



ACEMST1

LUMINAIRE FOR DIAGNOSIS



USER'S MANUAL

Versions:

ACEMST1 on the wall mount
ACEMST1 on trolley mount
ACEMST1 on the ceiling mount
ACEMST1 on rail mount
ACEMST1 on table mount

available with articulated and flexible arm
available with articulated and flexible arm
available with articulated arm
available with articulated and flexible arm
available with articulated and flexible arm



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1. GENERAL INFORMATION

1.1 Introduction

ACEMST1 is a single light lamp that uses the latest generation of high power LEDs as a light source. The light head is mounted on an adjustable arm – either articulated or flexible - and can be rotated, oriented and tilted in every direction.

1.2 Features

The ACEMST1 emits light without the UV component (ultra-violet rays, harmful to health), and the IR component (infrared rays) responsible for the heat of the luminous flux and therefore for the dehydration of the skin surface.

This lamp can be used for any type of diagnostics, thanks to the high luminous intensity adjustable over a wide range and the possibility of adjusting the color temperature (on ACEMST1.3 version). This allows to accurately identify all the details by adjusting the color temperature and brightness on the light field.

Furthermore, the compact size and easy handling are other important features of the ACEMST1. The "Gesture Control" (only for ACEMST1.3) allows the operator to adjust the parameters and turn the lamp on and off using only hand movements, without the need to physically touch the lamp body.

1.3 Use purpose and classification

ACEMST1 is a lamp for medical purpose used for patient lighting.

According to the particular technical standard EN 60601-2-41:2009/A1:2015
LUMINAIRE FOR DIAGNOSIS

luminaire to illuminate the body of the PATIENT locally in order to support diagnosis or treatment which could be interrupted without any hazard for the PATIENT in case of failure of the light.



NOTE It is not intended to be used in operating rooms.
REF.: EN 60601-2-41:2009/A1:2015

According to the general technical standard (EN 60601-1:2006/A1:2013) and particular technical standard (EN 60601-2-41:2009/A1:2015)

- Based on the kind of protection against electrical dangers:
 - Class I device (version: ACEMST1 /RC with articulated arm ceiling mounted).
 - Class II device (version: ACEMST1 with articulated or flexible arm on all mountings except the ceiling mount).
- Based on the kind of protection against solid foreign objects and water penetration: IP43.
- Based on the kind of use safety in the presence of combustible mixtures of anaesthetics with air, oxygen or nitrogen protoxide: device not suitable in the presence of the above-mentioned substances.
- Based on the use conditions: device for continuous use.

Medical devices classification in accordance with Regulation (UE) 2017/745 (Allegato VIII).

Class I medical device, short-term, active and non-invasive intended to ensure correct illumination of the patient, facilitating treatment and diagnosis (Annex VIII, Rule 10, paragraph 1).

See *Cap. 9 - Declaration of Conformity*.

1.4 Symbols used in this document

The safety instructions are indicated in this document through the use of symbols and keywords. Keywords such as DANGER, WARNING or CAUTION identifies the severity of the damage risk. The different triangular symbols underline them visually.



DANGER Failure to comply will lead to serious injury or even death.



WARNING Failure to comply will lead to serious injury or even death.



CAUTION Failure to comply could lead to serious or minor damage or damage to property.



NOTES Provides useful and confidential information.

The following symbols and keywords define the risks as precisely as possible.



Danger of explosion It warns against operations carried out on the system of pendants in environments inside which combustible mixtures of anaesthetic substances and air, oxygen or nitrous oxide and nitrogen derivatives are used.



Danger of electric shock Warns about the danger of electric shock that can cause serious even lethal damage.



Danger of falling of the system of pendants Warns about the possible fall of the system of pendants due to an excess of the load capacity.

1.5 Manufacturer information

The manufacturer of the product is:

ACEM S.p.A.
Via della tecnica, 29
40050 Argelato, Bologna – ITALY

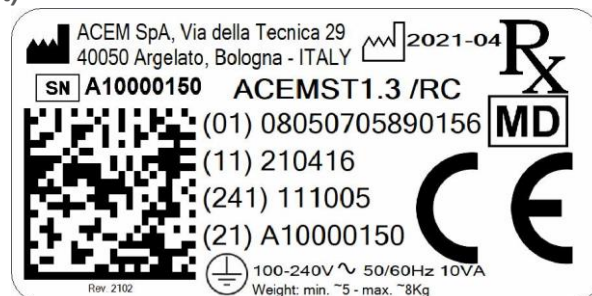
E-mail : info@acem.it
web: : www.acem.it
Ph : +39.051.721844
Fax : +39.051.721855

1.6 Product Label

Label Example for the Medical Device (Light Head + Support)

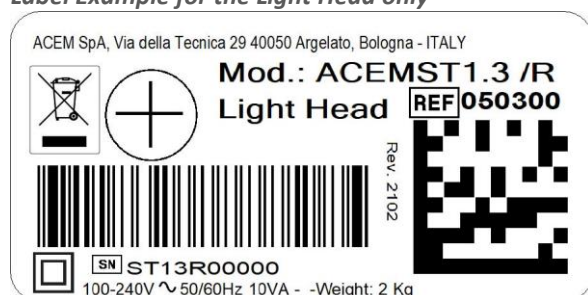


ACEMST1.3 on Trolley













ACEMST1.3 on Ceiling

Label Example for the Light Head only



NOTE: the example labels are referred to model ACEMST1.3 with articulated arm on Trolley and on Ceiling
 Same layout applies to all versions. Please see paragraph 2.1 for further information.

Symbol	Description
	Indicates the manufacturer of the medical device as defined in the EU Directives 90/385 / EEC, 93/42 / EEC and 98/79 / EC.
	Indicates the date of manufacture of the medical device.
	Indicates that it is mandatory to read the user manual (separate label on arm)
	Indicates the serial number of the manufacturer that allows identification of a specific medical device.
	Indicates the reference code of the type of equipment
	The CE marking indicates a manufacturer's declaration that the product complies with the essential requirements of the relevant European legislation on health, safety and environmental protection.
	Indicates that the device can only be sold, distributed or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices.
	Indicates that the device is a Medical Device
	Indicates the electrical protection class
	Indicates that the equipment must be disposed of separately. Refer to the "Disposal" chapter for more information.

1.7 Caution!!!

These instructions go together with the unit and must always be kept near the lamp for future reference. Read carefully these instructions before use for a proper and correct utilization of the lamp according to their destination both for patient and operator safety.

1.8 Use authorized personnel

ACEMST1 lamps are intended to be used by qualified technical and medical personnel.

The following figures are to be considered 'qualified personnel':

- People who have received training in the medical field or in the medical/engineering/clinical field.
- People who, thanks to their professional experience and their safety training, are able to evaluate their work and recognize their potential risks.
- In states where the requirements in the medical or medical / engineering / clinical sectors are subject to certification, qualified personnel must have obtained these certifications.



Any operation (use, adjustment, maintenance, cleaning or other) must be carried out only by qualified personnel.



CAUTION (for US market):

Federal law restricts this device to sale, distribution, and use by or on the order of a physician

The symbol Rx indicates that the device can only be sold, distributed or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices.

1.9 Inspection upon receipt and complaints

It is suggested to inspect the product and/or accessories upon their receipt to check possible flaws or damages due to shipment.

See chapter: "Visual inspection and functioning test before use"

Complaints can be accepted only if immediately communicated to the forwarding agent or representative.

See chapter: "Complaints"

1.10 Environmental conditions

1.10.1 FUNCTIONING

	MIN.	MAX.
TEMPERATURE	+10 °C	+40 °C
RELATIVE HUMIDITY	30%	75%
AIR PRESSURE	700 hPa	1060 hPa

1.10.2 TRANSPORT/STORAGE

	MIN.	MAX.
TEMPERATURE	-10 °C	+50 °C
RELATIVE HUMIDITY	20%	90%
AIR PRESSURE	700 hPa	1060 hPa

2. MODELS

2.1 Versions

ACEMST1 /R
w/ ARTICULATED ARM

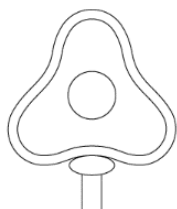


ACEMST1 /F
w/ FLEXIBLE ARM



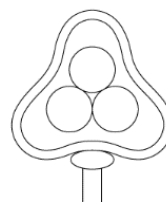
ACEMST1.1

ACEMST1 with
Single light source



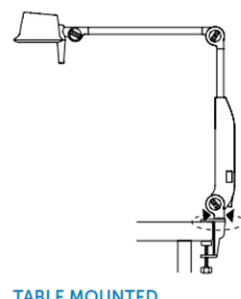
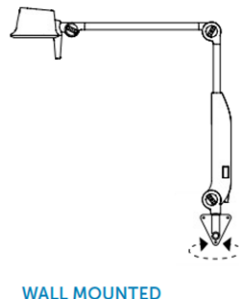
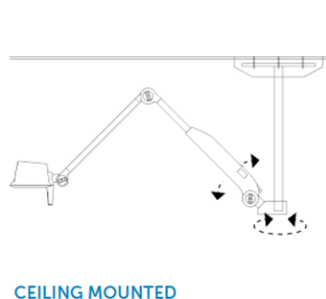
ACEMST1.3

ACEMST1 with
Triple light source



2.2 Configurations

CODE	MODEL	DESCRIPTION
110800	ACEMST1.1 /RR	ACEMST1.1 ARTICULATED ARM ON RAIL MOUNT
110801	ACEMST1.1 /RD	ACEMST1.1 ARTICULATED ARM ON TABLE MOUNT
110802	ACEMST1.1 /RW	ACEMST1.1 ARTICULATED ARM ON WALL MOUNT ¹
110803	ACEMST1.1 /RT	ACEMST1.1 ARTICULATED ARM ON TROLLEY MOUNT
110805	ACEMST1.1 /RC	ACEMST1.1 ARTICULATED ARM ON CEILING MOUNT
111000	ACEMST1.3 /RR	ACEMST1.3 ARTICULATED ARM ON RAIL MOUNT
111001	ACEMST1.3 /RD	ACEMST1.3 ARTICULATED ARM ON TABLE MOUNT
111002	ACEMST1.3 /RW	ACEMST1.3 ARTICULATED ARM ON WALL MOUNT ²
111003	ACEMST1.3 /RT	ACEMST1.3 ARTICULATED ARM ON TROLLEY MOUNT
111005	ACEMST1.3 /RC	ACEMST1.3 ARTICULATED ARM ON CEILING MOUNT
110900	ACEMST1.1 /FR	ACEMST1.1 FLEXIBLE ARM ON RAIL MOUNT
110901	ACEMST1.1 /FD	ACEMST1.1 FLEXIBLE ARM ON TABLE MOUNT
110902	ACEMST1.1 /FW	ACEMST1.1 FLEXIBLE ARM ON WALL MOUNT ³
110903	ACEMST1.1 /FT	ACEMST1.1 FLEXIBLE ARM ON TROLLEY MOUNT
111100	ACEMST1.3 /FR	ACEMST1.3 FLEXIBLE ARM ON RAIL MOUNT
111101	ACEMST1.3 /FD	ACEMST1.3 FLEXIBLE ARM ON TABLE MOUNT
111102	ACEMST1.3 /FW	ACEMST1.3 FLEXIBLE ARM ON WALL MOUNT ⁴
111103	ACEMST1.3 /FT	ACEMST1.3 FLEXIBLE ARM ON TROLLEY MOUNT



The pictures refer to the version with articulated arm. Are to be considered for illustrative purposes only.

NOTE: The ceiling mounted version is available only with articulated arm version (ACEMST1.1 /R_ and ACEMST1.3 /R_).

¹ This model includes both "standard" and "with extension" versions of wall mount.

² This model includes both "standard" and "with extension" versions of wall mount.

³ This model includes both "standard" and "with extension" versions of wall mount.

⁴ This model includes both "standard" and "with extension" versions of wall mount.

2.3 Packaging

The contents of the package and the number of boxes vary according to the model and support chosen.

Articulated Arm version		Packaging		
CODE	MODEL	N° Package	Content Package 1	Content Package 2
110800	ACEMST1.1 /RR	1	- Light head with articulated arm - Rail Bracket	-
110801	ACEMST1.1 /RD	1	- Light head with articulated arm - Table Bracket	-
110802	ACEMST1.1 /RW	1	- Light head with articulated arm - Wall Bracket (standard/with extended arm)	-
111000	ACEMST1.3 /RR	1	- Light head with articulated arm - Rail Bracket	-
111001	ACEMST1.3 /RD	1	- Light head with articulated arm - Table Bracket	-
111002	ACEMST1.3 /RW	1	- Light head with articulated arm - Wall Bracket (standard/with extended arm)	-
110803	ACEMST1.1 /RT	2	- Light head with articulated arm	- Trolley (Pole and base with wheels)
111003	ACEMST1.3 /RT	2	- Light head with articulated arm	- Trolley (Pole and base with wheels)
110805	ACEMST1.1 /RC	2	- Light head with articulated arm	- Ceiling Pole with cover
111005	ACEMST1.3 /RC	2	- Light head with articulated arm	- Ceiling Pole with cover

Flexible Arm version		Packaging		
CODE	MODEL	N° Package	Content Package 1	Content Package 2
110900	ACEMST1.1 /FR	1	- Light head with flexible arm - Rail Bracket	-
110901	ACEMST1.1 /FD	1	- Light head with flexible arm - Table Bracket	-
110902	ACEMST1.1 /FW	1	- Light head with flexible arm - Wall Bracket (standard/with extended arm)	-
111100	ACEMST1.3 /FR	1	- Light head with flexible arm - Rail Bracket	-
111101	ACEMST1.3 /FD	1	- Light head with flexible arm - Table Bracket	-
111102	ACEMST1.3 /FW	1	- Light head with flexible arm - Wall Bracket (standard/with extended arm)	-
110903	ACEMST1.1 /FT	2	- Light head with flexible arm	- Trolley (Pole and base with wheels)
111103	ACEMST1.3 /FT	2	- Light head with flexible arm	- Trolley (Pole and base with wheels)

3. START-UP

3.1 Safety advice

The lamp is not suitable to be used in explosion risk areas.

Use the lamp in proper premises only, built and equipped in conformity with the directions in force in point of safety (IEC 60364-7-710).



Valid for ACEMST1 with articulated arm version:

WARNING: to avoid the risk of electric shock, this appliance must only be connected to power supply networks with protective earth.



Do not look frontally inside the lamp when it is turned on and do not insert reflecting objects during its operation.

Do not turn the light beam directly or indirectly into third parties' eyes.

Due to the high lighting power there is the potential danger of dazzle and visual system damage.

For an efficient lighting, the distance between the light emission surface of the lamp and that of patient should not be inferior to 30 cm.



Do not place or hang objects on the head or arm of the lamp to avoid that they fall down on the operating area and cause the lamp an unstable position. This could also damage the mechanical parts of the lamp.



The light head (specially its superior part) must not be covered during operation; as a matter of fact this would block the thermal exchange with the environment and the lamp could get overheated.



Avoid bumps of mobile arms and light head. A strong bump can damage the lamp and paint pieces can split and fall on the operating field.

3.2 Installation and start-up

All ACEM lamps are provided with parts and components for installation and connection.

ACEMST1 assembly and installation must be carried out according to assembly instructions and only by ACEM collaborators or by assembly companies authorized by ACEM itself.



A non-state-of-the-art assembly could cause the lamp to come off from its support falling down and wounding patient and personnel during its functioning.

The electrical installation must comply with IEC 60364-7-710 directives requiring a protection by fuses as well as a switch for the simultaneous interruption on every pole of the lamp power supply.

For more detailed information please refer to assembly instructions.

The lamp is provided with plug or terminal block for mains connection on the flange in the ceiling mounted configuration.

The owner can start the lamp only if the manufacturer or supplier:

- a) has checked it with a functioning test on its area of use.
- b) has trained the person in charge of its functioning according to use instructions.

3.3 Trolley assembly

The trolley is composed of 3 parts:

The 5-arm base and castor wheels **A**.

The vertical pole (fixed section and extensible section) **B**.

B.

Fixing kit **C**.

Assemble the trolley following these instructions:

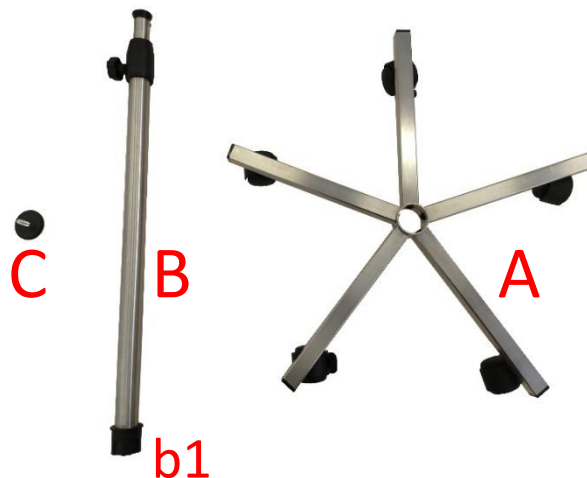
Insert the end **b1** of the vertical pole **B** into the seat in the center of the base **A** pushing it all the way down.

Use the fixing kit **C** to fix the pole to the base, screwing the bolt to the pole, from bottom to top.

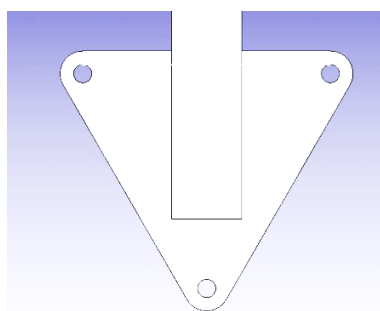
Tighten the bolt further, using a 5mm hex wrench (Allen).

The assembly is finished and the lamp can be installed.

See par. 3.9



3.4 Wall bracket assembly



The distance between holes is 88 mm. The diameter of the holes is 6.5 mm.

Find a proper position for the installation, and choose the right fixing elements (dowels and so on) according to wall material.



Mark the holes position on the wall - distance between each hole is 88 mm (you can use the bracket as template).

Once the bracket is in place check the anchoring stability for the sake of safety.

3.5 Ceiling pole assembly (for articulated arm version only)

Mount the pole to the ceiling according to the instructions in the relevant installation manual.

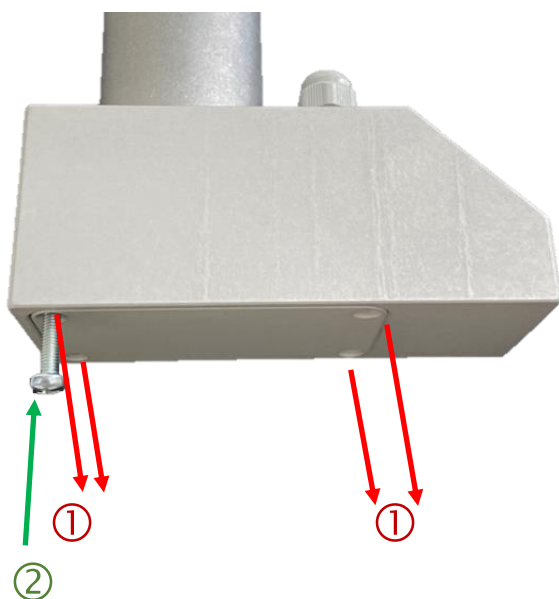


Valid for ACEMST1 with articulated arm:

ATTENTION: to avoid the risk of electric shock during assembly, the ceiling pole must be disconnected from the mains.



NOTE: make sure that the end of the pole or the lowest part is 2 m from the floor.

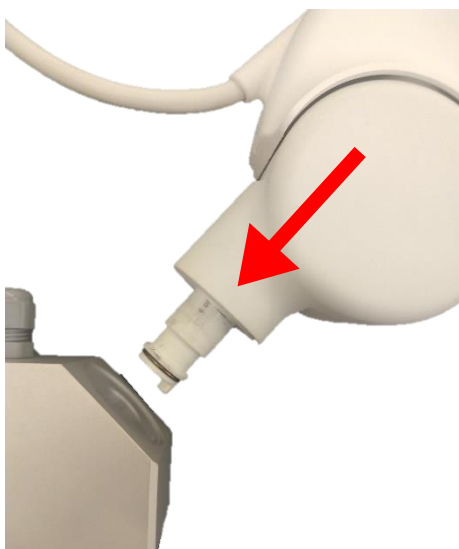


① On the bottom cover, remove the 4 screws holding it in place, like in figure.

② Insert the supplied M4 “service” screw into the hole as shown in the picture, and screw it in until it has the cover pulled off. Then pull out the bottom cover in a vertical direction. Avoid wobbling or lateral movements as they could damage the rotating connectors inside. Unscrew the M4 service screw.



The three-pole male rotating connector and the terminals for the electrical connection are already mounted on the plate.



Mount the lamp on the support....

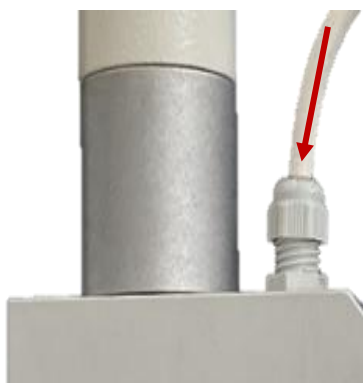


....by fully inserting the pin into the hole on the mounting.



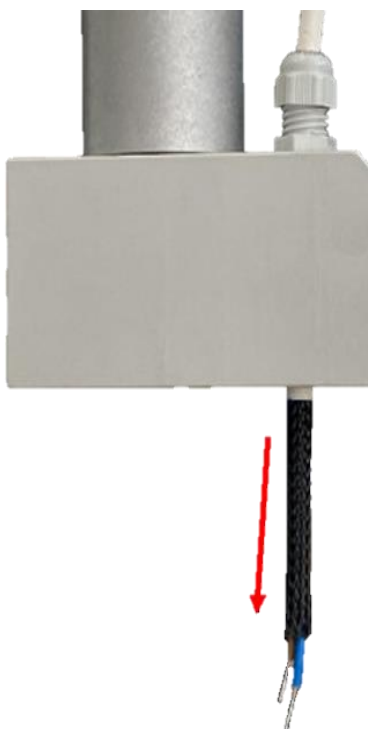
Take the safety screw + split washer supplied.

Use a No. 4 Allen Key **to screw and completely tighten the safety screw.**



Extract the cap from the cable gland and insert it into the electric cable of the lamp.

Lift the lamp to the + 45 ° position and insert the electric cable inside the cable gland.



Loosely screw the cap of the cable gland to allow the cable to slide.

From the underside of the support, gently pull the cable to facilitate subsequent connection operations.

Make the electrical connection on the terminals:



No tools are required because the connectors are PUSH-IN type.



Be careful to respect the wire colors.

Simply insert the BLUE and BROWN wires coming from the lamp fully into the respective terminals provided in the connection.

Take the wire to be inserted, locate the free hole on the corresponding terminal and insert the wire firmly, as far as it will go, into the terminal. Repeat the operation with the second wire.

Make sure the connection is tight by trying to extract both wires. In this case, repeat the operation.



Set up the proper spare length of the power cable in order to allow safe movements.

Lower the lamp to the lowest possible position
(-45°)

Adjust the spare length of the cable in order that it is not forced when the arm is bent to maximum downward span and allow safe movement.

Also ensure a safety margin: add 1 cm more than necessary.

Tighten the cable gland and lock the cable in place.

It is also important to be careful to accommodate the internal wiring, avoiding kinks or dangerous situations.

Close the bottom cover, being very careful to match the three-pole connector with the counterpart in the pole. Secure the bottom cover with the four supplied screws.

Carry out a series of handling tests and adjust the three brakes in the three joints using the knobs. The assembly of the device is complete.

3.6 Table clamp assembly

Please refer to specific installation manual

3.7 Rail clamp assembly

Please refer to specific installation manual

3.8 Lamp installation on support

The lamp is complete with an arm and a coupling for the support and is supplied ready for use.

To complete the installation procedure, after carrying out one or more steps described in the previous paragraphs, all that remains is to engage the lamp on its support (on trolley, at wall, and other).

Proceed by unscrewing the safety screw on the side of the support, until the seat is completely free (depending on the version of the support, a 4mm Allen key or a screwdriver may be required).

Proceed by inserting the arm pin into the hole in the support, as far as it will go.

When performing this operation, be careful to insert the lamp keeping the pin vertical and / or aligned with the hole, in order not to cause damage to the pin itself.

Screw the safety screw into its seat making sure to tighten it completely so that it cannot unscrew.

In this way, the arm is free to rotate (as expected), but cannot be accidentally removed from the holder. Check that the lamp is installed correctly and safely by trying to remove it from the holder.

The assembly of the lamp is finished.

3.9 Visual inspection and functioning test before use

A visual control must be carried out after installation:

Mobile mechanical parts check

Check the mechanical functioning of the lamp through orientation and rotation movements of the mobile mechanical parts.

Reflector check

Visually check that both external plastic components and light components inside are not damaged.

In case of damage the lamp MUST NOT be switched on and MUST NOT be used until repaired.

All LEDs of the light head must be enlightened when the lamp is turned on.

Visually check that no damage occur to the light head and controls, i.e. dents or scratches that could prejudice a correct functioning of the device.

4. USE

4.1 Symbols on Control panel



ON/OFF button



Light Intensity slider



Colour Temperature slider



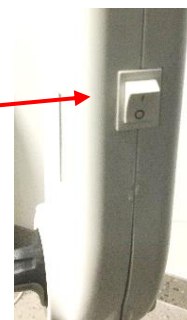
the function is available as gesture control

4.2 Switching ON/OFF

4.2.1 Articulated Arm Version

After connecting to the electrical outlet, the ACEMST1 can be turned off and on using the switch located on the rear side of the rigid arm cover.

(When the lamp is not in use, it is advisable to have the switch OFF (0)).



4.2.2 Flexible Arm Version

In the ACEMST1 version on flexible arm, the switch is not present. For this, the lamp is powered as soon as it is connected (with the power supply) to an electrical outlet.

4.2.3 Stand By Mode

Once connected and, in the case of the rigid arm version, the switch is turned on, the lamp is in "Stand by" mode, recognizable by the green LED on the touch control panel (both in the ACEMST1.1 and ACEMST1.3 versions), and is ready to be used.



"Stand-by" Mode on ACEMST1.1



"Stand-by" Mode on ACEMST1.3





Note: When the lamp is connected to the power supply (as in the previous paragraphs), it is configured in the state it was in when it was turned off.

Refer to the following sub-paragraphs for how to switch on the lamp according to the version used.

4.2.4 ACEMST1.1 – by Touch control panel




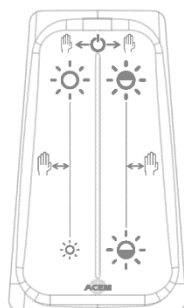
Press the  button on the right half of the Touch Control panel for 3 second to switch ACEMST1 to ON.


Press the  button on the right half of the Touch Control panel for 3 second to switch ACEMST1 to stand-by mode.

4.2.5 ACEMST1.3 - by Touch or Gesture Control

Touch Control

Press the  button on top of the Touch Control panel for 3 second to switch ACEMST1 to ON.
During the touch, a sequence of LEDs in a row will turn on to confirm the action.



Press the  button on top of the Touch Control panel for 3 second to switch ACEMST1 to stand-by mode.
During the touch, a sequence of LEDs in a row will turn on to confirm the action.

Gesture Control

To turn ON the light by a gesture, proceed as follow:

Under the light head, at a maximum distance of about 5 cm from the bottom, swing your open hand either from left to right and back or from right to left and back, to activate the on/off gesture switch.

The sequence must be completed within 2 seconds, after which the sequence must be repeated from the beginning.



during the sequence

Repeat the same procedure to turn the light to stand-by mode by gesture switch.

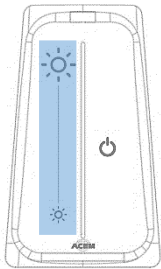
4.3 Light Intensity adjustment

It is possible to adjust steplessly the light intensity from 20% up to 100%.

4.3.1 ACEMST1.1 – by Touch Control Panel

The desired light intensity is set by moving your finger vertically on the left half of the Touch slider or directly touching in a position along the slider (see BLUE AREA in the pictures below).

The value set is confirmed by the LEDs in the centre of the panel.

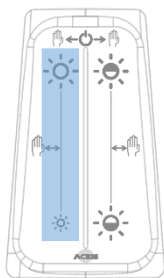


light intensity adjustment on ACEMST1.1

4.3.2 ACEMST1.3 - by Touch or Gesture Control

Touch Control

Please refer to previous paragraph (see above).



light intensity adjustment on ACEMST1.3

Gesture Control

On the left edge of the light-head there is a sensitive area able to detect hand proximity within 5-6 cm distance. Move the hand within left detection area.

As soon as hand is detected, a LED on the left side of control panel start to blink to show the system is now following hand movements and is reading it.

That goes on until the hand is kept moving inside the detection area.

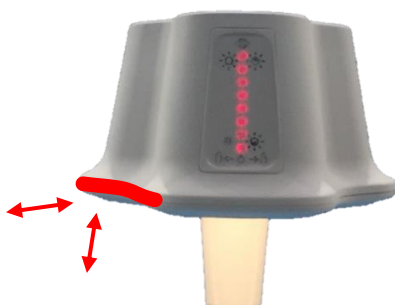
To set the adjustment, hold hand in the desired position for 1 second.

Then the LED becomes lit steady; adjustment is done.

The value set is confirmed by the LEDs in the centre of the panel.

Either horizontal or vertical movements of hand going forth and back from the edge, are accepted.

Moving hand toward the light-head, light intensity increase; otherwise moving hand off the light-head, light intensity decrease. (please refer to picture below to identify the left detection area and hand movements).



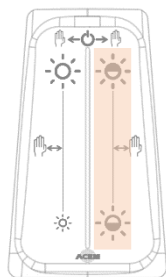
4.4 Colour Temperature adjustment (only for version ACEMST1.3)

It is possible to adjust steplessly the colour temperature in the range between 3.000 K and 5.500 K. Colour temperature adjustment is achieved by either the Touch control panel or by Gesture Control.

Touch Control

The desired Colour temperature is set by moving your finger vertically on the right half of the Touch slider or by directly Touch in a position along the slider (see RED AREA in the pictures below).

The value set is confirmed by the LEDs in the centre of the panel.



3.000 K



4.200 K



5.500 K

Gesture Control

On the right edge of the light-head there's a sensitive area able to detect hand proximity within 5-6 cm distance.

Move the hand within right detection area.

As soon as hand is detected, a LED on the right side of control panel start to blink to show the system is now following hand movements and is reading it.

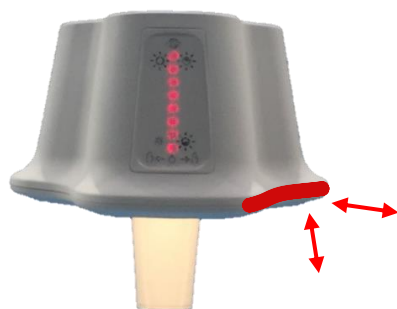
That goes on until the hand is kept moving inside the detection area.

To set the adjustment, hold hand in the desired position for 1 second, the LED becomes lit steady; adjustment is done.

The value set is confirmed by the LEDs' colour in the centre of the panel changing according to colour temperature.

Either horizontal or vertical movements of hand going forth and back from the edge, are accepted.

Moving hand toward the light-head, colour temperature increase; on the contrary, moving hand off the light-head, colour temperature decrease. (please refer to picture below to identify the left detection area and hand movements).



4.5 Positioning and orientation

With the ACEMST1 lamp, the light beam can be easily adjusted, oriented and fixed in the desired position using the handle on the light head.

Regardless of the type of arm, the light-head rotation around its pivot on ACEMST1.1 is 280° and the light-head rotation around its pivot on ACEMST1.3 is >360° without stop.

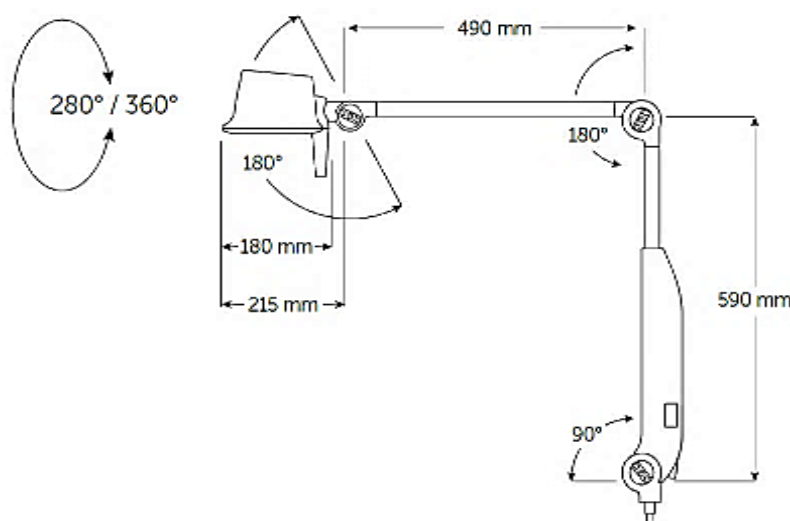
Articulated Arm Version

Thanks to the spring balancing system, the lamp is maintained in position without any other operation.

The articulated arm is provided with brakes in every joint in order to compensate the natural drift that could occur over the time.

Brakes must be adjusted once during installation.

Below are shown the extension of the arm and the rotation and inclination angles.

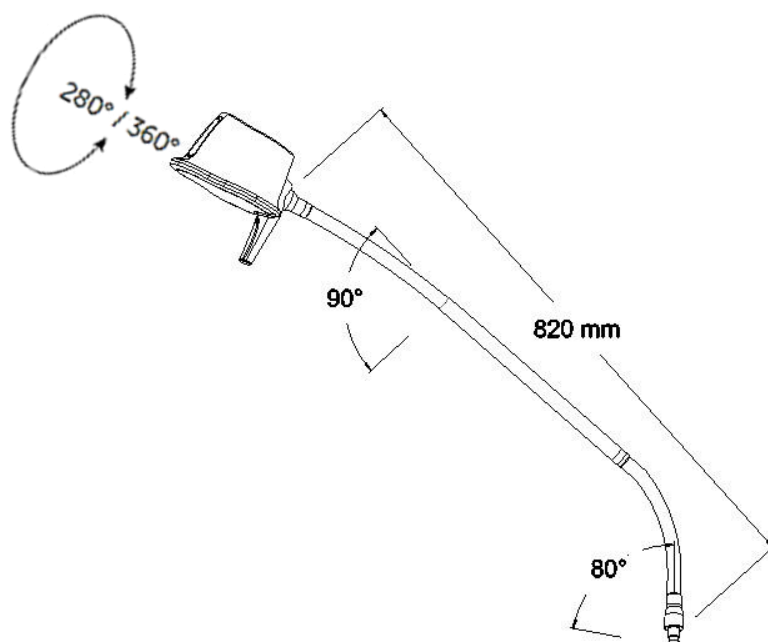


Flexible Arm Version

The flexible arm has two flexible sections balanced spring to be oriented in any direction.

No adjustment is required on the flexible arm; the lamp maintains the desired position.

Below are shown the extension of the arm and the rotation and inclination angles.



4.6 Arm brakes (only for Articulated Arm version)

In addition to the spring balancing system, the articulated arm features 3 brakes to allow adjustment of the effort during the orientation and positioning of the light head.

CAUTION! Brakes are factory set. Anyway, it is mandatory to check them all during installation and adjust properly before use.

The operations described must only be performed if the arm moves from the desired position over time.

To adjust the brake acting on the lower part of the arm, use handle in bottom position.

To adjust the brake acting on the upper part of the arm, use handle in middle position.

To adjust the brake acting on the light head, use handle in top position.



Clockwise adjustment increases brake force.

Counter-clockwise adjustment reduces brake force.

4.7 Trolley use

During use, the adjustable section of the vertical pole ("B" - par. 3.4) can be extracted by about 50 cm.

Either way, when you move the lamp from one area to another or when you are not sure of the obstacles along the route, the withdrawable part must be fully reported within the fixed section to maintain the vertical post at the minimum height;

Furthermore, before starting any movement, for safety reasons, it is necessary:

- fold the articulated arm back on itself
- bring the flexible arm to a vertical position.

5. MAINTENANCE

5.1 Cleaning, disinfection and sterilization

The cleaning and maintenance of the lamp must always be carried out when the device is NOT connected to the power outlet.

The surface can be easily cleaned with a damp cloth. Normal detergents can be used.

In case of disinfection, use only disinfectants containing less than 20% alcohol.

Do not pour liquids directly on the light head and arm; rather moisten the cloth with a small amount of detergent / disinfectant, and proceed with the cleaning operation.

5.2 Light head - front part replacement

The ACEMST1 comes with the possibility to choose among several colours' combination.

it is possible to replace the coloured front part after installation (see table in paragraph "technical data" for available colours).



Remove the transparent cover cap "A" and white cover cap "B".

Use a small plastic screwdriver into the small hole to pop it off.

Then, remove both the screws underneath.

Replace the part and proceed backwards to assemble the part.

5.3 Moving

If the lamp needs to be moved follow the below mentioned instructions:

CAUTION! The device contains delicate components, sensitive to strong mechanical stresses.

Therefore we warn that in order to be moved, handled in whole or in one of its parts, you must first ask permission to ACEM S.p.A.

To disassemble the components, follow the assembly procedures in this manual in reverse order.

The non-observance of the aforementioned procedure involves the immediate cessation of the relative warranty contract.

Light head packing

This is the most delicate part of the device and for this reason it must be absolutely properly handled and protected both during disassembly and transport, by operating as follows:

Rigid arm version: After extracting it from the support, insert the lamp complete with arm in an envelope and place it in the original packaging box, folded, placing it in the seats provided inside.

If necessary, also house the support (see "packing the supports"). Close the box with tape marked "fragile".

If the original box is not available, use a suitable size. After inserting the bagged lamp, fill the box with protective packaging material (for example bubble wrap or polystyrene). If necessary, also house the support (see "packing the supports"). Close the box with tape marked "fragile".

Flexible arm version: After extracting it from the support, insert the lamp complete with arm in a plastic bag and place it in the original packaging box, placing it in the seats provided inside.

If necessary, insert also the support (see "packing the supports").

Close the box with tape marked "fragile".

If the original box is not available, use a different one with suitable size.

ATTENTION: The arm has a certain degree of flexibility, nevertheless, when packing it, do not subject the flexible sections to strong twisting or excessive bending, so as not to affect future correct functioning.

After inserting the bagged lamp, fill the box with protective packaging material (for example bubble wrap or polystyrene).

If necessary, insert also the support (see "packing the supports").

Always close the box with tape marked "fragile".

Packing the supports

If it is also necessary to move the supports (for shipping or other), consider the following:

Standard Wall, Wall with extended arm, Table and Bar Support

These must be suitably protected (eg by bubble wrap) and put in the double bottom of the box used for the lamp, in the area delimited by raised edges.

Trolley packing

The trolley is composed by 3 parts:

The 5-arm base with castor wheels, the vertical pole (fixed section and extensible section) and Fixing kit.

Individually protect the 3 components by wrapping them in bubble wrap sheets and blocking the latter with adhesive tape.

Use a carton box of suitable dimensions and put the parts inside it carefully.

Fill the remaining empty spaces with material such as bubble wrap or polystyrene sheets or anything else that can act as a protection against mistreatment during transport.

Apply the correctly filled out shipping label on the box in a central position.

Ceiling pole packing

Prepare the original packaging box and, after inserting the pole, fill it with protective packaging material (for example bubble wrap or polystyrene) and close it with adhesive tape marked "fragile".

If this is not available, use an appropriately sized box and fill it with protective packaging material (for example bubble wrap or polystyrene) and close it with adhesive tape marked "fragile".

6. TECHNICAL DATA

6.1 Technical features

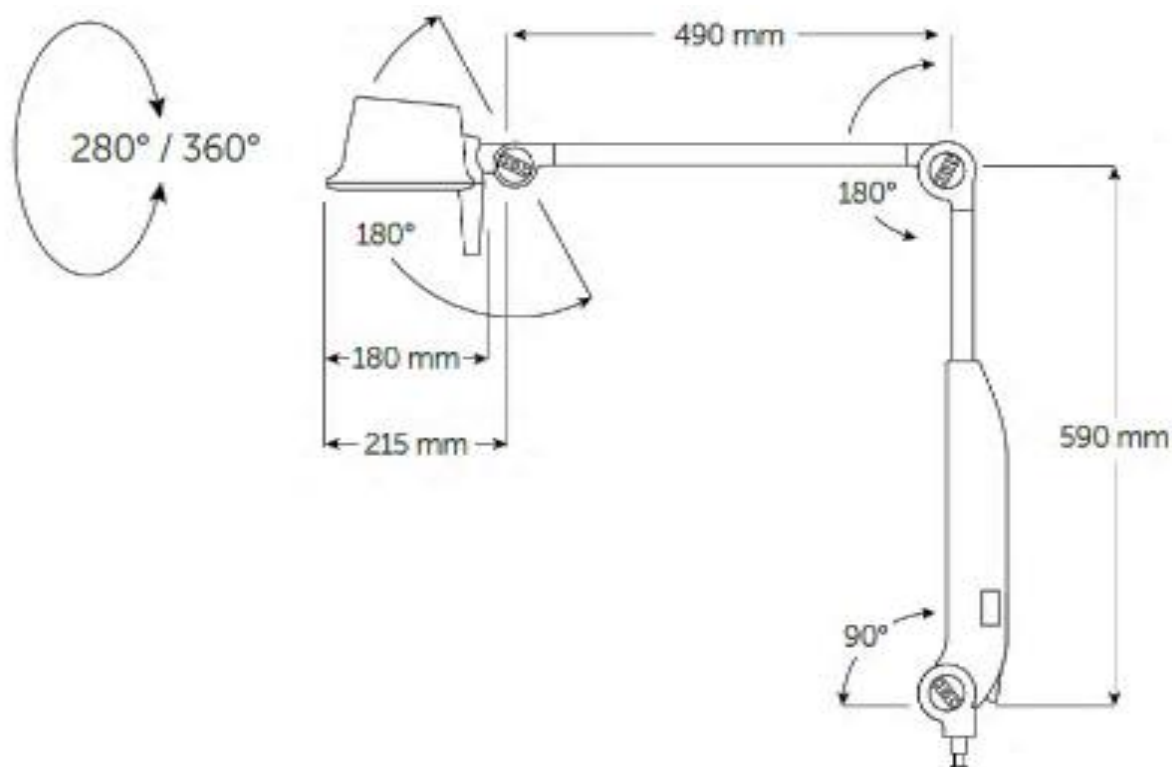
TECHNICAL FEATURES	ACEMST1.1	ACEMST1.3
Voltage	100-240 Vac– 50/60 Hz	100-240 Vac– 50/60 Hz
Power Consumption	10 VA	12 VA
Fusibili (articulated arm version only)	2 AT – 250 Vac – 5x20	2 AT – 250 Vac – 5x20
Maximum Light Intensity	18.000 LUX @ 100 cm 60.000 LUX @ 50 cm	30.000 LUX @ 100 cm 100.000 LUX @ 50 cm
Light Adjustment	20% - 100%	20% - 100%
Light Field Diameter (d10)	26 cm	26 cm
Colour Temperature, CCT	4.300 K	3.000 K - 5.500 K
Colour Rendering Index (Ra/R9)	98/90	98/90
LED Average Life	60.000 hours about	60.000 hours about
Light Head Diameter	18 cm	18 cm
Light Head and Arm Weight	2 Kg	2 Kg
Colour combinations	<ul style="list-style-type: none"> • White (RAL 9010) • Green (RAL 6019) • Blue (RAL 5024) • Pink (RAL 4003) • Light Grey (RAL 7035) • Dark Grey (RAL 7016) 	<ul style="list-style-type: none"> • White (RAL 9010) • Green (RAL 6019) • Blue (RAL 5024) • Pink (RAL 4003) • Light Grey (RAL 7035) • Dark Grey (RAL 7016)
Product Class (EN 60601-2-41)	I (ceiling version) II (all other versions)	I (ceiling version) II (all other versions)
IP degree	43 21 (only ACEMST1.X /F Wall Plug PSU)	43 21 (only ACEMST1.X /F Wall Plug PSU)
Light Head max temperature	40 °C	40 °C

Data according to Standard EN 60601-2-41:2009/A1:2015.
Note: all photometric values are subject to 5% tolerance.

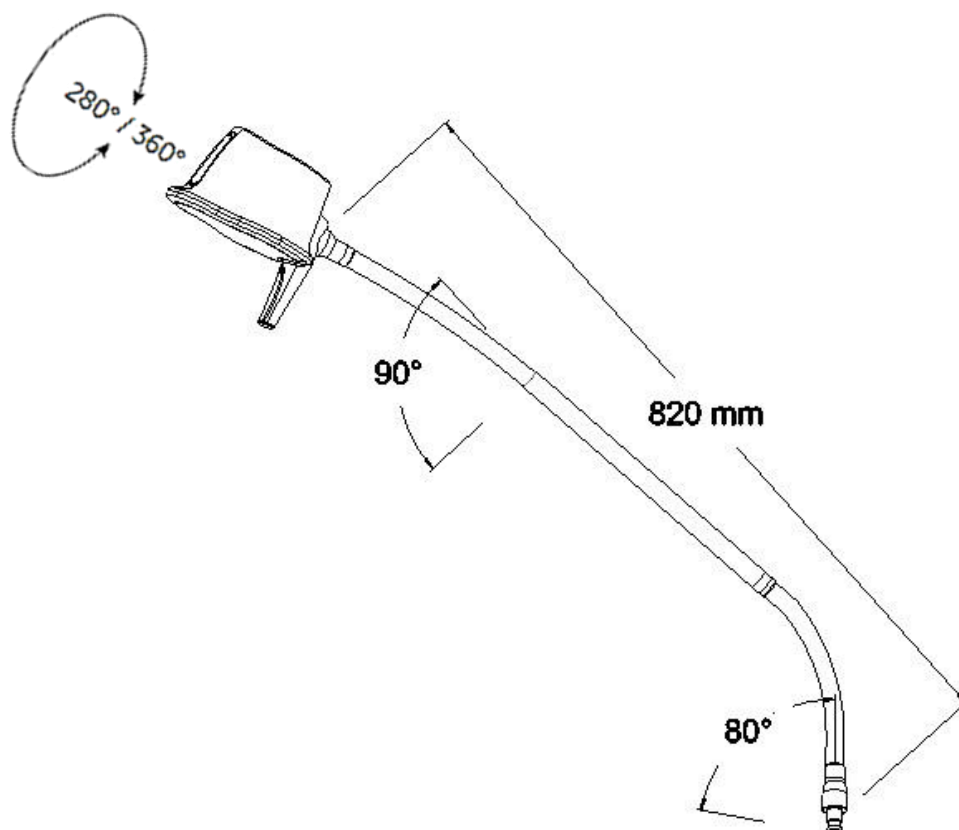
6.2 Weights of Supports

Trolley	5 Kg
Ceiling pole (depends on length)	3.0 – 6.0 kg
Wall	0.4 Kg
Wall with extension arm	1.6 Kg
Bar	0.25 Kg
Table	0.25 Kg

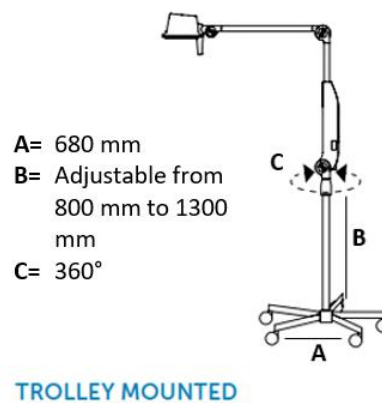
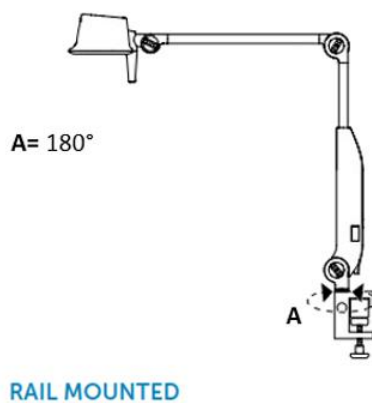
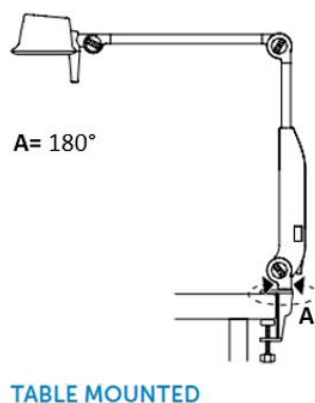
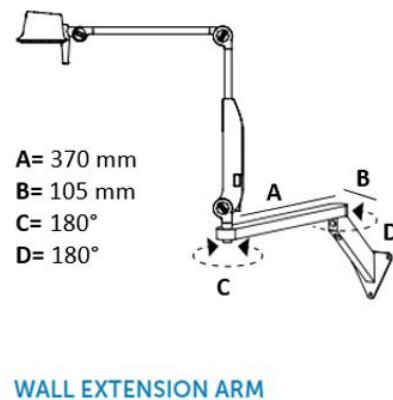
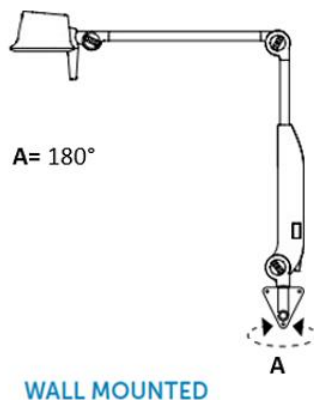
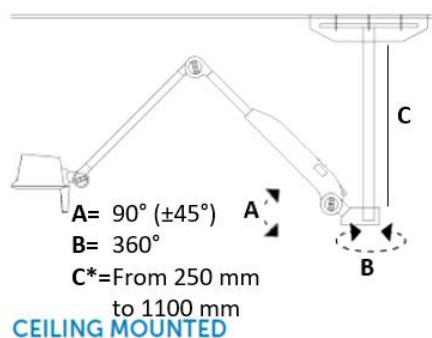
6.3 Articulated arm Movements



6.4 Flexible arm Movements



6.5 Configurations



(*) Note: The pole length must be chosen from those available.

6.6 EMC Requirements

ACEMST1 requires special precautions regarding EMC and must be installed in accordance with the EMC information contained in the accompanying documents. Portable and mobile radio communication equipment can affect the operation of the lamp.

The device should not be **adjacent or stacked with other appliances** and that, if it is necessary to use it near or on top of other appliances, the appliance or system should be observed to check the normal operation of the configuration in which is used.

6.6.1 Reference Standards

PRODUCT STANDARD REFERENCES	
Standard	Description
EN 60601-1-2:2015	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
BASIC STANDARD REFERENCES	
Standard	Description
EN 55011:2009/A1:2010	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
EN 61000-3-2:2006/A1:2009/A2:2009	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 61000-4-2:2009	Electromagnetic compatibility (EMC) Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-3:2006/A1:2008/A2:2010	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4:2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test
EN 61000-4-5:2006	Electromagnetic Compatibility (EMC) - Part 4-5: Testing and measurement techniques – Surge immunity test
IEC 61000-4-6:2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
EN 61000-4-8:2010	Electromagnetic compatibility (EMC) - Part 4- 8: Testing and measurement techniques - Power frequency magnetic field immunity test
EN 61000-4-11:2004	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests

6.6.2 Results Table

Test Report Number: 20RDP097

EMISSION REQUIREMENTS			
Type of Test		Standard	Result
<i>Conducted emissions</i>	<input type="checkbox"/> AC power	EN 55011	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> DC power		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> SIP/SOP		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
<i>Radiated emissions</i>	<input type="checkbox"/> 30÷1000MHz	EN 55011	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> 1÷3GHz		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> 3÷6GHz		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
<i>Harmonic current emissions</i>		EN 61000-3-2	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
<i>Voltage fluctuations and flicker</i>		EN 61000-3-3	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
IMMUNITY REQUIREMENTS			
Type of Test		Standard	Result
<i>Electrostatic discharge immunity (ESD)</i>		EN 61000-4-2	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
<i>Radiated RF electromagnetic field immunity</i>		EN 61000-4-3	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
<i>IMMUNITY to RF wireless communications equipment</i>		EN 61000-4-3	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
<i>Electrical fast transient immunity (BURST)</i>	<input checked="" type="checkbox"/> AC power	EN 61000-4-4	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> DC power		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> SIP/SOP		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
<i>Surge immunity</i>	<input checked="" type="checkbox"/> AC power	EN 61000-4-5	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> DC power		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> SIP/SOP		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
<i>Immunity to conducted disturbances, induced by RF fields</i>	<input checked="" type="checkbox"/> AC power	EN 61000-4-6	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> DC power		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
	<input type="checkbox"/> SIP/SOP		<input type="checkbox"/> C <input type="checkbox"/> N <input checked="" type="checkbox"/> NA <input type="checkbox"/> NE
<i>Immunity to power frequency magnetic field</i>		EN 61000-4-8	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE
<i>Immunity to voltage dips and short interruptions</i>		EN 61000-4-11	<input checked="" type="checkbox"/> C <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> NE

Result Legend

C	Device Complied with specification
N	Device NOT Complied with specification
NE	Test Not Executed
NA	The test is Not Applicable

7. DISPOSAL

At the end of its lifetime, the equipment must be disposed according to directives and procedures foreseen by the Law.

Directive 2012/19/UE on waste electrical and electronic equipment (WEEE)

Directive 2015/863/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

According to the a.m., notice is given that:

It is forbidden to dispose WEEE as unsorted municipal waste. Collect such WEEE separately;

When supplying a new product, distributors shall be responsible for ensuring that such waste can be returned at least free of charge on a one-to-one basis as long as the equipment is of equivalent type and has fulfilled the same functions as the supplied equipment.

In other cases, the customer is bound to return the equipment to a reuse centres, treatment and recycling facilities.

The equipment and its components, comply with the RoHS 3 directive on restriction of use of hazardous substances.

There are not potential effects on the environment and human health as a result of the presence of hazardous substances in the equipment

The symbol:



Also reported on equipment label, means that it must be disposed separately.

Penalties are applicable in case the equipment is disposed improperly or abusively to what's foreseen by the Law.

8. COMPLAINTS


Complaints for possible damage during transport will be accepted only if communicated immediately to the seller or the forwarding agent.

In case of return of the product use, if possible, the original packing of the lamp and always specify the following data:

- Name and address of the customer
- Serial number of the article
- Fault description

9. DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY VALID FOR THE EU MARKET ONLY

	TECHNICAL DOCUMENTATION		Rev	r2001
	UE DECLARATION OF CONFORMITY		Code	UE DOC_ACEMST1
	Luminaire for diagnosis		Date	01/07/2020
	ACEMST1		Page 2 / 2	

UE DECLARATION OF CONFORMITY


Name of the manufacturer	ACEM S.p.a.
Address of the manufacturer	Via della Tecnica 29
Contacts	+39 051 721844 info@acem.it
SRN	On hold

This declaration of conformity is issued under the sole responsibility of the manufacturer and states that the device

Type	Luminaire for diagnosis		
Brand	ACEMST1		
Models	Code	Models	Code
ACEMST1.1 /RR	110800	ACEMST1.1 /FR	110900
ACEMST1.1 /RD	110801	ACEMST1.1 /FD	110901
ACEMST1.1 /RW	110802	ACEMST1.1 /FW	110902
ACEMST1.1 /RT	110803	ACEMST1.1 /FT	110903
ACEMST1.1 /RTB	110804	ACEMST1.1 /FTB	110904
ACEMST1.1 /RC	110805	ACEMST1.3 /FR	111100
ACEMST1.3 /RR	111000	ACEMST1.3 /FD	111101
ACEMST1.3 /RD	111001	ACEMST1.3 /FW	111102
ACEMST1.3 /RW	111002	ACEMST1.3 /FT	111103
ACEMST1.3 /RT	111003	ACEMST1.3 /FTB	111104
ACEMST1.3 /RTB	111004		
ACEMST1.3 /RC	111005		
Basic UDI-DI identifier of the device	805070589ACEMST1EM		
Intended Use	Luminaire to illuminate the body of the PATIENT locally in order to support diagnosis or treatment which could be interrupted without any hazard for the PATIENT in case of failure of the light. NOTE: it is not intended to be used in operating rooms.		
Risk Class	Class I according to Annex VIII Regulation (EU) 2017/745		

meets the requirements of Regulation (EU) 2017/745

All documentation supporting this declaration is filed with the manufacturer.

Place and date	Argelato, 01/07/2020
Name and surname	Pier Paolo Tacconi
Role	CEO
Signature	 <p>ACEM S.p.A. VIA DELLA TECNICA 29 40020 ARGELATO (BO) ITALY TEL. +39 051 721844 / FAX. +39 051 721855 E-MAIL: info@acem.it</p>

10. WARRANTY

ACEM S.p.A.
Via della tecnica, 29
40050 Argelato, Bologna – ITALIA
Tel.: +39.051.721844 (r.a.) – Fax: +39.051.721855

Validity 24 (twenty-four) months

ARTICLE : Luminaire for diagnosis

MODEL : ACEMST1

The warranty is valid for a period of 24 (twenty-four) months starting from the date of the purchase receipt and cannot be extended for the inactivity of the device due to repair. Thus, the customer will have to communicate the working deficiency of the product to our seat within the aforesaid expiration or he/she will lose the right to make use of the warranty. Technical service under warranty is carried out by authorised technicians only.

When the customer asks for repairing under warranty this certificate will have to be shown together with the purchase receipt of the product proving its real place of origin.

The warranty exclusively covers the breakdowns of the product determining its wrong working. The guaranteed product will have to carry the same serial number of that indicated on the sales document or it will be invalidated.

Warranty means exclusively free repairing or replacement of components recognised as faulty in manufacturing or in material, labour included. Anyway, travelling, stay and/or transport expenses are in charge of the customer.

Warranty cannot be enforced in case of damage due to carelessness, use or installation that do not correspond to the supplied directions, tampering with the product and/or the warranty seal, damage due to accidental causes and/or to negligence by the buyer in particular as regards external parts.

Besides, it cannot be enforced in case of damage due to connections of the device with tensions different from those indicated or to sudden voltage changes of the mains with which the unit is connected as well as in case of damage due to inductive/electrostatic discharges or discharges caused by thunderbolt or other phenomena external to the device.

The warranty does not include parts that wear out after use, batteries (when supplied), cables, connectors, external parts and plastic bearings, without manufacturing defects.

After 24 (twenty-four) months from purchase warranty expires.

In this case service will be carried out debiting the replaced parts and labour expenses according to rates in force or to formalities provided by after-sales service.

For every contest the place of jurisdiction will be exclusively Bologna.

11. REVISIONS TABLE

Review List					
REV.	Description	Written / updated by	Approved by	Issued by	Issue Date
r2002	Document 1st release	LP	GS	PPT	23/06/2020
r2003	Ceiling mounting instructions added	LP	GS	PPT	23/09/2020
r2004	par. 3.9 and par. 4.5 Updated	LP	GS	PPT	22/10/2020
r2005	Par. 1.1, 1.2, 1.3, 1.8, 4.5, 4.6, 4.7 and 5.3 Updated. Par. 5.2 moved to Par. 4.6	LP	GS	PPT	02/12/2020
r2101	Par. 1.3, Par. 1.6 e Par. 6.1 Updated	LP	GS	PPT	07/01/2021
r2102	Added Par. 2.3 about packaging. Updated Par. 1.2, 4.2, 4.3, 4.5, 5.1, 6.5	LP	GS	PPT	19/03/2021
r2103	Updated Par. 1.3, Par. 1.6	LP	FS	GS	23/04/2021