

Operating Instructions

ATMOS Extraction Cups

English



Table of contents

1	Introduction.....	3
1.1	Notes on operating instructions.....	3
1.2	Explanation of pictures and symbols.....	4
1.3	Intended purpose	6
1.4	Function.....	7
1.5	Intended users.....	7
1.6	Scope of delivery	8
1.7	Transport and storage	9
2	Notes for your safety.....	10
2.1	General safety instructions	10
2.2	Danger for users, patients, and third parties	10
3	Setting up and starting up	12
3.1	Product overview.....	12
4	Operation	13
4.1	Initial start-up	13
4.2	Pump requirements.....	13
4.3	Hose requirements	13
5	Reprocessing.....	14
5.1	Safety instructions for reprocessing.....	14
5.1.1	General safety instructions	14
5.1.2	Danger for users, patients, and third parties.....	14
5.1.3	Preventing product damage.....	15
5.2	Preparing for and completing reprocessing	15
5.2.1	Before reprocessing the Extraction cup, malmstroem.....	15
5.2.2	Before reprocessing the ATMOS-Cup, extraction cup silicone.....	16
5.2.3	After reprocessing the extraction cups.....	16
5.3	Procedure.....	17
6	Maintenance and service	20
7	Troubleshooting	21
8	Accessories	22
9	Disposal	23
9.1	Expected service life	23
10	Technical data	24
10.1	ATMOS-Cup, extraction cup silicone	24
10.2	Extraction cup, malmstroem.....	25
11	Notes	27

1 Introduction

1.1 Notes on operating instructions



These operating instructions contain important information on how to operate your product safely, correctly, and effectively.

These operating instructions are designed for training and instructing new operating personnel in the use of the system and also for use as a reference manual. This document may be reprinted, either in part or in whole, only with written permission from ATMOS.

These operating instructions must always be kept available near the product.



Care, periodic tests, regular cleaning, and proper application are essential. They ensure the operational safety and usability of the product.

Maintenance, repairs, and periodic tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person must possess the test devices and original spare parts required to carry out these measures.



Read chapter '2 Notes for your safety' on page 10 before using the product for the first time. This will help you to avoid potentially dangerous situations.

The product bears the CE marking CE 0124 in accordance with EU Council Directive 93/42/EEC concerning medical devices and meets the basic requirements of Annex I to this directive.

The Declarations of Conformity and our General Standard Terms and Conditions can be viewed on our website at www.atmosmed.com.








The quality management system applied at ATMOS has been certified according to international standard EN ISO 13485.

These operating instructions are valid for the following products:





- ATMOS-Cup, extraction cup silicone, Ø 50 mm 404.0194.0
- ATMOS-Cup, extraction cup silicone, Ø 60 mm 404.0193.0
- Extraction cup, malmstroem, Ø = 40 mm 404.0155.0
- Extraction cup, malmstroem, Ø = 50 mm 404.0156.0
- Extraction cup, malmstroem, Ø = 60 mm 404.0157.0










1.2 Explanation of pictures and symbols

In the operating instructions

 DANGER	Warning of a danger that will result in immediate death or serious injury. Observe the necessary measures.
 WARNING	Warning of a danger that can cause death or serious injury. Observe the necessary measures.
 CAUTION	Warning of a danger that can cause minor injury. Observe the necessary measures.
NOTICE	Indicates a danger that may cause damage to the product or other objects. Observe the necessary measures.
 Warning of a danger that can cause injury or death.	
 Notice of potential material damage.	
 Useful information on handling the device.	
1. Call for action. Proceed step by step.	
» Result of an action.	
 Move/plug in this direction.	

On product and type plate

	Consult operating instructions
	This device complies with the relevant requirements of EU directives.
	Manufacturer
	Date of manufacture Country of manufacture

	Reference number
	Unique Device Identifier of a medical device
	Medical device
	Serial number
	Keep dry
	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

(01)	UDI-DI: Identification of the manufacturer and the device
(10)	Batch code
(11)	Date of manufacture
(21)	Serial number

1.3 Intended purpose

Product name:	<ul style="list-style-type: none"> • Extraction cup, malmstroem, Ø = 40 mm • Extraction cup, malmstroem, Ø = 50 mm • Extraction cup, malmstroem, Ø = 60 mm • ATMOS-Cup, extraction cup silicone, Ø 50 mm • ATMOS-Cup, extraction cup silicone, Ø 60 mm
Main functions:	<p>If a mother is unable to deliver her baby due to peridural anaesthesia, exhaustion, etc., a vacuum extraction with the suitable extraction cup can be performed.</p> <p>The extraction cup is placed on the baby's head, normally above the minor fontanelle, and the vacuum exerts temporarily on this part of the body.</p>
Intended use:	To support vaginal birth in case of stalled labour, childhood hypoxia or exhaustion of the bearing.
Intended users / user profile:	Trained medical staff (e.g. gynaecologist, midwives)
Intended patient target groups:	Female patients in childbearing age with and without restriction of any kind
Medical conditions to be diagnosed, treated or monitored:	<p>The application is only allowed under the following circumstances:</p> <ul style="list-style-type: none"> • Gravidity > 36 weeks • Amniotic sac has broken • A completely dilated cervix • Vertex presentation • Correct diagnosis of the occiput presentation • Steady contractions
Organ(s) applied to:	Natural female orifice (vagina)
Duration of application:	Temporary use on the patient (< 60 min)
Use environment:	The application site is the clinical area (e.g. OR and delivery room). The application of the device may only be performed by medical trained and introduced staff.
Patient selection criteria:	Patients who benefit from the vacuum extraction.

Indications:	To support vaginal birth in case of stalled labour, childhood hypoxia or exhaustion of the bearing.
Medical contra-indications:	Not adapted for the case of emergency or rescue operation.
Other contra-indications:	No application outside of the medical sector.
Warnings:	<p>The following complications may arise during vacuum extraction or suction:</p> <ul style="list-style-type: none">• Cerebral bleeding• Cephalhematoma• Abrasion of the skin on the child's head• Hematoma• Perineal, vaginal, cervical tears• Bleedings• Injuries of vessels and nerves• Suck of the suction instrument
The product is:	not active
Sterility / specific microbial state:	No sterile product
Single-use device / reprocessing:	The accessories are intended for multiple use. The accessories are reusable, for information on reprocessing and disinfection please see the operating instructions

1.4 Function

If a mother is unable to deliver her baby due to peridural anaesthesia, exhaustion, etc., a vacuum extraction with the suitable extraction cup can be performed.

1.5 Intended users

May be used only by trained healthcare professionals in clinical settings.

1.6 Scope of delivery

Name

REF 404.0194.0

ATMOS-Cup, extraction cup silicone, Ø 50 mm

1x ATMOS-Cup, Ø 50 mm

1x suction hose, silicone, Ø 6 mm, L = 1.30 m

REF 404.0193.0

ATMOS-Cup, extraction cup silicone, Ø 60 mm

1x ATMOS-Cup, Ø 60 mm

1x suction hose, silicone, Ø 6 mm, L = 1.30 m

REF 404.0155.0

Extraction cup, malmstroem, Ø = 40 mm

1x base plate with chain 404.0164.0

1x extraction cup, Ø = 40 mm 404.0168.0

1x extraction hose 404.0167.0

1x cross handle with locking pin 404.0148.0

REF 404.0156.0

Extraction cup, malmstroem, Ø = 50 mm

1x base plate with chain 404.0165.0

1x extraction cup, Ø = 50 mm 404.0169.0

1x extraction hose 404.0167.0

1x cross handle with locking pin 404.0148.0

REF 404.0157.0

Extraction cup, malmstroem, Ø = 60 mm

1x base plate with chain 404.0166.0

1x extraction cup, Ø = 60 mm 404.0170.0

1x extraction hose 404.0167.0

1x cross handle with locking pin 404.0148.0

1.7 Transport and storage

Transport the product only in a shipping box that is padded and offers sufficient protection.

If you notice transport damage, document and report it.

Environmental conditions for transport and storage: see chapter '10 Technical data' on page 24.

2 Notes for your safety

2.1 General safety instructions

Report all serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.

Only a fully functional product meets the safety requirements of users, patients, and third parties. Therefore, observe the following instructions on your product:

- Please read and pay attention to the safety instructions carefully prior to using the product.
- Please also pay attention to the safety instructions for the connected devices/ parts as well as to the safety instructions in the following chapters.
- There are no warranty claims for damages caused by the use of third-party accessories or consumables.
- These operating instructions correspond to the design of the instrument and the status of the underlying safety standards at the time of printing.
- Please check the articles for completeness and intactness.
- The ATMOS Extraction Cups may be used only by healthcare professionals.
- ATMOS is not liable for any personal injury and damage to property if:
 - no original ATMOS parts are/were used
 - the instructions for use in these operating instructions are disregarded
 - assembly work, new settings, alterations, extensions, and repairs have been carried out by personnel not authorized by ATMOS

2.2 Danger for users, patients, and third parties



Choking hazard for children due to accessories.

Children can strangle themselves or choke on small parts.

- Keep children away from hoses and chains.
- Keep children away from swallowable small parts. Examples of swallowable small parts are the cross handle and the locking pin.

⚠ WARNING

Avoid improper use.


Your patient can be severely injured.

- Use only original accessories and original spare parts from ATMOS.
- The product may be used only by medically trained persons who have been instructed in its medical application.
- If the head is higher than on the pelvic floor when the extraction cup is applied, it must be at least on the pelvic floor by the end of the second pull.
- With each pull, the entire head (not just the chignon with scalp) must continue to move.
- The baby's head must be mostly or fully delivered after no more than three contraction-synchronized pulls.
- Never pull twice if the head does not move further after the first pull.
- Vacuum extraction is not possible at high altitudes, as the required vacuum not be achievable under certain conditions. It is at the discretion of the specialist whether an extraction using the suction device can be carried out at the achieved final vacuum. If the final vacuum is too low, the extraction cup may come off the baby's head and seriously injure the baby.
- Before use, check all hoses and connections of the extraction cup.
- Never apply the cup more than twice.
- If the baby's head does not continue to move sufficiently during the second pull, a third pull must not be attempted under any circumstances.
- The baby's head must be delivered within 15 minutes of first applying the extraction cup.

⚠ WARNING

Product damage.

Your patient can be severely injured.

- Bent, cracked or otherwise visibly damaged extraction cups must be repaired or disposed of.
- Always wear disposable gloves when there is a possibility of coming into contact with secretions.
- Always wear disposable gloves when using the product.
- Never use components marked with  more than once. These components are intended for single use only.

3 Setting up and starting up

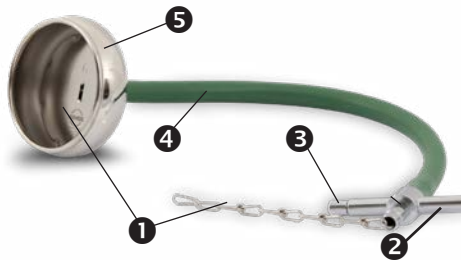
3.1 Product overview

Silicone cups



- 1 ATMOS-Cup
- 2 Suction hose

Stainless steel cups (malmstroem)



- 1 Base plate with chain
- 2 Cross handle
- 3 Locking pin for cross handle
- 4 Extraction hose
- 5 Extraction cup

Connections



Connect the suction hose / extraction hose to the extraction cup and to the secretion canister of the vacuum source to be used.

☞ Observe the requirements for the pump and the hoses; see chapter '4 Operation' on page 13.



4 Operation

4.1 Initial start-up

- ☞ Observe the safety instructions prior to initial start-up.
- ☞ It is the responsibility of the user to ensure compliance with proper surgical procedures and techniques. Each user must assess the appropriateness of the procedure based on their own knowledge and experience.

4.2 Pump requirements

- ATMOS Extraction Cups are designed for use with an external vacuum source having precise vacuum regulation to ensure proper vacuum levels. The vacuum source must have a display for continuous monitoring of the vacuum level.
- When using electrical suction devices having an airflow of more than 5 l/min, a canister with a capacity of at least 1 litre must be integrated between the extraction cup and pump. The vacuum source should be intended for medical purposes.
- ☞ The central vacuum supply (wall suction) must not be used.

4.3 Hose requirements

- The correct extraction hose connection between the ATMOS Extraction Cups and the vacuum source is essential for the safe and proper functioning of the instrument. It is important that the extraction hose is kink-resistant and does not interrupt the vacuum.
- In this case, the pump would indicate a vacuum, but it would not be present at the extraction cup. Therefore, only original ATMOS hoses should be used.

5 Reprocessing

5.1 Safety instructions for reprocessing

5.1.1 General safety instructions

We recommend that you always document all maintenance work and part replacements in writing.

It is the responsibility of the user to ensure that the required results of cleaning and disinfection are achieved. Validation and routine monitoring of the procedure will generally be necessary.

Reprocessing may be carried out only by persons who have the appropriate expertise. To carry out these measures, the person must have the necessary equipment.

5.1.2 Danger for users, patients, and third parties

WARNING

Risk of infection due to unsuitable aids or accessories.

Deadly diseases can be transmitted.

- Always wear your own personal protective equipment. The protective equipment consists of protective gloves, protective clothing, goggles, and mouth and nose protection for all steps in which the product components are still contaminated.
- Use only aids or accessories that can be easily reprocessed or ones that are disposable products.

WARNING

Risk of infection due to unsuitable reprocessing.

Deadly diseases can be transmitted.

- Make sure that all areas of the accessories can be easily reached.
- Use only suitable load carriers for mechanical reprocessing. This especially applies to accessories with cavities and lumens that are hard to reach.

5.1.3 Preventing product damage

NOTICE

Unsuitable aids or accessories.

The product may become damaged.

- Use only lint-free, soft cloths.
- Always use demineralised water for the final rinse.
- Observe the respective operating instructions of all aids and devices used.

NOTICE

Unsuitable cleaning agents and disinfectants.

The product may become damaged.

- Do not use any process chemicals containing the following ingredients **on plastic parts**:
 - Chloramides or phenol derivatives
- Do not use any process chemicals containing the following ingredients **on stainless steel**:
 - Organic or inorganic bases
 - Alkaline solutions

NOTICE

Incorrect mechanical cleaning and disinfection.

Corrosion due to moisture.

- When the programme is finished, remove the products immediately.

5.2 Preparing for and completing reprocessing

5.2.1 Before reprocessing the Extraction cup, malmstroem

Disassemble the product into the following individual parts for reprocessing:

- Extraction cup
- Locking pin
- Cross handle
- Traction chain with base plate
- Extraction hose

Proceed as follows:

Pull the locking pin out of the cross handle and remove the traction chain with the base plate. Pull the extraction hose off of the extraction cup and the cross handle.

5.2.2 Before reprocessing the ATMOS-Cup, extraction cup silicone

Disassemble the product into the following individual parts for reprocessing:


- ATMOS-Cup
- Suction hose

5.2.3 After reprocessing the extraction cups

1. Carry out a visual inspection. Repeat reprocessing if visible contamination remains.
2. Perform a function check prior to the next use.

5.3 Procedure

Replace the extraction cup after each patient and reprocess it.

	Instructions
<p>Warnings</p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p> WARNING</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p>NOTICE</p> </div>	<ul style="list-style-type: none"> • Newly delivered extraction cups are not supplied sterile and must be reprocessed before first use. • Always wear your own personal protective equipment (see chapter '5.1 Safety instructions for reprocessing' on page 14). • The equipment used (washer-disinfectors/sterilisers) must be regularly maintained and validated. • Please observe the information provided by the manufacturers of cleaning agents and disinfectants regarding concentration, contact time, and material compatibility (see chapter '5.1 Safety instructions for reprocessing' on page 14).
	Instructions
<p>Collecting and transporting</p>	<p>Transport used products in a shatter-proof, liquid-tight, and securely sealed container. The container must be easy to clean and suitable for thermal disinfection. To prevent encrustation and corrosion, prompt reprocessing is recommended.</p>
	Instructions
<p>Preparation before cleaning</p>	<p>If present, remove coarse contamination using a soft brush and rinse the extraction cups, including the lumens, with water for at least 60 seconds to prevent drying.</p> <p><u>Disassembly of Extraction cup, malmstroem:</u></p> <ol style="list-style-type: none"> 1. Pull the locking pin out of the cross handle and remove the traction chain with the base plate. 2. Pull the extraction hose off of the extraction cup and the cross handle.

	Instructions
Preparation before cleaning	<p><u>Disassembly of ATMOS-Cup, extraction cup silicone:</u></p> <p>Separate the ATMOS-Cup, extraction cup silicone from the extraction hose for reprocessing.</p>
	Instructions
Mechanical cleaning and disinfection	<p>The following parameters for mechanical cleaning and disinfection have been validated:</p> <ul style="list-style-type: none"> • Secure the product on a suitable load carrier. Position the extraction cups so that the cleaning agent can reach cavities, blind holes, and the suction channel, and can drain again from them. • Clean and disinfect using a suitable programme. <p>Mechanical cleaning:</p> <ul style="list-style-type: none"> • Pre-rinse: 1 min with cold water • Clean: 5 min, 55 °C / 131 °F with neodisher® MediClean forte (0.5% v/v) from Dr. Weigert • Neutralise: 2 min with cold water • Intermediate rinse: 1 min with softened, cold water <p>Mechanical disinfection:</p> <ul style="list-style-type: none"> • Disinfect: 5 min, 93 °C / 199 °F with demineralised water • Dry: 12 min, 110 °C / 230 °F <p>Washer-disinfector: in accordance with EN ISO 15883-1/-2 Programme: Miele Vario TD</p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin-top: 10px;">NOTICE</div> <ul style="list-style-type: none"> ☞ Make sure no visible contamination remains. Repeat reprocessing if necessary.

	Instructions
Sterilisation	<p>Sterilise the cleaned and disinfected extraction cups using a suitable procedure:</p> <ul style="list-style-type: none"> • Validated procedure: steam sterilisation / autoclaving • Pre-fractionated vacuum: 3x • Temperature: 134 °C / 273 °F; Time: 5 min • Dry: 10 min • Steriliser: in accordance with EN 285
	Instructions
Maintenance, checks, and testing	<ul style="list-style-type: none"> • The extraction cups must be checked for proper functioning and cleanliness (see chapter '6 Maintenance and service' on page 20). • Damaged extraction cups must be disposed of. Products that are still dirty must undergo another reprocessing cycle. <p><u>Extraction cup, malmstroem</u></p> <ul style="list-style-type: none"> • When replacing the extraction hose, make sure that the new hose section is 300 mm long.
	Instructions
Storage	<p>Store the extraction cups in a suitable location that provides a dry and dust-free environment and protects them from direct UV radiation.</p>
	Instructions
Service life	<p>The extraction cups have a service life of 60 reprocessing cycles. Once the cycles have been exceeded, the responsibility and liability for the functionality and condition of the extraction cups lie with the operator.</p>

6 Maintenance and service

The products do not require maintenance and periodic tests; a functional test is required.

ATMOS recommends: Use original spare parts to maintain warranty claims.

Before each use, ensure that the product functions safely and is in proper condition:

Extraction cup silicone	Extraction cup, malmstroem
The edge is smooth and undamaged	The extraction cup is not deformed
The material has no cracks	The extraction cup is assembled completely and correctly
	The extraction hose is undamaged and has no cracks

7 Troubleshooting

The product has been subjected to thorough quality control in the factory. However, if a fault should occur, you may be able to resolve it yourself.

Error symptom	Possible cause	Remedy
Not enough power	Leakage in the suction hoses or in the secretion canister lid	Check the secretion canister lid and hose connections for secure fit.

8 Accessories

Accessories	REF
Suction hose, silicone, Ø 6 mm, L = 1.30 m, 1 pc.	000.0013.0
Suction hose, silicone, Ø 6 mm, L = 2 m, 1 pc.	000.0361.0
Suction hose, silicone, Ø 6 mm, L = 1 m (minimum 5 m)	006.0009.0
Extraction hose, green, Ø 6 mm, L = 1.5 m	404.0146.0
Extraction hose, green, Ø 6 mm (minimum 5 m)	006.0010.0

9 Disposal

Packaging

Please recycle the product packaging.

Secretion and blood

Please dispose of contaminated parts in line with country-specific regulations.

In the Federal Republic of Germany, the requirements of the 'Implementation Aid for Disposal of Waste from Healthcare Institutions' apply, a statement issued by the Federal / State Working Group on Waste.

ATMOS Extraction Cups

The product does not contain any hazardous materials.

Clean and disinfect the product.


Dispose of the product professionally and in accordance with country-specific laws and regulations.

9.1 Expected service life

The ATMOS Extraction Cups have an expected service life of 60 reprocessing cycles. Regular thorough cleaning and disinfection of the extraction cups and their applied parts as well as operation of the products according to the operating instructions are assumed.

10 Technical data

10.1 ATMOS-Cup, extraction cup silicone

Product name	ATMOS-Cup, extraction cup silicone
Short description	To support vaginal birth in case of stalled labour, childhood hypoxia or exhaustion of the bearing.
Variants	<ul style="list-style-type: none"> • Ø 50 mm • Ø 60 mm
Special characteristics	<ul style="list-style-type: none"> • Vacuum stability: 0–100 kPa • Pump requirement: > 20 l/min; –90 kPa • Handle and suction cup made in one piece • To be used with a pump and tubing • The cup has a smooth external surface with a small longitudinal ridge to observe any rotation • Maintenance-free
Connection to	Bend-proof suction or extraction hose with ID 6 mm
Material	Medical grade silicone
Colour	<ul style="list-style-type: none"> • Blue – Ø 50 mm • Yellow – Ø 60 mm
Dimensions	240 mm
Weight	120 g
Packaging unit	<ul style="list-style-type: none"> • Extraction cup • Silicone hose Ø 6 mm, 1.5 m
Reuse	The accessories are intended for multiple use.
Reprocessing	<p>The product is shipped non-sterile, but can be autoclaved up to 134 °C.</p> <p>Max. number of reprocessing cycles: 60.</p> <p>For information on reprocessing, cleaning and disinfection, please see chapter '5 Reprocessing' on page 14.</p>
Risk classification (MDR)	Class IIa according to Rule 5
CE marking	

Environmental conditions: Transport/storage	
Temperature range	-10...+60 °C
Air humidity without condensation	30...95 %
Air pressure	700...1000 hPa
Environmental conditions: Operation	
Temperature range	-10...+60 °C
Air humidity without condensation	30...95 %
Air pressure	700...1000 hPa
Reference number (REF)	404.0193.0 ATMOS-Cup, extraction cup silicone, Ø 60 mm 404.0194.0 ATMOS-Cup, extraction cup silicone, Ø 50 mm

10.2 Extraction cup, malmstroem

Product name	Extraction cup, malmstroem
Short description	To support vaginal birth in case of stalled labour, childhood hypoxia or exhaustion of the bearing.
Variants	<ul style="list-style-type: none"> • Ø 40 mm • Ø 50 mm • Ø 60 mm
Special characteristics	<ul style="list-style-type: none"> • Vacuum stability: 0–100 kPa • Pump requirement: > 20 l/min; -90 kPa; intermediate jar 1.5 l • Maintenance-free
Connection to	Bend-proof suction or extraction hose with ID 6 mm
Material	Stainless steel
Dimensions	300 mm between extraction cup and cross handle
Weight	140 g

Packaging unit	1 PU = 1 Extraction cup, malmstroem, consists of: <ul style="list-style-type: none"> • 1x Base plate with chain • 1x Cross handle with • 1x Locking pin • 1x Extraction hose (300 mm)
Reuse	The accessories are intended for multiple use.
Reprocessing	The product is shipped non-sterile, but can be autoclaved up to 134 °C. Max. number of reprocessing cycles: 60. For information on reprocessing, cleaning and disinfection, please see chapter '5 Reprocessing' on page 14.
Risk classification (MDR)	Class IIa according to Rule 5
CE marking	CE 0124
Environmental conditions: Transport/storage	
Temperature range	-10...+60 °C
Air humidity without condensation	10...100 %
Air pressure	710...1060 hPa
Environmental conditions: Operation	
Temperature range	-10...+60 °C
Air humidity without condensation	10...100 %
Air pressure	710...1060 hPa
Reference number (REF)	404.0155.0 Extraction cup, malmstroem, Ø = 40 mm
	404.0156.0 Extraction cup, malmstroem, Ø = 50 mm
	404.0157.0 Extraction cup, malmstroem, Ø = 60 mm

11 Notes



MedizinTechnik

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