

foodproof® RoboPrep® 32 Operation Manual

Product No. MCH230000

Revision A, March 2024





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1. Introduction

1.1 About RoboPrep[®] 32

Thank you for purchasing RoboPrep 32 for your laboratory. This guide contains important information regarding the safe use of RoboPrep 32. Please read this manual carefully before operating the instrument for the first time, especially the safety information.

If there are any questions about how to install or operate the instrument, please contact our technical support team (<u>www.hygiena.com/support</u>).

1.2 Technology Introduction

RoboPrep 32 uses unique characteristics of how magnetic beads bind with nucleic acid under specific environmental conditions to purify target nucleic acid samples. The purification protocol includes four basic steps: sample lysis, nucleic acid binding, washing and elution. Using RoboPrep 32, most of the nucleic acid purification processes are done automatically inside the instrument. As a result of this automatization, the reproducibility and reliability of results are increased.

During the purification process, an 8-link rod comb attached to the tip comb rack, moves up and down repeatedly to mix the reagents by creating turbulence in the 96 Deep-Well Plate. When the permanent magnetic rods are inserted into the rod combs, the assembly lowers into the solution to collect the magnetic beads at the bottom of the comb. The whole assembly then moves to a different well, and the magnetic beads are released by retracting the permanent magnetic rods. RoboPrep 32 is equipped with an exclusive temperature control module that perfectly connects with the 96 Deep-Well Plate to enhance lysis and elution efficiency.

For further information or assistance, contact your distributor or the Hygiena[®] Diagnostics team.

1.3 Applications

RoboPrep 32 purifies DNA and RNA from a variety of samples that are broadly used in molecular biology, genetic screening, sequencing, food safety and other applications.

1.4 Waste Disposal Recommendations

You play an important role in contributing to reuse and recycling, as well as other forms of recovery of electrical and electronic equipment waste. Sorting this type of waste significantly reduces potential negative effects on the environment and human health from the presence of hazardous substances in electrical and electronic equipment.

At the end of the life cycle of this product, do not dispose of the product as unsorted municipal waste, even if it is decontaminated. It is imperative that you check local regulations for appropriate disposal procedures.



Warning: The above statement only applies to those in European countries with regard to the
 Waste Electrical and Electronic Equipment (WEEE) European directive.



1.5 Safety Information

It is essential that the warnings, cautions and safety requirements contained in this manual are read and understood by the operator before operating the system. Warning symbols have been placed on the system to draw your attention to potential hazard areas.

The following symbols and markings appear in this operation manual or on the instrument label (Type Label):

Symbol and Markings	Location	Description		
æ	Type Label and Instructions	Warning: Biohazard risk.		
Type Label and Instructions		Warning: Risk of injury to users.		
Instructions		Caution: Risk of damage to product.		
	Type Label	Warning: Burn Hazard/Hot Surface		
IMPORTANT!	Instructions	Important information that helps ensure proper function of kit, reagent or instrument.		

1.5.1 System Compliance

The RoboPrep 32 instrument conforms to the relevant European regulations for electrical safety and electromagnetic compatibility (EMC). This instrument complies with the emissions and immunity requirements of IEC 61326. It is advisable for the user to evaluate the electromagnetic environment before operating the instrument.

1.5.2 Safety Precautions

/!

- Warning:
 - Ensure the instrument is installed in a well-ventilated environment and away from any water source.
 - Ensure the power source matches the rating that is labeled on the instrument.
 - Turn off, remove the power cord and cover the instrument before a period of nonuse or any transportation.
 - The power cord is one of the emergency power supply controls; do not place the power cord in a location that is hard to reach.
 - If you hear or smell anything during operation, immediately disconnect the power and contact your local representative or agent.



Caution:

- Always use the packaging provided when shipping the instrument (See *Packaging and Shipping/Transportation Instructions* for detailed information).
- Never attempt to modify the RoboPrep 32 system without the manufacturer's permission.
- Do not place or drop objects on the RoboPrep 32 system. Also, refrain from bumping or knocking into it.



- The RoboPrep 32 system should only be repaired by authorized representatives or agents who use original spare parts certified by Hygiena Diagnostics.
- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

1.5.3 Poisonous and Harmful Substances

Biohazard:

- Always wear appropriate gloves, masks, safety goggles, etc., when handling any infectious samples.
- When handling or disposing of infectious materials, follow laboratory guidelines and the law to perform proper incineration, fusion, sterilization and/or disinfection of infectious waste.
- When you use a third party for waste disposal, outsource this work to an operator licensed to handle
 medical waste subject to special control and give them the manifest of the medical waste along with
 the waste.



Warning:

The ultraviolet source (254 nm) is an eye and skin hazard. Do not use the source without protection.

Note: Always wear a lab coat, gloves and safety glasses.

IMPORTANT!

At the end of the run, to avoid any reagent contamination, carefully remove the disposables containing prepared reactions or remaining reagents and ensure that each reagent tube is closed using the correct caps.

IMPORTANT!

To ensure the correct use of all reagents, always check the expiration date, required preparation, stability and the need for cooling blocks before use. It is the user's responsibility to ensure that all reagents are dissolved in liquid and homogeneous for accurate pipetting. For more information, refer to the instructions for the use of the reagents.



2. Intended Use and Specifications

This product and its accessories are for extended use in molecular biology research laboratories and diagnostic laboratories for nucleic acid extraction, purification and isolation.

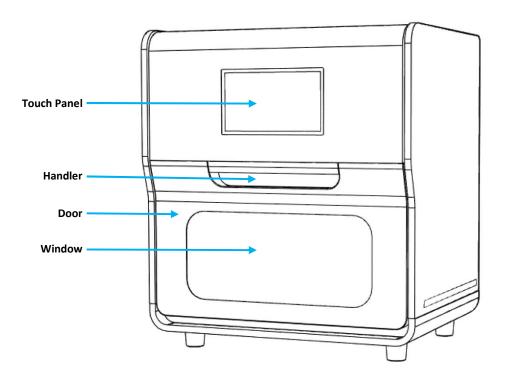
Specifications

Product Specifications	
Model Name	RoboPrep 32
Instrument Type	Bench-top automated nucleic acid extractor
Sample Processing	1 – 32 samples per batch
Consumable	2.2 mL 96 deep-well plate
Heat Block Temperature	15 to 80 °C (59 to 176 °F)
Mixing Speed	4 adjustable speeds
Mixing Depth	Adjustable, based on reagent volume
Reagent Type	Magnetic beads
Control Interface	7-inch touch panel
Protocols	2 protocols, 4 preinstalled default protocols and
	14 user-defined protocols
Validation	Validated for foodproof [®] Magnetic Preparation Kit I and III
Decontamination	Built-in UV light
Fuse	3.15 A, 500 V
Environmental Requirements: Oper	ration
Environmental Temperature	10 to 40 °C (50 to 104 °F)
Relative Humidity (RH)	<80% RH
Power Rating	AC 100 – 240 V, 600 VA, UPS optional
Environmental Requirements: Stora	age and Transportation
Environmental Temperature	–20 to 55 °C (–4 to 131 °F)
Relative Humidity	<80 °C (<176 °F)
Dimension and Weight	
Dimension	400 x 420 x 440 mm (15.7 x 16.5 x 17.3 in)
Weight	25 kg (55.1 lb)
EMC	EN61326-1
Safety	EN60101-1, EN60101-2

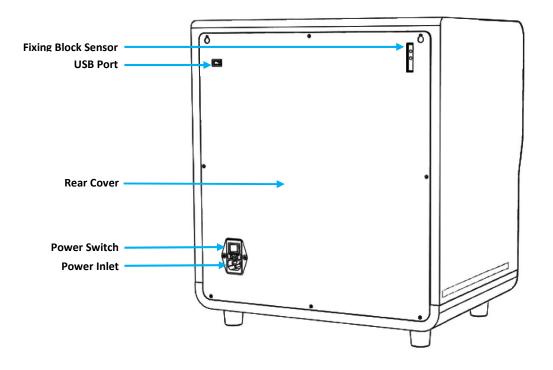


3. Instrument Overview

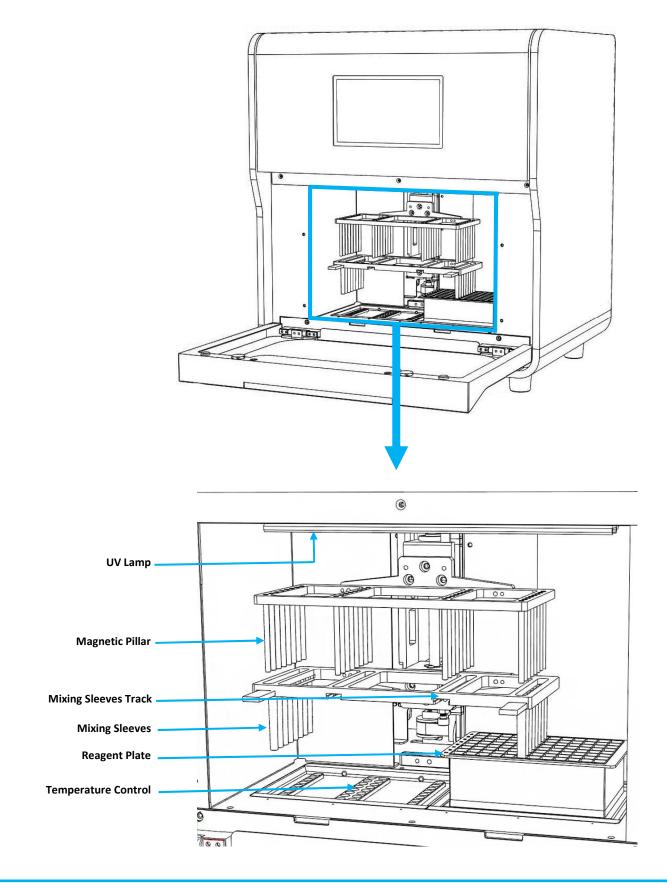
Front View



Rear View



Inside View



hygiena[®]



4. Installation

4.1 Packaging

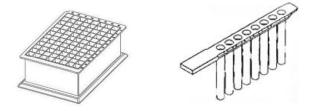
Check that the following parts are included in the package. Contact your local representative if you notice any missing part(s).

- Instrument
- Power Cord
- User/Operation Instructions (USB Stick)

Ensure all components are free of damage upon receipt. If any damage is found, contact your local representative for support.

Note: Hygiena Diagnostics' warranty does not cover damage from either transportation or improper handling and operation.

4.2 Labware

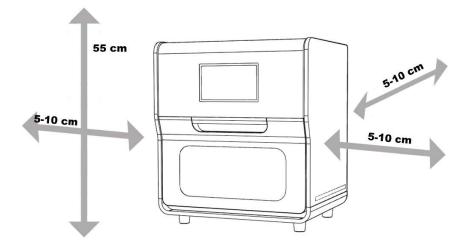


Use MLD230045, a consumable pack of 12 x DWP (deep well plates) and 24 x 8 Tip Combs, PP (polypropylene)

Note: Labware must be purchased separately. Contact your local representative for further information.

4.3 Operating Conditions

Use the RoboPrep 32 in an environment that meets the following conditions (spacing shown below):





The RoboPrep 32 System must be properly placed, adhering to the following conditions:

- 5 10 cm away from walls.
- Near an electrical outlet.
- Between 10 to 40 °C (50 to 104 °F) and at a stable temperature. (Warming a room suddenly or moving the instrument from a cold to a warm room may cause condensation inside the device that might result in abnormal extraction.)
- At <80% relative humidity (non-condensing).
- On a flat and stable surface, without external vibrations.
- Away from direct sunlight. (If necessary, block sunlight by closing curtains or blinds.)
- At a location that is well ventilated and not dusty.
- Away from objects that generate strong magnetic fields, such as motors, transformers, televisions, audio speakers, magnets, etc. (Magnetic fields can cause the RoboPrep 32 to malfunction.)



Caution:

- Do not use the RoboPrep 32 in a wet environment or where it could be splashed with water, which may cause device failure, fire or electric shock.
- When moving the RoboPrep 32, first disconnect from power. A damaged power cable may cause device failure, fire, injury or electric shock.
- Do not place the RoboPrep 32 on an unstable or slanted surface or in an area subject to vibrations, which may cause injury or device failure.
- Do not use the RoboPrep 32 in direct sunlight or near a heating device, which may shorten the life of the RoboPrep 32 System or interfere with normal function.

Description	Conditions
Temperature during operation	10 to 40 °C (50 to 104 °F)
Humidity during operation	<80% RH
Temperature gradient	≤12 °C/h (≤54 °F/h) (non- condensing)
Altitude during operation	≤1,600 m

RoboPrep 32 operating conditions

4.4 Initial Setup

1. Open the shipping box and remove the instrument and related accessories.

IMPORTANT!

The RoboPrep 32 weighs more than 25 kg (55 lbs.).

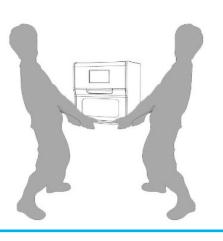
The instrument should be lifted and moved by two people. Hold the moving handles of the instrument from two sides to remove the instrument from the shipping box.

Do not hold the door or the plastic outer covering while transporting the instrument.



Caution:

Improper handling of the RoboPrep 32 will lead to instrument damage.



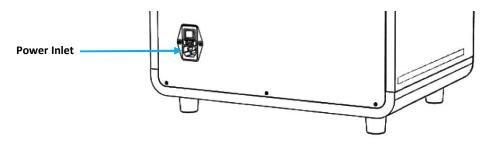


For correct and safe use of the RoboPrep 32, install it in a location that is near an electrical outlet and has enough space for installation and operation from the main switch.

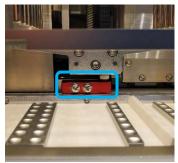
IMPORTANT!

Keep the shipping box and Fixing Block, as they are needed for transporting the RoboPrep 32 in the future.

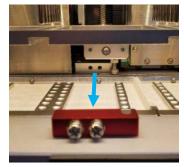
2. Connect the power cord to the instrument and the electrical outlet.



- 3. Remove the Fixing Block inside the instrument and place it in the Fixing Block Sensor Spot, following the guidelines below:
 - a. Use a Phillips-head screwdriver to release the screws.



b. Remove the Fixing Block.



c. Place the Fixing Block in the upper part of the back of the instrument in the Fixing Block Sensor Spot. This is required for the instrument to operate.





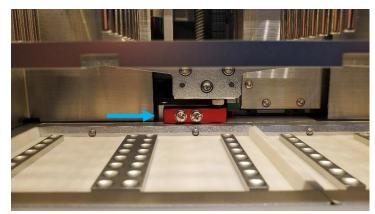
4.5 Transportation and Shipping of RoboPrep 32

When transporting or shipping the RoboPrep 32 to a new location, perform the following tasks:

- 1. Insert the Fixing Block.
 - a. Hold the Magnetic Pillar frame to the left.



b. Install the Fixing Block.



- c. Use a Phillips-head screwdriver to tighten the screws.
- d. Close the door.
- 2. Disconnect the plug from the outlet and remove all attached parts (e.g., power cord) from the instrument.



Warning:

A damaged power cable may cause device failure, fire, injury or electric shock.

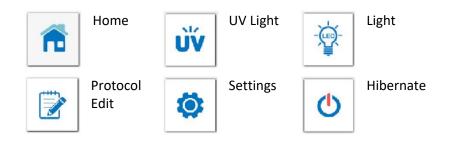
3. Pack the RoboPrep 32 instrument, including accessories, in its original shipping box or another equivalent packaging.



4.6 Functional Descriptions

4.6.1 Main Menu







Protocol Editing 4.6.2

After pressing 📝 , the icon will change colors 📝 , and you can select '1' to '12' to edit your protocol.



No:	1-1 Pro	otocol Name:							
RUN	Well No. (0-6)	Name	Standby (0-30Min)	Mix (1-30Min)	Volume (100-1000ul)	Mix Speed (1-3)	Mag (0-120Sec)	Temp. (40-80°C)	Paus
	0								
	0								
	0								
	0								
	0				1				
	0								
	0								
	0								



4.6.3 LED Light

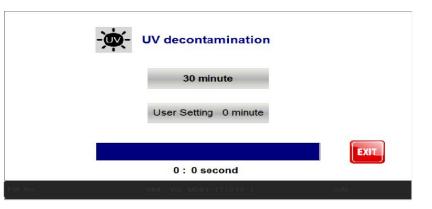


After pressing 🙀 , the icon will change colors 🧖 , and the instrument's light will turn off.



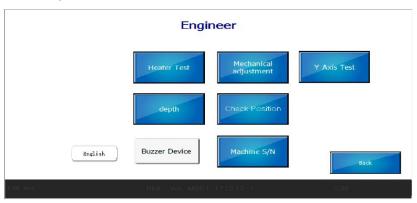
4.6.4 UV Light

After pressing 👸 , press '30 minute' to start the default 30-minute decontamination process or press 'User Setting' to set your custom time.



4.6.5 Settings

After pressing 🔅 , you can adjust, check or test the instrument.





4.6.6 Sleep Mode

After pressing 🕐 , the instrument will go into sleep mode. To wake up the instrument, touch the screen again.

Note: Before going into sleep mode, press 🙀 to turn off the LED light.

5. Getting Started

Preparation 5.1



Biohazard:

Always wear appropriate gloves, masks and safety goggles during and after any biohazardous operations and during the extraction process, even when touching the device since the device may become contaminated.

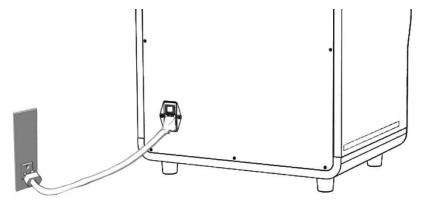
IMPORTANT!

Prior to the extraction, wear appropriate gloves, mask and safety goggles if required by the operation. Be careful not to contaminate the sample material with sweat, saliva, etc., during the sample preparation steps and closely follow the extraction kit instructions.

5.2 Operation

5.2.1 **Operation Procedure**

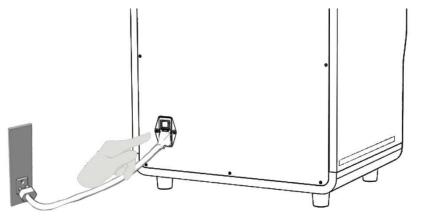
1. Ensure that the power cable is securely connected to the RoboPrep 32 and the electrical outlet.



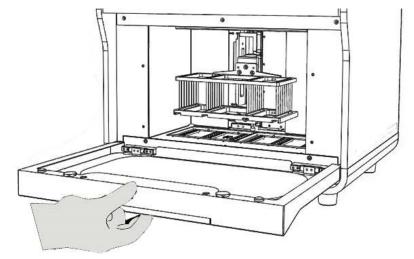


2. Turn the power switch on and wait for the Touch Panel to display 'RoboPrep 32 Initializing'. The system will automatically run self-testing procedures and go into ready mode.

Note: The system must complete self-testing before the main functions can be run.



3. Open the door. p



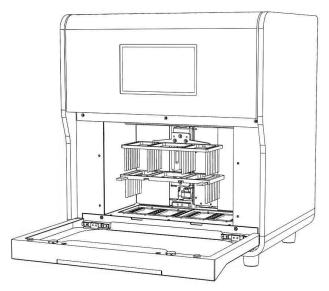


4. Set up the mixing sleeves on the mixing sleeve track.



Caution:

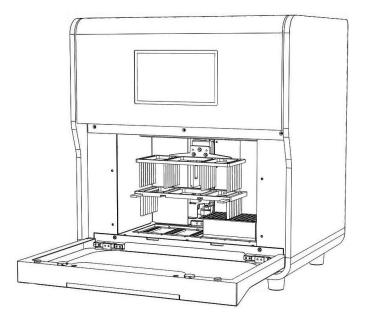
Make sure the sleeves have entered completely.



5. Add samples and reagents to the 96 Deep-Well Plate as required for your experiment.



6. Place the reagent plate(s) into the instrument.





7. Close the door and select the protocol.



Select the preinstalled protocols, edit the preinstalled protocols or draft a protocol by yourself.

The following figures are from a representative protocol in RoboPrep 32:

RUN	Well	Name	Standby	Mix	Volume	Mix	Mag	Temp.	Pause
	No.		(0-30	(1-30	(100-	Speed	(0-	(40 to	
	(0-6)		min)	min)	1000 µL)	(1-3)	120 s)	80°C)	
\mathbf{X}	1	Lysis	0	15	520	3	0	80	X
\boxtimes	1	Binding	0	15	835	3	30	0	
\times	1	Binding	0	0	835	0	30	0	
\boxtimes	2	Wash-1	0	3	750	3	30	0	
X	2	Wash-1	0	0	750	0	30	0	
\boxtimes	3	Wash-2	0	3	750	3	30	0	
\boxtimes	3	Wash-2	0	0	750	0	30	0	
\mathbf{X}	4	Wash-3	0	1	750	3	30	0	
\boxtimes	6	Elution	0	15	300	3	60	80	
\times	4	Waste	0	1	750	3	0	0	

Now	:	\bigcirc
Time: 0 hr 0 min 0 sec	Remain Time: 0 hr 40 min 40 sec	$\mathbf{\mathbf{b}}$

8. Press **b** to start the extraction process.

Note: The total and remaining process times will be displayed on the screen (see above).

9. When the extraction procedure is finished, transfer the extracted products located in wells 6 and 12 into nuclease-free tubes.



Note: Store the purified nucleic acid at 4 °C (short-term, less than 10 days) or aliquot and store at -70 °C (long-term) before performing any downstream analysis.



- 10. Remove and discard used consumables as biohazardous waste.
- 11. If you will not be using the instrument in the short-term, press (1) to enter sleep mode.
- 12. Follow the suggested maintenance routines.

5.2.2 Pause and Restart Procedure

1. If you want to pause the procedure, press (II).



Time: 0	hr 0 min	0 sec	Remain Time: 0 hr 40 min 40 sec	

5.2.3 Stop Procedure

1. If you want to stop the procedure, press (1).

Γ	Now :	\frown
	Time: 0 hr 0 min 0 sec Remain Time: 0 hr 40 min 40 sec	
2. Then, press 🗙		
Г	Now :	\sim \Box

3. A prompt to Interrupt the program will be displayed.

Time: 0 hr 0 min 0 sec

Interrupt	
No	
Yes	
HMI Ver, M061-171213-1	S/N:

Remain Time: 0 hr 40 min 40 sec

4. Press 'Yes' to end the program.



6. Protocol Editing

6.1 Editing Menu

1. In the main menu, press 📝 . The icon will change colors 📝 , and you can select '1' to '12' to edit your protocol.

▲ 🖻		-	ÙΫ́	٢	٩
Protocol Sele	ction				
Ţ.		₩ E			
MPKI	MPK III	MPK VI			
1	2	3	4	N	EXT
FW Ver.	HMI Ver,	ZixP-221222-0		S/N:	
		-@	ŬŸ	٢	٩
Protocol E	dit				

2. Select the desired procedure by using the touch screen to make edits or create a new procedure.

f	ł					ÙΫ			0
No:	1-1	Protocol Name:							
RUN	Well No. (0-6)	Name	Standby (0-30Min)	Mix (1-30Min)	Volume (100-1000ul)	Mix Speed (1-3)	Mag (0-120Sec)	Temp. (40-80°C)	Pause
	0								
_	0								
	0								
_	0								<u> </u>
_	0								
_	0								
-	0								-
			I	I					
		Init	Save	Loa	d 1			Nex	đ



No:	1 1	Protocol N	lame:											
_	Well No.	[Stan	idby	Mi		Volum	ne Mi	x Speed	il N	lag	Tem	
RUN	(0-6)	Nam	ne	(0-30		(1-30	1in) (100-100		(1-3)		20Sec)	(40-80	
	0	7	8	9	Es	-	-				-			-
	0	4	5	6		1								
	0			_	←		-		+		-		<u> </u>	_
	0	1	2	3			-				+	_		
	0	0		Cl	ear									
	0				1	H								
		+	-	€			oad		1				N	lext
										Sk.		-		
A										Ù	/	\$	>	Ċ
no:		Protocol Ni	ame:							U	<u> </u>			Ċ
No:	1-1 Well No. (0-6)	Protocol Nam		Stan (0-30		Mi: (1-30!		Volun 100-10	ne M 00ul)	UX ix Spee (1-3)		Kag 20Sec)	Ten (40-8	0°C) Pa
-	Well No. (0-6)		ne	(0-30	Min)	Mi: (1-301	1in) (100-10	00ul)	UX ix Spee (1-3)	d (0-1	Mag 20Sec)	Ten	0°C) Pa
RUN	Well No. (0-6) 1 0		A		Min)	Mi: (1-301		100-10	G	UX (1-3)	d (0-1 2	Mag 20Sec)	Ten (40-8	0°C) Pa
RUN	Well No. (0-6)		A	(0-30 B	Min) C J	мі: (1-301 К	(in) (E L	F M	G N	U (1-3) 1 4	d (0-1 2 5	Mag 20Sec) 3 6	Ten (40-8	0°C) Pa
RUN	Well No. (0-6) 1 0 0		A H O	(0-30 B I P	Min) C J Q	мі: (1-301 В К R	E L S	100-10	G	U (1-3) 1 4 7	d (0-1 2 5 8	Mag 20Sec) 3 6 9	Ten (40-8	0°C) Pa
RUN	Well No. (0-6) 1 0 0		A H O V	(0-30 B	C J Q X	мі: (1-301 К	E L S Z	F M T	G N	U (1-3) 1 4	d (0-1 2 5 8 0	Mag 20Sec) 3 6	Ten (40-8	0°C) Pa

3. After entering the desired procedures, make sure the protocol number is not a duplicate and press 'Save' to save the protocol.

6.2 Editing Options

Parameter	Options/Selections Available
Protocol Name	Accepts both letters and numbers and a maximum of 10 characters. Duplicate protocol names are not accepted.
Well	Choose the well for a customized procedure.
Procedure Name	The description of the procedure. Accepts both letters and numbers and a maximum of 10 characters. Duplicate protocol names are not accepted.
Standby	The time that the mixing sleeves stay above the reagent buffer. Normally used to dry the beads after magnetic separation.
Mix	The time that the mixing sleeves will spend inside of the well to mix.
Volume	The reagent buffer volume of each well.
Mix Speed	The speed of mixing sleeves during the mixing procedure; choose from 3 different speeds.
Mag	The time for which the magnetic pillar adsorbs the magnetic beads.



Temperature	The temperature of wells 1 and 6.
Pause	The current procedure will pause after it is finished. Before starting the next procedure, press 'Start'.

7. Cleaning and Maintenance

7.1 Cleaning Procedures

- After each run, remove used plastic consumables.
- At the end of each day, remove any fluid from the inside of the instrument with a damp cloth moistened with 70% ethanol and disinfect the inside with the UV light.

Note: Press **v** and select the disinfecting time.

• Gently clean the instrument body by removing dust with a dry, soft cloth. If the outside is heavily soiled or contaminated with potentially infectious material, clean the instrument with a soft paper tissue soaked with either 0.5% sodium hypochlorite solution or 70% ethanol.

7.2 Maintenance Schedule

Two types of maintenance must be performed on the RoboPrep 32 instrument as described in the following table:

Maintenance Type	Performed by	Schedule
Routine cleaning of the instrument body		
Outside	• User	Bi-weekly
• Inside	• User	 Daily
Preventive	Service engineer	Annually



8. Troubleshooting

Problem	Cause	Solution		
No display after the power	Power disconnected	Check the AC power cord connections at both ends. Make sure you are using the correct cords.		
switch was turned on	Blown fuse	Replace the fuse.		
	Malfunctioning power switch	Replace the switch.		
	Other	Contact your local representative.		
The Touch Panel turned on, but the self-testing program did	Forgot to remove the Fixing Block from the instrument	Turn off the instrument and remove the Fixing Block.		
not run	Technical problem	Contact your local representative.		
A beeping alarm sounded or 'System error' message appeared on the display	Self-check error	Contact your local representative.		
Dicplay arror	Firmware installation failed	Contact your local representative.		
Display error	Display connection failed	Contact your local representative.		
Cannot enter using the Touch Panel	Touch Panel malfunction	Contact your local representative.		

9. Supplementary Information

9.1 Liability

WARRANTY AND DISCLAIMER OF LIABILITY

Limited Warranty and Disclaimer of Liability. Hygiena Diagnostics GmbH warrants that this product is free from defects in materials and workmanship for 12 months and only if the following are complied with:

(1) The product is used according to the guidelines and instructions set forth in the product literature.

(2) Hygiena Diagnostics GmbH does not warrant its product against any and all defects when: the defect is as a result of material or workmanship not provided by Hygiena Diagnostics GmbH; defects caused by misuse or use contrary to the instructions supplied, or if the product is contaminated by improper storage or handling.

(3) All warranties of merchantability and fitness for a particular purpose, written, oral, expressed or implied, shall extend only for a period of one year from the date of manufacture. There are no other warranties that extend beyond those described on the face of this warranty.

(4) Hygiena Diagnostics GmbH does not undertake responsibility to any purchaser of its product for any undertaking, representation or warranty made by any dealers or distributors selling its products beyond those herein unless expressed in writing by an officer of Hygiena Diagnostics GmbH.

(5) Hygiena Diagnostics GmbH does not assume responsibility for incidental or consequential damages, including, but not limited to responsibility for loss of use of this product, removal or replacement labor, loss of time, inconvenience, expense for telephone calls, shipping expenses, loss or damage to property or loss of revenue, personal injuries or wrongful death.



(6) Hygiena Diagnostics GmbH reserves the right to replace or allow credit for any modules returned under this warranty.

9.2 Trademarks

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9.4 Contact and Support

If you have questions about this or any other product of Hygiena Diagnostics, contact our Technical Support staff (<u>www.hygiena.com/support</u>). Our commitment is to provide our customers with rapid and effective assistance. Contact us if you have suggestions for enhancing our product performance or using our products in new or specialized ways. Such customer information has repeatedly proven invaluable to us and the worldwide research community.

9.5 Reference Number

The reference number and original Hygiena Diagnostics GmbH article number: D 210 32.

10.Change Index

Version 1, January 2019: First version of the package insert.

Revision A, February 2024: Rebranding and new layout. Updated instrument imagery for the new model. D 210 32 22 -> INS-MCH230000-REVA.



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