

Leonardo PF POSITIONAL FEEDBACK

USE AND MAINTENANCE MANUAL

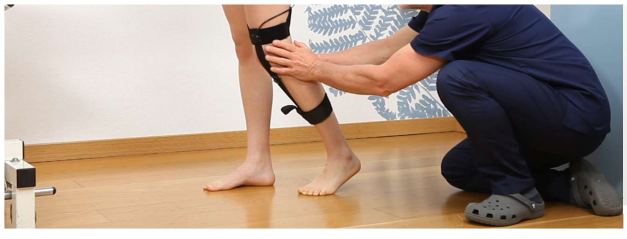
UDI-DI BASE: 805595442LEOP5

SRN CODE: IT-MF 000050193

Creator-manufacturer: P.T. Crippa Alessandro

REV. 001

01.2026





Commentato [1]: THIS CODE IS THE COMPLIANCE CODE IN THE DECLARATION OF CONFORMITY FILE

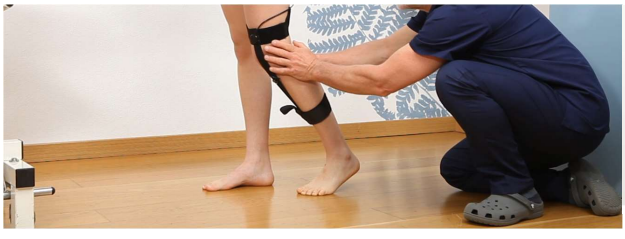
CLASSIFICATION AND BASIC UDI
SRN CODE

Applicable Regulation
(Applicable Regulation)

EU REGULATION 2017/745 concerning devices doctors and subsequent amendments and additions
(EU REGULATION 2017/745 concerning medical devices
and following updates)

Classification (Annex VIII, EU 2017/745)
Classification (Annex VIII, EU 2017/745)

Class I (Rule 1)
Class I (Rule 1)
UDI-BASE 805595442LEOP5





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1. GENERAL INFORMATION

This manual contains information for the practical, correct, and safe use of the device and is intended for use by specialized personnel and the product user. We recommend that you read the entire manual carefully before using the product.

If you have any doubts or questions, please contact your dealer who will be able to advise you correctly.

The importance of reading and understanding the user manual is highlighted on the product by the following symbol:



1.1 MANUFACTURER



Manufacturer:	CRIPPA ALESSANDRO VIA PADRE PAOLO MERONI 16 ALBAVILLA (CO)
SRN Code	IT-MF 000050193

The manufacturer operates in compliance with the UNI EN ISO 13485:2016 quality standard.

2. PRODUCT DESCRIPTION AND GENERAL INFORMATION





2.1. DESCRIPTION

The biofeedback devices included in the case are useful for therapists to assess motor behavior and develop specific therapeutic programs. They facilitate the patient's task by amplifying essential information, providing visual, acoustic, or vibratory feedback on the behavior of various body areas and major joints. The components can be easily assembled and allow for therapeutic adjustments and proper training.

2.2. INTENDED USE

This kit is intended for rehabilitation purposes. Use of the device for purposes other than those defined in this manual is prohibited. The manufacturer declines all responsibility for damage to persons or property resulting from improper use of the device or any use other than that described in this manual. The manufacturer reserves the right to make changes to the product and the manual without notice in order to improve features and performance.

2.3. USERS

The preferred users are rehabilitation therapists, occupational therapists, or healthcare / sports professionals engaged in recovery processes . It is the specialist's responsibility to assess the physical fitness of the patient for whom the product is intended. Use under the supervision of a healthcare professional is always recommended.

2.4. PATIENT GROUPS AND CLINICAL CONDITIONS

The tools are useful For personalized treatments for patients with neurological and orthopedic conditions. The kit allows for the formulation of targeted therapeutic proposals, both in the post-acute phase and in patients with good recovery, through complex and challenging exercises.

2.5. APPLIED PARTS





- The Class 1 laser beam is considered harmless because the radiation emitted is always below the maximum permitted standards (MPE, Maximum Permissible Exposure). However, it is recommended to avoid pointing it directly at the eyes.
- All electrical parts of the device, including sensors and circuits responsible for auditory, visual, and tactile feedback, operate at low voltage and pose no risk to the user.
- No part of the device comes into direct contact with blood or other bodily fluids.

2.6. ENVIRONMENT OF USE

- The device is intended for indoor use, in outpatient settings, physiotherapy offices or at home under the supervision of qualified personnel.
- Not intended for use in wet or outdoor environments.
- Avoid direct exposure to intense sunlight or heat sources.

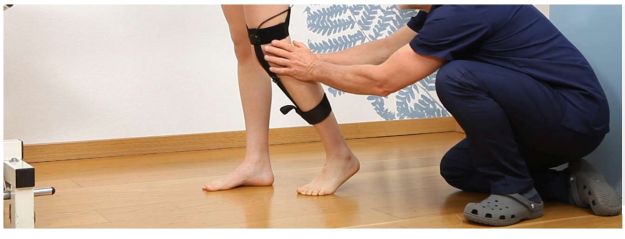
2.7. STORAGE

- Store in a dry place at room temperature
- Do not place heavy objects on the device or apply excessive pressure to the surface.
- Make sure the items are positioned correctly before closing the case.
- Protect from dust and materials that may discolor or damage the tablet.

2.8. MANUFACTURER'S DECLARATIONS

The manufacturer declares that:

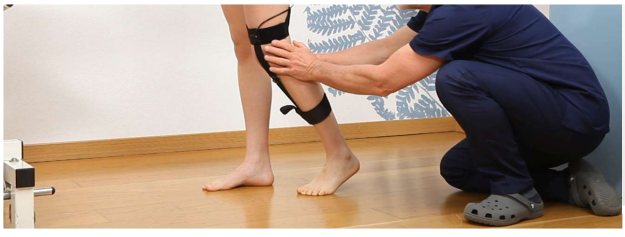
- the device is not a measuring instrument;
- the device is not intended for clinical investigations;
- the device is not sterile and is not disposable
- for correct operation and for user safety, it is necessary that ordinary maintenance operations are carried out as described in the relevant paragraph;
- The device cannot be used for purposes other than those indicated in this manual.





3. GENERAL WARNINGS

- Always refer to this manual for proper use of the device. The manual should be kept near the device for easy reference.
- Dropping or impacting the device may cause breakage.
- Be careful when closing the case: fragile components can break if bumped or compressed.
- The product has a useful life of 10 years, provided that the use and ordinary maintenance operations prescribed in this manual are correctly carried out.
- Components subject to normal wear, such as Velcro straps, which may deteriorate depending on the manner and frequency of use, are excluded from the above-mentioned lifespan.
- Always check the condition of the device before use. Do not use if any components are damaged or missing.
- The device is designed to be used by only one person at a time; any special situations require attention and, if necessary, additional assistance.
- Do not modify the device or use parts/accessories not supplied or approved by the manufacturer.
- Before performing an exercise, check that the patient has the necessary skills to respond to the task safely.
- Remain close to the subject for weight-bearing exercises, if the situation requires it.
- Avoid exposure to intense heat sources or direct sunlight.
- Keep the device away from substances that may damage it.





- LASER 29. Before using it for the first time, unscrew the cylindrical body of the laser and insert the battery inside , respecting the correct polarity indicated.

Commentato [2]: decide where to insert this part

- 31. WIRE PROTRACTOR. Before using for the first time, remove the protective tab that interrupts the battery connection. When the battery is exhausted, unscrew the screw on the back of the device and replace it with a new one of the same type.

- The CENTRALINA 32 is equipped with a built-in rechargeable battery. To charge the battery, insert a smartphone charging cable into the charging jack (centralina 32 G). Connect the other end of the cable to a power source.

3.1. ACCIDENTS

If the device is damaged, discontinue use and contact the manufacturer.

3.2. SYMBOLS ON THE DEVICE

	Manufacturer		Production date
	Unique Device Identifier		Medical Devices
	Unique reference of the model		Marking
	Serious number		Follow the Instructions for use

3.3. SYMBOLS IN THE MANUAL

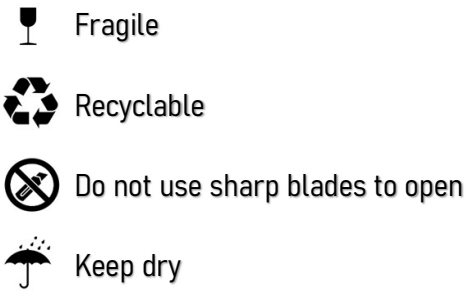




- Warning symbol: Indicates that the instructions next to it must be followed carefully to ensure safety and correct use.



3.4. SYMBOLS ON PACKAGING

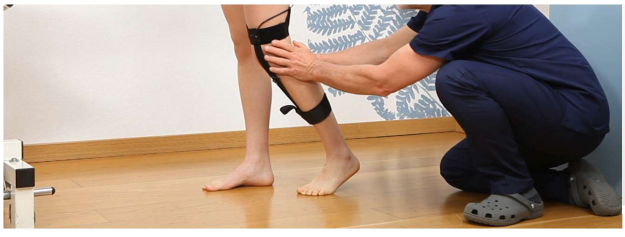


3.5. SPECIAL WARNINGS

- Do not use the device if it is damaged or incorrectly configured.
- Do not use the device in the presence of flammable substances or extreme environments.
- Do not immerse electrical components in water.

3.6. CONTRAINDICATIONS AND SIDE EFFECTS

- There are no known side effects.
- Always read the warnings before use





- Always check patient suitability before use



3.7. LIMITS OF USE

- Use the device only for its intended purpose.
- Pay attention to the user's stability and the surrounding environment.

3.7.1. RESIDUAL RISKS

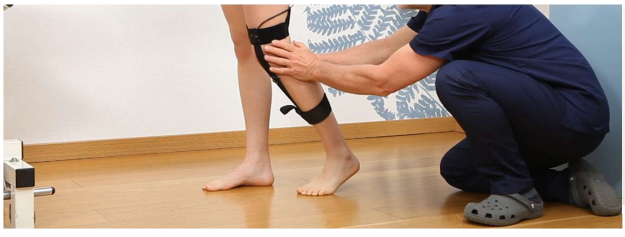
- The integrity of the device is not guaranteed if dropped, impacted, or used inappropriately. Delicate components may break or become detached.

3.7.2. FIRE PREVENTION

- Do not expose the device to flames, intense heat sources or flammable materials.

3.7.3. PREVENTION OF ENVIRONMENTAL AND PERSONAL DAMAGE

- Discontinue use if any part of the device becomes damaged.
- Dispose of the device according to local regulations.





3.8. EMERGENCY FUNCTIONS

In case of sudden malfunction, discontinue use immediately and remove the user from the tablet.

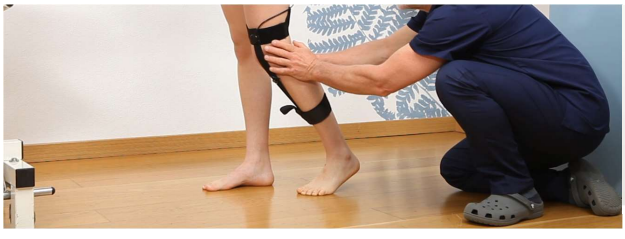
3.9. COMMON FUNCTIONS

- proprioception
- strength/recruitment
- spasticity
- rigidity
- transfers
- balance
- I walk

4. PACKAGE CONTENTS AND PRODUCT FEATURES

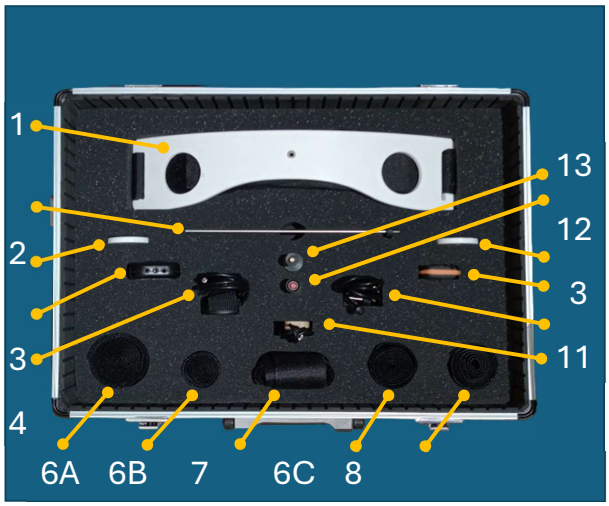
The product is delivered in cardboard packaging suitable for ensuring its integrity and functionality.

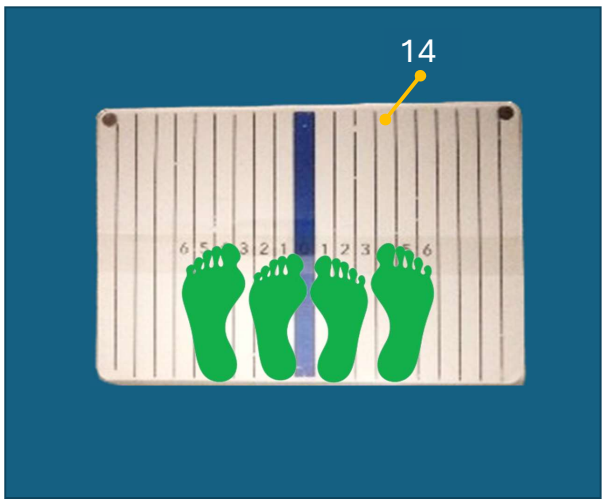
To open the package and remove the contents, pay attention to the warnings and symbols on the package itself.





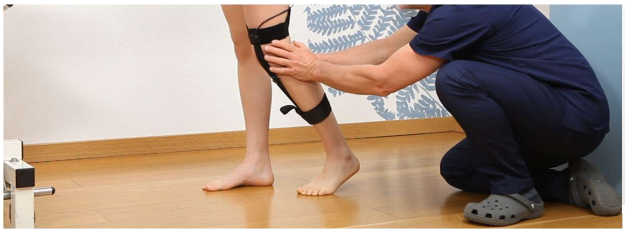
4.1. COMPONENTS





1	PELVIC VIEWER
2	ANTENNA
3	SUPPORT
4	FEEDBACK CONTROL UNIT
5	GONIOMETER
6A	VELCRO BANDS 110 CM
6b	VELCRO BANDS 40 CM
6C	VELCRO BANDS 60 CM
7	VELCRO TRUNK BANDS
8	VELCRO ANKLE BAND
9	COIN VIBRATION
10	INCLINOMETER
11	GONIOMETER
12	LASER
13	LASER HOLDER
14	GRAPHIC PANEL

1	VISUALIZZATORE PELVICO
2	ANTENNA
3	SUPPORTO
4	CENTRALINA FEEDBACK
5	GONIOMETRO
6A	FASCE CON VELCRO cm 1
6B	FASCE CON VELCRO cm 4
7	FASCE CON VELCRO PE
6C	FASCE CON VELCRO cm 6
8	FASCIA CON VELCRO PER
9	PASTIGLIA VIBRANTE
10	INCLINOMETRO
11	GONIOMETRO A FILO
12	LASER
13	PORTA LASER
14	PANNELLO GRAFICA



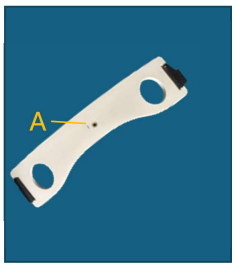


4.1.1. DETTAGLIO COMPONENTI

PELVIC VIEWER 1

N°Pezzi:

A 1 Compass for screwing laser holder (13), antenna (2), inclinometer (10)

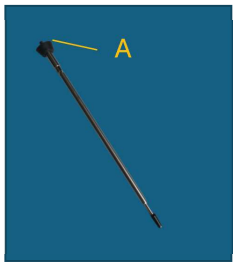


INCLINOMETER 10, or LASER HOLDER 13 or the ANTENNA 2 can be screwed into compass A. Depending on the elements inserted into compass A, behaviors on different planes can be amplified. The inclinometer on the frontal and sagittal planes, the laser for rotations on the sagittal and horizontal planes, the antenna for anterior/posterior and lateral movements

ANTENNA 2

N°Pezzi:

A threaded terminal to be inserted into the pelvic viewer (1) or the support (3)



The ANTENNA is screwed onto the compass of SUPPORT 3 or that of PELVIC VIEWER 1 A. Using the different trajectories, numbers and graphic references present on the panel, numerous scenarios can be created for the control on the horizontal plane of the pelvis aimed at load shifts, balance control, guidance of advancement movements, rotation for the reorganisation of correct movement patterns.

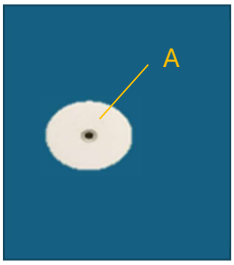




SUPPORT 3

N°Pezzi:

A threaded socket for laser holder insertion (13), inclinometer (10), antenna (2)

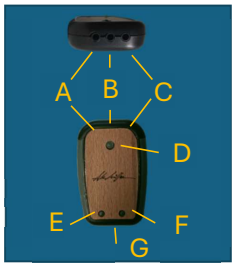


The SUPPORT is positioned on the different types of flat BANDS. The LASER HOLDER 13, the INCLINOMETER 10, or the ANTENNA 2 can be screwed into compass A. Depending on the elements inserted into compass A, the behaviors on the different planes can be amplified. The inclinometer on the frontal and sagittal planes, the laser for rotations on the sagittal and horizontal planes, the antenna for antero-posterior and lateral displacements.

FEEDBACK CONTROL UNIT 4

N°Pezzi:

- A Input for acoustic feedback
- B Vibrating pad input
- C Input for visual/vibratory feedback
- D Led Feedback
- E Charged battery
- F Low battery LED
- G Charging plug



By inserting plug A of the GONIOMETER 5 or the INCLINOMETER 10 into hole A of the FEEDBACK CONTROL UNIT, the acoustic FB is activated. If you insert them into hole C, the visual Feedback (FB) is activated; this mode is useful as a visual FB for the patient or the operator but it is also useful for adjusting the goniometric range or the inclinometer without the patient noticing the activation of the buzzer before performing the exercise. Once the correctness of the joint range has been verified, you can move the plug to hole A to activate the acoustic FB. If you wish to provide a vibratory FB, leave the plug in hole C and insert plug A of the VIBRATING PAD 9 into hole B of the Control Unit.

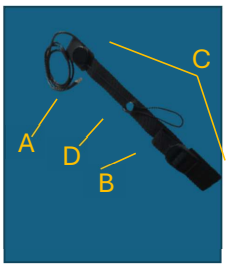




The pad is placed in contact with the skin and secured with tape on the identified muscle group. You can also use two different FB modes, one acoustic and one visual or vibratory, by inserting all three plugs into the holes on the control unit.
To fully charge the battery inside the control unit, connect a charging cable (a cell phone cable is suitable) to connector G. When the battery is nearly empty, LED E lights up, while LED F lights up when the battery is charging.

GONIOMETER 5

N°Pezzi	
A	plug for insertion into the control unit (4
B	elastic adjuster
C	Velcro base for attachment to Velcro bands
D	cable regulator



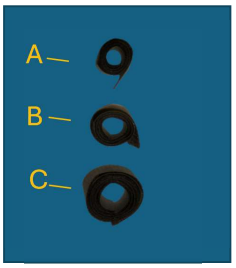
The GONIOMETER acts as a Feedback (FB) providing information regarding the reaching or exceeding of an angle at the various major joints of the body. It is positioned using the VELCRO STRAPS 5 proximally and distally at the level of the joints. The choice of band A/B/C is related to the diameter of the segment around which it is to be positioned. The adjustment is made by squeezing the cable regulator D which releases the cable and allows it to slide to the desired length. The elastic regulator B serves as a "friction" to allow that, once the cable length has been reached and the FB has been activated, one can proceed further without damaging the device. By inserting the plug A into the hole C of the FB 32 CONTROL UNIT, the cable regulator can be used to adjust the length and activate the visual FB. Once the correct joint range has been verified, the plug can be moved into hole A to activate the acoustic FB. If you wish to provide a vibratory FB, leave the plug in hole C and insert plug A of the VIBRATING COIN 38 into hole B of the Control Unit. The pad is placed in contact with the skin and secured with tape on the identified muscle group.





VELCRO BANDS 6

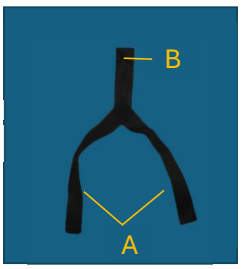
N°Pezzi:	
A	1 fascia lunghezza 40 cm
B	1 fascia lunghezza 60 cm
C	1 fascia lunghezza 110 cm



The VELCRO BAND 5 C is placed around the trunk at sternal level and closed at the back. The VELCRO BAND 5 B can be used on the head to position the SUPPORT 30 to connect the LASER HOLDER 28 or the INCLINOMETER 40. The VELCRO BAND 5 A/B can be used on different body segments to position the SUPPORT 30 to connect the LASER HOLDER 28 or the INCLINOMETER 40 or the GONIOMETER 10 C.

VELCRO TRUNK BAND 7

N°Pezzi:	
A	velcro da agganciare alla fascia 5C anteriormente
B	velcro da agganciare alla fascia 5C posteriormente



The VELCRO BAND 5 C is placed around the trunk at sternal level, closing it at the back. The VELCRO TRUNK BAND 5 is attached to the Band C at the front with the two ends (A). While at the back, the female Velcro part of the VELCRO TRUNK BAND (B) is placed between the two parts of the band C. The SUPPORT 30 is attached to the female Velcro B of the band 5 at the back or to the Band C at the front between the two shoulder straps A of the VELCRO TRUNK BAND

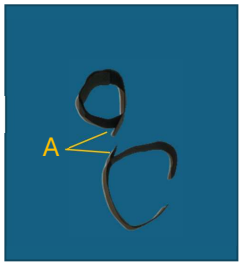




VELCRO ANKLE BAND 8

N°Pezzi:

A free element for goniometer connection (10)



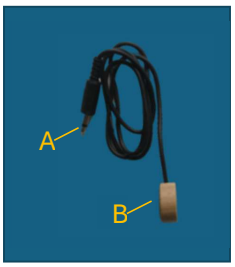
Attach the VELCRO ANKLE BAND to the malleoli. Attach the ends C of the GONIOMETER 10 to free element A. The elastic regulator B is positioned at its maximum length so as not to damage the goniometer, and the cable is also adjusted to its maximum length, and then its length can be modified according to the patient's stride length. If the patient has an asymmetrical stride, he or she will only hear a sound on the side with the longer stride. Ask the patient to align their stride length by activating the acoustic feedback on the other side as well. If the patient takes an excessively long stride or stumbles, the Velcro fastening will allow the device to be released immediately.

COIN VIBRATION 9

N°Pezzi:1

A plug for insertion into the 32B control unit

B vibrant element



To provide vibration feedback, insert plug A of the COIN VIBRATION 38 into hole B of the COIN VIBRATION, and the plug of the INCLINOMETER 40 or GONIOMETER 10 into hole C of the CONTROL UNIT. If desired, you can use both devices by inserting one of them into hole A of the CONTROL UNIT 32 to obtain acoustic feedback. The pad is placed in contact with the skin and secured with tape on the identified muscle group.

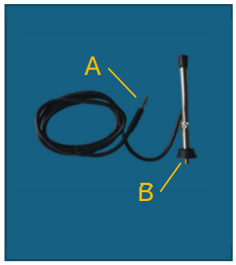




INCLINOMETER 10

N°Pezzi:1

- A — plug for insertion into the control unit 32
- B — threaded terminal to be inserted into the tablets (1 -2-3) or into the pelvic viewer (6) or into the support (30)

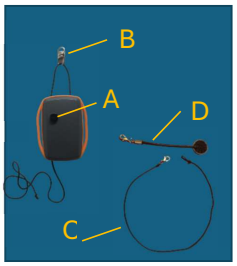


The INCLINOMETER 40 provides a FB relating to the absolute movements of the segment on which it is positioned. It is screwed onto the SUPPORT 30 or the PELVIC VIEWER 6. It can also be screwed onto the B/C/D bushings of the PLATES 1/2/3. To screw and adjust the antenna, always rotate clockwise. After screwing it onto the chosen support, insert the plug into the CONTROL UNIT. As with the Goniometer, it is possible to provide the different types of FB by inserting the plug into one of the two holes in the Control Unit. The inclinometer activates the FB when the vertex of the antenna exceeds the horizontal. It is therefore possible to work on the Sagittal or Frontal planes, in relation to the positioning plane of the antenna. It is not useful for recording rotations on the horizontal plane; it does not amplify lateral/lateral or anterior/posterior movements. The range is adjusted by changing its inclination.

GONIOMETRO A FILO 11

N°Pezzi:

- A — button to adjust the length of the wire
- B — ring for inserting choker C elastic element D
- C — crew neck
- D — elastic element



The 31 WIRE GONIOMETER acts like a goniometer, providing a FB for angular changes across different joints/areas. It contains both the power supply and the vibrating pad (the only type of FB possible with this device). Apply double-sided tape to the back of the wire goniometer. Place the tape on the skin over which the box will be applied.

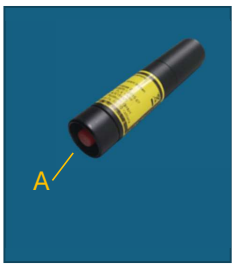




The elastic element D must be positioned with tape on the other segment/district. Adjustment is done by pressing button A and adjusting the length of the cable. For exercises related to the retraction of the lower cervical spine, apply the box at the level of the sternum. Insert the choker into ring B and close it at the back of the neck. At this point, adjust the length of the cable so that the vibrating FB is activated when the correct alignment of the cervical tract is achieved. Before using it for the first time, remove the tab that interrupts the battery connection. When the battery runs out, unscrew the screw on the back of the element and replace it.

LASER 12

N°Pezzi:
A Switch



The laser is turned on and off by pressing it against the bottom of the LASER HOLDER 28. Insert the batteries before using it for the first time. The laser is useful for amplifying rotations in the sagittal and horizontal planes; it does not amplify lateral/lateral, anterior/posterior movements, or inclinations on the frontal plane. The Class 1 laser beam is considered harmless because the radiation emitted is always below the maximum permitted standards (MPE, Maximum Permissible Exposure). However, it is recommended to avoid pointing the laser directly at the eyes.

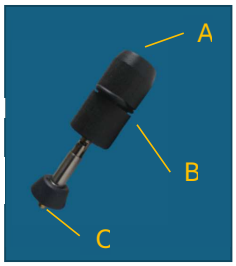




LASER HOLDER 13

N°Pezzi:

- A — space for laser insertion (29)
- B — rubber sheath to stabilize the laser
- C — threaded terminal to be inserted into the sockets



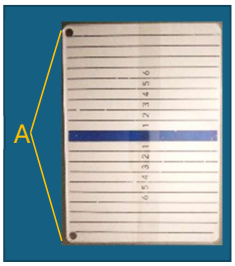
Screw the threaded terminal C of the LASER HOLDER to the sockets of the PELVIC VIEWER 1 or of the SUPPORT 3. It can also be screwed to the sockets B/C/D of the TABLETS 1/2/3. The LASER 12 must be inserted into the LASER HOLDER A with the switch (5A) in the lower part.

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GRAPHIC PANEL 14

N°Pezzi:

- A — 2 magnets to stabilize the transparent panel after inserting the graphic elements



Place the various graphics under the transparent Plexiglass panel, overlapping them to create references for the patient to follow, for example, with the antenna connected to the pelvic viewer or references for the LASER POINTER or other. To perform Mirror Therapy exercises, remove the transparent panel and hold the mirror panel vertically on its long side.





