

PROMILL™ T50B USER MANUAL





Instruction manual must be read prior to operating the MEDISCA ProMill™ T50B.

For use in prescription pharmacy compounding only, in accordance with applicable law. MEDISCA makes no warranty or representation regarding the use of this product or fitness for any particular purpose, and any such use is entirely the responsibility of the pharmacist in the exercise of his / her professional expertise and judgment. Accordingly, in no event will MEDISCA be liable for any damages from the use or misuse of the product. Purchaser's sole remedy in the event of product defect or other damages shall be the refund of the purchase price of the product. Product may vary from actual image.

This manual is intended for use by qualified compounding personnel engaged in the service, inspection, maintenance and handling of the equipment.

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THANK YOU for choosing MEDISCA as your three roll mill supplier. This manual provides detailed information on how to operate, maintain, and troubleshoot your three roll mill.

Contact MEDISCA for further assistance on the operation and maintenance of your machine, or if you have any comments on the content of this manual. Our primary concern is to satisfy the needs of our customers and your feedback is of great value to us.

CONTACT INFORMATION:



Canada Toll-Free: 1.800.665.6334
USA Toll-Free: 1.800.932.1039
International: (+1) 514.333.7811
Website: www.medisca.com

1.0 SAFETY INFORMATION

WARNING

Your safety and the safety of others are very important. Before operating this machine, please read and obey the following safety messages to reduce the risk of damage and personal injury.

1.1 Safety Symbols

SYMBOL	NAME	DESCRIPTION
⚠ DANGER	DANGER	You can be killed or seriously injured if you don't immediately follow instruction.
! WARNING	WARNING	You can be killed or seriously injured if you don't follow instructions.
	PINCH POINT HAZARD	Pinch point Keep clear including (but not limit to) hands, clothing, hair, jewelries, etc.
	GROUND	Grounding connection.

1.2 Important Safeguards

- **1.** Read all instructions.
- 2. To avoid risk of electrical shock, do not power on MEDISCA ProMill™ when water or other liquids leak or spill.
- **3.** Keep the MEDISCA ProMill™ away from children.
- **4.** Unplug the MEDISCA ProMill™ from outlet when not in use, before putting on or taking off parts, and before maintenance.
- **5.** Keep hands, hair, and clothing, as well as spatulas away from the rollers during operation to reduce the risk of injury to persons and / or damage to the MEDISCA ProMill™.
- **6.** Any type of jewelries or accessories and alike should not be worn during operation.
- 7. Do not operate the MEDISCA ProMill™ after malfunctions. If the MEDISCA ProMill™ needs repair, please contact MEDISCA.
- **8.** Do not use the MEDISCA ProMill™ outdoors.
- **9.** Do not move the MEDISCA ProMill™ during operation.
- **10.** The ProMill must have a minimum clearance of 15 cm on all sides during operation to facilitate unplugging the mill from the power supply in case of emergency.
- **11.** Use the hex key to calibrate the roller gap ONLY when needed.
- **12.** Do not dismantle the MEDISCA ProMill™. Opening the casing can expose you to high voltage and will void all warranties. Incorrect reassembly will cause danger to the ensuing operation.
- **13.** Use and comply with the chemicals safety data sheet (SDS) at all times while operating the MEDISCA ProMill™.



1.3 Electrical Requirements



Electrical Shock Hazard.

Plug into a grounded 3-prong outlet.

Do not remove ground prong.

Do not use an adapter.

Only use a 3-prong extension cord.

Failure to follow these instructions immediately can result in machine malfunction, fire, electrical shock injury, or death.

Volts: 110 VAC / 220 VAC (specified on the name plate, located on reverse side of MEDISCA ProMill™)

Hertz: 60 Hz / 50 Hz (specified on the name plate, located on reverse side of MEDISCA ProMill™)

SAVE THESE INSTRUCTIONS. THIS PRODUCT IS DESIGNED FOR LAB USE ONLY.



- The U.S. OSHA and Canadian SCC requires electrical equipment to be certified.
- TUV SUD is a testing laboratory recognised by OSHA and SCC.
- TUV SUD tested and certified the ProMill as per the required safety standards IEC 61010-1- Part 1 & IEC 61010-2-051- Part 2

2.0 INTRODUCTION

2.1 Mill Description

A three roll mill is a machine that uses shear force created by three horizontally fixed rollers, rotating in different directions and at different speeds. This force is used to refine, disperse, or homogenize a variety of products, ranging from light creams to dense viscous ointments. These machines are widely used in pharmaceuticals, electronics, ceramics, cosmetics, nanomaterials, carbon / graphite, paints, printing inks, chemicals, glass coatings, dental composites, pigments, coatings, adhesives, sealants, and food products.

This state of the art designed and TÜV Certified MEDISCA ProMill™ features high volume throughput, a digital control panel with variable speed control and counter time capabilities, and self-calibrating gap distances. The MEDISCA ProMill™ comes equipped with safety features such as an emergency stop and engine overload protection. Its compact size makes it ideal for laboratories where device footprint is limited.

The MEDISCA ProMill™ offers high throughput, up to 11 liters per hour. This high level of output rate combined with the large hopper of 1.75 L will enable you to process more material. Note that this output rate will vary depending on the material being milled, roller speed, and gap distances. The rollers top speed is 690 RPMs, which is controlled by a variable frequency drive and push button display, for seamless ease-of-use to run at any desired speed. The control panel also includes count-up and count-down timers, as well as roller reverse.

The unique gap calibration allows users to manually calibrate the gaps of the rollers should any misalignment occur. This saves users from having to buy a brand new machine or send the machine in for maintenance. Gap calibration requires no special training and tools required for calibration are supplied with each MEDISCA ProMill™.

The MEDISCA ProMill™ is equipped with the MEDISCA ProMill™ Cleaning Tool to facilitate your cleaning operation. This first of a kind, patent pending cleaning device will expedite and simplify your cleaning. Microfiber cloth can easily be replaced.



2.2 Technical Specifications

MILL SPECIFICATIONS				
DIMENSIONS : W x D x H (in / mm)	14.2 x 7.5 x 9.5 / 360 x 190 x 240			
WEIGHT (lb / kg)	46 / 21			
ELECTRICAL REQUIREMENTS	115 / 230 V, 60 / 50 Hz (Check Name Plate on Rear of Unit)			
MAX OUTPUT (L / h)	7.5 – 11.4 *			
MOTOR POWER (hp/W)	0.13 / 100			
MILL POWER RATING	3 A / 115 VAC = 345 W 1.7 A / 230 VAC = 391 W			
GAP MARKINGS	0 – 9			
GAP INCREMENT (microns)	9			
GAP RANGE (microns)	81			
GAP SIZING, MINIMUM (microns)	10 – 91 (factory shipped)			
GAP SIZING, MAXIMUM (microns)	400 – 481 (using self-calibration)			
ROLLER DIAMETER (in / mm)	2 / 50			
ROLLER LENGTH (in / mm)	8 / 203			
ROLLER SPEED RATIO (Front : Center : Rear)	3.3:1.8:1			
ROLLER MAXIMUM SPEED (rpm)	690			
ROLLER MATERIAL	Aluminum oxide			
RAW HOPPER VOLUME (L)	1.75			
APRON PLATE MATERIAL	Polypropylene			
HOPPER MATERIAL	ABS			
EXTERNAL MATERIAL	2-Part Epoxy Protective Coating			
ROLLER COOLING / HEATING	No			
FUSE RATING	8 A			
BREAKING CAPACITY	80 A @ 250 VAC			

RECOMMENDED OPERATING ENVIRONMENT			
WORKING TEMPERATURE	0~+40°C		
WORKING HUMIDITY	20 ~ 85 % RH non-condensing		
STORAGE TEMPERATURE	-25 ~ +70 °C short period		
STORAGE HUMIDITY	10~95 % RH		
ALTITUDE	Up to 2000 m above sea level		
ATMOSPHERE	No corrosive gases or dust. Cannot be used in a radioactive area, magnetic field, vacuum or other special environment.		

^{*} Actual capacity will depend on viscosity / thickness of substance being milled. Published values are for MEDISCA HRT Cream Base at factory shipped gap calibration.

2.0 INTRODUCTION

2.3 Parts and Features

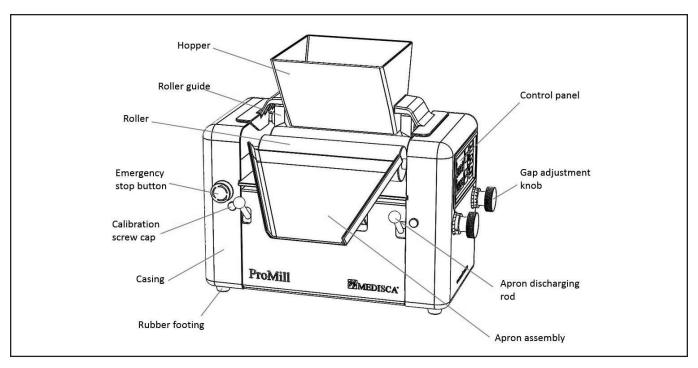


FIGURE 1: MEDISCA ProMill™ Overview

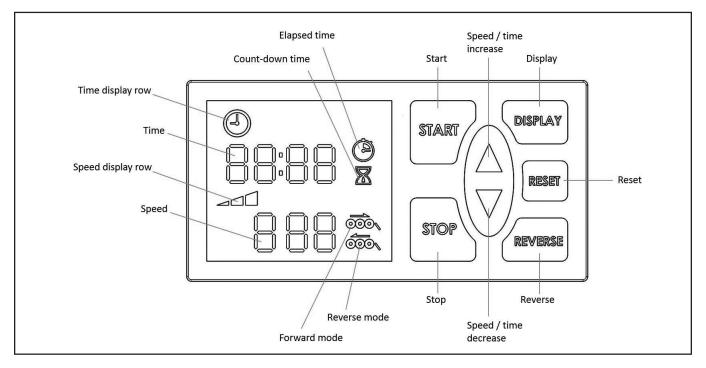


FIGURE 2: Control Panel

2.3.1 Splash Tray

Slide the splash tray through the slots before the apron is installed. Slots are located on the front face of the MEDISCA ProMill™. Note that the splash tray can be installed in only one direction and orientation.

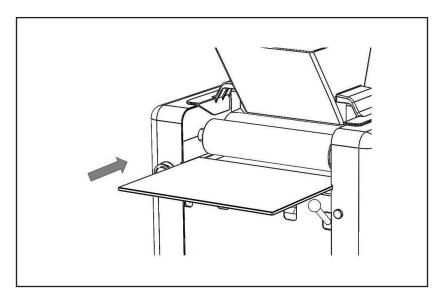


FIGURE 3: Inserting Splash Tray

2.3.2 Roller Guides

- **1.** Do not install roller guides while the mill is in operation.
- 2. Place the roller guides in-between the center and back rollers. (A)
- 3. Slide the rod of the roller guide into the opposing hollow pipe. Repeat for the second roller guide. (B)
- 4. Different effective milling areas can be specified using the three incremented grooves. (C)

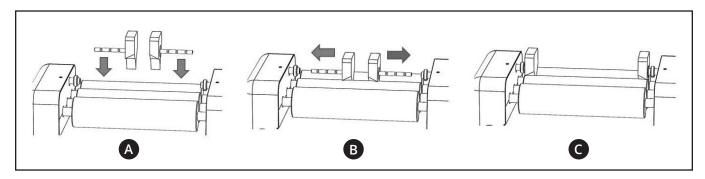


FIGURE 4: Inserting Roller Guides

2.0 INTRODUCTION

2.3.3 Apron

- **1.** Do not install apron while mill is in operation.
- 2. Push down the discharge rods. (A)
- 3. Hook the apron legs to the pins. (B)
- 4. Release the discharging rods. (C)

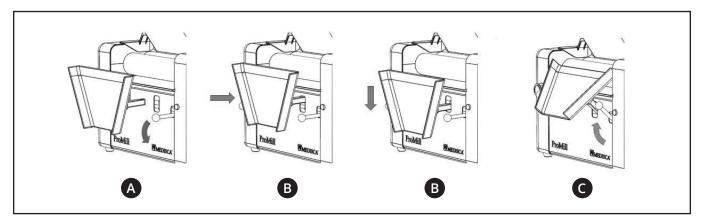


FIGURE 5: Installing the Apron

2.3.4 Hopper

Place the hopper on top of the mill. Make sure the hopper legs fit into the anchoring slots.

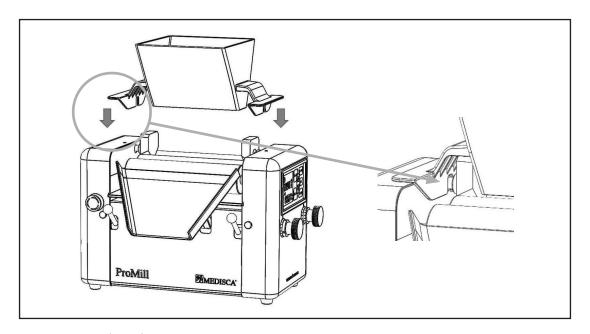


FIGURE 6: Attaching the Hopper

3.0 USING YOUR MEDISCA PROMILL™



Injury Hazard.

Unplug the mill before touching the rollers.

3.1 Handling of Mill

Mill transportation must be in original crate with packaging materials. When removing the mill from the crate, ensure all accessories and parts are off the unit. When lifting the mill use two or more people. Grip the mill by the bottom left and right panels of the enclosure and lift. Avoid pulling or lifting the mill from the rollers as this may damage the unit.

3.2 Roller Gap Distances

Do not adjust the gaps while the mill is running.

Gap size is adjusted by turning the gap adjustment knobs from 0 to 9. At 0 the gap is at its minimum, while at 9 the gap is at its maximum.

Ensure the rear gap setting is equal to or larger than the front gap. The rear gap is to be no greater than 3 increments higher than the front gap setting.

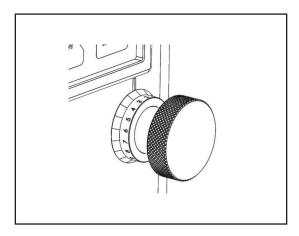


FIGURE 7: Gap Adjustment Knob

3.0 USING YOUR MEDISCA PROMILL™

3.3 Forward with Count-up Timer

Refer to FIGURE 2 when following the instructions below.

- **1.** By default, the MEDISCA ProMill™ will run in count-up mode. Should the mill be in count-down mode, press "DISPLAY" to switch to count-up mode.
- **2.** Press "START" to run the MEDISCA ProMill™ in forward direction.
- **3.** Count-up timer begins automatically.
- 4. Press "SPEED / TIME INCREASE" or "SPEED / TIME DECREASE" to increase or decrease speed.
- **5.** Press "STOP" to stop the MEDISCA ProMill™.
- **6.** To reset count-up timer to zero, press "RESET" button.

NOTE: The MEDISCA ProMill™ will stop once the timer has reached the maximum count up time of 99 minutes and 60 seconds. In order to resume the milling operation reset the count up time and press start.

3.4 Forward with Count-down Timer

Refer to FIGURE 2 when following the instructions below.

- **1.** Press "DISPLAY" to switch to count-down mode.
- 2. Press and hold "RESET" to highlight seconds. Press "SPEED / TIME INCREASE" or "SPEED / TIME DECREASE" to increment / decrement seconds. Press "DISPLAY" to lock-in seconds. Minutes now blink and are ready for selection. Press "SPEED / TIME INCREASE" or "SPEED / TIME DECREASE" to increment / decrement minutes. Press "DISPLAY" to lock-in minutes. Count-down timer is now set and ready for use.
- **3.** Press "START" to run the MEDISCA ProMill™ in forward direction.
- **4.** Count-down timer begins.
- 5. Press "SPEED / TIME INCREASE" or "SPEED / TIME DECREASE" to increase or decrease speed.
- **6.** Press "STOP" to stop the MEDISCA ProMill™.
- **7.** To reset count-down timer to set value, press "RESET" button.
- 8. When end of timer is reached, an audible beep is made and the MEDISCA ProMill™ stops automatically.

3.5 Dislodging Foreign Objects From the Mill

The reverse function is intended to dislodge foreign objects, such as paper towel or alcohol wipes, that may have gotten stuck between the rollers. At any time during operation, press and hold "REVERSE". Rollers will stop then run in reverse at a constant speed of 30, until finger is removed from "REVERSE" button. Once finger is removed from "REVERSE" rollers stop. Once the foreign object is dislodged and the mill stopped, turn the Mill back on by pressing "START".



3.0 USING YOUR MEDISCA PROMILL™

3.6 Tips for Successful Milling

- 1. Use mortar and pestle before milling.
- 2. Do not use the MEDISCA ProMill™ to crush large solids such as pellets, tablets, pills, etc.
- **3.** Select appropriate roller gaps: Rear gap should be equal to or larger than the front gap. The rear gap should be no greater than 3 increments higher than the front gap setting.
- **4.** Load cream preparation between the middle and back rollers or in hopper.
- 5. If needed, begin milling at lower speeds to establish optimal gap settings.
- **6.** Most cream preparations can be milled at speeds between 60 to 100.
- **7.** For very sticky / tacky preparations, or large particle size it is recommend to have a pre-mill run with wider gap settings before reducing the gap size.
- 8. Never adjust the gaps and do not release the apron while the mill is running.

3.7 Modification to the Mill

Under no circumstances shall the MEDISCA ProMill™ components, accessories or parts be modified or altered from its original intended use.

3.8 Using the Mill with Flammable Liquids

The user must read the flammable liquid safety data sheet (SDS) prior to using them with the MEDISCA ProMill™. The user must ensure a fire extinguisher is present near the MEDISCA ProMill™ at all time during the operation of the MEDISCA ProMill™. The MEDISCA ProMill™ must not be unattended during the usage of flammable liquids.

4.0 CLEANING AND CARE

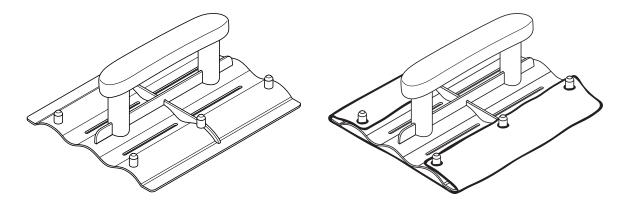
4.1 Cleaning Manually

- Stop and unplug the mill.
- 2. Remove and clean the hopper, apron, roller guides, and splash tray separately.
- Wipe the rollers with towel until clean. If needed, apply isopropyl alcohol on the roller surface to help remove agglomerates and disinfect.

4.2 Cleaning with MEDISCA ProMill™ Cleaning Tool

- 1. Do not unplug the mill.
- Remove the hopper. 2.
- 3. Set front and rear roller gaps to 0.
- 4. Start the mill at a speed of 50.
- With the apron, roller guides, and splash tray installed, slowly pour 100 mL soapy water into the rear gap while 5. the mill is running forward. This will help wash off most of the excess cream / ointment on the rollers.
- 6. Stop the mill and remove the apron and roller guides.
- 7. Set front and rear roller gaps to 9.
- 8. Install micro-fiber on cleaning tool by affixing the holes on the fiber into the respective pegs on the cleaning tool.
- Place cleaning tool on rollers and dampen micro-fiber by pouring isopropyl alcohol into the four access port 9. located in the valleys of the cleaning tool.
- 10. Run the mill at speed 1, while holding the cleaning tool in place. If needed pour additional isopropyl alcohol through access ports while mill is running and cleaning tool is in place.
- 11. After approximately 1 minute, stop the mill, lift up the tool and access cleanliness. If additional cleaning is required, repeat steps 8 – 9.

NOTE: Always make sure the apron, roller guides, splash tray, and rollers are in good condition, and no spillage occur before the cleaning. If spillage of soap water is observed, stop adding soap water and stop the mill immediately. Unplug the mill. Clean and dry surfaces thoroughly.



MEDISCA ProMill™ Cleaning Tool: Patent Pending

4.3 Roller Calibration

- **1.** Ensure the machine is powered off and unplugged from the power socket.
- **2.** Turn both gap adjustment knobs to 6.
- 3. Use the supplied feeler gauge to swipe the 60 micron (0.06 mm) blade through the full length of the front gap. The roller gap should allow the 60 micron (0.06 mm) blade to pass, but stop the 70 micron (0.07 mm) blade from swiping through. If 60 microns (0.06 mm) does not pass you will need to increase the gap. If 70 microns (0.07 mm) pass you need to decrease the gap.
- **4.** Use the hex key provided to calibrate the roller gap setting. There are two holes covered by white screw caps on either side of the casing, front and rear, where you can insert the hex key (see figure 8). The two holes at the front of the mill are for calibrating the front gap (see figure 9 and 10), and the two holes at the rear of the mill are for calibrating the rear gap. Remove the screw caps with a screw driver. Turning the hex key clockwise will widen the gap. Turning the hex key counter-clockwise will narrow the gap (see figure 11 and 12).
- **5.** Repeat steps 3 and 4 for the rear gap. When the 60 micron (0.06 mm) blade can be swiped through the rear gap from one end to the other without stopping, and the 70 micron (0.07 mm) blade does not, the gap is calibrated.
- **6.** For validation, turn both gap adjustment knobs to 2. Ensure that the 20 micron (0.02 mm) blade can be swiped through the front and rear gaps from end to end, and that the 30 micron (0.03 mm) blade does not.
- 7. Perform a test run to ensure that the rollers are not touching. Turn both gap adjustment knobs to 0 and run at maximum speed. If any unusual noise is heard, the rollers are likely touching, and the calibration procedure needs to be repeated. If mill functions normally, it is calibrated and ready for use.

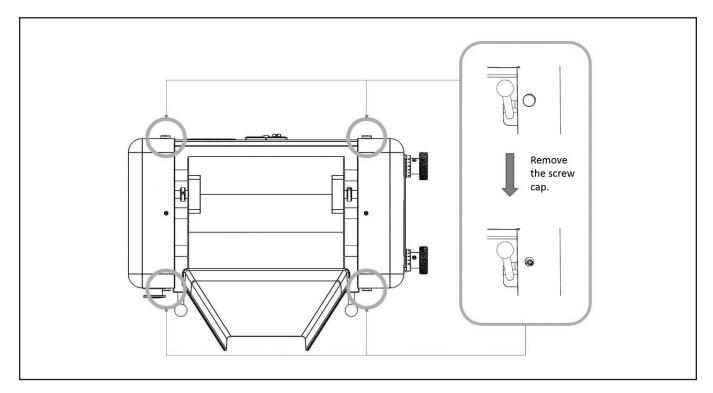


FIGURE 8: Removing the Screw Caps for Calibration

4.0 CLEANING AND CARE

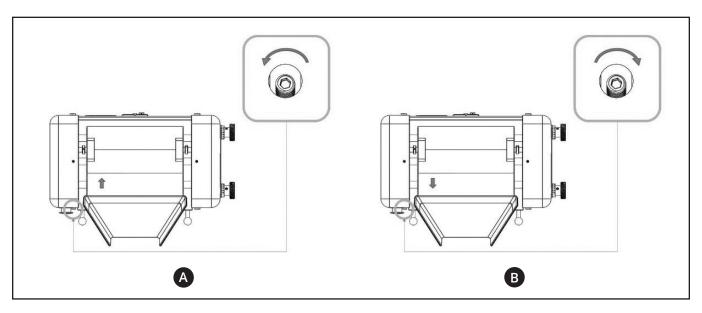


FIGURE 9: Left Front Gap Calibration.

- A) Decrease gap size
- B) Increase gap size

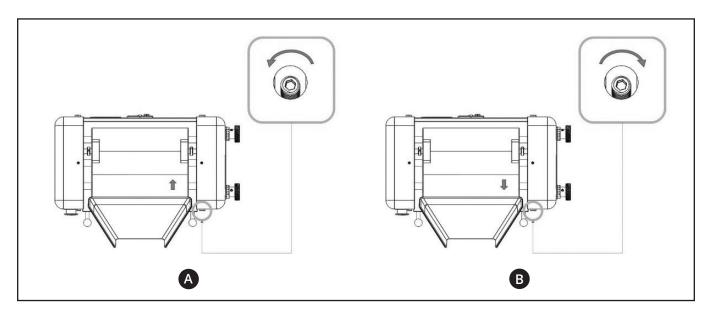


FIGURE 10: Right Front Gap Calibration.

A) Decrease gap size

B) Increase gap size

4.0 CLEANING AND CARE

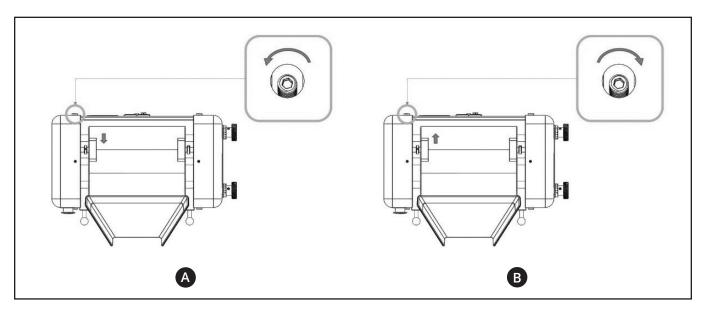


FIGURE 11: Left Rear Gap Calibration.

- A) Decrease gap size
- B) Increase gap size

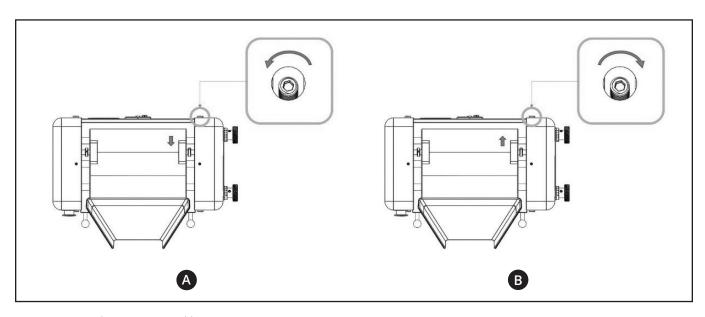


FIGURE 12: Right Rear Gap Calibration.

- A) Decrease gap size
- B) Increase gap size

5.0 TROUBLESHOOTING

Please read the following before calling your service center.

WHY DOES THE MEDISCA PROMILL™ NOT TURN ON?

Check that the emergency stop button is not depressed, and release if necessary by twisting button clockwise. If this does not work, check the power supply fuse located under the socket on the rear of the machine. Ensure that the mill is powered off and unplugged before doing so.

2. WHY IS THE CREAM / OINTMENT LEAKING?

- A) Verify if the apron blade is providing sufficient contact to the front roller. If there is any gap, remove and reinsert the apron.
- B) Inspect the contact between the roller guides and the rollers. If the cream / ointment keeps moving towards one end, swap the two roller guides.
- C) Load less cream / ointment for each run.
- **D)** Ensure the front and the back rollers are calibrated. Refer to section 4.3, "ROLLER CALIBRATION" for procedure.

3. WHY IS THE CREAM / OINTMENT MOVING OUTWARDS TO THE SIDES OF THE ROLLERS?

Ensure the rear gap setting is equal to or larger than the front gap. The rear gap is to be no greater than 3 increments higher than the front gap setting.

4. WHAT IF AN OBJECT GETS JAMMED INTO THE ROLLER GAP?

Adjust the rollers gaps to maximum. Press and hold the REVERSE button. Gently pull out the obstruction.



A. STANDARD EQUIPMENT WARRANTY

MEDISCA warrants that its equipment will be free of any defect in materials or workmanship for the period of (1) year. Warranty begins from the date of installation by end user. The warranty is extended to customers and applies to all customers who purchased, installed, and used the equipment for the purpose for which was originally designed.

B. WARRANTY CLAIMS

During the applicable Standard Equipment Warranty Period outlined above, customers exclusive remedy for any breach of the Standard Equipment Warranty will be, at MEDISCA's sole discretion and option, the repair or replacement of the defective product. To be entitled to rights under the Standard Equipment Warranty, the customer must notify MEDISCA in writing within ten (10) days after discovering a suspected defect in the equipment or parts thereof, but in any event prior to the expiration of the applicable Standard Equipment Warranty Period. Following its receipt of any such customer notice, MEDISCA will determine whether the reported problem is covered by this Standard Equipment Warranty. If MEDISCA determines that the problem is covered, MEDISCA will authorize repair or replacement of the equipment or parts thereof, as deemed appropriate by MEDISCA in its sole discretion. Unless otherwise specified by MEDISCA in writing, repaired or replaced equipment (or parts thereof) are covered only for the remainder of the term of the applicable Standard Equipment Warranty. Once a return has been approved by MEDISCA for repair or replacement of the equipment or parts thereof, MEDISCA shall assume the transportations costs.

C. EQUIPMENT WARRANTY EXCLUSIONS

The above warranties cover only defects arising under normal use and do not include malfunctions or failures resulting from misuse, abuse, neglect, alteration, problems with electrical power, usage not in accordance with instructions, acts of nature, or improper installation or repairs made by anyone other than MEDISCA or an authorized third-party service provider. MEDISCA does not warrant or guarantee, and is not responsible for (i) defects, failures, damages or performance limitations caused in whole or in part by (A) power failures, surges, fires, floods, snow, ice, lightning, excessive heat or cold, highly corrosive environments, accidents, actions of third parties, or other events outside of MEDISCA's control, or (B) customers abuse, mishandling, misuse, negligence, improper storage, servicing or operation, or unauthorized attempts to repair or alter the equipment in any way. Alterations and / or Modifications to any part of MEDISCA's product, without MEDISCA's written authorization unconditionally VOIDS the MEDISCA Standard Warranty.

D. EQUIPMENT WARRANTY EXCLUSIONS

EXCEPT AS EXPRESSLY PROVIDED IN THIS STANDARD WARRANTY AND TO THE MAXIMUM EXTENT PERMITTED BY LAW, MEDISCA HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS, CONDITIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING BY WAY OF EXAMPLE AND NOT LIMITATION, THE IMPLIED WARRANTIES OF TITLE, MERCHANTABILITY, NONINFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL MEDISCA BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES WHATSOEVER, INCLUDING LOSS OF PROFITS, WHETHER ARISING IN CONTRACT, TORT, WARRANTY OR OTHERWISE, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH HERE WILL APPLY EVEN IF THE REMEDIES OF ERROR CORRECTION, REPAIR OR REPLACEMENT, REPERFORMANCE OF SERVICES AND REFUND OF PAYMENTS COMPLETELY FAIL OF THEIR ESSENTIAL PURPOSE. NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, THE LIMIT OF MEDISCA LIABILITY (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BY STATUTE OR OTHERWISE) TO CUSTOMER OR TO ANY THIRD PARTY CONCERNING THE MEDISCA EQUIPMENT SOLD TO CUSTOMER AND WARRANTED HEREUNDER, MEDISCA PERFORMANCE OR NONPERFORMANCE, OR IN ANY MANNER RELATED TO THIS STANDARD WARRANTY POLICY STATEMENT, FOR ANY AND ALL CLAIMS WILL NOT IN THE AGGREGATE EXCEED THE ACTUAL AMOUNTS RECEIVED BY MEDISCA FOR THE SPECIFIC PRODUCT WITH RESPECT TO WHICH SUCH CLAIM IS MADE.



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