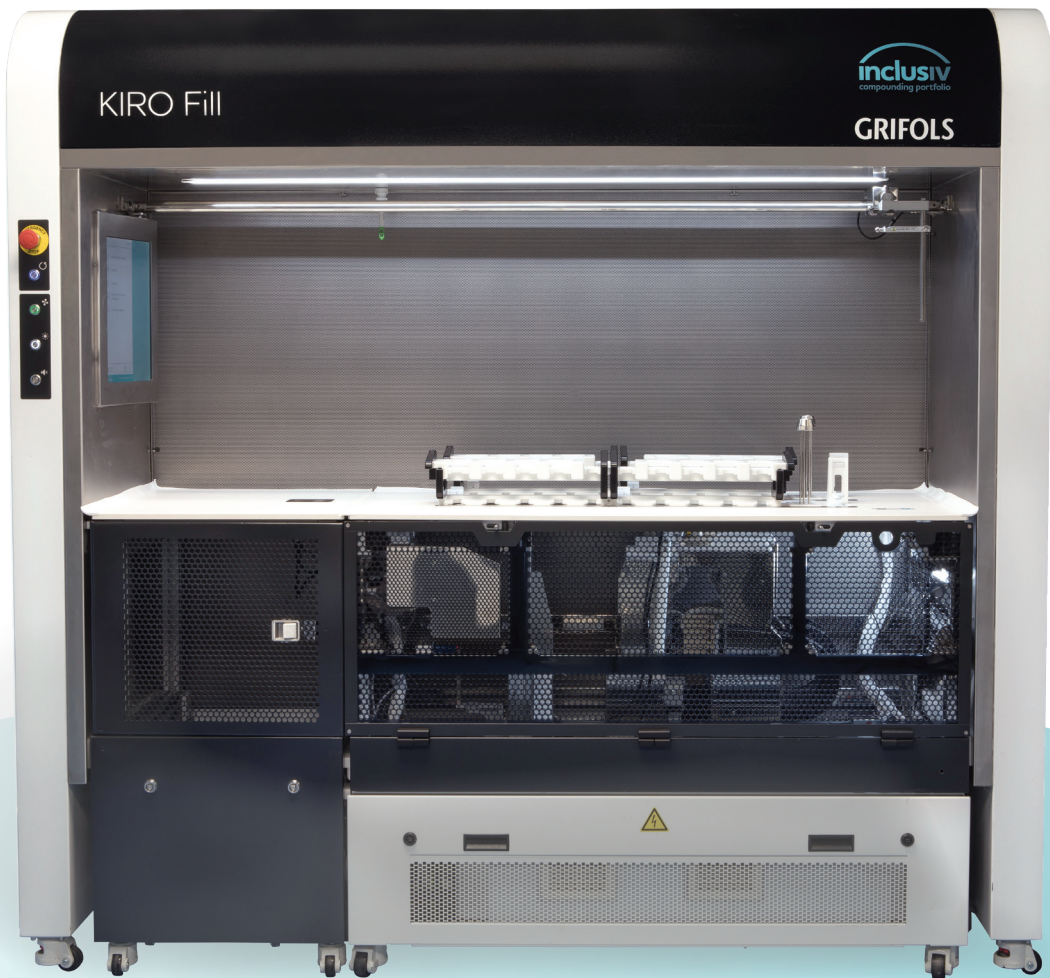


KIRO[®] Fill

Automatic Compounding Device



GRIFOLS

KIRO® Fill Features:

Material preparation and identification area

- Touchscreen for user instructions and confirmations
- Barcode/datamatrix and radio frequency identification (RFID) systems to identify and control source and final containers used

Loading/unloading area

- Manual loading and unloading
- Barcode scanning of raw materials
- RFID for in-process tracking
- Up to 20 loading positions for final products:
 - Syringes (3 mL, 5 mL, 10 mL, 20 mL, 30 mL and 50 mL)
 - Luer bags (50 mL, 100 mL, 250 mL and 500 mL)
- Source bags and vials of different brands and sizes supported
- LED-guided positioning

Compounding area

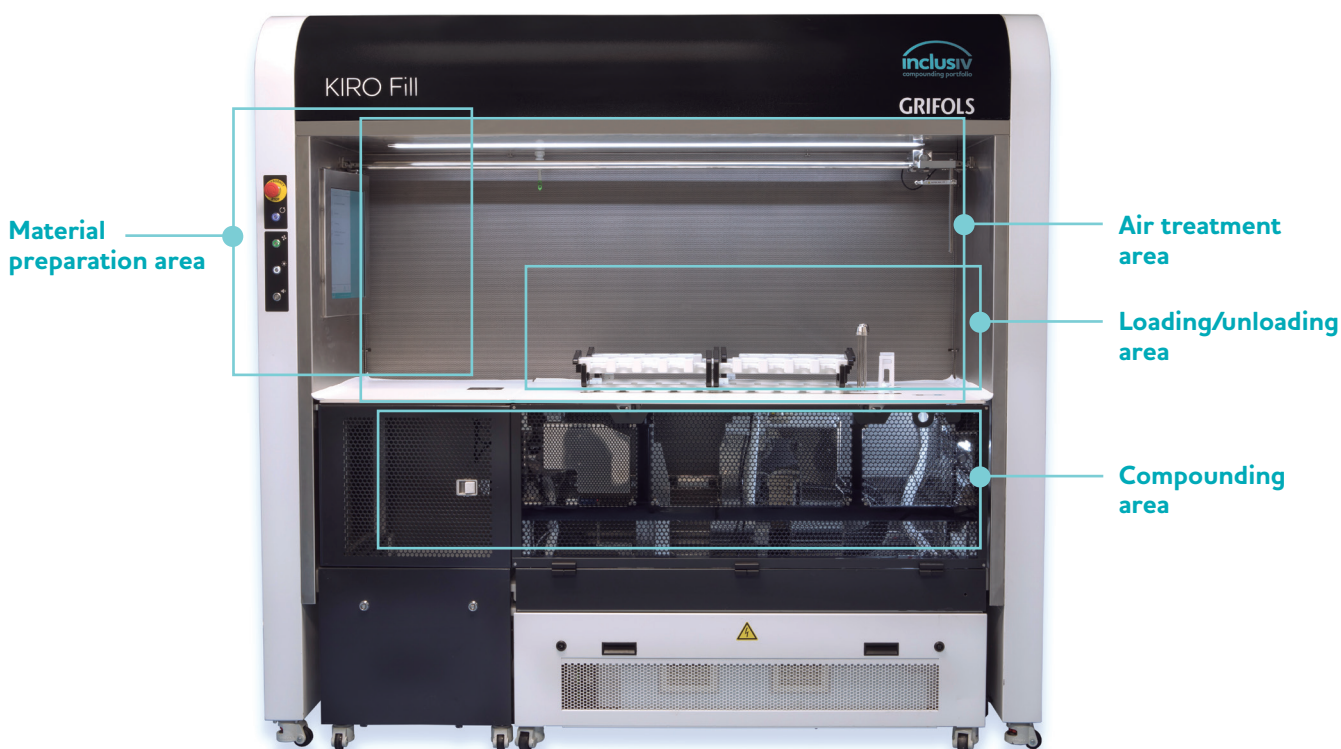
- Two automated units working in parallel handle transfer syringes to withdraw solutions from source containers and fill syringes or bags via luer lock connections
- Automatic capping of syringes with tamper evident, luer-lock or luer slip caps
- Control of used source containers and drug left-overs
- Gravimetric control over the source bag that weights the bag before and after every dose withdrawal

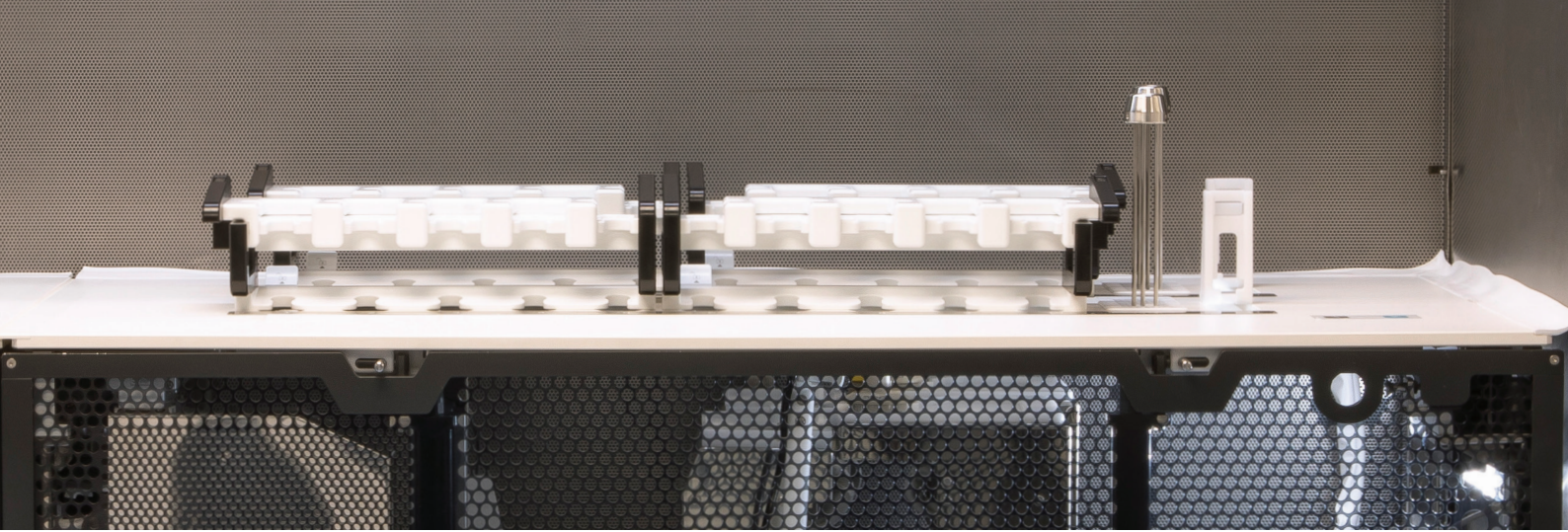
Air treatment area

- ISO 5 aseptic environment in material preparation, loading, and unloading areas and in lower compounding area
- Horizontal air flow with HEPA H14 filters
- Continuous monitoring of:
 - Air flow operation
 - Temperature
- Optional monitoring of non-viable particle counts

KIRO® Fill contributes to enhanced patient safety, optimizes operational efficiencies, and complies with relevant regulatory standards and best practice guidelines.

KIRO® Fill meets needs for non-hazardous batching of syringe and bag doses. Its unique design enables KIRO® Fill to accommodate other final containers such as elastomeric pumps or cassettes.





Solutions Designed to Keep Your Patients Safe

Your most important responsibility is patient safety, but you are also challenged with controlling costs, protecting staff, and maximizing workflow efficiencies while ensuring regulatory compliance of your sterile compounding environment.

As a strategic part of **inclusiv**, a comprehensive IV compounding portfolio of integrated technology, software, and service solutions designed to enhance patient safety, **KIRO® Fill** can help protect patients and staff.

KIRO® Fill is an automated compounding device designed to enhance patient safety and optimize operational efficiencies during the production of non-hazardous compounded sterile preparations.

KIRO® Fill reduces manual steps and adds automation where it makes the most sense.



KIRO® Fill Key Benefits:

Safety

- ISO 5 aseptic compounding environment protects sterility during production of non-hazardous compounded sterile preparations
- Automation minimizes risk of contamination and increases dosing accuracy
- Repetitive stress and needle-stick injuries are mitigated
- Guided and software controlled manual loading and unloading of supplies for enhanced patient safety
- Gravimetric control over the source bag ensures accuracy of doses prepared

Control and Traceability

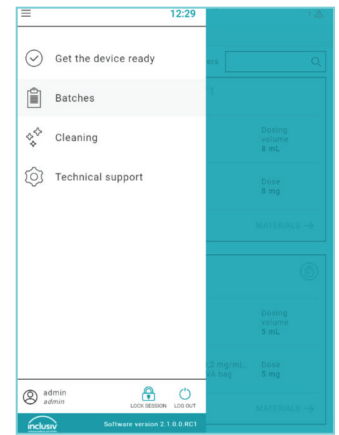
- Loading and automated compounding processes are controlled by means of barcode scanning and RFID identification
- Batch reports and labels for the compounded preparations generated to ensure traceability through production

Flexibility and Efficiency

- Unique design and small footprint facilitate high throughput and optimization of workload, workflow, and staff time while consuming minimal valuable cleanroom space
- Integrates two automated units working in parallel
- Accommodation of a large variety of sizes and types of source and final containers
- Batch compounded sterile preparations
- Optimized use of medication and left-overs

Regulatory Compliance

- Compliance with USP and GMP regulations supported by standardizing aseptic procedures, facilitating personnel and process qualification
- Airflow operation and temperature control to meet GMP requirements
- Fully serviced during deployment, qualification, and periodic maintenance, including dosing accuracy tests and air flow certifications addressing smoke tests under dynamic conditions for USP <797> compliance
- KIRO® Fill meets electrical safety requirements by being UL listing marked per IEC 61010 and EMC certified per IEC 61326-1

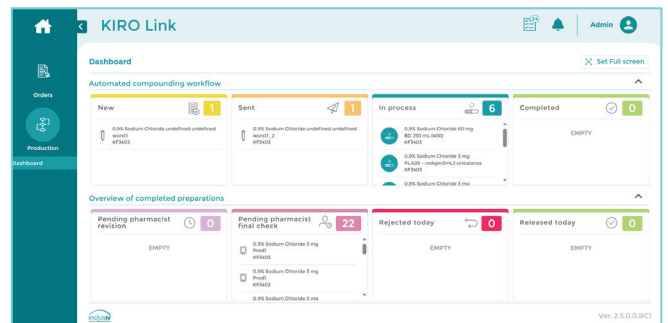


KIRO® Link

Automated Pharmacy Workflow Management using a web-based software application accessible from any workstation, enabling the user to:

- Monitor progress and manage compounding queues
- Visualize automated compounding reports
- Access database and configuration parameters
- Obtain production reports and metrics

Provides connectivity through various interface protocols and messaging standards, including HL7®.



Technical Information

- **Size (w x d x h):** 82.32" x 38.07" x 78.66" (2091 mm x 867 mm x 1998 mm)
- **Minimum clearance (w x d x h):** 121.65" x 73.26" x 88.58" (3090 mm x 1861 mm x 2250 mm)
- **Weight:** 650 kg (1390 lb)
- **Required minimum floor load rating:** 200 kg/m² (40.9 lbf/ft²)
- **Power:** 230 VAC ± 10%, 50 Hz, 1.6 kVA, 7 A in Europe (120 VAC ± 10%, 60 Hz, 3 kVA, 14 A in US)
- **Electrical safety:** UL Listing Mark per IEC 61010 and EMC Certification per IEC 61326-1

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Product registration and availability vary by country. For more information, please contact your Grifols' representative.

ABOUT THE PORTFOLIO

inclusiv is a comprehensive IV compounding portfolio of integrated technology, software, and service solutions designed to support your needs for sterile compounding from the design and building of your sterile compounding environment, to the preparation and verification of your products, through the ongoing management and optimization of your pharmacy operation.



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