MarrowMatic
AUTOMATED SYSTEM FOR SAFER SAMPLE PREPARATION

ARROW
Biotech

INSTRUCTIONS FOR USE (IFU)

MarrowMatic™ – General Laboratory Equipment

Document ID: **IFU-MM-001**
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MANUFACTURER DETAILS & SUPPORT

Manufacturer:

ARROW Biotech s.r.l.s.

Corso F.Ferrucci 46

10138 Torino (Italy)

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Email: info@arrow-biotech.com

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1. DOCUMENT CONTROL & WARRANTY

1.1 Document Information

1.2 Warranty Disclaimer

The manufacturer guarantees this instrument against defects in materials and workmanship for a period of 12 months from the date of installation. This warranty does not cover damages caused by:

- Improper use or calibration.
- Unauthorized modifications or repairs.
- Operation outside the specified environmental conditions.

In case of troubles after the warranty period please refer to the retailer or direct supplier to receive indications how to proceed with replacement.

2. INTENDED USE & PRINCIPLE OF OPERATION

2.1 Intended Use

MarrowMatic™ is a general-purpose laboratory equipment intended for automated processing and preparation of biological samples (like bone marrow, marrow blood, other biological fluids and fine needle aspirate biopsies) to obtain specifically optimized cell suspensions for flow cytometry, cytogenetic and cell culture analysis.

MarrowMatic™ is intended for research use only (RUO) or general laboratory applications. It is not intended for use in diagnostic procedures, clinical decision-making, or therapeutic applications.

2.2 Intended Users

The device must be operated exclusively by qualified laboratory technicians, clinicians, or trained biologist personnel.

2.3 Indications for Use

The system is used in laboratory environments to standardize sample mixing, dissociation and straining workflows, minimizing manual handling and reducing human error.

2.4 Contraindications

MarrowMatic™ is not intended for:

- Direct patient contact or in vivo applications.
- Processing of explosive, highly flammable, or chemically unstable substances.

3. TECHNICAL SPECIFICATIONS & ENVIRONMENTAL CONDITIONS

3.1 Electrical Characteristics

- **Power Supply Voltage:** 100–240 V AC (±10%)
- **Frequency:** 50 / 60 Hz
- **Power Consumption:** Max 150 W
- **Fuse Protection:** 1x T3A 24V
- **Overvoltage Category:** Category II (IEC 61010-1)

3.2 Storage and Shipping Conditions

The device must be kept inside its original packaging during transit.

- **Storage Temperature:** -10°C to +50°C
- **Shipping Temperature:** -20°C to +60°C
- **Relative Humidity:** 10% to 85% (non-condensing)
- **Atmospheric Pressure:** 700 hPa to 1060 hPa

3.3 Operating Environmental Condition

- **Ambient Temperature:** +15°C to +30°C
- **Maximum Relative Humidity:** 80% up to 31°C (linear decrease to 50% at 40°C)
- **Altitude:** Up to 2500 meters above sea level

4. REGULATORY COMPLIANCE & CE MARKING

This instrument complies with the essential requirements of the following European Union Directives and International Standards:

- **CE Marking:** Complies with Machinery Directive 2006/42/EC and Low Voltage Directive 2014/35/EU for general lab use.
- **EN IEC 61010-1:** Safety requirements for electrical equipment for measurement, control, and laboratory use.
- **EN IEC 61326-1:** Electrical equipment for measurement, control, and laboratory use — EMC requirements.
- **RoHS Directive (2011/65/EU):** Restriction of hazardous substances.

5. SAFETY PRECAUTIONS & GENERAL WARNINGS

5.1 Hazard Symbols Used in this Manual

SYMBOL	MEANING
WARNING	Indicates a potentially hazardous situation which could result in serious injury.
CAUTION	Indicates a situation which could result in equipment damage or sample loss.
ELECTRICAL	Warning of potential electrical shock hazards.
BIOHAZARD	Warning of potential exposure to biological risk and infectious materials.

6. PRODUCT LABELING & SYMBOLS

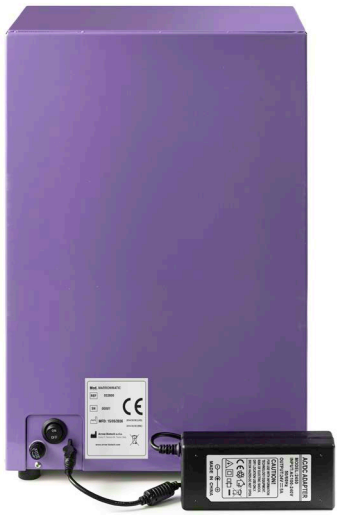
The following symbols are applied to the identification label of MarrowMatic™ (see carefully label picture):

SYMBOL	MEANING	STANDARD REFERENCE
	Consult Instructions for Use: Read the manual carefully before operating.	ISO 7000-1641
	Manufacturer: Identifies the legal manufacturer.	ISO 7000-3024
	Date of Manufacture: Shows the production date.	ISO 7000-2497
REF	**Serial Number:** Unique identification code of the device.	ISO 7000-2498
	WEEE Compliance (RAEE Waste): Crossed-out wheeled bin with a solid bar underneath. Do not dispose of the device as unsorted municipal waste. It must be collected separately for electrical and electronic equipment recycling.	EN 50419
CE	**CE Marking:** Declares compliance with all applicable European Union harmonization legislation.	Regulation 765/2008

7. OPERATING MODALITIES & PROCEDURES

Follow these steps sequentially to achieve optimal cell separation and standardization:

1. Place the device on a stable, flat laboratory bench.
2. Ensure at least 10 cm of clearance around air vents.
3. Connect the power cable to wall outlet AC.
4. Turn on the main power switch located on the rear panel.
5. Wait for the automatic system self-test routine to complete.



7.2 Sample Preparation and Kit Selection

1. **Bone Marrow Aspirates:** Select a sterile **MM-Kit 1** cartridge.
2. **Fine-Needle Biopsies / Tissue:** Select a sterile **MM-Kit 2** cartridge.
3. Transfer the biological specimen into the selected kit chamber under a laminar flow hood if necessary.
4. Proper volume in the mother tube must be between 0,6 and 3,2 ml.
5. When the needle-tip is inserted into the mother tube, pay attention to push it down to the bottom.

7.3 Operative mode

1. Connect the power supply.
2. Switch on
3. Press **OPEN**: the MarrowMatic™ drawer will open a little.

4. Pull it out completely.

5. Insert the prepared kit into the designated drawer.

6. Push the drawer firmly until the locking mechanism clicks into position.
7. Select the standardized processing cycle pressing **SELECT PROGRAM** (Marrow or Biopsy) according to the sample and the MM-Kit prepared for running.
8. Press the **START** button to initiate the mechanical dissociation & straining.
9. Wait until the status indicator confirms cycle completion.
10. At “process terminated” the drawer opens a little after a sound signal.
11. Open the drawer completely to remove the processed sample and recover the daughter tube.

8. CLEANING AND DECONTAMINATION (BIOHAZARD PROTOCOL)

8.1 General Safety Guidelines

- **ELECTRICAL SHOCK HAZARD:** Always turn off the device and disconnect the main power cable from the wall outlet before performing any cleaning or decontamination procedures.

- **CAUTION:** Do not spray, pour, or spill liquid disinfectants directly onto the instrument housing or into internal electrical components to avoid short circuits.

- **BIOHAZARD RISK:** Always wear personal protective equipment (PPE) including laboratory coats, safety goggles, and appropriate gloves during cleaning operations.

8.2 Maintenance Frequency

Cleaning and decontamination tasks must be performed periodically. The exact frequency is determined at the sole discretion of the laboratory manager, based on the specific workload, internal protocols, and biosafety guidelines of the facility.

8.3 Decontamination and Cleaning Procedure

1. Ensure the instrument is powered off and completely disconnected from the electricity grid.
2. Prepare a single-use disposable cloth.
3. Moisten the single-use cloth with a sodium hypochlorite solution (bleach) or a similar appropriate commercial laboratory disinfectant.
4. Gently wipe all external surfaces of the MarrowMatic™ housing to remove dirt and possible biological residues.
5. Extract the drawer from the processing chamber.
6. Thoroughly wipe the surface of the drawer with the prepared single-use cloth.
7. Allow the surfaces to air dry completely or dry them with a clean paper towel before reconnecting the power supply or resuming laboratory operations.

EU DECLARATION OF CONFORMITY

1. Product Model / Type:

Product Name: MarrowMatic™
Model/Type: General Laboratory Equipment for Sample Dissociation
Cat. Number: 32600

2. Manufacturer Details:

Manufacturer: ARROW Biotech s.r.l.s.
Address: Corso F. Ferrucci 46, 10138 Torino (TO), Italy
Contact: info@arrow-biotech.com | Tel: +39 011 4454646

3. Object of the Declaration:

The object of the declaration described above is an automated mechanical system intended for general laboratory purpose (GLP), specifically for the automated processing, mixing, and dissociation of biological samples to obtain cell suspensions. This product is a general laboratory instrument and is not intended for medical diagnostic procedures, clinical decision-making, or therapeutic applications.

4. Statement of Compliance:

This declaration of conformity is issued under the sole responsibility of the manufacturer. The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Directive 2014/35/EU (Low Voltage Directive - LVD)
- Directive 2014/30/EU (Electromagnetic Compatibility Directive - EMCD)
- Directive 2011/65/EU and amendment (EU) 2015/863 (RoHS Directive)

5. References to Harmonized Standards:

The following harmonized standards and technical specifications have been applied to demonstrate conformity with the essential requirements of the above Directives:

- EN ISO 12100:2010 – Safety of machinery — General principles for design — Risk assessment and risk reduction.
- EN IEC 61010-1:2010 + A1:2019 – Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements.
- EN IEC 61326-1:2021 – Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements.
- EN IEC 63000:2018 – Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

6. Additional Information:

The technical documentation file is maintained at the operational headquarters of the manufacturer (Via Carignano 65, 10040 Rivalta, TO, Italy).

Signed for and on behalf of: ARROW Biotech s.r.l.s.
Place of Issue: Torino, Italy
Date of Issue: June 2026

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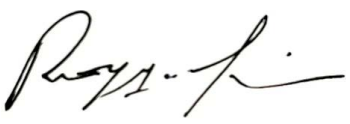
Name / Position: [Gianmarco Roggero, Chief Executive Officer]



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