BOSCAROL
Emergency Medical Systems

SUPPORT AND CHARGING BRACKET FOR BSU

OBWB

FOR MEDICAL SUCTION UNIT OB2012, OB1000 and OB3000

OPERATING INSTRUCTIONS

PRODUCT BY:

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Manufacturer and device information:

- Oscar Boscarol applies a quality management system in accordance with international standards ISO 13485 and ISO 9001.
- The OB WB is not a medical device and is intended as an auxiliary system for fixing and restraining medical devices OB3000, OB2012 and OB1000.
- The device is intended for exclusive use on these devices

Information on these operating instructions:

- This document contains important information for the safe, effective and compliant use of the medical device.
- Use the information reported to train users and confirm their training
- This manual may not be altered (even in part). Only the manufacturer of the device may make changes where necessary.
- These instructions should always accompany the device. We recommend using the electronic version and making it available on operators' PDAs, tablets and mobile phones.

These operating instructions apply to the following devices:

OB WB

BSU810								

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0 MEANING OF SYMBOLS AND PICTOGRAMS

0.1 Symbols used on the device and in this user manual

	Important warnings: important information for the correct use of the device and to avoid the risk of injury to the operator, patient and/or damage to the device
	Warnings: information to which attention should be paid
	Notes or information for correct use of the device
1.	List of actions to be performed: follow them step by step
	Read these operating instructions carefully and completely
	Indicates the need for the user to consult these operating instructions for information such as warnings and precautions that cannot be displayed on the device in question
	Manufacturer
	Production date
	Do not dispose of the device with normal household waste. European Community Directive 2012/19/EU - Waste Electrical and Electronic Equipment (WEEE).
	Required maintenance service (contact the manufacturer and/or its authorised service centres)
	Use this device only within the specified temperature range. Use outside these limits may impair the function, safety and anchorage of the medical device for which it is intended.
	Limits of use in relation to humidity
REF	Order number (device code)
	Please read the operating instructions in other languages available on the indicated website
LOT	Production batch
SN	Serial number
	Indoor use only

	Danger: **Do not connect** the bracket to mains voltage.
	Continuous current

1 WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

These operating instructions have been prepared using simple, easy-to-understand language. If you have difficulty in interpreting what is written, contact the manufacturer for further clarification.

 **Phone +39 0471 93 28 93**  **info@boscarol.it**

- Please read these instructions carefully before using and installing the device.
- The wall bracket is designed to allow the OB2012, OB1000 and OB3000 aspirators to be attached to emergency vehicles, hospitals, clinics and/or other medical facilities.
- The bracket cannot be used to fix other medical devices than those of the BSU family produced by Oscar Boscarol srl.
- The OBWB wall bracket, appropriately connected, with the supplied cable, to the external power source (SELV type only) allows the internal battery to be recharged and the suction unit to be powered.
- The bracket must be installed in accordance with the instructions in this manual and in compliance with the requirements of EN 1789:2021. Failure to do so may jeopardise the safety of patients and users. The bracket is tested to withstand positive and negative accelerations of up to 10 g.
- Never alter the mechanical, electrical and structural parts of the bracket. Such interventions make the device dangerous and do not allow its correct use, also damaging the fixed and powered device.
- No technical intervention by the user is allowed on the device. The only operations allowed are those indicated in these operating instructions. Any technical problems, periodic inspection and repairs should be referred to the authorised service department and/or the manufacturer.
- Always use only spare parts, supplied by the manufacturer (Oscar Boscarol srl), in order to ensure maximum efficiency and safety of the device.
- Do not remove and/or modify the coupling and release spring in order to ensure that the anchored device is held up to negative acceleration forces of 10g.

	**If the user or patient becomes aware of a danger in use, a side effect, an accident caused by the device or a critical issue (operational and design) not covered in these instructions for use, he must immediately report this to the manufacturer at the following e-mail address: raq@boscarol.it**
	**The bracket is designed in accordance with the requirements of EN 1789 for wall mounting of the BSU Boscarol OB1000, OB2012 and OB3000 family of suction units. The power supply is 12÷15 Vdc (OB2012-OB1000) and 11 to 30 Vdc for the OB3000 suction unit. Never connect the bracket to mains voltage or outside the accepted range of voltage values**

2 IMPORTANT INFORMATION

	The device has been designed and tested in accordance with the latest standards. Connecting the device to vehicle electrical systems that are not compliant and/or not carried out by a professional installer may damage the device and cause damage to the electrical system itself.

	The device must be checked at least once every **12 months** by the authorised service centre or the manufacturer. The device must be inspected electrically and mechanically every **2 years**. This may only be carried out by an authorised service centre or by the manufacturer. The lifetime of the device, if all safety maintenance is carried out, is **10 years** from the date of manufacture.
	Contamination of the device: It is strictly forbidden to send contaminated devices to the manufacturer, installer or authorised service centre. Any device received in such a condition will be refused and returned to the sender with all the appropriate consequences. Health authority will be informed of possible contamination.

3 OB WB SUPPORT AND CHARGING BRACKET

The device must be installed in emergency vehicles. This operation may only be carried out by authorised personnel and vehicle fitters, after having performed a careful risk assessment (see ISO 14971 latest edition) related to the specific type of process. After installation the device must be tested. Tests of a dynamic nature or conducted with computer simulations (must be validated) to ensure the tightness and fixation of the device, which must withstand acceleration/deceleration forces of up to 10 g. Never use a damaged or altered device.

4 DEVICE DESCRIPTION

The OBWB wall bracket has been designed and manufactured to allow the medical suction units OB2012, OB1000 and OB3000 to be fixed to the wall. It can be fixed in ambulances and medical vehicles, hospitals and/or surgeries. The bracket is equipped with an electrical cable that has to be connected to the appropriate direct current source (SELV) depending on the type of aspirator:

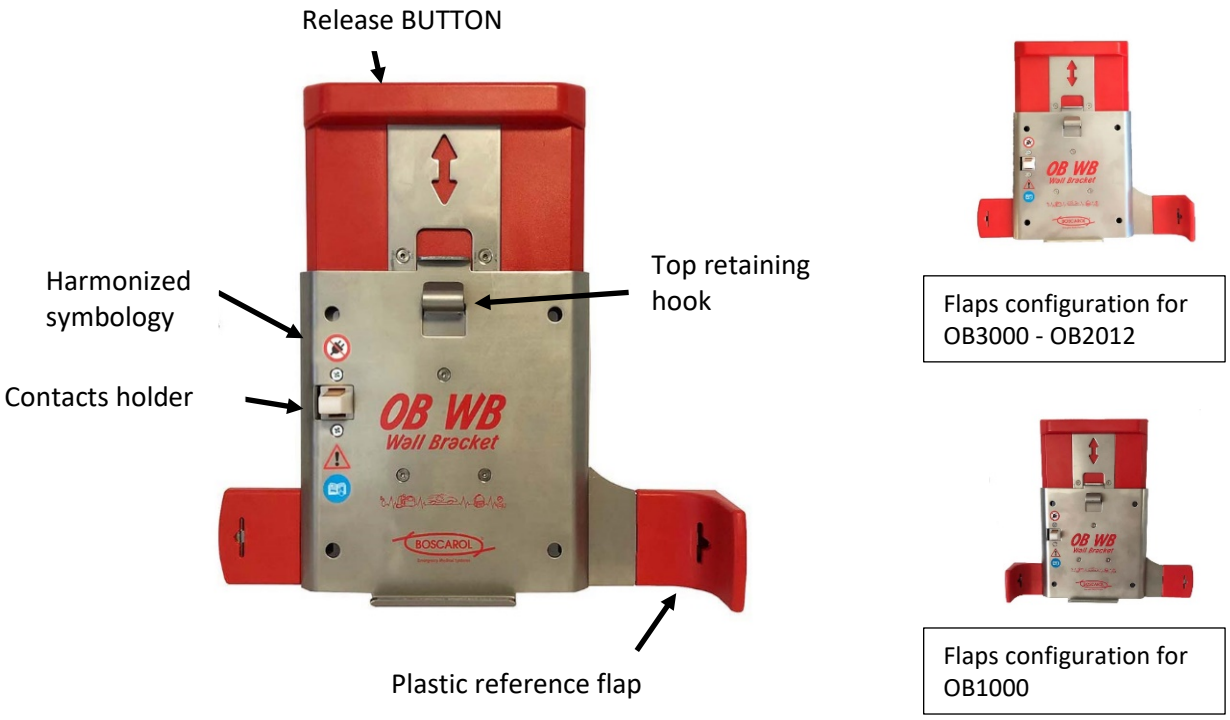
- Aspirator OB 1000 and OB 2012 ⟶ 12 V DC
- OB 3000 suction unit ⟶ 10 to 30 VDC (direct current)

The connection to the external direct current electrical source allows the device to be powered and the internal battery to be recharged at the same time. Easy fixing, safety and compliance with current standards guarantee the user easy and safe use, safeguarding users and patients in the event of accidents and/or overturning of the rescue vehicle.

SELV power source	**Power source**: The power source must comply with the requirements imposed by laws and regulations. Power supplies that have not passed compliance testing for medical devices cannot be used. The conformity of the external power supply must refer to IEC 60601-1, IEC 60601-1-2 and all other standards involved in the verification referring to medical devices.

4.1 Operation, controls and electrical connections

The OBWB bracket is constructed to reduce the risks of device insertion and typical critical use in moving vehicles. It is manufactured from a steel plate folded in several separate stages and has no welding or screw assembly.
The bracket is made up primarily of three metal parts and a hook-and-loop button made of shockproof ABS. The primary part has holes for fixing it to the wall, while the latch/release button is attached to a steel plate that slides vertically on the base plate. The retention security of the device is guaranteed by a calibrated spring with a defined elastic coefficient that allows it to be effective up to acceleration/deceleration forces of 10 g.
The figure on the next page shows the bracket complete with all its parts.



The two red plastic flaps on the lower part are designed to allow the attachment of all aspirators of the BSU family (Boscarol suction unit). The OB2012 and OB3000 suction units have the "L" flap reference on the right, while the OB1000 suction unit has it on the left (see picture above). In the event of incorrect assembly, simply pry a flat screwdriver into the slot in the plastic part and remove it. Reinsert it correctly by pressing it into the metal part of the bracket (see picture below).

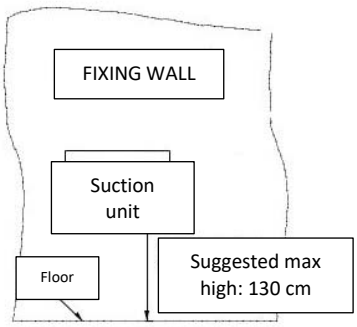
The power supply and charging system (see contact holder in the figure above) is designed in such a way as to exclude the possibility of a short circuit between the two contacts (positive and negative) and to guarantee a discrete resistance even in the event of incorrect insertion in the bracket. The contacts are made of copper-coated stainless steel (to reduce electrical contact resistance). The electrical cable of the bracket is suitable for use with SELV voltage and must **never be** connected to the mains voltage.
Protect the power supply line with a fuse of suitable rating (fuse with a break value of 15 A recommended). Electronic protection systems can be used. The suction unit is equipped with a suction pump consisting of an electric motor and it is therefore important to bear in mind the effects caused by switching it on and off (effect of inductance).

4.2 Installing the wall bracket in vehicles

The installation of the bracket on board emergency vehicles requires a preliminary study and tests on the structure of the vehicle. Standard EN 1789:2021 imposes specific conformity tests for medical devices installed in the vehicle. The following factors must always be taken into account:

1. The wall bracket and device must be installed in such a way that acceleration/deceleration forces of up to 10 g do not allow the bracket, with the device anchored and secured, to detach from the wall. Appropriate reinforcement of the body or structure of the patient compartment must always be considered by the fitter when designing and drafting the risk analysis.
2. According to EN 1789:2021, the device must be able to be operated and controlled when the operator is seated and secured with the safety belt. Suitable surrounding spaces must be designed to comply with this requirement.

3. The position of the bracket on the wall must also take into account the height of the operators and the need to use two hands to safely hook or unhook the device (see photo on the right). It is advisable not to install the bracket higher than 130 cm from the floor of the vehicle.



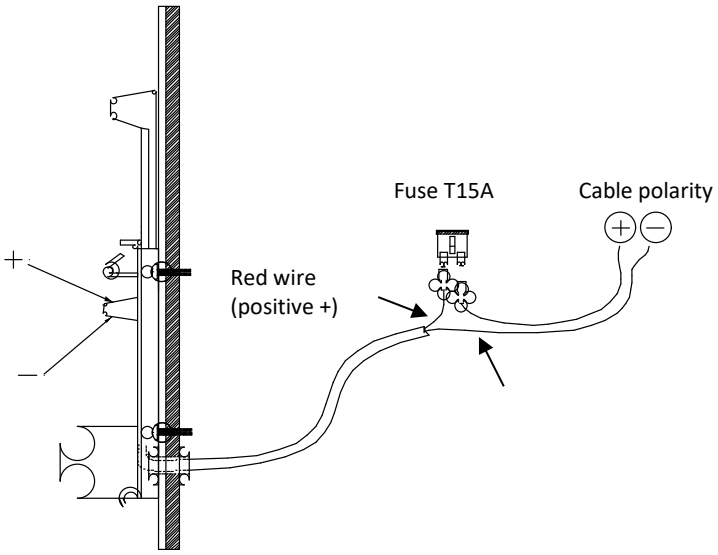
4.3 Dimensions of the device complete with bracket

Before proceeding with the installation of the bracket it is necessary to carefully evaluate the overall dimensions of the suction unit depending on the model.
Otherwise it may happen that after fixing the bracket to the wall it is not possible to fix the suction unit due to its dimensions that protrude from the shape of the bracket itself.

Installation risks	The support and power supply bracket has a smaller size than the anchored device. Before attaching it to the wall always consider how much space is required depending on the type of suction unit. It must always be possible to attach/remove the device safely and with relative ease. The dimensions of the suction units can be found in the respective user manuals, which can also be downloaded from the website: https://www.boscarol.it/ita/eifu.php.

4.4 Power cable connection

The OBWB bracket is equipped with an electrical cable for connection to the vehicle's electrical source. This cable is designed to be inserted into the wall where the bracket is fixed.
Connect the electric cable to the 12 Vdc power source for the OB2012 and OB1000 suction units and 11÷30 Vdc for the OB3000 suction unit only. The connection of the cable must always be carried out on lines with a suitable section and protected by an appropriate electrical safety device, normally a fuse or similar component with a value of not less than 15 A. This protection will intervene in the event of short circuits, malfunctions of the bracket and/or the connected suction unit. The connection to the power source must be made respecting the polarity of the power cable (see photo on the side). Incorrect connection will not cause device failures or malfunctions but will not allow regular operation and recharging of the medical device.
In accordance with IEC 60601-1-2 about electromagnetic compatibility, the instructions for use of the medical device must be observed.



Risks of interference	The positioning and fixing of the OBWB bracket and the medical device should consider the possible effects of electromagnetic interference that may develop when the device, in its final fixing position, is placed near or adjacent to other electrical medical devices. It is recommended that a minimum distance of not less than 30 cm between devices should always be observed. The risk analysis carried out at the design stage of the vehicle shall also take account of these effects (EMC).

4.5 How to attach the suction unit to the OB WB bracket

The OBWB wall bracket has been designed and manufactured to make operation simple and easy. The usability study conducted has minimised the risks involved in attaching or detaching the medical device.
It is always preferable to use two hands when attaching and detaching the medical device.
The figures on the next page illustrate the correct operations to be carried out. The picture shows the OB2012 suction unit, which is the heaviest version of the BSU family.

Final position

Suction unit insertion and extraction operations (OB2012 model pictured):

- After grasping the suction unit with two hands as shown in the first photo, place the bottom of the suction unit on the skid of the wall bracket.
- Place the device on the right side on the plastic flap (red) as shown in the picture. For the OB1000 suction unit refer to the left side of the wall bracket.
- Place the device in a vertical position and with your hand inserted in the upper handle, place your fingers on the red button and push it downwards. At this point, press the suction unit into place and release the button, which must slide upwards.
- Before removing your hands from the suction unit, make sure that it is properly secured (by pulling slightly forward, the suction unit must be locked). Make sure that the bracket guide is positioned at the highest upper point.
- The final position of the suction unit is shown in the photo above right.
- To remove the suction unit from the bracket, put your hand into the handle and use your fingers to press the red button. With the other hand grasp the device and rotate it slightly downwards to remove it from the bracket.

Never force insertion of the suction unit. Once the device has been secured, check that the battery is recharged by checking that the indicator light on the front of the suction unit is on (green = end of charge, yellow = charging in progress.

4.6 Functionality test of the wall bracket

The test operations described in this paragraph allow the user to check the functionality of the support from a mechanical and electrical point of view. If the test fails or if the state of charge and power supply does not comply, contact the authorised service centre. This check should be carried out at least once a day at the beginning of your work shift. Perform these checks monthly or when necessary:

- Check the operation of the bracket (without suction unit) by repeatedly pressing the lock and unlock button. The movement must be smooth and there must be no jamming of the mechanism.
- Always ensure that the fixing screws are fully tightened (using a screwdriver of a suitable diameter for the screw).
- Ensure that the two red plastic fins are fully inserted into the metal housings provided.
- Insert the suction unit into the bracket as shown in the previous photos.
- Visually check that the indicator light on the front of the secretion suction unit is on.
- Switch on the suction unit and check its operation

WARNINGS	If the test described above is not passed, contact the authorised service department or the manufacturer immediately. Do not tamper with the mechanical parts, the contact box and/or the safety spring. Tampering with the wall bracket and/or its mechanical and electrical devices will seriously compromise the safety and effectiveness of the device in the field.

5 REUSE AND MAINTENANCE

5.1 After docking the device

Always check that the indicator light on the front of the suction unit is on, confirming that the suction unit is powered and the internal battery is being recharged. Always make sure that the suction unit is properly seated in the wall bracket.

Pulling the suction unit towards you must not cause it to come loose. In the event of an accident, always have the wall bracket and suction unit checked by the authorised service centre or manufacturer.

5.2 Cleaning the bracket

The bracket does not require any special cleaning, but disinfection may be necessary. In this case, proceed as follows:

- Wear personal protective equipment (FFP2 masks, etc.).
- Disconnect the fuse or the power cable of the bracket
- Blow out the bracket with a compressed air source (not exceeding 2 bar) to remove any residue or scale.
- Use non-aggressive disinfectants to clean the bracket (use disinfectants suitable for medical devices). Facilitate this by using brushes or rags soaked in disinfectant.
- When finished, dry all clean parts and reconnect the power supply.
- Perform all tests described in chapter 4.6

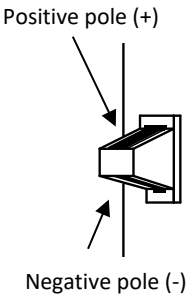
In order to properly disinfect and decontaminate the device, we recommend that you purchase specific, approved disinfectants for cleaning medical devices that are not harmful to humans or the environment. Do not use abrasive substances.
Oscar Boscarol srl can supply you with such disinfectants (also suitable for our suction units). These disinfectants, available in various formats (wipes, sprays, liquids) are laboratory tested and guarantee the deactivation of viruses, bacteria and microorganisms. Used periodically, they destroy and prevent the formation of dangerous biofilms (surface layers that easily harbour bacteria, moulds, viruses and microorganisms).

Deformation of the electrical contacts	In the event of oxidation or alteration of the contacts, contact the authorised service centre or the manufacturer.
	For more detailed information, please contact us by email at info@boscarol.it.

5.3 Checking the power supply

The wall bracket is also designed to allow powering and charging of the OB2012, OB1000 and OB3000 suction units. The supply voltage must be between 12 and 15 Vdc for the OB2012 and OB1000 aspirators and between 11 and 30 Vdc for the OB3000 aspirator. Any electrical checks on the vehicle's power supply system must always be carried out by experienced and qualified personnel.
To check the voltage present on the contacts, use a voltmeter set for DC voltage range and measure the voltage present on the two contacts of the bracket. The voltage measured must be as indicated in this user manual and in the following figure. If there is no voltage or if there is a reversal of polarity, proceed as follows:

- If the polarity is reversed, the device cannot be recharged and powered. Contact an authorised service centre or the vehicle manufacturer.
- If there is no voltage present, contact an authorised service centre or reset the fuse.
- If functional faults occur when switching on the device, contact a service centre or the vehicle manufacturer.



5.4 Dismantling the wall bracket

When replacing or removing the wall bracket, always contact an authorised service centre or the vehicle manufacturer.

5.5 Demolition and decommissioning

The device contains electrical parts that must be recycled according to the European Directive WEEE 2012/19/EU - Waste Electrical and Electronic Equipment and implemented in Italy by Legislative Decree 49/2014. The device also complies with Directive 2011/65/EC, which restricts and prohibits the use of certain harmful substances in electronic and electrical equipment. No harmful substances that violate the above-mentioned Directive are used in the production and assembly of the electronic boards, in the wiring and in the connection of the electrical cables.

6 SPARE PARTS

There are no spare parts available for the device that can be bought and installed by users. You should always contact the service centres or the manufacturer if you need to maintain or repair the device.

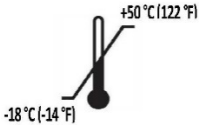
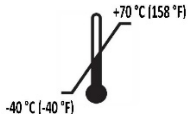
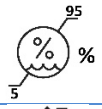
7 TECHNICAL ASSISTANCE SERVICE

No electrical and/or mechanical parts contained in the OBWB bracket are intended to be repaired by the dealer, customer and/or user. Do not disassemble or tamper with the electrical and/or mechanical parts. Always contact the authorised service department or the manufacturer for a list of authorised service centres. Any intervention, even minimal, on the device will void the warranty. Unauthorised interventions on the device may compromise its compliance with the laws in force and reduce the safety of users and patients.

8 TECHNICAL SPECIFICATIONS AND REFERENCE TO STANDARDS

Classification and type of device	Accessory for BSU family devices **Not a medical device**
Supply voltage:	SELV
Compulsory periodic safety inspection	Every 24 months
Crash test of ambulance restraint systems	EN 1789:2020

Dimensions OBWB	
Maximum device size	240 mm (w) x 250 mm (h) x 50 mm (d) 9.44 in (l) x 9.84 in (h) x 1.96 in
Device weight	Max. 800 g.
Tolerance on all values	±5 %

Conditions of storage and use		
	Operating temperature range	-18 to 50° C (-0.4 to 122 °F)
	Temperature range for storage and transport	-40 to 70° C (-40 to 158 °F)
	Relative humidity for storage, transport and use	5÷95%, non-condensing
	For indoor use only	

9 WARRANTY

The company Oscar Boscarol srl warrants the OBWB wall bracket for a period of twenty-four (24) months from the date of purchase by the original user, against any defects due to workmanship, materials or construction.

The following are excluded from this guarantee: the electrical contact assembly, the electrical connection cable, normal wear and tear of the mechanical parts, discolouration, colour changes, serigraphy and all other aesthetic irregularities that do not affect the functionality of the bracket itself.

During the warranty period, the purchaser who discovers a defective product shall send it with a written notification of the defect to the undersigned company or its authorised dealer who will, at its discretion, repair or replace the defective parts or replace the entire product. All shipping and transport costs shall be borne exclusively by the purchaser.

Conditions of validity of the guarantee:

In order to benefit from the warranty, you must fill in the product registration form, which is included in the package, and send it by post, fax or e-mail to the address:

OSCAR BOSCAROL SRL V. E. Ferrari, 29 - 39100 BOLZANO
Fax: +39 0257760142 - E-mail: production.manager@boscarol.it

In order for the guarantee to be valid, the purchaser must submit the following documents:

- presentation of a copy of the invoice and/or purchase declaration containing the serial number of the device and the date of purchase;
- detection by the service department of a fault and/or defect attributable to the materials used or to faulty workmanship
- absence of tampering, modifications and/or anything else that does not comply with the original product

Oscar Boscarol srl is responsible for the safety, reliability and operation of the suction unit only if:

- all service, repair, modification and preventive maintenance work is carried out by Oscar Boscarol srl or its authorised service centres
- the device is used in a correct manner, exclusively and strictly in accordance with the provisions of this user manual
- the electrical system to which the device is connected is built in accordance with the relevant national and European standards and laws

With reference to what is described in these warranty conditions, Oscar Boscarol srl cannot be held responsible for accidental or indirect damages, if modifications, repairs, unauthorized technical interventions have been made on the device or any of its parts have been damaged by accident, misuse and/or abuse. There are no other express or limited warranties of merchantability, fitness or otherwise beyond those described in this user manual.

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