i.v.TOOLS

KIRO oncology

Automated compounding for intravenous oncology treatments

GRIFOLS

MANAGEMENT ENVIRONMENT COMPOUNDING ADMINISTRATION

The correct preparation and administration of compounded sterile preparations (CSPs) is a complex process that must be conducted by highly skilled professionals in a specialized environment.

Grifols is a global healthcare company with more than 75 years of experience and a record of maintaining the highest quality and safety standards in all of its manufacturing processes. Grifols is therefore uniquely qualified to help make compounding safer.

Grifols' i.v.TOOLS is the set of products, technologies, processes, management tools, and related services designed to enhance quality, safety, and efficiency in compounding.

i.v.TOOLS products are designed to improve institutional compliance with guidelines and regulations. In addition, we provide customized services and consultation on all aspects of compounding, including environmental design and monitoring, operational analysis and workflow, process implementation, and regulatory compliance.

Grifols' high standards of quality and excellent service make a decisive contribution to minimizing the risks associated with sterile compounding.

KIRO oncology

KIRO® Oncology is the next-generation system for automated sterile compounding of oncology drugs, including chemotherapy and biologicals.

Unique features

Two robotic arms perform separate tasks simultaneously.

Self-cleaning for decontamination of hazardous chemicals.

Syringes, final containers and drug vials from different manufacturers can be used simultaneously.

The lean design minimizes the movement of disposables in the compounding area.

Main benefits

Improved Patient Safety

Accuracy: KIRO® Oncology performs gravimetric controls at each step of the compounding process, and releases final products based on their accuracy to the prescribed dose.

Verification & Traceability: Barcode readers and cameras located inside the cabinet and in the user area precisely identify vials, IV bags, and disposables by comparing images and barcodes with those stored in the system database.

Aseptic compounding and Quality Assurance: KIRO® Oncology provides a continuous ISO 5 environment during materials loading and automatic compounding of sterile preparations, protecting the user and also the environment. It can be integrated as a biosafety cabinet in USP797 and GMP compliant facilities to support their monitoring and qualification procedures.

Reduced Technician Risk

Self-cleaning: KIRO® Oncology is the only system with a self-cleaning process for the decontamination of hazardous chemicals.

Protection: KIRO® Oncology protects the operator from repetitive stress injuries and from exposure to hazardous drugs. The cabinet is only opened for loading and unloading; and closed during the entire compounding and cleaning processes.

Automatic disposal of hazardous residues: KIRO® Oncology has a built-in dual-port waste transfer system that safely eliminates contaminated waste into self-contained bags. Waste disposal is compatible with the use of standard hazardous waste containers.

Improved Pharmacy Management

Economy: Partially used vials are held in the cabinet for subsequent doses, thereby making optimum use of expensive drugs. The built-in software ensures that partially used vials can be fully tracked. Additionally, during automatic preparation, the operator is free to perform other tasks.

Flexibility: The KIRO® Oncology system supports a wide range of compounding materials:

- Vials: All vial sizes from 0.5 to 100 mL.
- Syringes: Luer lock syringes (1, 3, 10, 20, & 50 mL).
- Final containers: Infusion bags, syringes, elastomeric pumps & cassettes.

Efficiency: The KIRO® Oncology system can prepare both patient specific and small batches using liquid or lyophilized drugs.
Two robotic arms run in parallel to perform different tasks at the same time.

Connectivity: The KIRO® Oncology database can be connected to EMR/EHR systems through various interface protocols and messaging standards, including HL7.

Regulatory Compliance

KIRO® Oncology helps to be in compliance with USP & GMPs regulations by standardizing aseptic compounding procedures, facilitating personnel and process qualification, and minimizing risks when preparing hazardous admixtures.

Electrical safety: UL Listing Mark per IEC 61010 and EMC Certification per IEC 61326-1.

KIRO oncology

Equipment

KIRO® Soft

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

- View automatic and manual compounding queues.
- Monitor compounded products and dispensing activities.
- Access databases and configurable operation parameters.
- Obtain information via reports and metrics.
- Set up user alerts and test records.

Compounding area:

- Two robotic arms.
- 12-port carousel for the vials in use.
- Preparation bay for up to 8 infusion bags, cassettes, or elastomeric pumps.
- Syringe holder for up to 8 syringes.
- Syringe capping station with 4 capping positions.
- Holding area for up to 10 partially used vials.
- Gravimetric device for in-process weighing.
- Two peristaltic pumps for diluent filling of empty containers and reconstitution of lyophilized drug vials.
- Two cameras for syringe and vial identification, respectively.
- Barcode reader for product identification.
- A touch pad for manual loading validation by the user.

User interface area:

- User touchscreen interface.
- Gravimetric device to double check weighing.
- Barcode reader for product identification.
- Two label printers (bags and syringes).

Air treatment area:

- ISO 5 compounding area.
- Environmental protection by HEPA exhaust filter and negative pressure in recirculation chamber.
- User protection by enclosed compounding environment under negative pressure.

Waste area:

- Two waste disposal units.
- Two additional Bag-In Bag-Out filters for air cleaning before recirculation.

Installation requirements

- KIRO® Oncology dimensions (w x d x h): 2100mm x 1133mm x 2235mm (6.7 ft x 3.7 ft x 7.2 ft).
- Minimum clearance (w x d x h): 3000mm x 2500mm x 2500mm (9.8 ft x 8.2 ft x 8.2 ft).
- Weight: 1200Kg (2645 lb).
- Area's Floor Load Rating: 650 kg/m^2 (133 lbf/ft^2).
- Air flow rate between 100 m^3/h (3500 ft^3/h) and 600 m^3/h (21000 ft^3/h).
- Power: 230 VAC ± 10%, 50Hz, 3kVA, 13 A (120 VAC ±10%, 60Hz, 3kVA, 25 A).
- Ethernet port.

KIRO oncology

i.v.TOOLS

COMPOUNDING

Grifols' sterile manufacturing expertise applied to the compounding pharmacy

0000/00
00/00/00

Grifols International, S.A.
Parc empresarial Can Sant Joan Av. de la Generalitat, 152-158 08174 Sant Cugat del Vallès Barcelona - SPAIN Tel. (34) 935 710 500
www.grifols.com

GRIFOLS