inclusiv™
compounding portfolio



KIRO® Assist
Manual Compounding Assistant

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Prepare & Verify

Compounding Software



KIRO® Assist is a manual compounding assisting software

KIRO® Assist

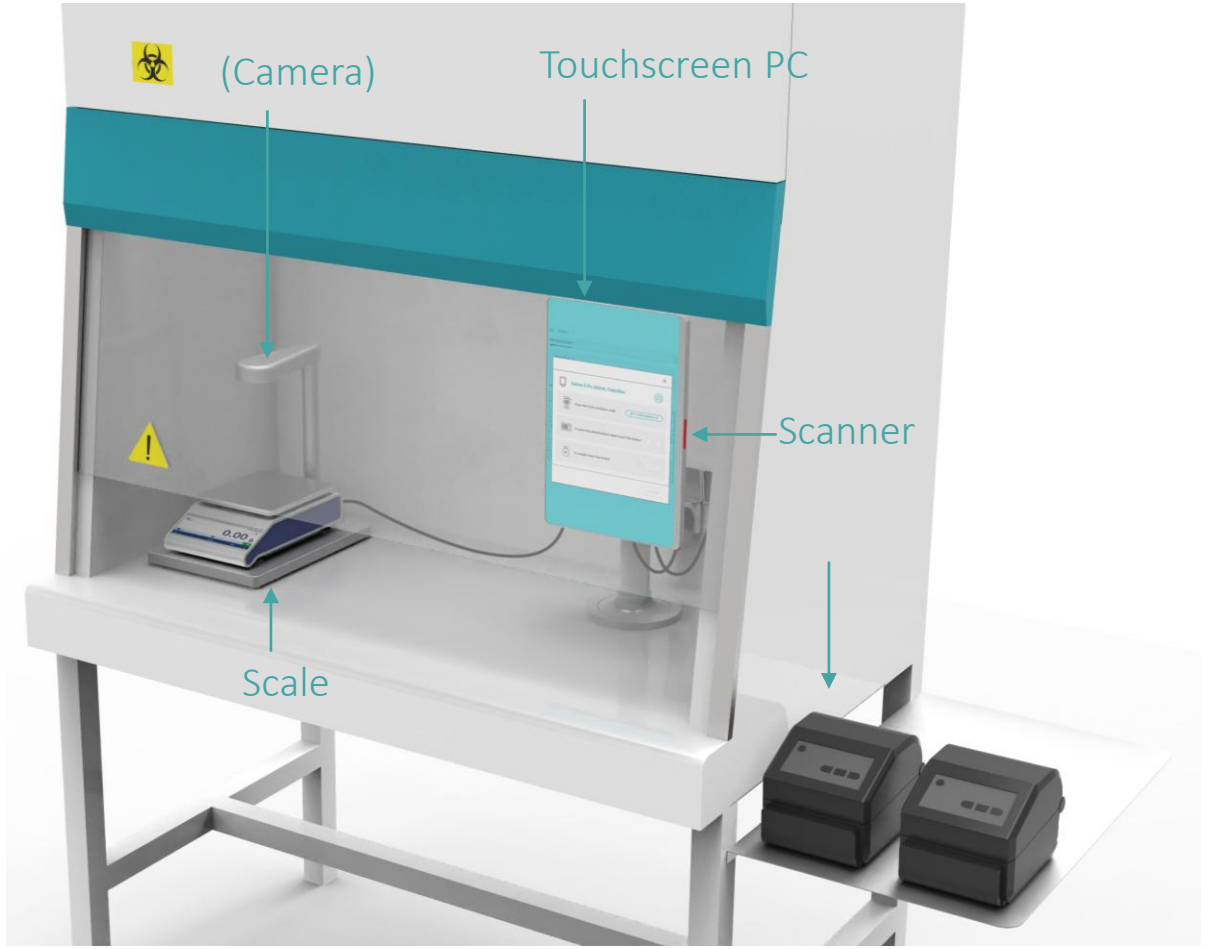
Designed to:

- ❑ **Respond to complex and changing needs**
- ❑ **Enhance patient safety**
- ❑ **Facilitate regulatory compliance**
- ❑ **Optimize operational control and efficiencies**

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Enhance patient safety

- **Drug** and **container identification** by barcode reading (and camera)
- **Precise screen instructions** for user guidance (and camera for process step controls)
- **Compatible with ISO Class 5 cabinets**
- **Gravimetric control** for drug dosing control



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Facilitate regulatory compliance

- Process traceability reports to **manage inspections and recalls**
- Compatible with septic compounding environment according to **USP797** and **GMP** requirements
- **Compatible with Kiro Link web-based application** to manage production workflow



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Optimize operational control and efficiencies

Avoid human error:

- The system guides the user **step by step**
- Manual tasks are controlled by **screen confirmations**
- **Barcode scanning** control materials used
- **Labelling controlled by software**

Manual process can be **checked remotely in Kiro Link:**

- **Orders, used materials and preparation results** accessible through Kiro Link
- **Production workload** in different manual stations and automated systems managed through Kiro Link
- Compounding personnel and pharmacists interacts with a **single interface** in manual stations and automated systems



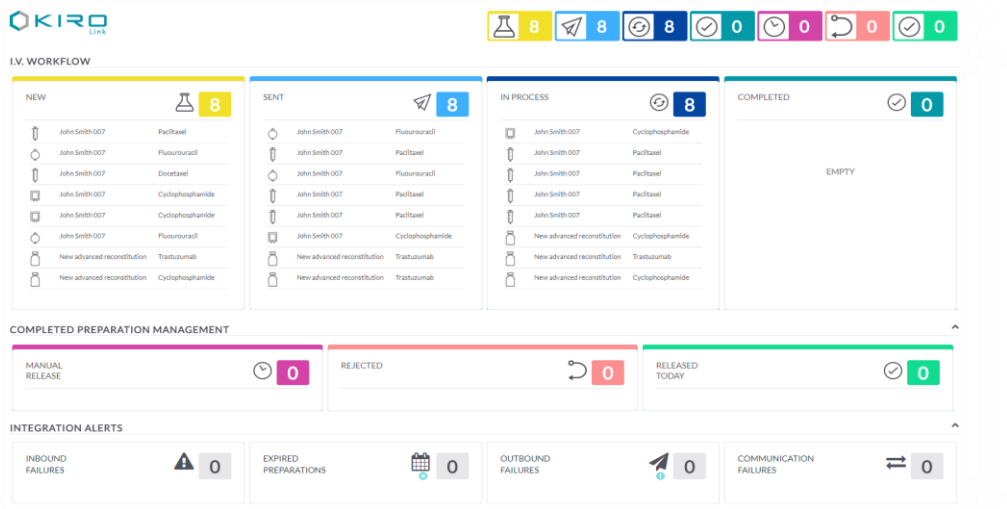
Optimize operational control and efficiencies

KIRO® Link web-based platform to manage production:

Bi-directional integration with HIS or CPOE

Onsite or remote IV workflow management:

- Real-time **tracking and control** of compounding orders
- Creation of **patient-specific** and **batch orders**
- **Assignment** of compounding orders to one or multiple devices
- **List of grouped compounding materials**



Data access:

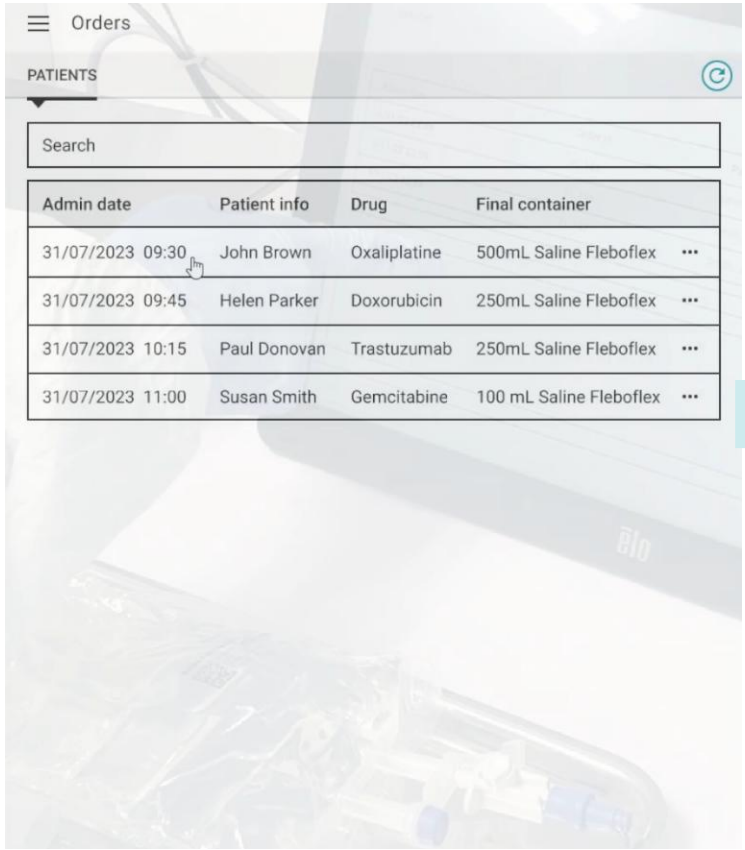
- Access to **database** information and **compounding reports**
- Full **audit trail** of user actions and interfacing events
- Centralized user authentication with LDAP

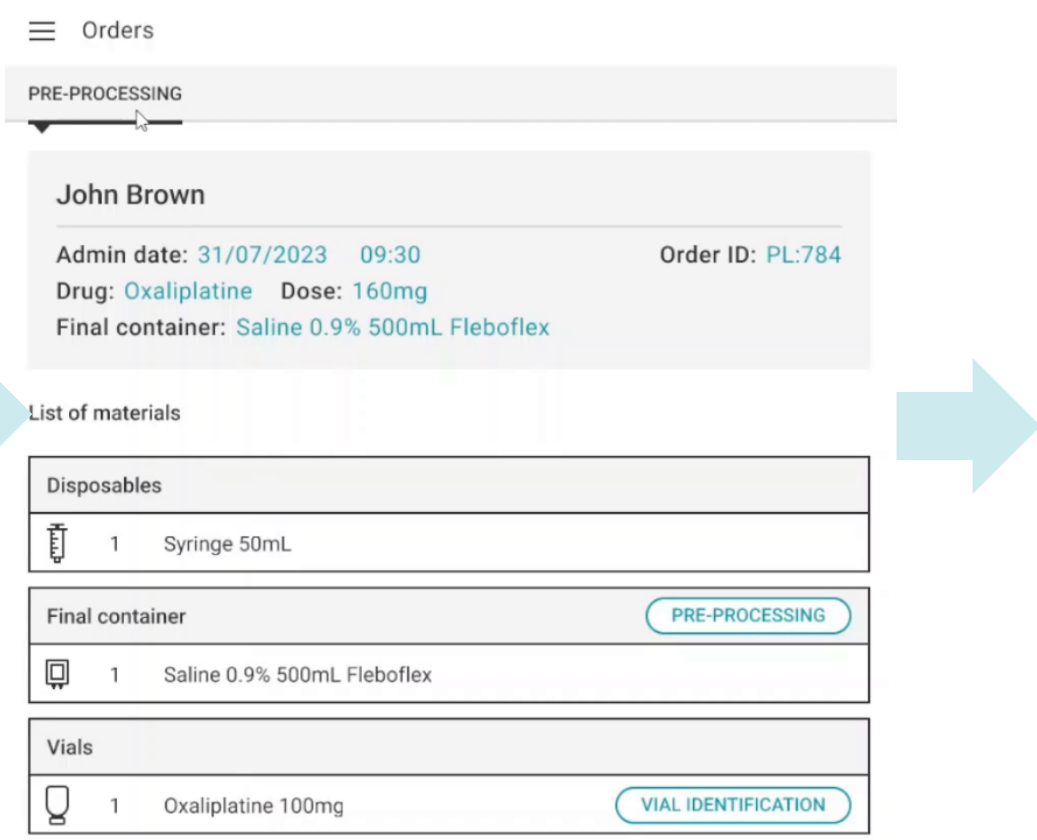


HIS: Health Information System CPOE: Computerized Prescriber Order Entry LDAP: Lightweight Directory Access Protocol

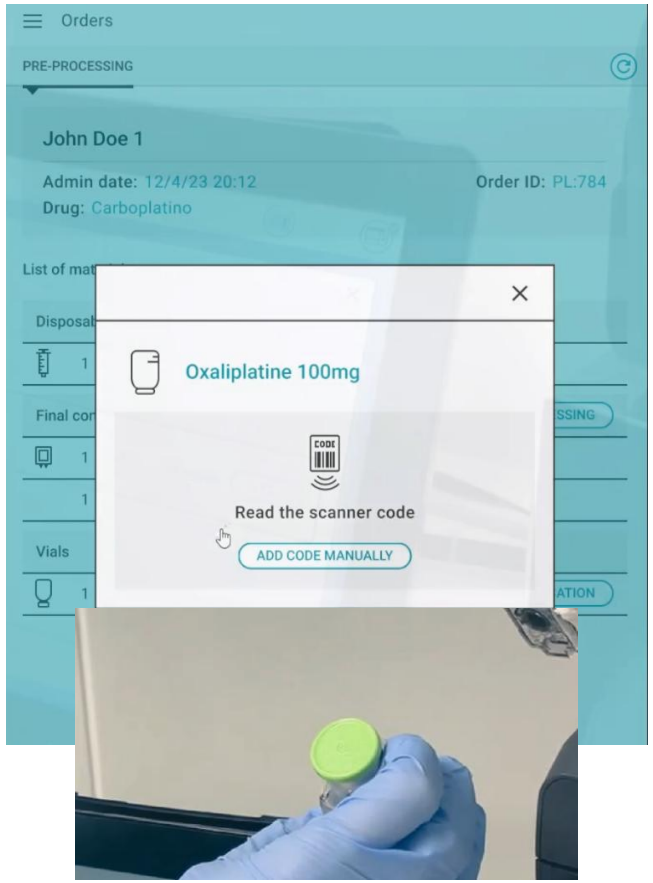
How it Works

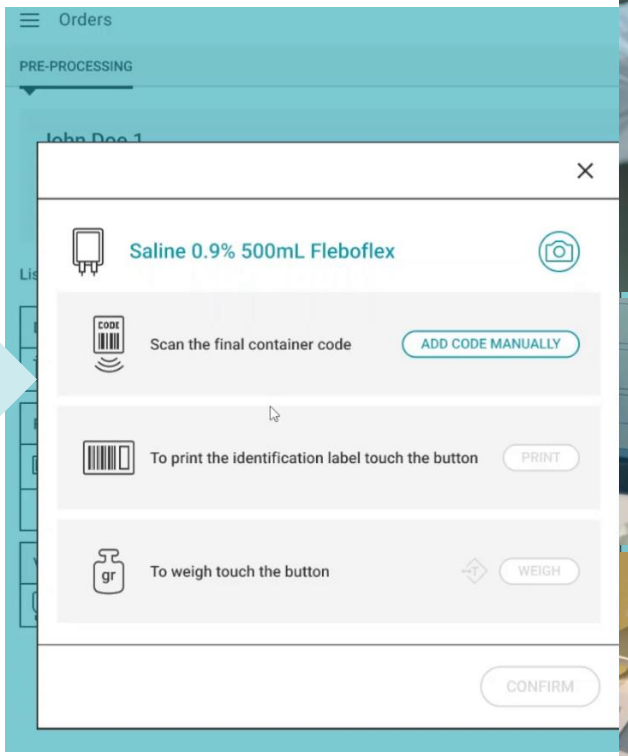
1. Order and material management





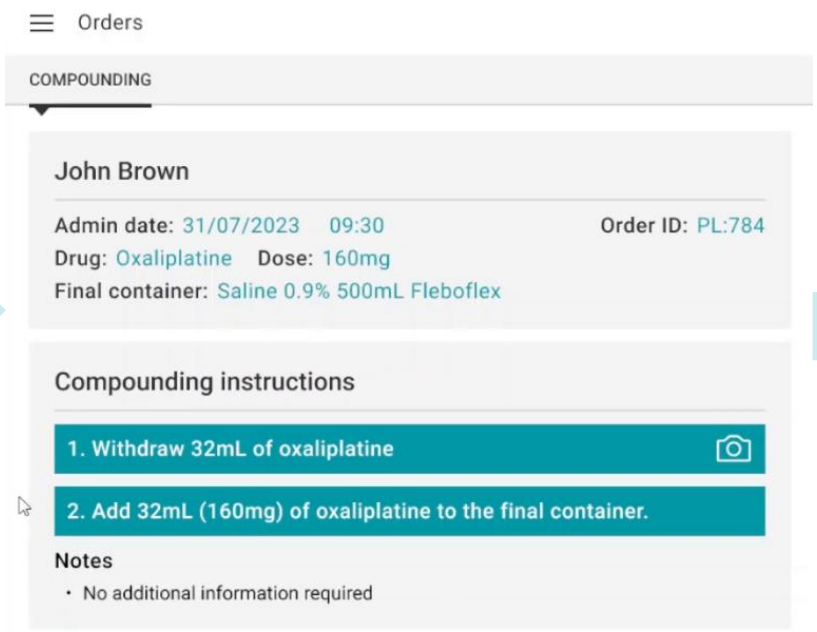
2. Pre-processing





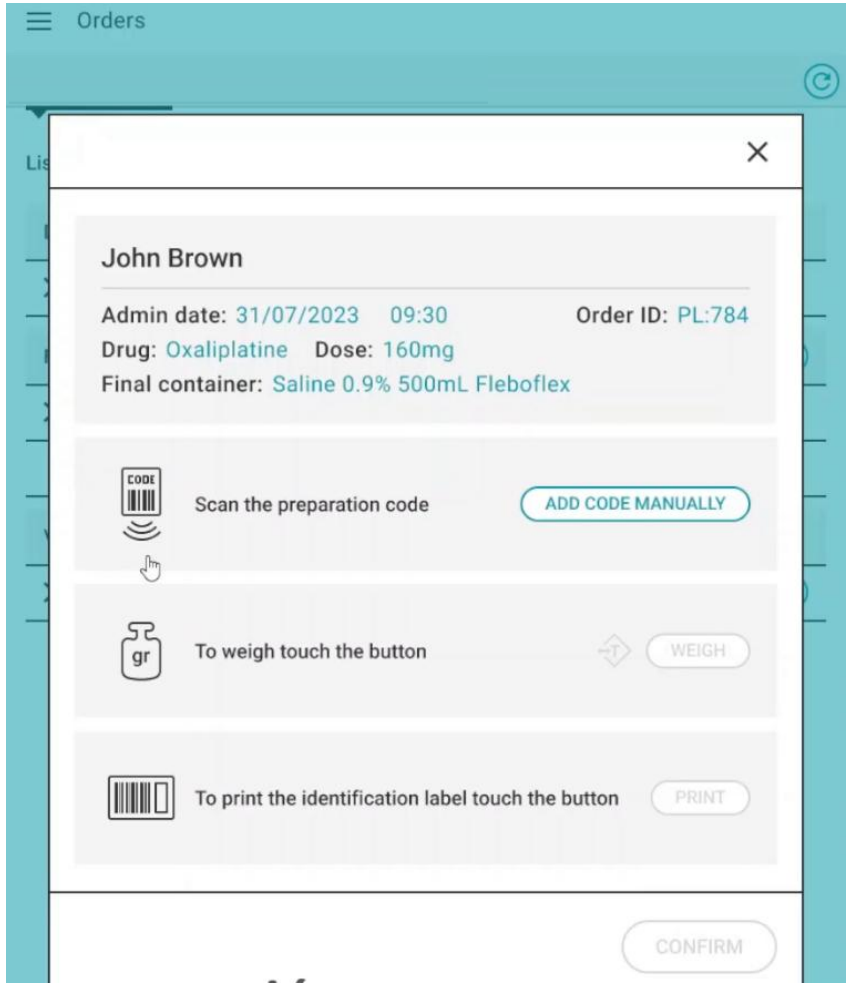


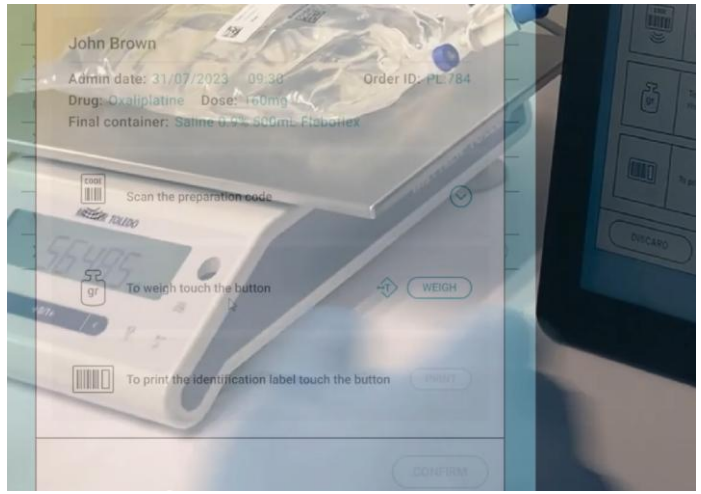
3. Screen guided manual compounding





4. Post-processing

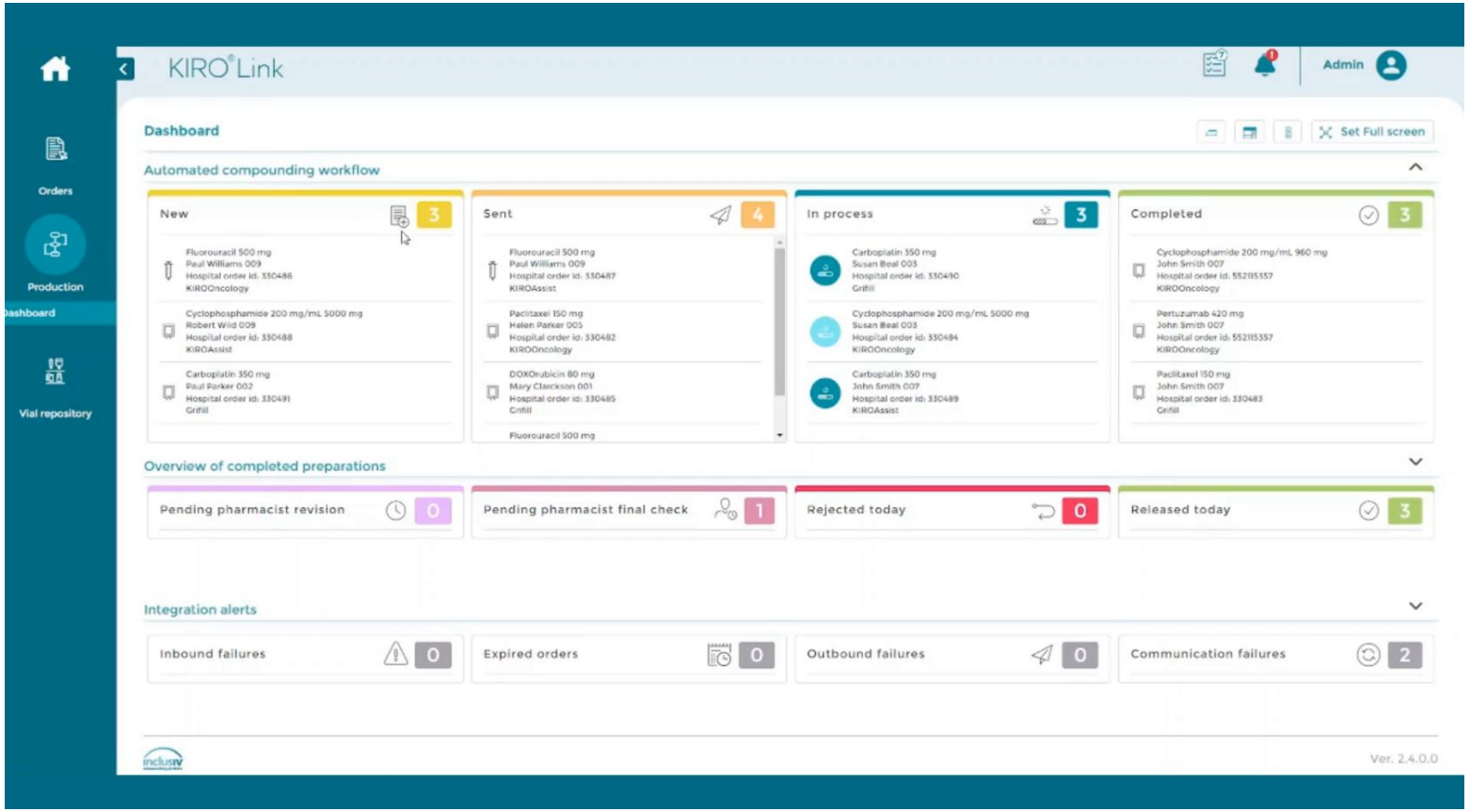


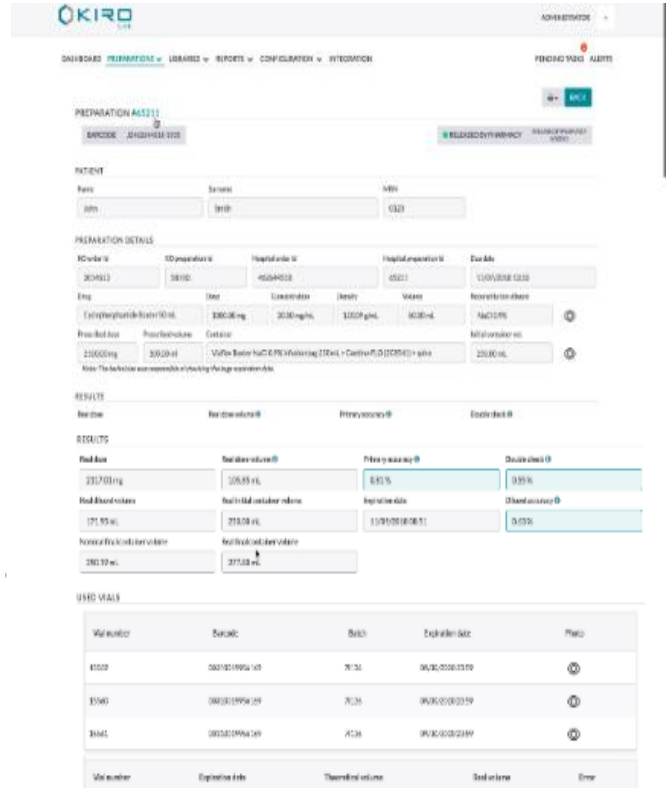






5. Compounding report





What to expect

Technical information

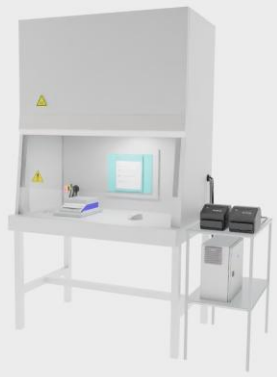
IT Requirements:

- ✓ Ethernet port (RJ45) to enable data exchange and remote support
- ✓ Two virtual servers (production and test), static IP address, netmask, domain name system (DNS) and gateway

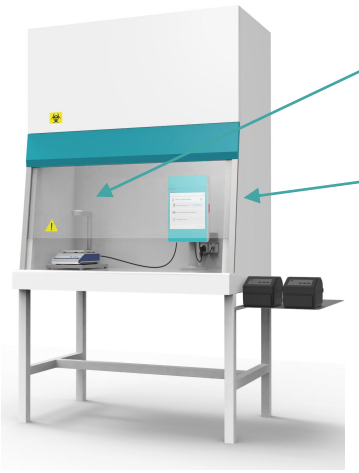
Power:

- ✓ Phase 1 - Two standard power connections within the cabinet & 3 standard power connections outside the cabinet: 230 VAC ± 10%, 50 Hz, 1.6 kVA, 7 A in Europe (120 VAC ± 10%, 60 Hz, 3 kVA, 14 A in US)
- ✓ Phase 2 – No additional requirements

Phase 1



Phase 2



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Validated drugs

ONCOLOGY DRUGS & MAbs (66)			OTHER DRUGS* (21)
Aflibercept	Ganciclovir*	Basiliximab	Amikacin
Azacytidine	Gemcitabine	Bevacizumab	Anidulafungin
Bendamustine	Idarubicin	Brentuximab	Abatecept
Bleomycin	Ifosfamide	Cetuximab	Acyclovir
Bortezomib	Irinotecan	Daratumumab	Caspofungin
Busulfan	Leucovorin	Eculizumab	Cefazolin
Carboplatin	Liposomal Doxorubicin	Infliximab	Cefotaxime
Carfilzomib	Melphalan	Ipilimumab	Ceftazidime
Cidofovir*	Mesna	Nivolumab	Ceftriaxone
Cisplatin	Methotrexate	Obinutuzumab	Cefuroxime
Cladribine	Mytomycin C	Panitumumab	Daptomycin
Cyclophosphamide	Mitoxantrone	Pembrolizumab	Deferoxamine
Cytarabine	Oxaliplatin	Pertuzumab	Meropenem
Dacarbazine	Paclitaxel	Ramucirumab	Micafungin
Daunorubicin	Paclitaxel albumin	Rituximab	Mycamine
Decitabine	Pemetrexed	Tocilizumab	Piperacillin and Tazobactam
Docetaxel	Raltritrexed	Trastuzumab	Tobramycin
Doxorubicin	Topotecan	Vedolizumab	Tigecycline
Epirubicin	Vinblastine		Vancomycin
Eribulin	Vincristine		
Etoposide	Vinorelbine		
Fludarabine	Voriconazole*		
Fluorouracil	Zoledronic Acid		
Fosaprepitant*			

The system covers a wide variety of drugs:

- **Chemotherapy drugs**
- **Monoclonal Antibodies (mAbs)**
- **Non-hazardous medications**

> 600 vial types/brands (> 250 US NDCs) library:

- ✓ Vial measurements
- ✓ Density data
- ✓ Reconstitution parameters
- ✓ Expiration dates

* Non-oncology drugs NDCs: National Drug Codes

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Implementation plan



KIRO Assist is easily connected to current KIRO Oncology workflows

Stage	Tasks and Milestones	Estimated Time (weeks)	Customer Site Staff	Supplier Staff
PREINSTALLATION	Kick-off meeting	1-3	All	Project Manager
	Application, configuration, and integration		Pharmacy	Project Manager
	IT deployment and integration (if applicable)		IT	IT Service Engineer
INSTALLATION	Delivery and assembly, Start-Up , Installation Verification and Validation	3	Facilities, Pharmacy	Field Service Engineer, Application Specialist
TRANSFER	User training	4	Pharmacy	Application Specialist
	Integration validation (if applicable)	4	Pharmacy, IT	Application Specialist, IT Service Engineer

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KIRO® Oncology main users - 1 Kiro Assist beta site

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Mount Sinai
Alberta Health Services
Yale-New Haven Hospital
Assistance Publique Hôpitaux de Paris
institut Curie
Akademiska Sjukhuset
Radboudumc university medical center
HUS Helsinki University Hospital
Mazowiecki Szpital Wojewódzki im. św. Jana Pawła II w Siedlcach Sp. z o.o.
aslimnica Rīgas Austrumu klīniskā universitātes slimnīca
UWHealth
Seattle Cancer Care Alliance
BronxCare Health System
St. Luke's Health
Onkologikoa
Hospital de Salamanca
La Fe Hospital Universitari i Politècnic
Clínic Barcelona Hospital Universitari
Vall d'Hebron Hospital



Users Club



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Why KIRO Assist?

KIRO Assist provides safety and efficiency for complex and urgent preparations

Increased patient safety

- Accuracy of final preparations ensured through **gravimetric control**
- **Barcode scanning materials** ensures correct materials and drugs are loaded
- **Reduces concentration and stress level** of paper-based manual processes

Operational control and efficiency

- **Easily adaptable to preexisting cabinets and manual compounding workflows**
- **Provides safety** to preparations not suitable for automation due to workload, delivery needs or complexity
- **Easy to integrate into current HIS or CPOE using Kiro Link**
- Easy to adopt by compounding and supervising pharmacy personnel

Compliance

- **Automated identification of materials** used (and process steps)
- **Full traceability of dosing accuracy and compounding materials** accessible in Kiro Link reports



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Grifols is a global healthcare company that since its founding in Barcelona in 1909 has enhanced the health and well-being of people around the world. Our four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services in more than 100 countries.

The Hospital Division empowers hospital pharmacies to provide safe, high-quality healthcare for patients worldwide. The division offers a broad range of parenteral solutions for intravenous therapy and clinical nutrition products used in the care of patients, as well as medical devices for interventional therapy. Our latest-generation management-processes solutions for hospital pharmacy include mobile and web-based software applications and automated drug compounding systems to increase process safety and enhance compliance.

Grifols, with nearly 24,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership in the industry.

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