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lactina®

electric breastpump

service instructions





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Valid as of October 2008 Lactina is a registered trademark of Medela, Inc.

1. General Description

Medela's Lactina® Select breastpump has been specially developed to meet the most stringent demands where hygiene and mobility are concerned. The operating principle of the Medela Lactina is to simulate the natural, physiological conditions encountered in breastfeeding.

The pump motor and the suction source are completely separate. All components which can come into contact with the milk are part of the accessories and can be very easily disconnected from the drive unit for cleaning or sterilization. The accessory kit can also be used separately as a manual pump.

Lactina Select includes the following general specifications:

- with variable vacuum.
- with variable speed, i.e. the number of suction cycles per minute can be regulated.
- powered by regular electric outlet (120 VAC) or by using the optional Medela Power Pack that provides 12 VDC with its rechargeable battery or the vechicle lighter adapter.

The Lactina breastpump is for indoor use only.

Disposal

This breastpump is made of technical plastics and metals which cannot be separated. It has to be disposed of in accordance with local regulations.

WARNING

- Do not use or sit the pump where it is exposed to direct sunlight or any other source of heat.
- This equipment is not suitable for use in the presence of flammable materials.
- If the power cord is damaged, it has to be replaced by a qualified service person.
- Before taking off the back of the Lactina housing for service purposes, do not forget to switch off the pump and to disconnect the power cord from the main supply.

Warranty

This product is warranted by Medela, Inc., to the original retail purchaser to be free from defects in material and workmanship for the period of three (3) years from the date of purchase. In the event of a defect or failure to conform to this warranty, Medela will, at Medela's option, repair or replace this product without charge for such replacement, on parts or labor. The Purchaser shall bear all responsibility and expense for returning this product to Medela, including risk of loss prior to receipt by Medela, and shipping, packing, and insurance costs.

Medela will have no obligation under this warranty to repair any malfunction or damage arising from any misuse, abuse, or alteration of this product. Without limiting the generality of the foregoing, bending, or dropping of this product or its components, visible cracking of the equipment housing will be presumed to be defects resulting from misuse or abuse. Accessories that are not expressly manufactured by Medela and subsequently attached to the equipment will immediately void this warranty.

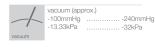
ANY AND ALL IMPLIED WARRANTIES ARE LIMITED TO THE DURATION OF THREE YEARS FROM DATE OF PURCHASE. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO YOU.

THE LIABILITY OF MEDELA FOR BREACH OF ANY WRITTEN OR IMPLIED WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF THIS PRODUCT, AND MEDELA WILL HAVE NO LIABILITY UNDER ANY CIRCUMSTANCES FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS OR EXCLUSIONS MAY NOT APPLY TO YOU.

THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS AND YOU MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

2. Technical Description

2.1.1 Technical Specifications





5.29lbs 2.4Kg



cycles Latina Select

40 - 60 / min.



Operation



100 - 240V 50 / 60 Hz 50VA

Alternating current



Transport/Storage



T 1.25 A / 6.3 x32 / 250 V



Operation



Medela Art Nr. 928.7001 16W T 1.25 A



Transport/Storage







kPa





Must not be disposed of together with household refuse



Protection class II Type B







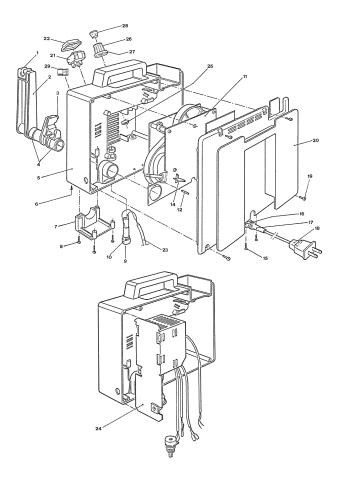


FDA (GMP) ISO 9001 ISO 13485 CE (93/42/EEC)





2.1.2 Spare Parts List

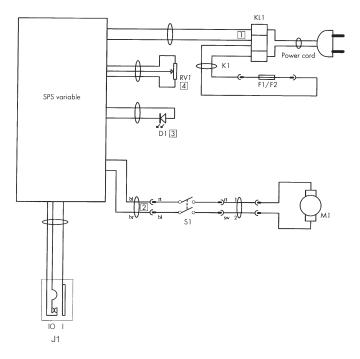


Item	Description	Order #
1.	Rubber clamp	820.0009
2.	Pumping arm, complete	800.0111
3.	Cotter	810.0179
4.	Bearing	810.0153
5.	Case complete variable SPS	800.0244
6.	Elastic buffer	812.0025
7.	Cover insert	810.0113
8.	Fillister head self-tapping screw type 1, 2.9 x 13	426.5002
9.	Fuse T 1.25 A USA	931.0012
10.	Fuse holder complete, USA	900.0382
11.	Gearbox with commutator motor 12 V	600.0923
12.	Bearing pin	599.0028
14.	Spring holder (special tool for fitting)	522.1433
15.	Countersunk self-tapping screw M 2.9 x 6.5	429.0002
16.	Cord clamp	599.0005
17.	Cord sleeve	824.1326
18.	Power cord USA	928.0026
19.	Fillister head screw with cross-slot M4 x 8	411.1001
20.	Back	810.0107
21	Run-Stop rocker switch	934.0159
22.	Protecting cover (transparent)	812.0007
23.	Mains connecting cable	900.0332
24.	SPS variable for 016	901.0034
25.	Spacing piece complete	810.0351
26.	Knob	699.0065
27.	Nut cover with line	699.0064
28.	Cover for knob	699.0066
29.	Green LED lens	942.0009

^{*}Not all items listed above may be available for purchase.

The company reserves the right to change technical specifications and designations and/or order numbers without prior notice.

2.1.3 Electric Circuit Diagram



2.1.4 Dismantling

Important:

Before taking off the back of the Lactina® housing for service purposes, do not forget to switch off the pump and to disconnect the power cord from the mains supply.

Gearbox unit:

- Remove the back (20) after releasing the screws (15 and 19).
- Release power cord with cable tension relief (16 to 18) from the back (20) and gearbox unit (11).
- Turn the gearwheel until the pumping arm (2) is swung in fully.
- Swing out the pumping arm (2) fully by hand.
- Lock the return spring by inserting the spring holder (14) obtainable from Medela in the slot provided for this purpose (see exploded view diagram).
- Swing in pumping arm (2).
- Withdraw bearing pin (12).
- Swing out pumping arm (2) again fully.
- Detach electrical connections on right-hand side from main terminal and withdraw.
- Remove gearbox unit (11).

Electronics:

- Remove gearbox (11) as described above.
- Compress retainer of switch case and press out switch (21) from inside to outside.
- Remove SPS red + blue connections from switch (21).
- Disconnect motor leads from switch (21).
- Withdraw LED (D1) (fuse holder 9/10 + 23 is also preferably dismantled beforehand).
- Detach SPS cable (24) from its holders.
- Remove cover (28) from knob (26 + 27).
- Release screw in knob (26 + 27) and remove knob.
- Release nut under knob (26 + 27) and draw off potentiometer inwards.
- Swing in pumping arm (2) fully.
- Hold pump case (5) by handle and withdraw SPS (24) with other hand

Pump arm:

- Remove gearbox (11), preferably also SPS (24) according to description above.
- Dismantle cover insert (7) after releasing the screws (8).

2.1.5 Assembly

Assembly is performed in the reverse sequence to dismantling. The following points should also be noted:

- Sequence of cable routing from top to bottom: mains lead from SPS, potentiometer (RV1), switch, LED (D1).
- The SPS must be placed right at the rear of the case and the cables must be pressed fully into their holders.
- Insert potentiometer (RV1) in spacing piece (25) in positioning pin from inside to outside. The potentiometer must lie flat on the spacing piece. Place nuts on from outside and tighten.
- Turn potentiometer clockwise to stop, fit knob (26 + 27) and turn clockwise until line is at 7. Tighten screw.
- Before fitting the back check whether the internal parts of the pumping arm (2) do not touch anywhere.
- Connections on right-hand side of mains terminal strip (KL1) from top to bottom: Power cord no. 1, power cord no. 2 and SPS brown, SPS blue.
- Connections on left-hand side of mains terminal strip from top to bottom: black, blank, white.
- Fitting of the cover insert (7) is simplified if the pumping arm (2) is not swung in completely, but only set to the final position together with the cover insert (7).

Breastpump Systems

Breastmilk Initiation System for Symphony or Lactina	67340S
Symphony / Lactina	67116 67116-06 67116S 67340S
Lactina	67094 67094-06 67094S
Symphony / Lactina Rental Kit	67206-03

2.1.6 Final Test Procedure

a) General checks

- 100% check (visual) of type designation, serial no., DC plate 12 V and labeling on back.
- 100% check with respect to air gap between swivel arm and case with leaf gauge. Permissible air gap 0.2–1.5 mm; if the air gap is outside this range reject unit and replace.
- 100% check with respect to gap between case and back, permissible gap 0.8 mm.
 If gap > 0.8 mm, the back must be adjusted or replaced.
- 100% check high voltage test.
 Test points: 4 screw heads on back
 2 screw heads case floor
- 100% check rubber protection to switch for tightness.
- 100% check tightness of rotary knob with cover.

b) Running test A 100% check

Allow unit to run for 4 hours without cylinder. Set on position 4 (standard). LED must light.

c) Running test B 100% check

Check for running noise:

Functional check:

- Mains plug inserted (SPS active)
 - Switch at "RUN" unit runs and LED lights
 - · Switch at "STOP" LED lights, unit stationary
- DC inserted (12 V) (SPS not active)
 - · Switch at "RUN" unit runs, LED does not light
 - Switch at "STOP" LED does not light, unit stationary

Uses

- To initiate and maintain a milk supply as well as collect breastmilk at work or during other absences from the baby.
- To initiate and maintain a milk supply if direct breastfeeding is not possible.
- To relieve engorgement. Single pumping with simultaneous massage is helpful to relieve engorgement.

Cleaning and Sterilization

Unless instructed otherwise by your healthcare provider.

IMPORTANT

This product's kit is a single-user item unless properly sterilized between users. Use by more than one user without adequate sterilization may pose a health risk and voids the warranty.

Hygiene

Wash hands before touching breasts or containers, and avoid touching the inside of containers or lids.



Preparation

Follow these cleaning instructions unless you are told otherwise by your healthcare professional. Prior to cleaning, take apart all parts of your breastpump accessory kit. Be especially sure to remove the yellow valve from the breastshield and separate the white membrane from the valve prior to cleaning.

Prior To First Use

The Lactina® sanitized or sterilized kit versions do not require washing before first use.

To Sterilize in the Hospital:

All disassembled parts can be autoclaved to a maximum of 272° F for 3 minutes at 29 PSIG or 250° F for 15-20 minutes at 15 PSIG.

To avoid damage during and immediately after sterilization:

- Sterilize parts without applying external pressure to them.
- Allow parts to cool before applying external pressure.

If gas sterilization is used, residual testing is recommended to determine the proper length of aeration.

To Sanitize at Home:

Disassemble and sanitize by boiling for 10 minutes.

After each use:

- Disassemble and wash all parts that come in contact with the breast and milk in warm soapy water.
- · Rinse in clear water.
- Air-dry on clean towel and cover parts when not in use.

All parts may also be washed in top rack of dishwasher.

For Quicker Cleaning:

Medela offers Quick Clean™ Micro-Steam™ bags for daily kit disinfection.

Tubing Care:

Inspect tubing after each pumping session for condensation and/or or milk.

If condensation appears in tubing:

To eliminate condensation after you have completed pumping, continue running the pump with the tubing(s) attached for another 1-2 minutes or until dry, while you attend to storing your pumped breastmilk.

If milk appears in tubing:

- 1. Turn off the pump and unplug from power source.
- Remove and disassemble the tubing and kit parts. Wash in soapy water then rinse in cold clear water.
- 3. Shake water droplets out and hang to air-dry. For faster drying, attach tubings to pump and run pump 1-2 minutes or until dry, or pour a small amount of isopropyl alcohol through the tubings to dry.
- Make sure that valve membranes are undamaged and clean. Replace if necessary.
- 5. Use a damp cloth to wipe the pump. Do not immerse the pump in water.
- When components are completely dry, reassemble breastpump and kit.

4. Precautionary Measures / Troubleshooting

The breastpump should only be used in a dust-free environment. Do not use or set the pump where it is exposed to direct sunlight or any other source of heat.

What to do when...

- the pump does not run when it is switched on:

Check whether the Lactina® breastpump is properly connected to the electric supply. Check the fuse. Be sure that the pump is plugged in.

- pump action is too weak:

Suction strength can be adjusted using the vacuum regulator. Maximum suction is achieved by setting the pointer on the regulator ring to MAX. If suction strength is still inadequate at this setting, please check whether:

- the vacuum regulator ring has been turned beyond the stop, has been displaced, is no longer a close fit or is dirty on the inside.
- the rubber seal of the piston is seating correctly and is in good condition.
- the valve has been correctly fitted to the breastshield. Is the valve membrane clean and closing properly when in resting position?
- the cylinder has been screwed tightly into the cylinder holder (or into the breastshield in the case of manual operation).
- there is no leak in the tube connection between cylinder holder and breastshield
- the breastshield fits closely to the breast.

- the vacuum cannot be regulated:

The two holes in the cylinder under the vacuum regulator ring may be blocked with dirt. Clean them using a brush and soapy water. The points listed above should also be checked.

- the vacuum is not released at the end of the suction stroke: The ventilation hole at the bottom of the cylinder may be blocked.

The ventilation hole at the bottom of the cylinder may be blocked with dirt; or the piston has not been drawn right to the end during manual operation.

- the piston does not return after the suction phase:

Check whether the suction circuit is blocked or whether there is a kink in the tubing.

5. Adjusting Vacuum

The Lactina® Select features a knob to adjust the pumping speed. Choose a fast pumping rhythm to start your milk flowing (setting 7 corresponds to highest speed level). Once your milk starts to flow or you sense milk ejection you may adjust the rhythm by decreasing speed slightly (e.g. setting 4).





To adjust vacuum set the vacuum regulator to minimum and start pumping. Adjust the vacuum to your Maximum Comfort Vacuum™. This is the highest vacuum you can use and still feel comfortable (different for every mother). To find your Maximum Comfort Vacuum increase vacuum until pumping feels slightly uncomfortable (not painful), then decrease.

6. Service Information

Important:

Before starting the procedure described below, do not forget to switch off the pump and to disconnect the power cord from the main supply!

The design of your Medela Lactina breastpump means that routine servicing is not normally uneccessary. All bearings are maintenance-free and, when used as directed (i.e. only in a dust-free environment and in the normal operating position), there is almost no dirt entering the drive unit. Cleaning the outside of the pump is the only care needed, particularly around the pivot arm and the guide slot for the cylinder holder.

To ensure that the breastpump will provide trouble-free operation for years to come, it should be examined periodically according to the following checklist.

Checklist:

- The specification of the fuse employed as well as the power supply to which the pump is connected must match the data on the pump specification plate.
- Fit the accessories to the breastpump as described in the instructions for use (included with the accessory kit). The breastshield should then be connected to a vacuum gauge.
- 3. Connect the power cord to the main supply and switch on the unit. The pivot arm must operate with a pumping motion.
- 4. The following values must be attained: Suction rate: Lactina Select

approx. 40–60 cycles/min., mains approx. 50 cycles/min.,

battery

Suction strength at MAX setting:

Location sea level	0 m above sea level	500 m above sea level	1000 m above sea level	2000 m above
Factor	1.00	0.94	0.88	0.78
Lactina Select (+/- 20 mmHg)	255 mmHg	240 mmHg	225 mmHg	199 mmHg

6. Safety Tests

The following safety tests should be performed yearly:

1. Visual check

The breastpump should be examined for damage and dirt on the inside and outside and repaired or cleaned if necessary.

2. Functional test

Every function of the breastpump must be controlled according to the Instructions for Use and Service Instructions.

3. Electrical tests

 Enclosure leakage current: This test should be performed under normal conditions and under the conditions of Single Fault.
 Conditions of Single Fault: The interruption of each supply conductor one at a time.

- · Patient leakage current.
- The dialectric strength between live parts and the housing. This
 insulation shall be double insulation.

The allowable values are defined according to the chart below:

Test		Allowable Value		Chapter IEC 601-1
Enclosure leakage current		NC 0,1 mA	SFC 0,5 mA	19.1 19.2 19.3
Patient leakage current	DC AC	NC 0,1 mA NC	SFC 0,5 mA SFC	19.1 19.2 19.3
		0,1 mA	0,5 mA	19.4
Dialectric Strength	50 <u td="" ≤150v<=""><td colspan="2">3000V (double insulation)</td><td>20.1 20.3</td></u>	3000V (double insulation)		20.1 20.3
150 <u (double="" 4000v="" insulation<="" td="" ≤250v=""><td></td><td>20.4</td></u>			20.4	

NC: Normal Condition
SFC: Single Fault Condition
U: Reference voltage

7. Terms of Guarantee

Medela guarantees the perfect quality and finish of each Lactina® breastpump for a period of 3 years from the factory delivery date. During this period, all faulty components will be replaced free of charge. This guarantee does not extend to components which are subject to wear and tear or which have been damaged due to incorrect use.

Further conditions according to International Standard IEC 601.1, Item 6.8.2b:

The manufacturer may only be held responsible for inadequate safety, reliability and performance of the unit if

- assembly
- additional items
- adjustments
- alterations or repairs

have been carried out by persons authorized by the manufacturer and

- the electrical installation within the room concerned satisfies IEC requirements (in the course of preparation).
- the unit is used as specified in the instructions for use.
- accessory kits used on Lactina breastpumps are authorized by Medela, Inc.