Biovalley Investments Partner

Innovative technology for the compounding of **patient-specific chemotherapy drugs**

ChemoMaker®+

Designed to ensure **operator safety**, **quality** therapies, easy **manageability** and **reduced costs**.

ChemoMaker+ is an innovative system designed to compounding anticancer drugs fully automated, **overcoming the criticalities of manual compounding and improving the quality of oncological therapies**.

Highlights

- Fully automated
- Management of bags, syringes, elastomeric pumps
- Dosing accuracy up to 1.0%
- Safe for operators and patients
- Easy installation

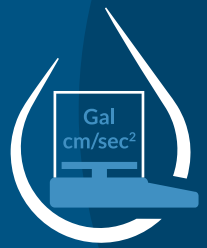
Main **features**

- Table-top equipment
- Can be placed under a laminar flow hood
- Compounding of chemotherapy drugs in the liquid phase
- Drug vials up to 100 ml
- Multidose drug bags up to 1000 ml
- Up to 12 compoundings and 16 drugs per batch
- Up to 30 compoundings per hour
- Built-in gravimetric cell
- Double check (Barcode + RFID)
- Optimized drug use
- 2 patents pending

Table-top equipment

Barcode

RFID



Gravimetric cell

For a better quality of oncological therapies.
Accuracy, safety, efficiency and cost optimization.

Given the high toxicity of the drugs used in the oncological field, the ability to **ensure compoundings are made safely and precisely** in the interest of both patients and operators **represents a particularly critical element.**

The challenge

The challenge is to improve patient safety and reduce the risk for operators, increasing efficiency and optimizing costs.

Compounding chemotherapy drugs is a critical activity for healthcare facilities, which are typically faced with:

- Significant occupational risks for operators involved in compoundings due to the high toxicity of the drugs handled
- High cost of anticancer drugs
- Possibility of accidents related to the inadvertent exchange of drugs or containers for administration
- Potential adverse events due to poor accuracy in dosing of anticancer drugs

What *ChemoMaker+* is

ChemoMaker+ is

an innovative system for the automated compounding of anticancer drugs, capable of overcoming most of the criticalities associated with manual compounding.

It is a **compact system**, which can be inserted directly **into a pre-existing class II laminar flow hood** and requires no especially dedicated spaces or set-up work.

ChemoMaker+ allows to

- Compound large numbers of therapies
- Speed up set-up times
- Maintain high dosage accuracy
- Reduce risks for operators

An accurate formulation.

ChemoMaker+ guarantees a **high level of dosing accuracy** through a **controlled automatic** system.

The accuracy of the formulation is guaranteed by a real-time gravimetric control system (patent pending) capable of ensuring dosing accuracy up to 1%, i.e. one order of magnitude more than the precision required by the European Pharmacopoeia for manual compoundings.

The drug is dosed directly in the final containers for administration (bags, syringes, elastomeric pumps) and the process is completely automated, without the need for any subsequent manipulations by operators.

Advantages over manual compounding

- Automatic verification of the entire compounding cycle
- Reduction of contamination risks for pharmacy operators
- High dosing accuracy, verified for each compounding
- Human error prevention, less risk for patients
- Optimization of the consumption of unused drugs, with consequent reduction in costs
- *ChemoMaker+* can manage up to 12 final containers (including containers of different types) and 16 drugs at a time

ChemoMaker+ innovation in short

Manual compounding vs *ChemoMaker+*

Two operators required for the compounding process	Once activated, the system does not require the constant presence of an operator
Double operator control required at each stage of the compounding process	The double check is ensured by the combination of the RFID + Barcode control, plus the Gravimetric control
Only one compounding at a time	Up to 12 doses and 16 drugs per batch, guaranteeing up to 30 compoundings in one hour
Constant contamination risk for the operators	Thanks to the automated system, the risks for the operator are reduced
Risk of human error in compounding and control	The automated management of the entire compounding cycle prevents human errors

ChemoMaker+ vs Competitors

CHARACTERISTICS	ChemoMaker+	1st GENERATION SYSTEMS
Size and weight	table-top, 30 Kg	4 m^3, > 1.500 Kg
Cleaning	simple: removable, easy to sterilize	difficult
Speed	up to 30 doses/h	15-20 doses/h
Operator safety	high	high
Patient safety	barcode + RFID	barcode

A **safe system** for both **operators** and **patients**.

The total absence of manipulation by the operator and a system of cross-checks make the compounding of formulations extremely safe for both operators and patients.

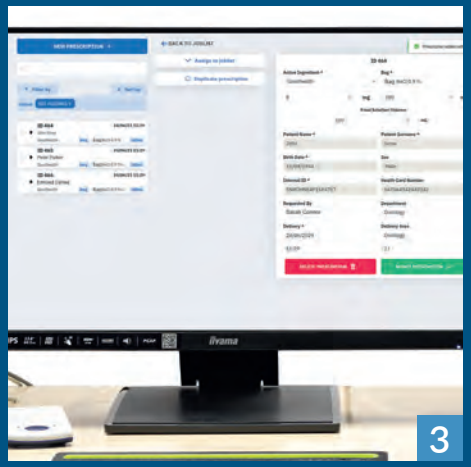
ChemoMaker+ **allows** for the **automatic dosing** of the antiblastic drug in the liquid phase by means of a **closed circuit fluidic system** based on **sterile disposable cartridges**, which guarantees the **sterility of the drug transfer process** from the vial to the final container and **ensures the containment of chemical contamination in the surrounding environment**.

ChemoMaker+ overcomes the criticalities of the compounding process and management of oncological therapies, still largely based on manual operations, in a simple and effective way.
In line with a modern and advanced approach to healthcare management, *ChemoMaker+* reduces risks for both patients and operators by reducing and virtually eliminating the risks connected with:

- errors in the formulation of the anticancer drugs
- the difficult management of unused quantities of very expensive drugs
- the occupational risks for operators involved in the compounding of chemotherapy drugs

The Process

- **1.** Drugs and final containers are selected based on prescriptions
- **2.** The drugs are identified with a double control system: Barcode and RFID
- **3.** The final containers are assigned to each patient's specific therapy
- **4.** The drug vials and final containers are loaded onto the automated system
- **5.** ***ChemoMaker+*** automatically carries out the compounding process
- **6.** The system automatically generates the labels containing all the identification data of each patient



Traceability

The **double control** system is designed to **increase patient safety** by managing the compounding of the formulations starting from the prescriptions, without the intervention of an operator.

Each dose is identified through **codes that ensure traceability by means of Barcodes** showing all the data of the compounding and of the patient for whom it is intended, which can be verified at the time of administration so as **to prevent any inadvertent exchanges between different therapies**.
The system also uses sensors and RFID tags, which are integrated in the cartridge and holder to ensure the **absolute safety of the compounding process.**

Final container
barcode reading

Final container holder
RFID tag reading

Drug
barcode reading

Medication cartridge
RFID tag reading

Integrated RFID tag reading system

A system **easy to integrate**

The *ChemoMaker+* system is controlled by **proprietary software** *ChemoPlan*, which **acquires the prescriptions and allows to plan the work cycles** of the machine.

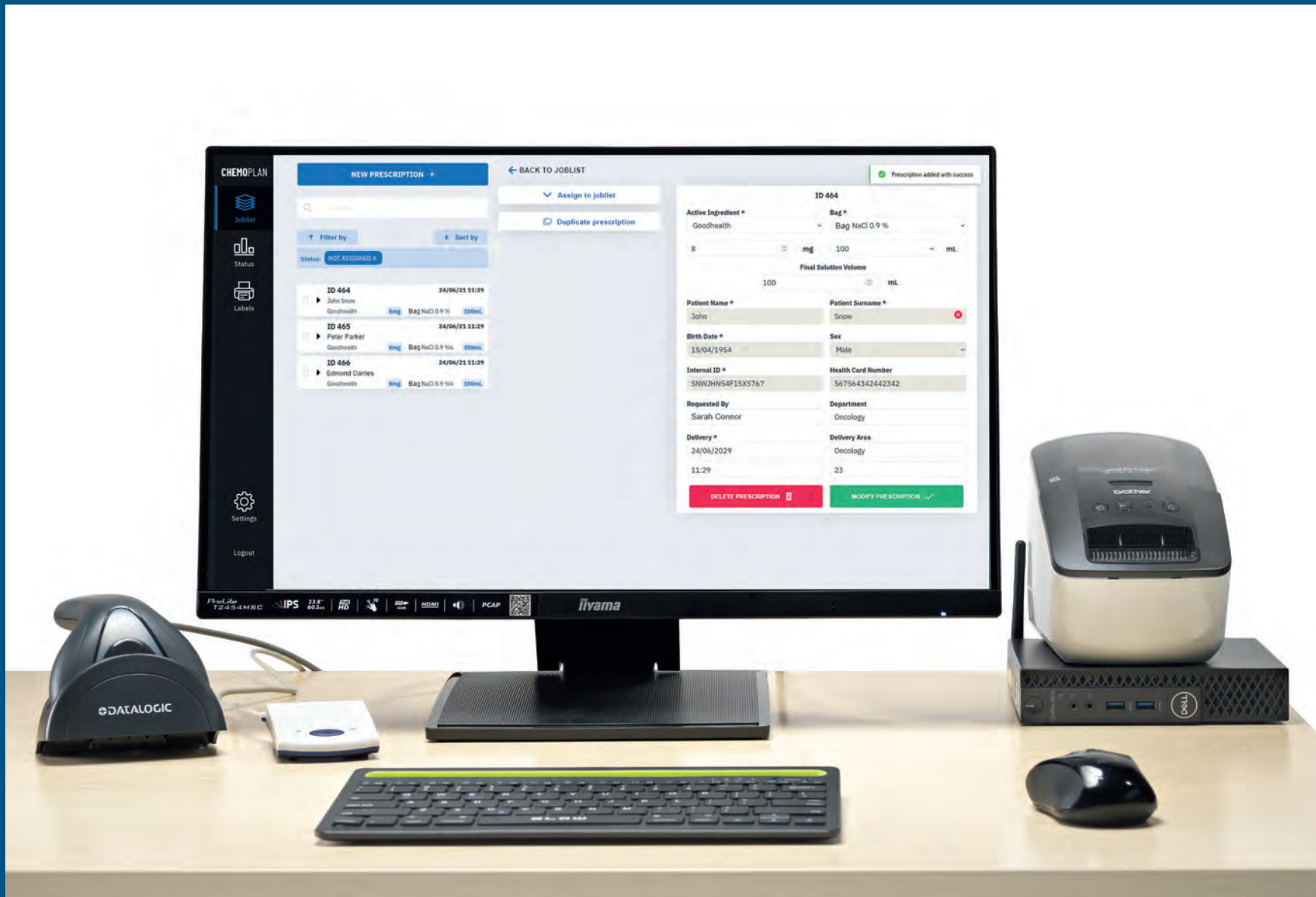
ChemoPlan **can be interfaced** with the main **prescription management software** of the hospital pharmacy.

The system is designed to ensure the highest safety standards.

- The software acquires the prescriptions and allows to plan the work cycles
- It can be interfaced with the main prescription software (HL7 Protocol)
- The drug database is customizable
- The A.I. of the software optimizes the use of drugs

ChemoPlan

ChemoPlan is pre-installed on the computer supplied with ***ChemoMaker+***, already complete with all the accessories necessary for operation.



ChemoMaker+ in detail

Protective turret
It contains the mechanical actuators, the sensors and the gravimetric cell.

Final container rotor
Made of anodized aluminium fixed to the base unit by means of a tightening knob and designed to accommodate various types of containers: bags, syringes, elastomeric pumps.

Drugs rotor
Made of anodized aluminium and fixed to the base unit by means of three tightening knobs. It can accommodate up to 16 different drugs in containers of up to 100 ml.

Base unit
Composed of a closed metal frame containing the electronic boards, electrical components and rotor drive motors.

LCD monitor
An interactive touchscreen monitor that allows the operator to interact directly with the machine.

Brake
The unit is equipped with a mechanical brake that acts on the wheels that allow easy movement on flat surfaces.

Dimensions

72x65x45 cm

ChemoMaker+
is a compact system that can be **inserted directly into a pre-existing** class II laminar **flow hood**

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