Attached 4

CE

User manual and installation
Audiometric booth

PRO28F

Compliant with regulation **EU 2017/745**
as Medical Device (Class I)

S.N. Pxxxxxxx



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Description

Two Available sizes: --96 x96 x 192 e 210 h -- 110 X 110 X 205 h-- 124 x 129 x 205 h-- Lightweight and transportable solution ready for use in a few minutes thanks to the simple assembly with 16 screws. Made with a new interior in washable 3D woven fabric and new increased materials that increase the soundproofing power to 35 dB. It is ideal for basic audiometric tests in outpatient clinics, hospitals, audiology centers and industrial environments. Equipped with reversible door with magnetic closure, universal cable passage module, lighting.

Optional: foldable internal table and external table, pivoting castors with brake, visual on door, integrated ventilation, 6.3 female/female jack cable set, jack connection module with USB.

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Use and contraindications, notice

- The sound-proof booth can be used only for audiometric examinations or similar and not for other medical purposes with applied components (i.e. electrodes) to the patient. It is necessary having different specifications in this case.
- Make sure the wheel brakes (if equipped) are engaged.
- The booth must be used only by trained personnel.
- Man performing the test must always see the patient inside the booth.
- It is forbidden to smoke and to light any flame inside the booth.
- The wrong booth installation or the position near-by flammable materials disclaim all manufacturer responsibilities.

PUMA srl disclaims any responsibility for misuse, incorrect re-installation or improper use of the booth.

Warnings:

Connect the booth to an adequate electrical implant and compliant with the norm CEI 64-8; the plug must be inserted in a 230V electrical socket, protected against overload and short circuit and with differential switch.

The silent booth cannot be installed in places classified with "explosion hazard" (EN 60079-10-1 and EN 60079-10-2) and in rooms "used for medical use" classified as group 2 (CEI 64-8 standard / 710 art. 710.2.7).

Installation is permitted in "ordinary" rooms and in "medical" rooms classified as group 1 (CEI 64-8 / 710 art. 710.2.6); the power supply must happen with an automatic switch with a sensitivity differential of 30 mA of "type A" with a maximum rated capacity of 16A (230V) curve "C".

The electrical system is regulated in order to be able to connect electro-medical devices.

notice

According to the regulation EU 2017/745, annex 1, section III, paragraph 23.4, we advise you to report any incident related to the use of
the medical device both to the competent authority of the state in which it is used,
and to us as manufacturers at the following address: info@pumasrl.it

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Equipment connection panel

The new connecting panels allow:

- Direct contact between the booth internal and external equipment without further interruptions or type jack connections.
- Fast replacement of equipment with different connections.
- The ability to add cables throurgh.

Use



1) Remove the lid seals acting on the two screws by rotating with Allen key which is provided. Do the same action inside the booth.





2) Place the cables of all the appliances through the central hole.





3) After placing them, let them fall and close both the lids (external and internal) previously removed. Now tighten the screws with the Allen key.



4) Connect the selected equipment

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Connection cables for universal connection panels (optional)



Tripolar connection jack cables fully insulated allowing an immediate connection with the main audiometric instruments between the inside and the outside of the cabin.
To be used with the universal connection panels.



Jack panel for instruments connection (optional)



A tripolar jack connection plate is available on request.
10 jack inputs + USB suitable for most of diagnostic and clinical instruments.



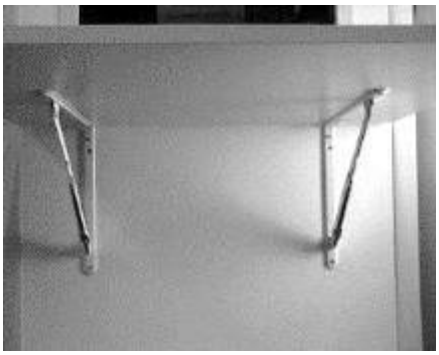
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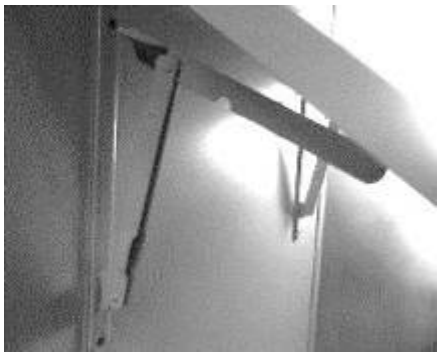
Folding table (optional)

maximum capacity kg 12.

Tilting table has large dimensions and it is suitable for small spaces inside and outside the booth

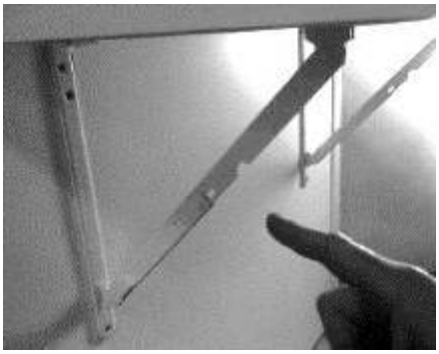


It's supported by two folding shelves and can be easily opened.
Easily opening device extending to the rail end.





The safety joints can be blocked in their rails pushing the table down.
The supporting blocks in their final position will be straight.







To fold the table, lift it from the open position, then help manually the rails to shut down.

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Ventilation system (optional)



The silenced ventilation system integrated in the ceiling is also optional. Inside the ceiling, a real ventilation unit provides the necessary air exchange.
Simultaneous switching with interior lighting.

Window on the door (optional)



In addition to the standard window positioned to the side, it is possible to request an additional window installed on the door.
Glass dimensions cm 17 x 118 H.

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Maintenance and Cleaning

Routine maintenance:
The soundproof booth does not require any specific maintenance. The replacement of the broken lighting device can be performed by trained personnel. (electrician).

Medical rooms maintenance and periodical check-ups:
The maintenance of electrical systems should be committed to qualified companies which have the technical and professional requirements according to the DM 37 of 22.01.2008, art 4.
You should check periodically the system, in details you should check the grounding system efficiency every second year by measuring its resistance value, with reference to what is stated by the IEC 64-710, the medical room systems should be regularly checked by a trained technician. For this reason you should performs the following checks:

- measurement of insulation resistance according to IEC 64-8/6, minimum every two years
- potential equalization at intervals not exceeding three years
- measurement of the resistance of the supplementary equipotential connection at intervals not exceeding three years
- the operation of safety power equipments according to the manufacturer's instructions and in any case at intervals not exceeding one year
- the efficiency of the grounding system at intervals not exceeding two years
- the efficiency of the electrical operation of residual current devices at intervals not exceeding one year

The tests and their results should be recorded in a signed and stamped register by the technical performer with the date of execution of the same.

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Cleaning:
The outside of the booth can be cleaned as any furniture.
To clean the internal carpet and the fabric on the walls use specific products commercially available.

Warning:

- The user is the solely responsible for the use the of device and for any consequences deriving there from.
- Do not expose the device or its accessories to liquid or high humidity
- Do not expose the booth to extreme temperatures.
- Avoid exposure to direct sunlight or heat sources. Overheating of electrical components may cause fire or equipment damages.
- The opening or unpacking of all components or any of their accessories, regardless of the reason may cause damage not covered by warranty.
- To avoid electrical shock, do not operate on active or electrified parts. Request the assistance of qualified personnel.
- The replacement of power fuses can be performed only by trained or expert personnel.
- In case of power fuse replacement, the rated current of the device must not be greater than 6 ° g.
- Don’t block the ventilation fan when using the booth.
- To dispose used batteries and electrical and electronic components, please observe the local regulations and promote recycling where possible.
- Disposal instructions for old products: Directive on electrical and electronic equipment waste (WEEE Directive) aims to ensure that products are recycled by using best available techniques in treatment, recovery and recycling to ensure people health and an intense environmental protection. Do not dispose of such products together with your household waste. Inform yourself about the local separate collection of waste regarding electrical and electronic equipments marked by this symbol.



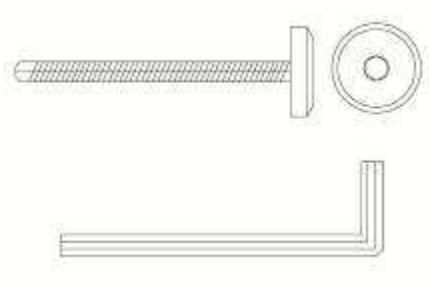
- Bring the complete product (including its cables, plugs and accessories) in the designated WEEE collection facilities or to approved landfills.

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Assembly instructions

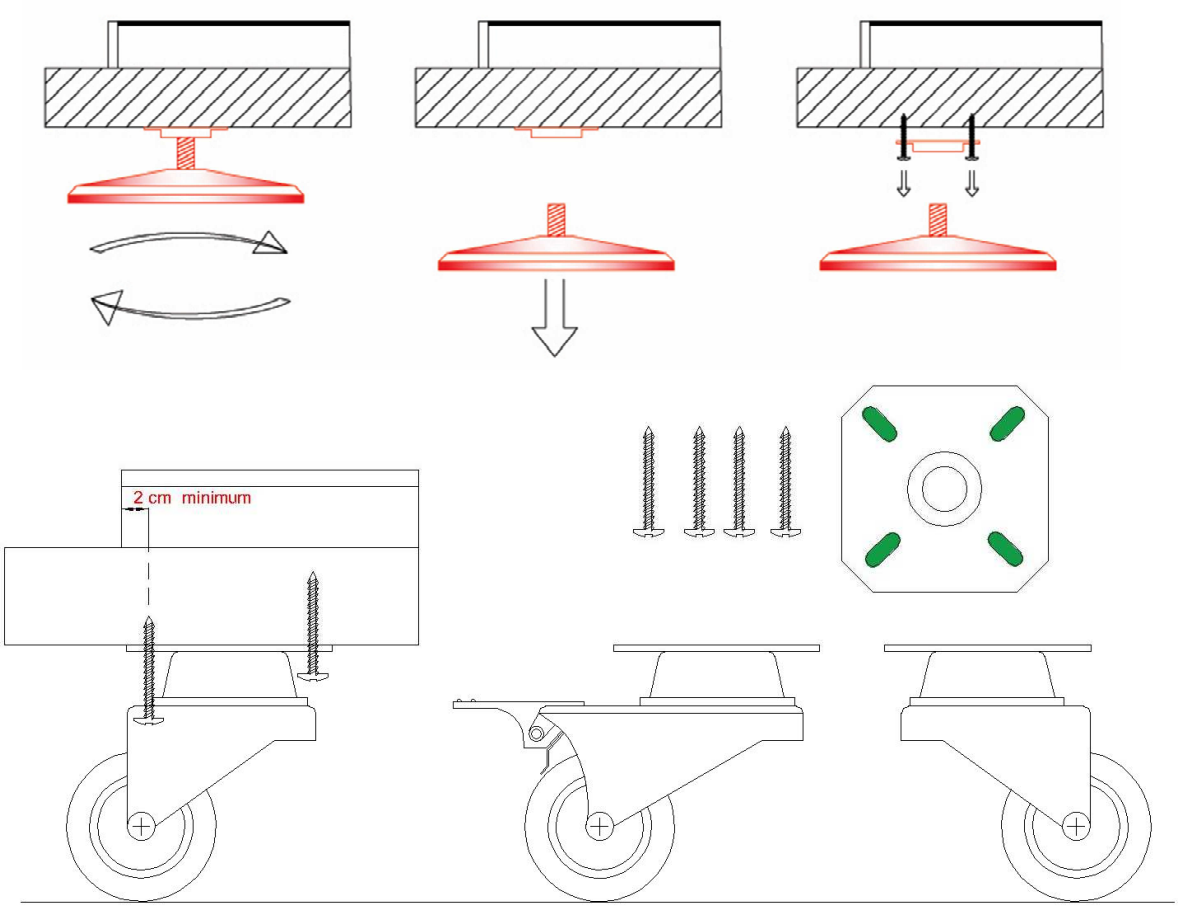
Assembly should be performed by trained personnel. Assembling the booth please follow carefully the drawings. Read all instructions before beginning. The screws and the Allen key as well are provided.

Use screws and Allen key provided.



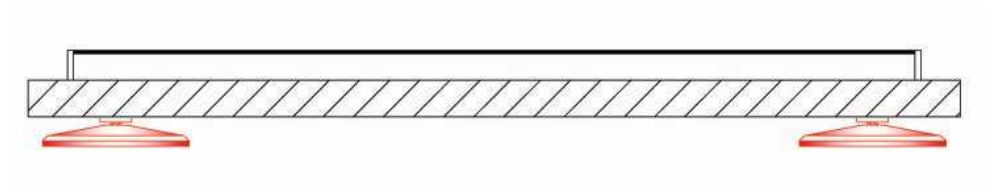
Replacement of the adjustable feet with the castors

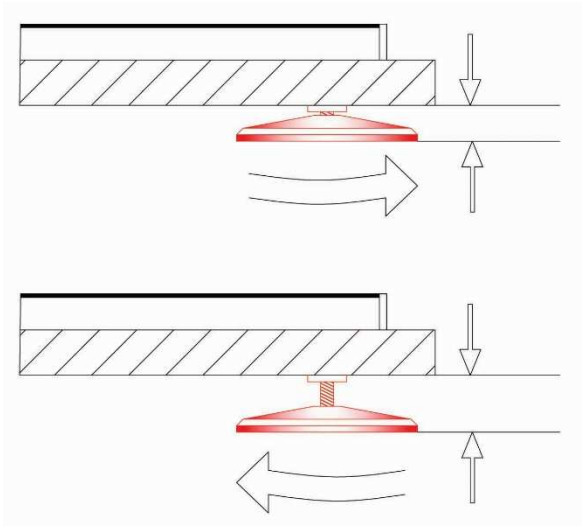
NOTE 1: the cabin is supplied as requested by the customer with adjustable feet or with wheels. However, it is possible to install the castors at a later time by following the procedure below.
Note 2: the wheel assembly layout is purely indicative; the wheels may be of a different model in which case the assembly drawing will be supplied with the kit.



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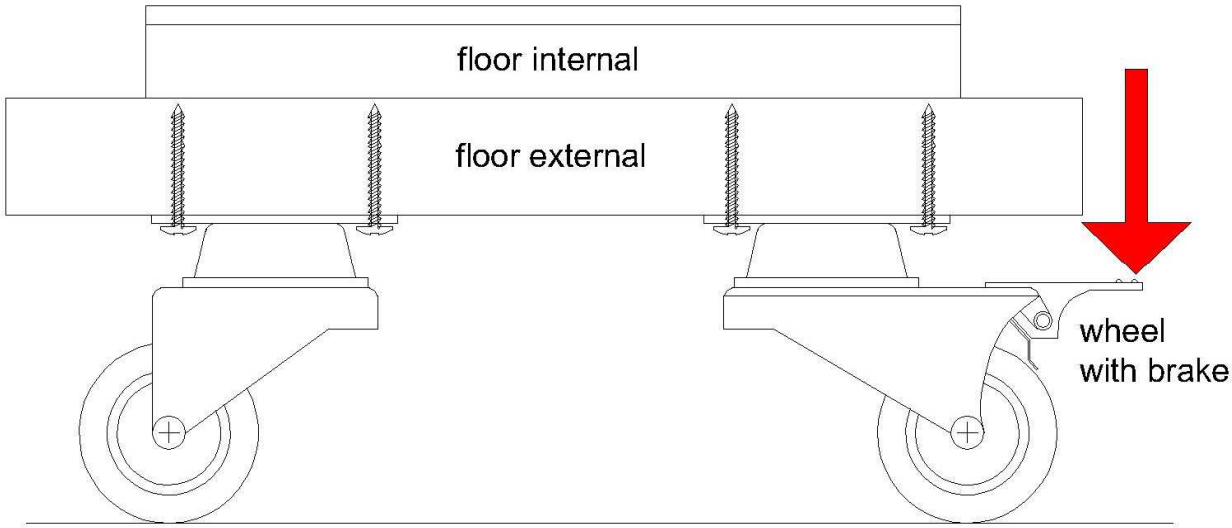
Standard basement with adjustable feet





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Basement with castors (optional)



four swivel wheels, two with brakes

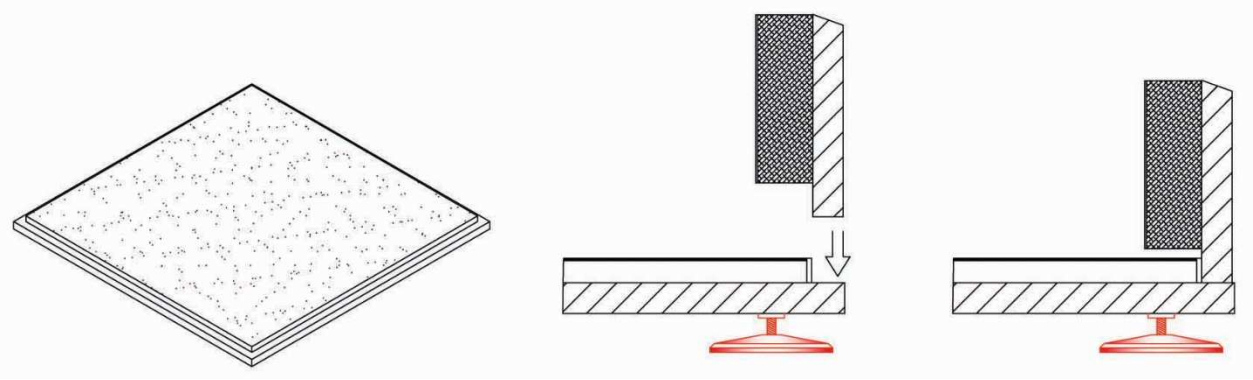
ATTENTION

LOCK THE BRAKES BEFORE INSTALLING THE BOOTH

LOCK THE BRAKES WHEN USING THE BOOTH

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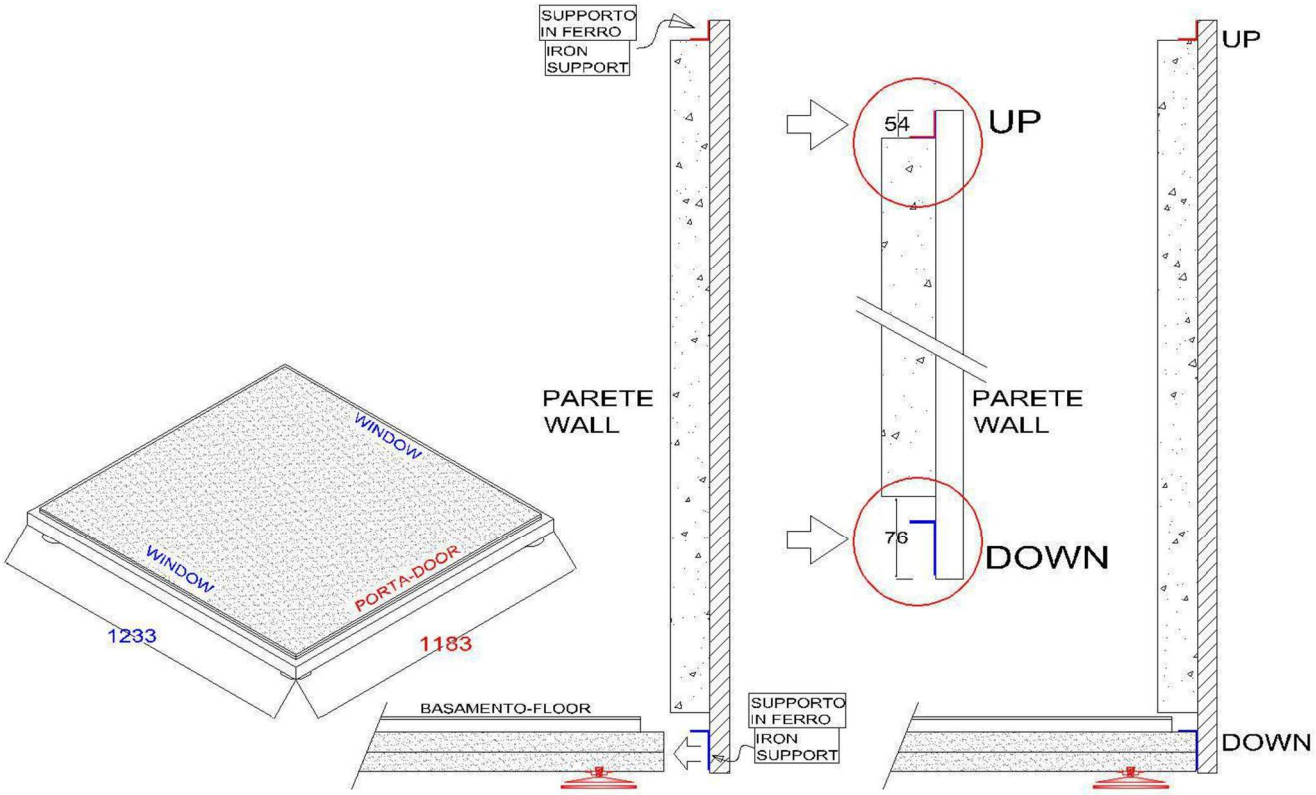
pro 28 CM 96 X 96 (SQUARE BASE)
Lay the walls on the protruding base (see drawing)



PRO 28 124 X 129 (RECTANGULAR BASE)--- PRO 28 110 x 110 (SQUARE BASE)
Lean the walls against the base on the iron support

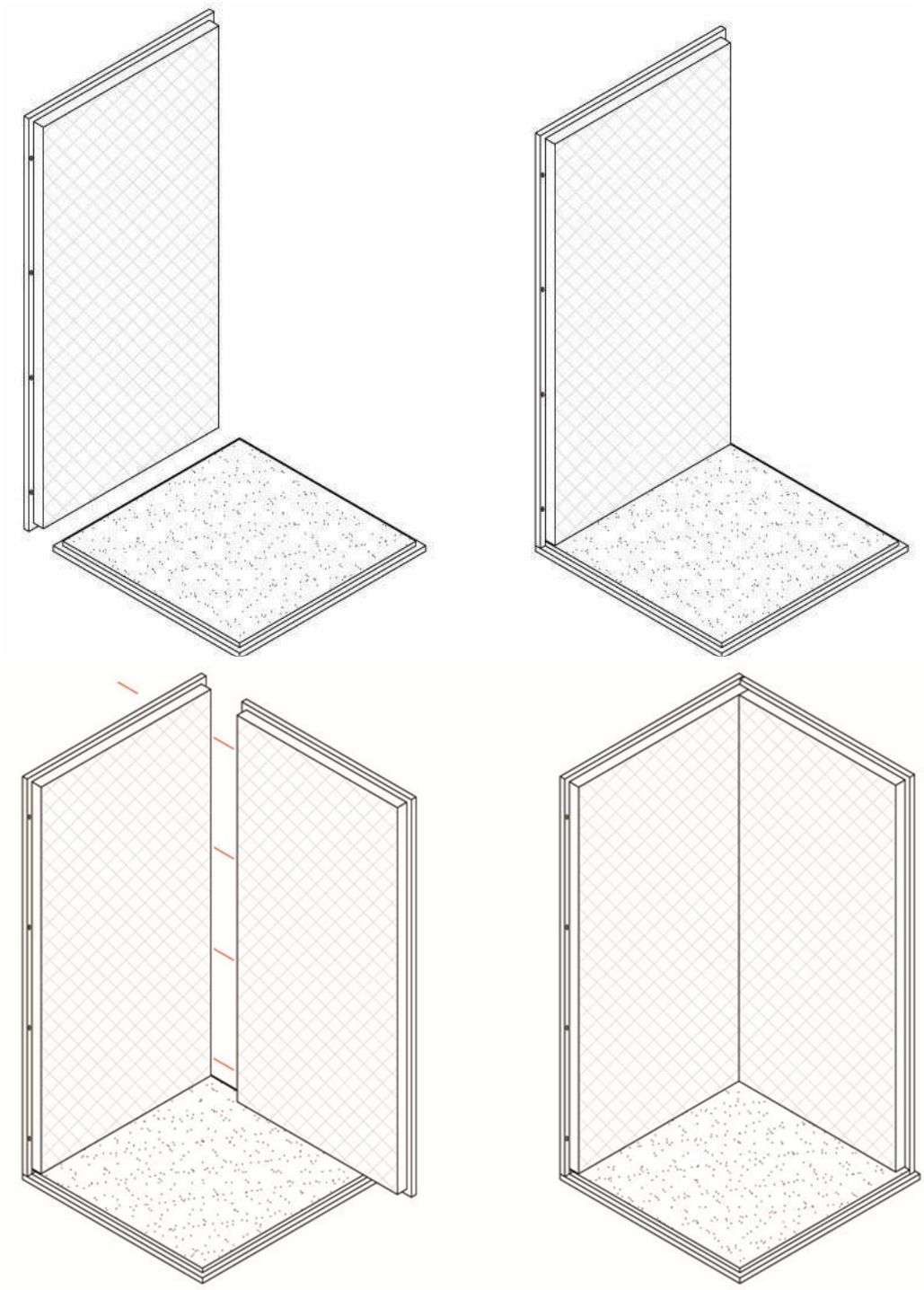
NOTE: THE WALL REMAINS OUTSIDE THE BASE (see drawing)

EXCEPT OF THE DOOR THE WALLS <u>ARE NOT REVERSIBLE</u>
<u>PLEASE RESPECT UP POSITION</u>

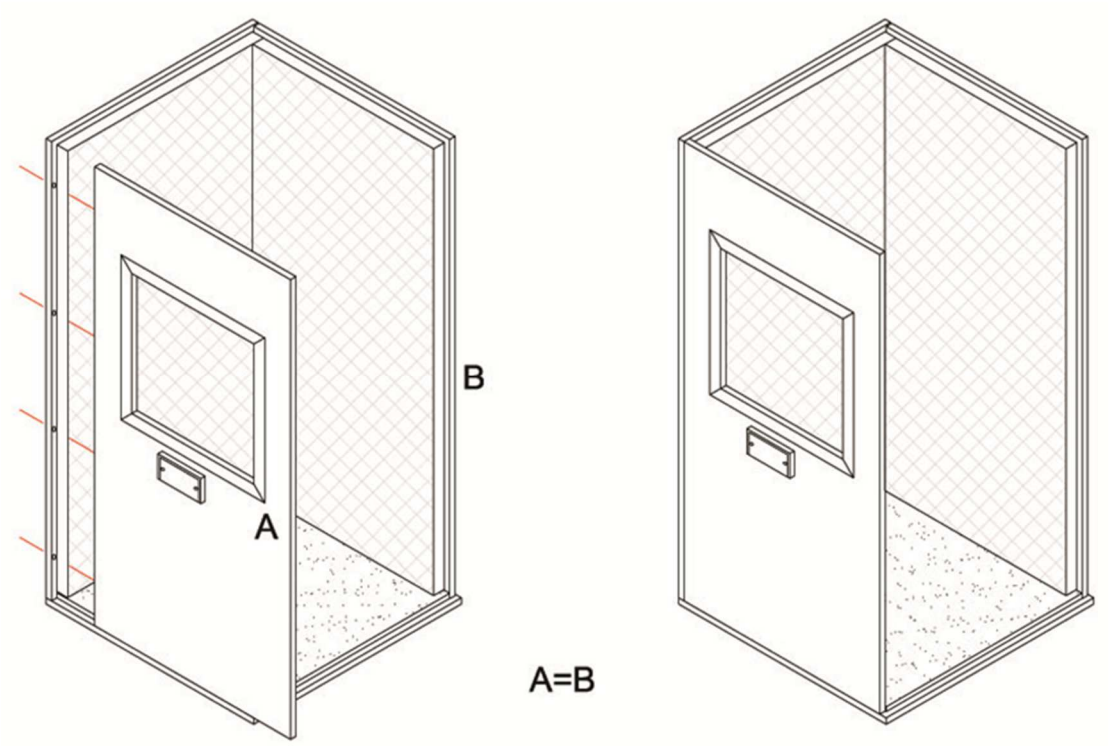


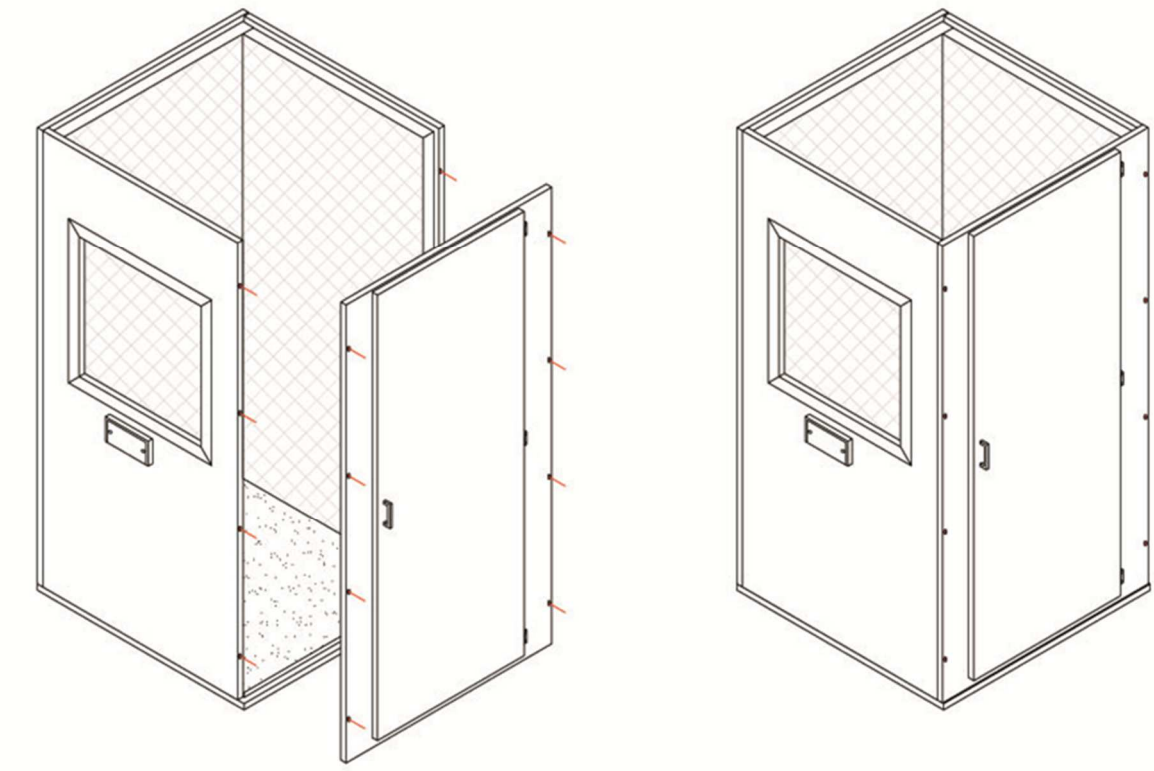
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Wall assembly sequence for both versions
ATTENTION: The 124 x 129 and 110 x 110 model does not have reversible solid walls.
Respect the TOP



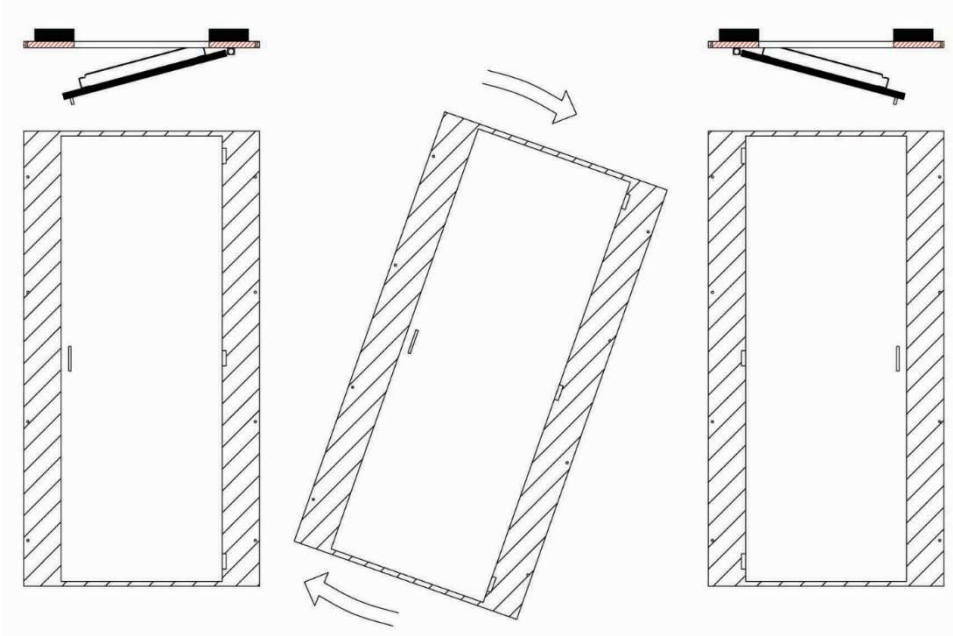
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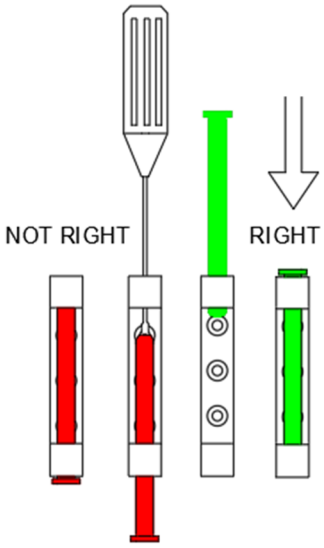




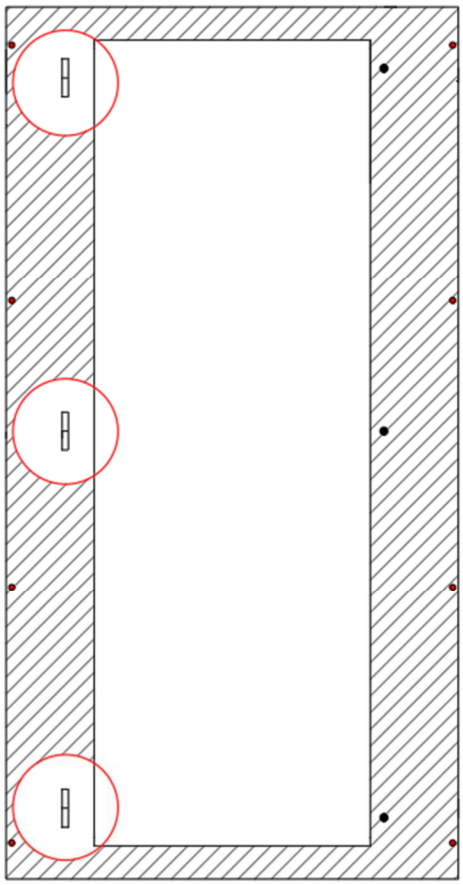
REVERSIBLE DOOR

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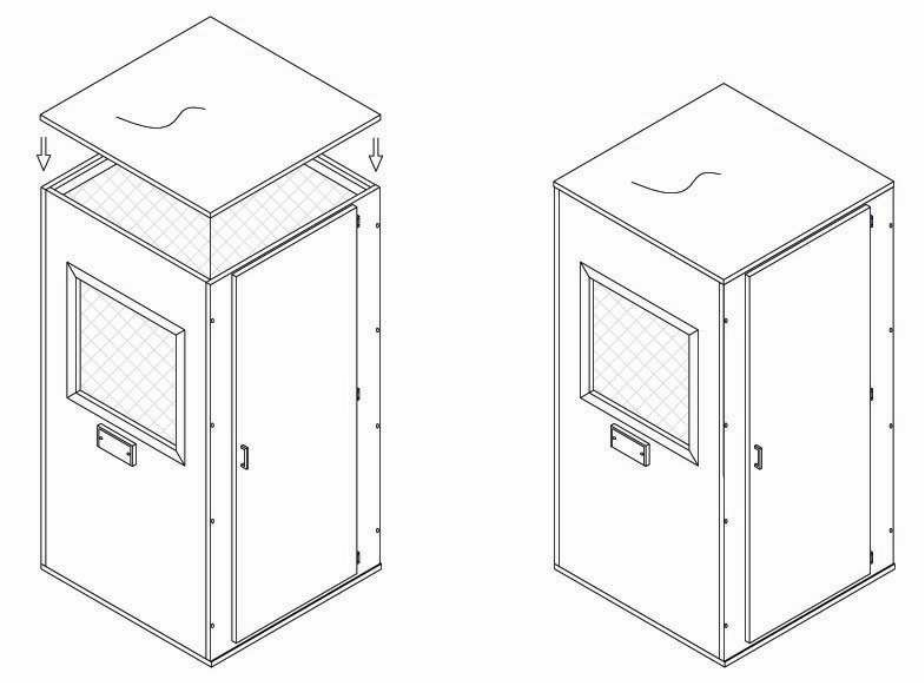
NOTA:
i perni dei cardini della porta devono sempre essere inseriti dall'alto.
Nel caso si ruotasse la parete porta per cambiare il senso di apertura
è necessario sfilari i perni UNO ALLA VOLTA aiutandosi con un cacciavite e riinserirli dall'alto



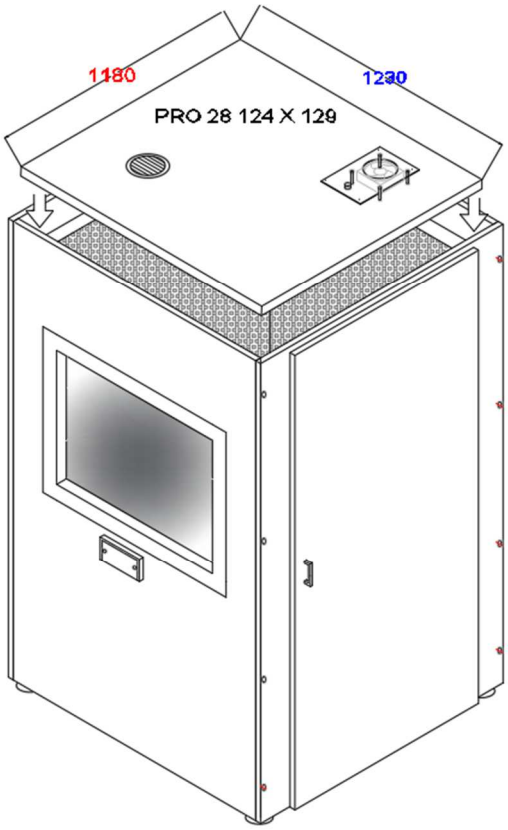
NOTE:
the door hinge pins must always be inserted from above.
If you rotate the door wall to change the opening direction it is necessary to remove the pins ONE AT A TIME using a screwdriver and reinsert them from above

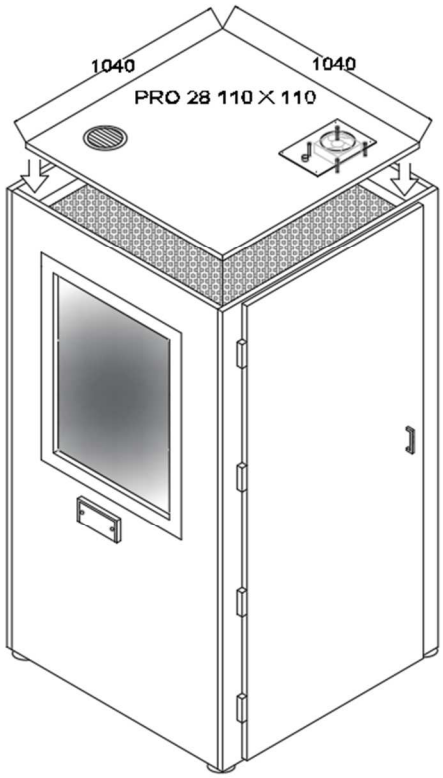
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CEILING PRO 28 96 X 96 (square roof resting on the walls)



PRO 28 CEILING 124 X 129 (rectangular recessed ceiling)
PRO 28 CEILING 110 x 110 (square recessed ceiling)





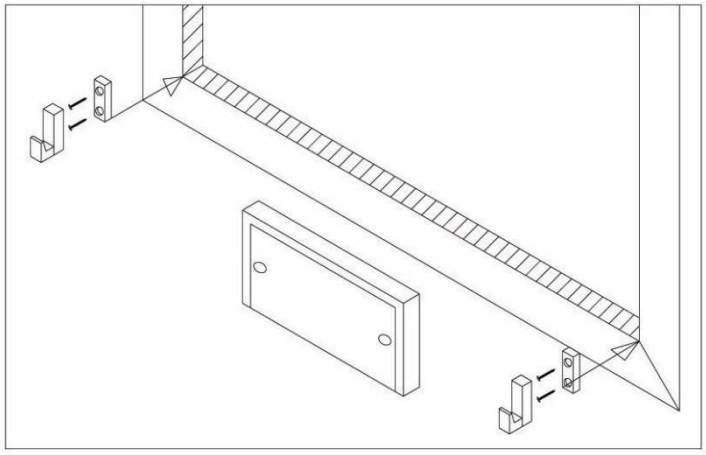
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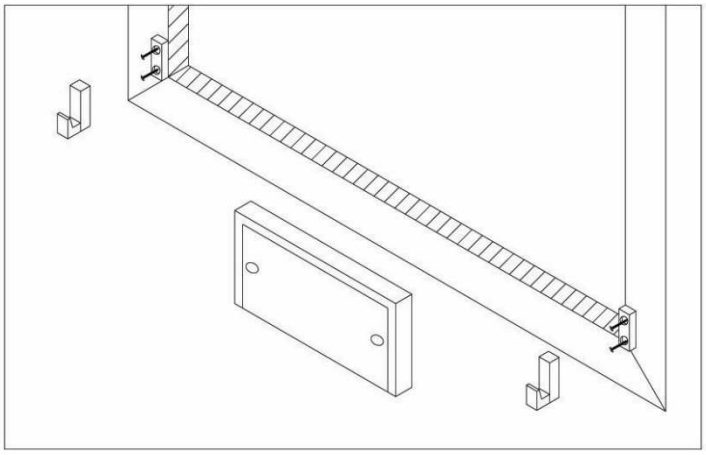
Security stickers

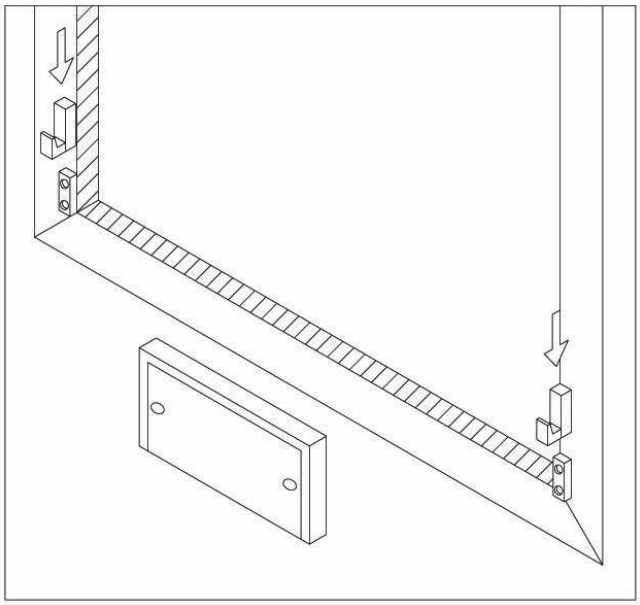
At the end of the operation, apply the warning stickers as follows: place the "ATTENTION TO THE STEP" and "PUSH" symbols at eye level on the inside of the door. Apply the yellow and black band on the step.

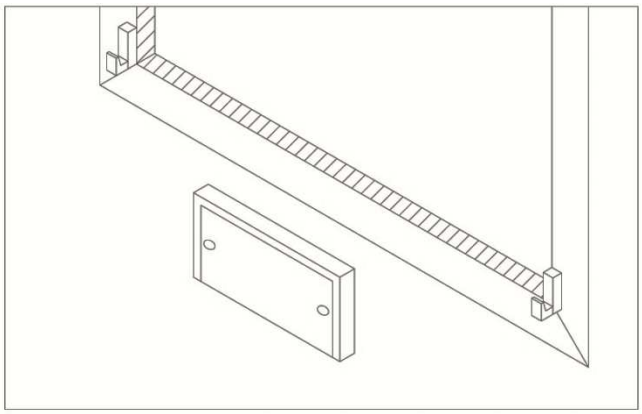


Hooks for headphones (internally)



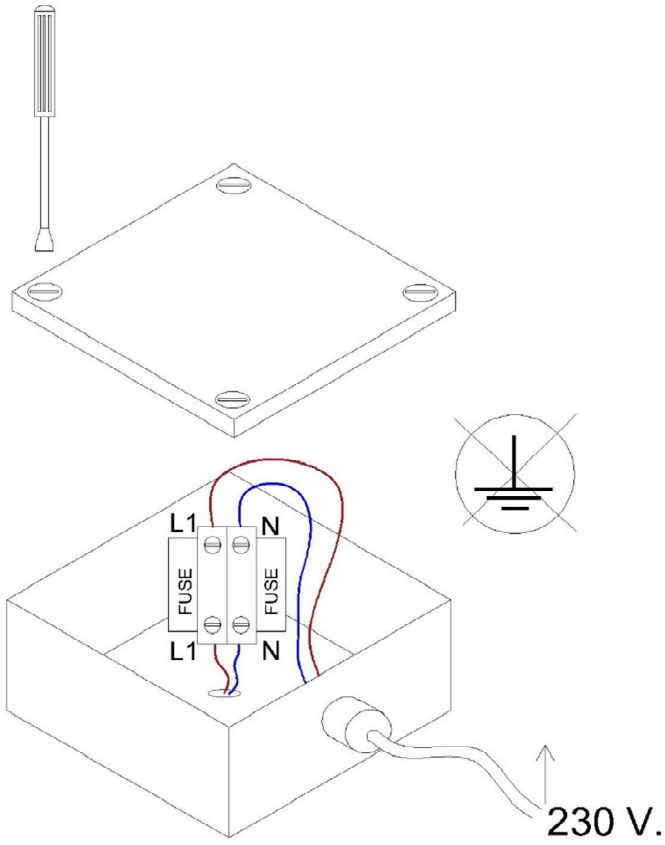






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Electrical implant connection

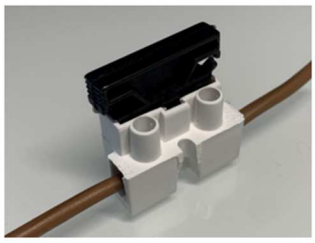
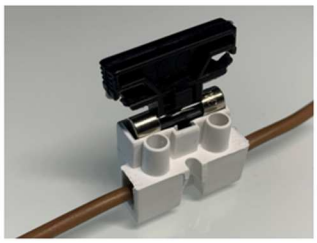
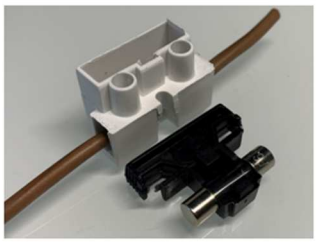
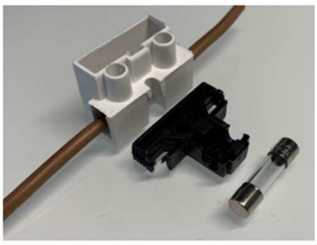


FUSE REPLACEMENT:
THIS OPERATION MUST BE CARRIED OUT BY QUALIFIED STAFF.

PUMA srl declines all responsibility for the connection of electrical parts if not assembled by qualified personnel.

For all versions:

Fuse replacement (5x20-0.2A)
located inside a junction box on the roof of the cabin
(fuses are present on both the phase and neutral)
MAKE SURE THE SYSTEM IS NOT UNDER VOLTAGE

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Interior light replacement





The internal light is mounted on two elastic clips Holding the LED tubular

It is necessary to use a screwdriver to pry the clips both from the outside and from the inside to release the tubular





Once the LED tube has been unhooked, remove the electrical cable from its connection





Reassemble the luminaire by performing the reverse operation.

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Post-installation checks

1. Checking the tightness of the 16 mounting screws
2. Proper Door Operation
3. Applied safety stickers
4. Universal panel with corresponding 4 mm Allen key (if equipped)
5. Reclining table operation (if equipped)
6. Mains connection
7. Lighting operation
8. Operation of the air exchange system (if equipped)
9. Presence of poet identification label under the visual at the bottom right
10. Delivery of all documentation (paper or sent by email)

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