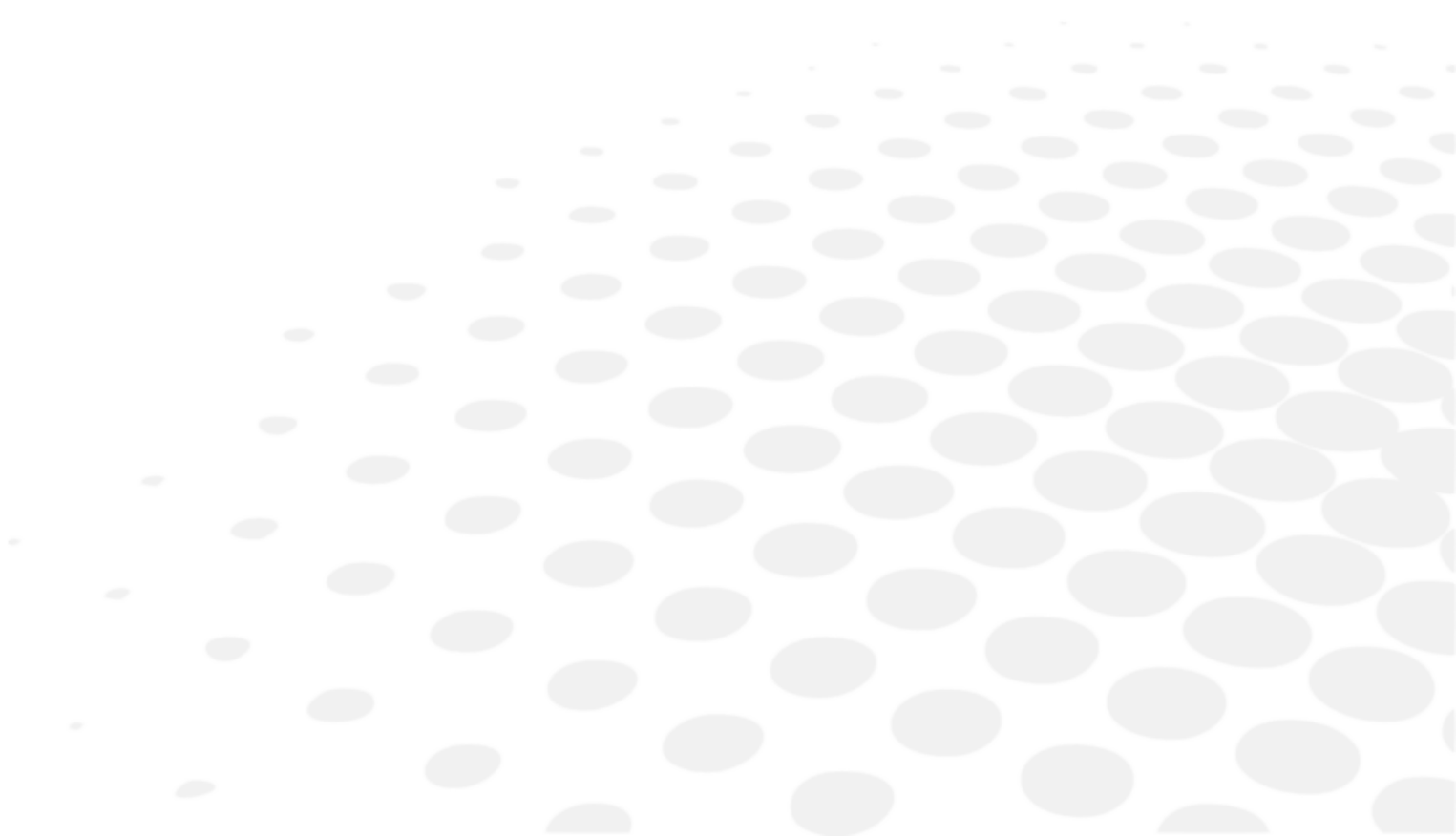
In the operating position, an indicator light shows the instrument is on.

All datas will appear on the same device side (the left and right eye monocular pupillary distances, the total distance PD and the viewing distance).

Such datas should be recorded on the mounting card to minimize the risk of error.

In case of defective binocular vision, a left eye or right eye occluder can be used to take separate measurements of each eye. (The control switch for this is underneath the instrument on the opposite side from the forehead rest).

V. MAINTENANCE



1. Cleaning

The device is of a light colour and should be kept clean.

To avoid accidents, remove batteries of the product before cleaning.

Wipe external surfaces lightly with a damp cloth using water or dish washing liquid.

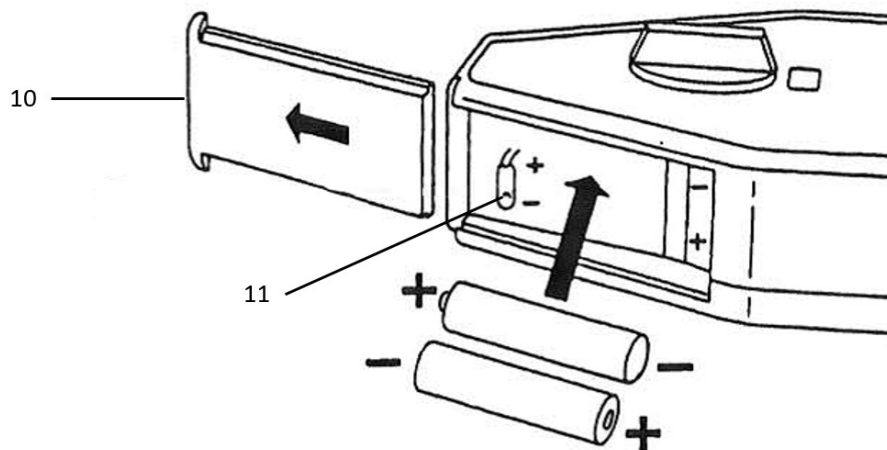
To avoid all danger of discolouration and incidents related to machine functions, never use diluting agents, solvents, benzene, acetone or any other organic or mineral solvents.

The nose pads (5) may be removed to be replaced and a spare set is provided in the box.

The nose pad and the forehead should be cleaned after each patient. To do so, use a soft cloth with alcohol.

2. Loading the batteries

Open the flap (10) and place the two batteries 1,5V LR06 head to tail between the flexible metal strips (11).

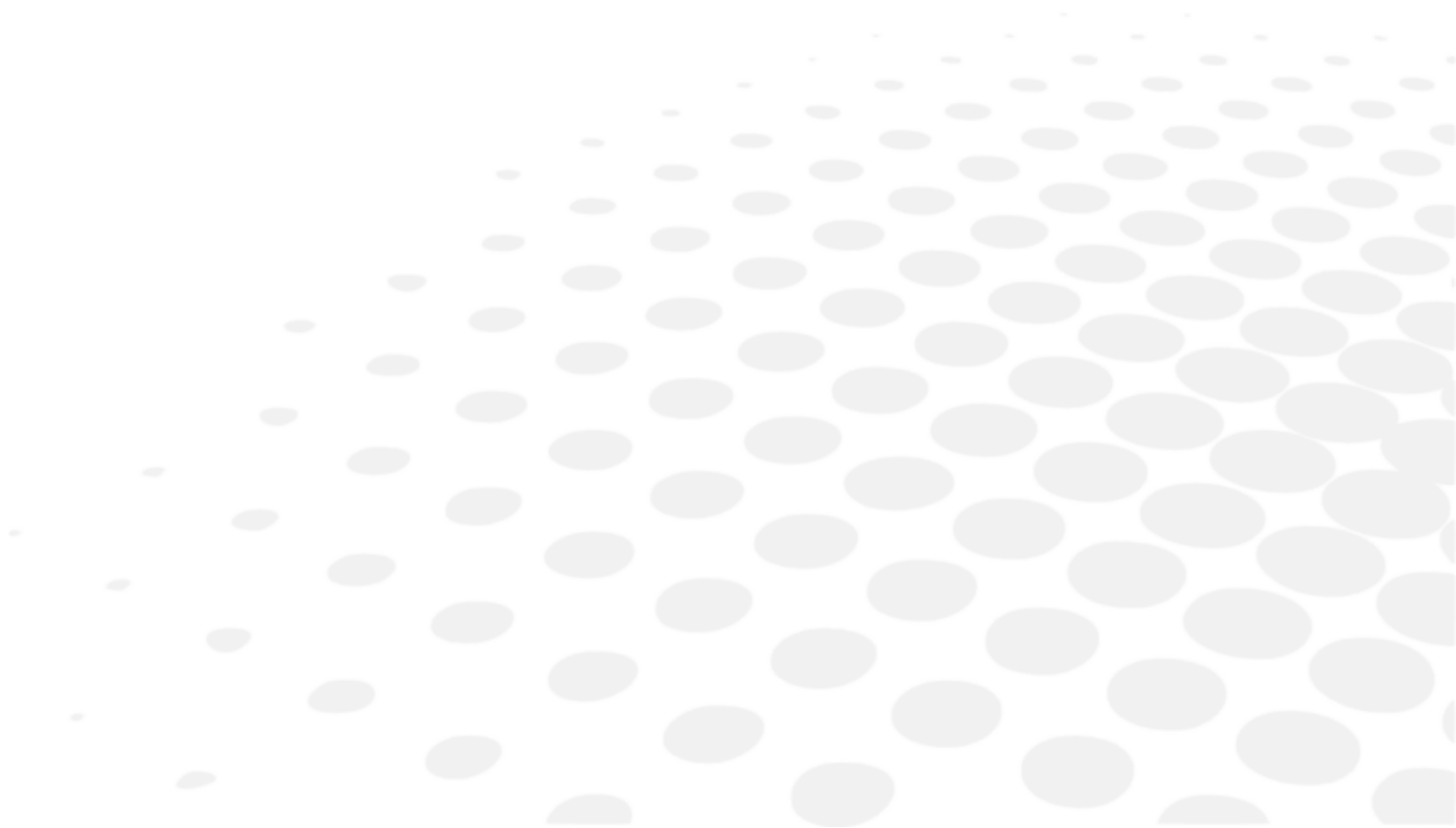


If you are not using the product for a long time, do not forget to take off the batteries from their original position.



Be sure to replace the battery cover before using the product in accordance to the signage.

VI. QR CODE



The latest version of the user manual in the appropriate language is available on a web space. Upon request, a paper version can be provided for free.

- en The complete user manual is available on a web space. To access it, please scan the QR code below using a dedicated application.
- fr Le manuel utilisateur complet est disponible sur un espace web. Pour y accéder veuillez scanner le QR code ci-dessous à l'aide d'une application dédiée.
- ar لتتمكن من الوصول إليه، يُرجى مسح رمز الاستجابة السريعة أدناه باستخدام تطبيق مخصص لذلك.
- be Поўная інструкцыя карыстальніка даступна ў інтэрнэт-прасторы. Каб атрымаць доступ, адсканіруйце QR-код ніжэй пры дапамозе спецыяльнай праграмы.
- bg Пълното ръководство за потребителя е достъпно на уеб пространство. За достъп, моля, сканирайте QR кода по-долу с помощта на специално предназначено приложение.
- cs Celá uživatelská příručka je k dispozici na webu. Pro přístup k ní oskenujte níže uvedený QR kód pomocí specializované aplikace.
- da Den komplette brugermanual findes på et websted. Du får adgang til den ved at scanne QR-koden nedenfor ved hjælp af en dertil beregnet applikation.
- de Die vollständige Bedienungsanleitung ist auf einem Speicherplatz verfügbar: Für den Zugriff darauf scannen Sie bitte untenstehenden QR-Code mittels einer dafür vorgesehenen Anwendung.
- el Το πλήρες εγχειρίδιο χρήσης διατίθεται σε έναν ιστοχώρο. Για να μεταβείτε σε αυτόν, σαρώστε τον παρακάτω κωδικό QR μέσω μιας ειδικής εφαρμογής.
- es El manual de uso completo está disponible en la web. Para acceder, escanee el código QR que se encuentra a continuación con la ayuda de una aplicación.
- et Täielik kasutusjuhend on saadaval veebis. Juurdepääsuks palun skannige allolevat QR-koodi, kasutades selleks spetsiaalselt rakendust.
- fi Täydellinen käyttöohje on käytettävissä verkossa. Avaa käyttöohje skannaamalla QR-koodi asianmukaisella sovelluksella.
- hr Potpuni korisnički priručnik dostupan je na webu. Da biste mu pristupili, skenirajte QR-kod u nastavku namjenskom aplikacijom.
- hu A teljes használati útmutató megtalálható a webes felületen. A hozzáféréshez, kérjük, olvassa le a lenti QR-kódot a megfelelő alkalmazás használatával.
- id Panduan pengguna yang lengkap tersedia di web space. Untuk mengaksesnya, silakan pindai kode QR berikut dengan menggunakan aplikasi khusus.
- it Il manuale utente completo è disponibile su uno spazio Web. Per accedervi, scansionare il codice QR seguente mediante un'applicazione dedicata.
- ja ユーザーマニュアル完全版はウェブサイト内で閲覧いただけます。そちらにアクセスするには、専用アプリケーションを使用して以下のQRコードをスキャンしてください。
- ko 완전한 사용자 매뉴얼이 웹사이트에 있습니다. 전용 앱을 사용해 아래의 QR 코드를 스캔하면 접근할 수 있습니다.
- lt Išsamas naudotojo vadovas ieškokite interneto svetainėje. Kad jį atvertumėte, specialia programėlė nuskaitykite toliau pateiktą QR kodą.
- lv Pilnā lietotāja instrukcija ir pieejama tīmeklī. Lai tai piekļūtu, lūdzu, noskenējiet tālāk redzamo QR kodu, izmantojot tam paredzētu lietojumprogrammu.

ms	Manual pengguna yang lengkap boleh didapati di ruangan web. Untuk akses, sila imbas kod QR di bawah menggunakan aplikasi yang berkenaan.
nl	De volledige gebruikershandleiding is beschikbaar op een website. U kunt de handleiding bereiken door de QR-code hiernaast te scannen met een geschikte applicatie.
no	Den komplette brukerhåndboken er tilgjengelig på et webområde. For å få tilgang, må du skanne QR-koden nedenfor ved hjelp av en dedikert applikasjon.
pl	Kompletna instrukcja użytkownika jest dostępna na stronie internetowej. Aby uzyskać dostęp, zeskanuj poniższy kod QR przy użyciu dedykowanej aplikacji.
pt	O manual do utilizador completo está disponível num espaço web. Para aceder, queira digitalizar o QR code seguinte com a ajuda de uma aplicação dedicada.
pt (brazil)	O manual do usuário completo está disponível na área web do cliente. Para acessar, scanear o código QR abaixo usando a respectiva aplicação.
ro	Versiunea integrală a manualului de utilizare este disponibilă pe un site web. Pentru a-l accesa, scanați codul QR de mai jos cu ajutorul unei aplicații dedicate.
ru	Полное руководство пользователя доступно на сайте. Чтобы получить к нему доступ, сканируйте QR-код ниже с помощью специального приложения.
sk	Celý používateľský manuál je dostupný na internete. Aby ste sa k nemu dostali, naskenujte QR kód nižšie pomocou na to určenej aplikácie.
sl	Celoten uporabniški priročnik je na voljo na spletnem mestu. Za dostop do njega skenirajte spodnjo kodo QR z uporabo namenske aplikacije.
sr	Potpuno korisničko uputstvo je dostupno na vebu. Da biste mu pristupili, skenirajte QR kôd u nastavku pomoću namenske aplikacije.
sv	Den fullständiga handboken finns på en plats på Internet. Skanna QR-koden nedan med en lämplig app för att få åtkomst till den.
th	มีคู่มือผู้ใช้ฉบับสมบูรณ์ให้ที่เว็บไซต์ เพื่อเข้าถึงข้อมูล กรุณาสแกนรหัส QR ด้านล่างนี้โดยใช้แอปพลิเคชันเฉพาะงาน.
tr	Kullanma kılavuzunun tamamı internette bulunmaktadır. Kılavuza erişmek için, bu amaca yönelik bir uygulama kullanarak aşağıdaki QR kodunu taratın.
uk	Повний посібник користувача доступний на сайті. Щоб отримати до нього доступ, скануйте QR-код нижче за допомогою спеціального додатку.
vi	Cẩm nang hướng dẫn sử dụng hoàn chỉnh hiện có trên không gian web. Để truy cập, vui lòng quét mã QR bên dưới sử dụng ứng dụng chuyên dụng.
zh	操作手册全文可在一个网络空间内查询。如要访问该空间，请使用一个专门的应用软件扫描QR条码。





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