Health Robotics
Architecting the i.v. Room of the Future

i.v.STATION™ Product Specification

D Com 103

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Typographical conventions

Throughout this document, blocks of text may be accompanied by an icon. These blocks contain notes, cautions or warnings. They are used as follows:

	**The NOTE icon indicates important information on the product, using the product, or part of the documentation that will of benefit to the user or that will help to make better use of the i.v.STATION™ system.**
	**The WARNING icon indicates the potential for physical harm caused by the i.v.STATION™ system and tells you how to avoid the problem.**
	**The CAUTION icon indicates information about how to avoid either potential damage to the i.v.STATION™ hardware or loss of data. Minor personal injury or damage to property can result if proper precautions are not taken.**

1 INTRODUCTION

This document comprises information regarding the i.v.STATION™ system (designed and manufactured by Health Robotics S.r.l. (HR)) and technical information necessary for a successful delivery and installation of the machine.

 **NOTE**	**Health Robotics has reserved the right to modify its products as to optimize the performances and processes described.** **Technical details are subject to modifications without preliminary notification.**

2 GENERAL OVERVIEW

i.v.STATION™ is an automated robotic system designed for the preparation of injectable drugs within an ISO-5 air-controlled environment.

The automated functions include the following:

- Automatic dosing of medications from their commercial containers (vials only, ampoules are not supported);
- Automatic reconstitution of powder drugs with appropriate diluents;
- Identification of final containers (syringes, IV bags) with Bar-Code labels;
- Handling of the preparation cycle within a ISO 14644-1 Class 5 air quality environment.
- Overnight sterility control by UV-C lamps;
- Controlled access with real-time identification of authorized users by multiple ID / password credentials (optional support of common readers such as biometric face recognition, magnetic or RFID badge).

3 OPERATING FEATURES

- Eliminates most of the manual steps in the preparation, compounding and dispensing of drugs, limiting human intervention to loading original uncapped drug vials, solutions, IV bags, syringes (with capped needle already mounted), syringe caps, printable labels and disposable IV powder reconstitution tubing sets, and retrieving ready-to-administer IV patient doses;
- Fulfills all process steps without the need of ancillary external devices (laminar flow cabinets, isolators, weighting scales, etc.);
- Maintains an ISO-5 clean room environment throughout the process as required by specific regulations (use of integrated air circulation technology, HEPA absolute filtering, UV-C lamps, etc.);
- Handles drugs both in liquid and powder form;
- Automatically performs powder vial reconstitution;
- Automatically disposes of wastes (empty vials, needles, etc.) into dedicated containers;
- Produces single drug or multiple drug doses, batch or patient specific, into syringes as final containers
- Produces single drug or multiple drug doses, batch or patient specific, into i.v. Bags as final containers
- Verifies correct drug dosage, through double gravimetric control (vial weight check and final container, syringe or Bag, weight check);
- Automatically labels compounded syringes and I.V. Bags with unique barcode identification;
- Adopts unique identification means (barcode scan and vial label recognition) to avoid accidental exchanging of drugs or final preparations;
- Adopts computer vision techniques to detect accidental errors when loading components (detect capped vials, syringes without needle, wrong syringes, wrong vials, etc.)
- Avoids cross contamination among different drugs;
- Optimizes machine time and reduces idle time linked to loading and unloading operations; machine is operational and can perform preparations while loading and unloading;
- Allows user to give priority to urgent preparations, automatically re-defining the planned work-list; special tools are available to assign priority to individual or groups of preparations (based on same product or same patient criteria);
- Handles all machine operations through an intuitive PC touch-screen user interface;
- Fully interfaces and integrates with the existing hospital information system and pharmacy information systems;
- Adopts advanced measures to grant protection for private data and avoid unauthorized access; and
- Provides complete logs of all processing phases for each preparation for full traceability and quality assurance requirements.

4 PERFORMANCE

- Average throughput: Produces up to 40 batch or patient-specific I.V. Bags or syringes per hour;
- Minimum dosage: 0.5mL;
- Dosing accuracy (average): Better than ±95% (Error less than 5%);
- Repeatibility: Better than 95% (Failed doses less than 5%).

 **NOTE**	**Average throughput refers to simple liquid transfers, i.e. to preparations that only require the transfer of a liquid from one vial to a syringe or to an i.v. bag. Throughput may vary when the preparation process involves diluted preparations (drug plus diluent), powder vials to be reconstituted, or preparations that require transferring liquid from many vials.**
 **NOTE**	**Actual throughput depends on drug types, dose complexity, and reconstitution time (shaking time and resting time) of powder drugs. Throughput for powder preparations might vary according to the number of vials to be reconstituted and their related reconstitution time. The machine is able to perform powder reconstitution as a parallel task while performing other preparations.**
 **NOTE**	**Due to the special grouping feature available in i.v.STATION™, i.v. bag batches are not limited to actual batch preparations, but also include on-the-fly groups of patient-specific doses that make use of the same drug regardless of whether the quantity of drug and/or the i.v. bag size is the same. These preparations can be processed automatically in a Batch order to obtain maximum throughput.**

5 SOURCE CONTAINERS AND FINAL CONTAINERS

5.1 Final containers

- Syringes from 1 cc up to 60cc (42 syringe slots on carrousel);
- Soft Plastic IV Bags (PVC and PVC-free) from 50mL up to 1L (25 Bag slots on carrousel).

5.2 Source Containers

- Drug Vials 1 mL to 100 mL (28 vial slots on carrousel) ;
- Powder Drug Glass Vials can be loaded on each of the 28 vial slots on carrousel and automatically reconstituted by 2 parallel programmable shakers.

 **NOTE**	**Limitations in the actual usable volume for large syringes may exist depending on the syringe model. Limitations may exist for larger bags depending on height and width of the product, as well as for bags with particular port design. Limitations may exist for glass and drug vials; please check the list of the approved materials for the details of current physical constraints. Please also check the list of**

	supported products or provide a sample product to obtain approval for the use on the i.v.STATION™ robot.

6 SYSTEM STRUCTURE

i.v.STATION™ consists of the following main components (Figure 1):

- Drug dosing and compounding area;
- Syringe loading/unloading ;
- Drug vial loading/unloading;
- IV bag loading/unloading;
- Dose Labelling unit (including Bar-Codes) (2 printers);
- Syringe capping;
- Electronic compartment;
- Air treatment unit and HEPA filter - Class H14;
- Automatic waste management.

A 12” LCD touch screen is mounted on the front panel of the unit.

A main HEPA filter (class H14) is located in the upper part of the unit for the treatment of external air.

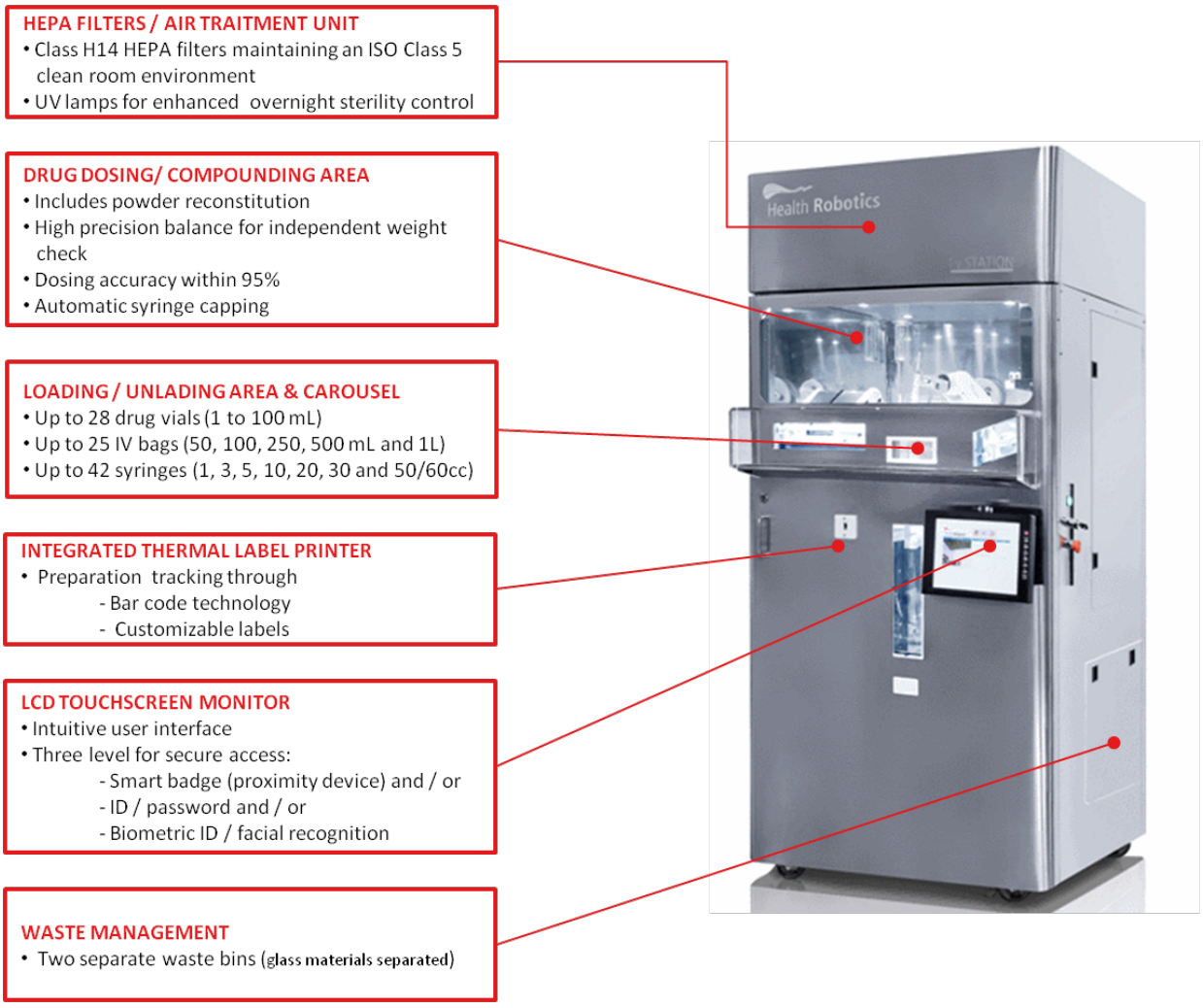


Figure 1 - i.v.STATION™ components

7 APPROVED MATERIALS FOR INTENDED USE

This chapter describes the technical characteristics of materials safely handled by i.v.STATION™. The use of materials with different characteristics can bring i.v.STATION™ to malfunction and to potential hazardous situations. Supported materials as follow **(currently available unless otherwise stated)**.

 **NOTE**	**The following list is based on the test and validation of the products available on the market at this time. Individual manufacturers may change the physical specifications, shape and performance of their products at any time. Compliance of materials is therefore subject to verification by Health Robotics or an authorized distributor or representative of Health Robotics s.r.l. prior to utilization on Health Robotics products**
 WARNING	**The use of materials not conforming to the specifications unless approved and certified by Health Robotics can result into equipment malfunction and potential hazards. It is forbidden by FDA (Food and Drug Administration)regulation.**

7.1 Standard Drug Vials

i.v.STATION™ supports drug vials within the following dimension ranges (see Table 1 and Figure 2) dimensions other than Height, Base, Flip-off and Cap Height are only shown for illustrative purposes).

ID	Description	Value (mm)	Zosyn
A	Cap Height	6 ÷ 11	9
B	Neck Height	>= 5	6
C	Vial Height	32 ÷ 110	100
D	Base Diameter	15 ÷ 88	87
E	Cap Diameter	<= D	28
F	Neck Diameter	10 ÷ 40; <D	24
G	Rubber Diameter	>= 7	7

Table 1 - Vial dimension ranges

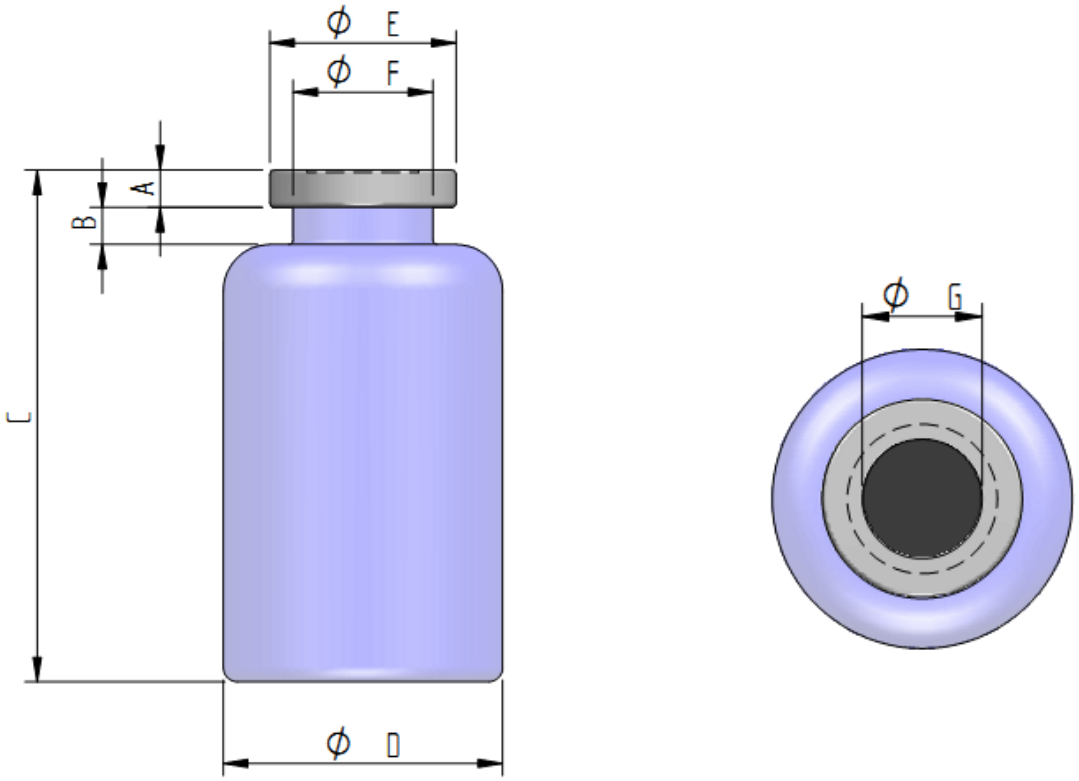


Figure 2 - Drug vials dimension range

NOTE	**i.v.STATION™ does not support plastic or glass ampoules.**

7.2 Special Drug Vials

Zosyn 40.5 GRAM VIAL.

7.3 Syringes

 **NOTE**	1. **i.v.STATION™ supports syringe with a male Luer-Lock connection** 2. **Limitations in the actual usable volume for 60mL (e.g. 50mL max.) syringes may exist.**

Manufacturer: **Becton Dickinson**

Model: Plastipak™ (Luer-Lok™)

Supported sizes (nominal volume)	Part Number
1 mL	309628
3 mL	300910
5 mL	300911
10 mL	300912
20 mL	301189
30 mL	301229
50mL (60cc)	300865

Manufacturer: **Terumo (Japan)**

Model: Luer - Lock Tip

Supported sizes (nominal volume)	Part Number
5 mL (only for syringes preparation)	ss-05Lz
10 mL (restrictions may apply)	ss-10Lz
20mL	ss-20Lz
30mL	ss-30Lz
50mL (restrictions may apply)	ss-50Lz

Manufacturer: **B|Braun**

Model: Omnifix (Europe)

Supported sizes (nominal volume)	Part Number
AVAILABLE 1Q 2012 SUPPORTED SIZES AND PART NUMBERS TO BE DEFINED	

7.4 Syringe needles

Manufacturer: **Becton Dickinson**

Model: BD PrecisionGlide™ needle, 18G x 1 ½ in., America (Part Number: 305195)

BD Microlance™ needle, 18G x 1 ½ in., Europe (Part Number: 304622)

Manufacturer: **Terumo**

Model: Terumo needle, 18G x 1 ½ in., 38mm, Worldwide (Part Number: NN1838)

7.5 Tubing sets for withdrawal of liquid from ivbags

Manufacturer: **Sidam** (CE-marked)

Model: 01011213 (Europe, plus ROW with CE-mark)

Manufacturer: **ICU Medical**

Model: 011-H3091 (Europe, plus ROW with CE-mark)

Model: B1473 (Canada and America)

7.6 Tubing sets for diluents injection (powder reconstitutions)

Manufacturer: **Sidam** (CE-marked)

Model: 1001717 (Europe, plus ROW with CE-mark)

Manufacturer: **ICU Medical**

Model: 011-H3090 (Europe, plus ROW with CE-mark)

Model: B30116 (Canada and America)

 **NOTE**	**For North America or countries that do not recognize CE-mark as medical device certification, Health Robotics assumes that hospital pharmacies will purchase the above sets directly (sect. 5.4 and 5.5) from ICU Medical, or their regular suppliers of medical consumables, given the standard nature and wide availability of the individual components within the Tubing sets.**

7.7 I.V. Solutions Soft Plastic Bags (saline, glucose, dextrose)

Manufacturer: **Baxter**

Model: Viaflex® (America, Oceania)

Supported sizes (nominal volume)	Part Number
50mL	2B1301
100mL	2B1307
250mL	2B1322Q
500mL	2B1323Q
1000mL	2B1324X

Manufacturer: **Baxter**

Model: Viaflo® (Europe, Asia)

Supported sizes (nominal volume)	Part Number
50mL	LE1306
100mL	LE1307
250mL	LE1322
500mL	LE1323
1000mL	LE1324

Manufacturer: **Baxter**

Model: Aviva® (America)

Supported sizes (nominal volume)	Part Number
AVAILABLE 1Q 2012 SUPPORTED SIZES AND PART NUMBERS TO BE DEFINED	

Manufacturer: **Grifols**

Model: FleboFlex® (Europe)

Supported sizes (nominal volume)	Part Number
50mL	631242
100mL	631291
250mL	631333
500mL	631549
1000mL	631531

Manufacturer: **Hospira**

Model: VisIV® (America)

Supported sizes (nominal volume)	P/N
50mL	0409-7984-06
100mL	0409-7984-11
250mL	0409-7985-25
500mL	0409-7983-30
1000mL	0409-7926-48

Manufacturer: **B|Braun**

Model: Excel® & PAB® (America, Oceania)

Supported sizes (nominal volume)	P/N
50mL	S8004-5384
100mL	S8004-5264
250mL	L8002
500mL	L8001
1000mL	L8500

Manufacturer: **Terumo**

Model: To be defined (Asia)

Supported sizes (nominal volume)	Part Number
AVAILABLE 1Q 2012 SUPPORTED SIZES AND PART NUMBERS TO BE DEFINED	

Manufacturer: **Otsuka**

Model: To be defined (Asia)

Supported sizes (nominal volume)	Part Number
AVAILABLE 1Q 2012 SUPPORTED SIZES AND PART NUMBERS TO BE DEFINED	

7.8 Syringe caps

Manufacturer: **B|Braun**

Model: TEC1000 Tamper Evident Cap (Part Number: 418004)

7.9 Waste containers

Manufacturer: **AP Medical**

Model: PBS 12L

- Yellow color for Europe
- Red color for Canada and America

 **NOTE**	**Use of equivalent containers available locally, approximate dimensions: 310 x 248 mm (height x diameter), is subject to Health Robotics verification and approval.**

7.10 Printer labels

Manufacturer: **ARO S.p.A.**

Model: 40x40 mm (syringes) and 56x65 mm (IV Bags) direct thermal labels roll, white protected paper, peelable, 25mm core, 100mm max diameter

 **NOTE**	**Use of equivalent label rolls available locally, is subject to Health Robotics verification and approval.**

8 Installation Requirements Specification

8.1 Transportation and shipping

The i.v.STATION™ standard shipping crates (Ref. "D R&D 107 - i.v. STATION Packaging") are shown in Figure 3 and Figure 4.

The Main Unit (MU) is packaged in crate 1 (Figure 3) whereas the top Air Treatment Unit (ATU) and miscellaneous materials are packaged in create 2 (Figure 4).

The dimensions for the light transportation containers with 30 [mm] (1.2 [inch]) thick foam insulation are (Width X Depth X Height):

- Crate 1 (MU): 1095 X 1095 X 1995 [mm] (43.1 X 43.1X 78.5 [inch])
- Crate 2 (ATU): 1095 X 1095 X 1095 [mm] (43.1X 43.1 X 43.1 [inch])

Total weight 858 kg (1891.57lbs).

NOTE	**Different packaging and transportation options may be available in accordance with local requirements.**

Figure 3 - Shipping crate 1

Figure 4 - Shipping crate 2

8.2 Uncrating

i.v.STATION™ must be installed by qualified personnel. For reduction of noise and vibration during installation and assembly, and as to maintain the cleanliness of the installation area, remove the shipping crate and dispose of the packaging materials before moving the i.v.STATION™ to its final destination. The i.v.STATION™ recommended unpacking procedure is described below. (Ref. "D Ser 21 – i.v. STATION™ uncrating").

 **CAUTION**	**A minimum of two persons are required to lift or move the parts of the i.v.STATION from the packing container. Use proper lifting and moving techniques.**
 **NOTE**	**Before discarding the packing material, make sure you locate, and safely store, all the items found inside the shipping crates.**
 **NOTE**	**If the device is in a trial period do not have crates disposed of. They can be disassembled and stored separately.**

8.3 Standard installation requirements

8.3.1 Customer responsibilities

The procurement of works and materials to prepare the site is under the responsibility of the customer. Delay and waste of manpower can be avoided by completing pre-installation works before delivery and unpacking of the i.v.STATION™.

In general the facility preparation takes time: make sure to start pre-installation activities at least two weeks before the desired delivery date in order to allow enough time for any necessary adaptation.

It is the purchaser's responsibility:

- to obtain any local government permits required to install and operate the i.v.STATION™ pharmaceutical compounding system (PCS);
- to procure works and materials required for the operation of the facility;
- to complete site preparation activities before delivery of the system;

- to pay the costs for any alteration or modification of the facility that is not specifically provided as part of the sales contract.

All electrical installations that need to be performed prior to positioning the equipment at its final destination must be performed by licensed electrical contractors.

 **CAUTION**	**Customers should only allow qualified personnel to install the equipment and perform related electrical servicing. Qualified personnel are defined as persons who are authorized to commission, ground, and tag circuits, equipment, and systems in accordance with established safety practices and standard regulations.**

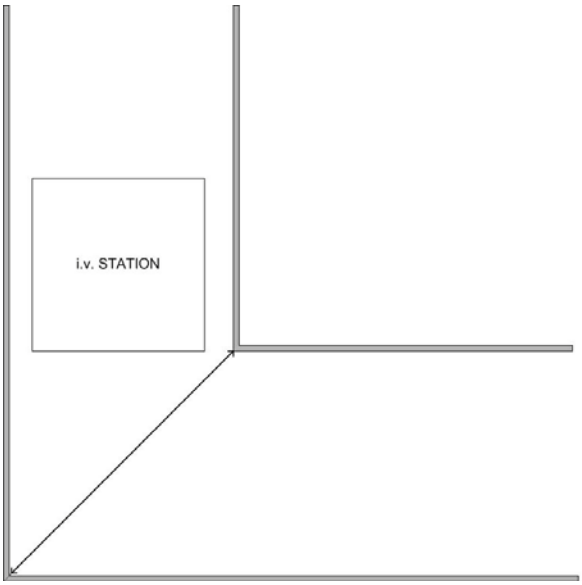
Other connections between pieces of electrical equipment, calibrations, and testing must also be performed by qualified personnel. The products involved (and the accompanying electrical installations) are highly sophisticated and special engineering competence is required. All electrical work on these products must comply with the requirements of applicable electrical codes.
Contact a Health Robotics representative to evaluate in detail the need for this cabling

 **WARNING**	**To achieve compliance with IEC 61010-1 whether desirable or required by local regulation, an additional electrical connection between the frame ground (Green and Yellow cable) of the i.v. STATION™ to the building facility ground is required.**

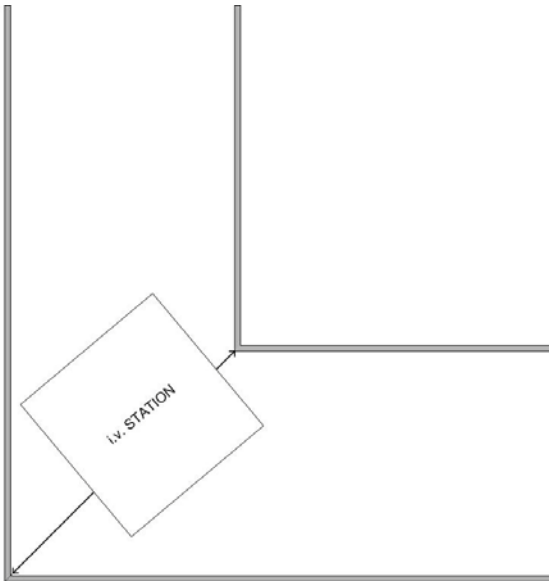
8.3.2 Location and facilities requirements

Make sure the floor load capacity (of the path to the final position) is compatible with the weight of the complete system.
The floor load shall be approximately 661 [kg/m^2] (135 [lbs/sq ft]) not including the estimated weight of up to 50kg, of the materials loaded for a generic compounding task. Dynamic component of load at full load equal to 2kN (449.62 pounds-force [lbf] for each of the four supports, located at a distance of 820mm [32.28 inches] along the front side and 745 mm [29.33 inches] along the lateral side of the device.
Please refer to the Floor load specifications paragraph 8.5
The i.v.STATION™ device does not need to be mounted on a special chassis or installation frame, and may be transported within the building for short distances, from the entrance of the facility to the room where it will be operated, using the built-in wheels.

The access path from the delivery point to the final position shall be carefully inspected for possible obstacles to the transportation of the i.v.STATION™ through the hospital doors, corners and corridors.



Access path from a corridor.



Access path behind a corner.

The minimum dimensions of the corridors shall be:

- minimum width: 1200 [mm] ≅ 47 [in];
- minimum height: 2100 [mm] ≅ 82 ¾ [in]];
- minimum diagonal width: 1700 [mm] ≅ 67[in].

The TOP ATU must be assembly in final position.

The door shall have openings at least 1220 [mm] ≅ 48 [in] wide and 2050 [mm] ≅ 80 ¾ [in] high. However, to avoid further specialized works for reassembling the machine frame, it is highly desirable to have wider and higher openings.

CAUTION	**The i.v.STATION™ shall be assembled at its final destination and installed in the building facility by trained technical personnel only, with the support of the Health Robotics.**

8.3.3 Main power supply connection

The person in charge within the specific site shall provide adequate power supply connection for the i.v.STATION™.

The i.v.STATION™ should be connected to a power line complying with the herewith provided power and current requirements. Please note that power supply line characteristics depend from VCA supply, and that wall socket type depend from voltage.

Installation North America and Japan	Installation Europe
single phase [VAC] 100 -10% to 110 [VAC] +10%	single phase [VAC] 230 ±10%
Wall socket type: NEMA L5-20R	Wall socket type: CEE 7/4 Type F
Amperage line: 20A	Amperage line: 10A
Necessary available power: 1,5 kVA	Necessary available power: 1,5 kVA

The main power line should include a residual current device (RCD)[1] provided with high sensitivity 30mA and selective or time delayed break time. Over current protection type B o type C will need to be provided as well.

In North America the RCD device for current leakage protection is also known as ground fault circuit interrupter (GFCI), ground fault interrupt (GFI) or appliance leakage current interrupt (ALCI). It is important that the chosen device (GFCI, GFI or ALCI) has the same characteristic of an RDC device.

8.3.4 Environmental temperature limits

The thermal load of the device is 5000 BTU. The customer is responsible for checking with a local specialist that the thermal load added by the device in its final location does not drive the room temperature beyond the operational limits of the device.

8.4 Clearances

8.4.1 Clearances for standard installation

The following drawings specify the minimum space clearances for areas where i.v.STATION™ will be placed for normal operating conditions.

	**The minimum space clearances for i.v.STATION™ are recommended values for optimal operation and maintainability of the machine: any reduction of these values should be approved by the Health**

[1] Standard IEC 60755 (General requirements for residual current operated protective devices)

NOTE	**Robotics technical support, as to avoid poor performance. Greater clearances may be required to efficiently perform long term preventive maintenance procedures.**

 **NOTE**	**For installations requiring the anchoring of the device to the floor, please see also paragraph 8.4.1.**

Respect of the following specifications will guarantee that all user access doors to the unit can be fully opened. If the following specifications are not followed then it will be difficult to access the diluent solution and waste areas. Additionally if top and back clearance requirements are not met then the ability of the unit to take in and exhaust air will be hampered and this could compromise the airflow integrity . It should be possible to move the device to a position where the left side and back areas are accessible to a technician for preventive or corrective maintenance tasks.

Device dimensions (W x D x H)	
International System of Units	1000 X 1000 (1131 front shelf included) X 2310 [mm]
Imperial Units	(39.4 X 39.4 (44.5 shelf included) X 90.9 [inch])

Clearance lengths	
Minimum clearance for installation (Width X Depth X Height)	
International System of Units	1850 x 2350 x 2410 [mm]
Imperial Units	(72.8 x 92.5 x 94.9) [inch];
Recommended clearance	
International System of Units	2500 x 2900 x 2560 [mm]
Imperial Units	(98.4 x 114.2 x 100.8) [inch]

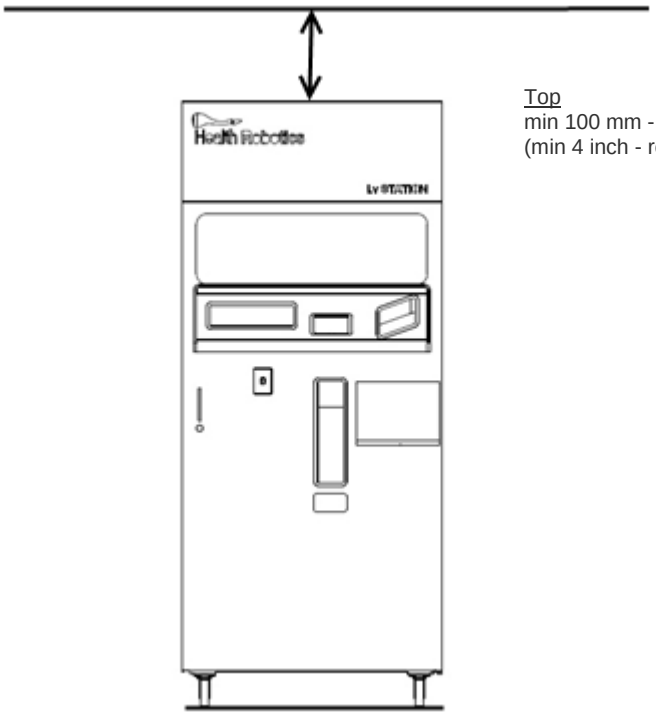


Figure 5 - Installation clearance (front)

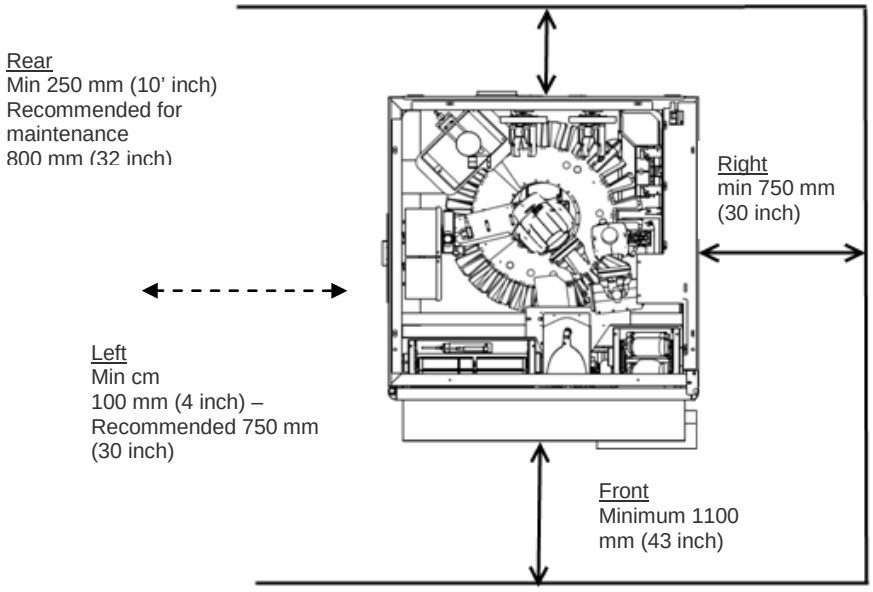


Figure 6 - Installation clearance (front)

8.4.2 Clearance for areas with anchoring requirements

The following paragraph specifies the minimum space clearances for areas where i.v.STATION™ will be bolted to the ground for seismic areas. In these regions local or federal regulations specify that the unit cannot be unanchored to the ground at any time. For this reason the minimum clearances specified for a regular site are not applicable as these values assume the ability to move the machine for maintenance activities. Using the following specifications allow all doors on the unit to be fully opened and allow a technician to access and work with the back of the machine as well. If the following specifications are not followed the possibility exists that when a problem arises there will be no access to the necessary portions of the unit and the technician will have no choice but to remove the unit from its anchoring to repair the problem.

Device dimensions (W x D x H)	
International System of Units	1000 X 1000 (1131 front shelf included) X 2310 [mm]
Imperial Units	(39.4 X 39.4 (44.5 shelf included) X 90.9 [inch])

Clearance lengths (Width X Depth X Height)	
International System of Units	2600 x 2900 x 2560 [mm]
Imperial Units	(102.4 x 114.2 x 100.8) [inch];

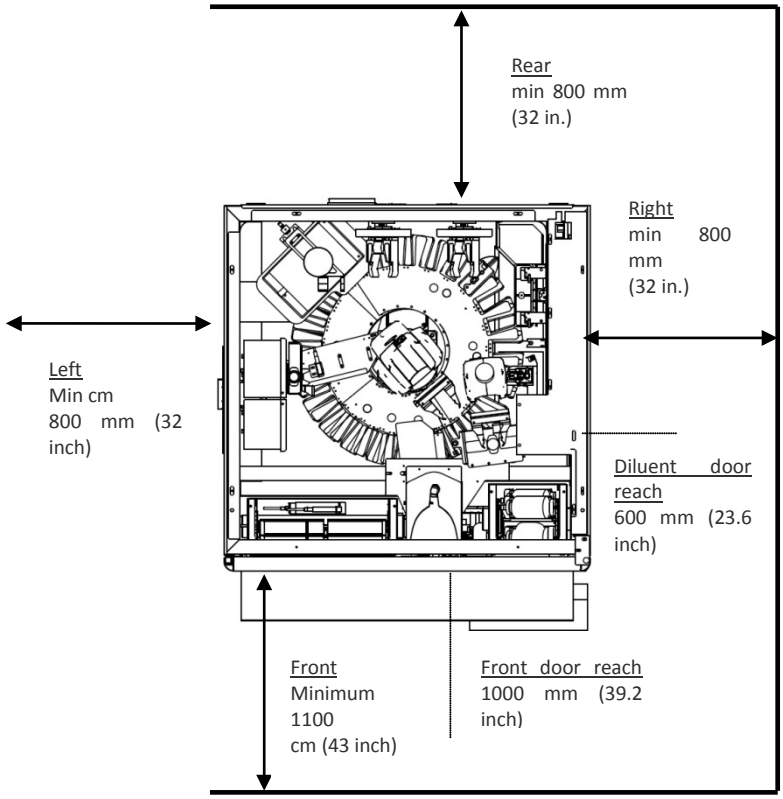


Figure 7 - Installation clearance (top)

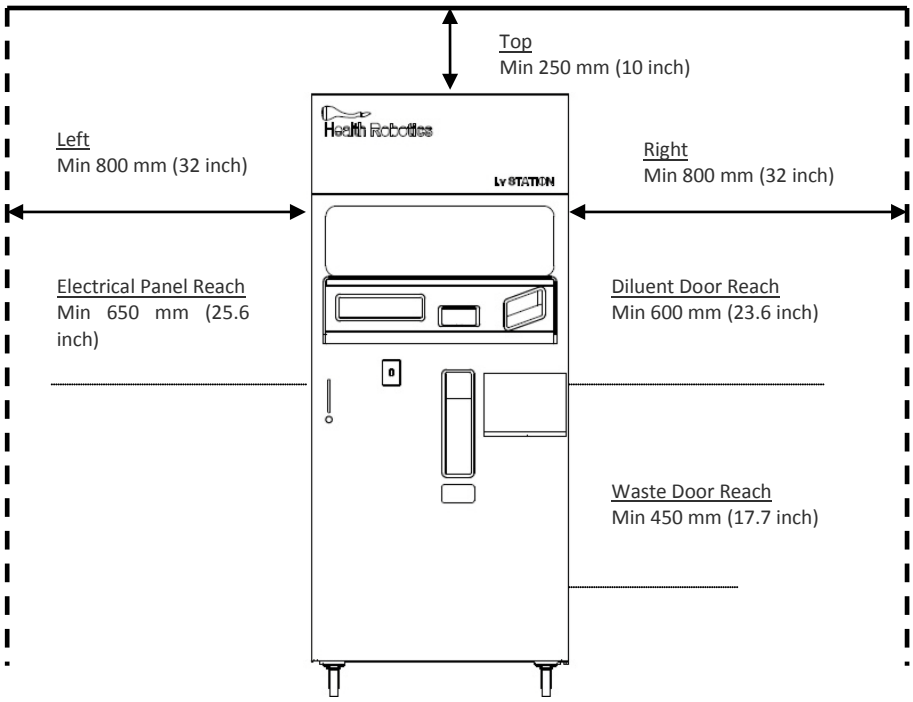


Figure 8 - Installation clearance (front)

Below is the drawing for an example of floor security anchors.

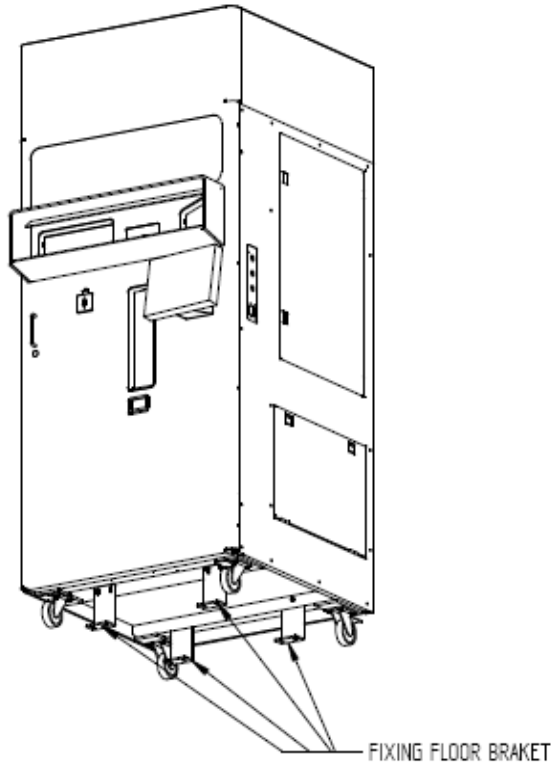


Figure 9 - 3D

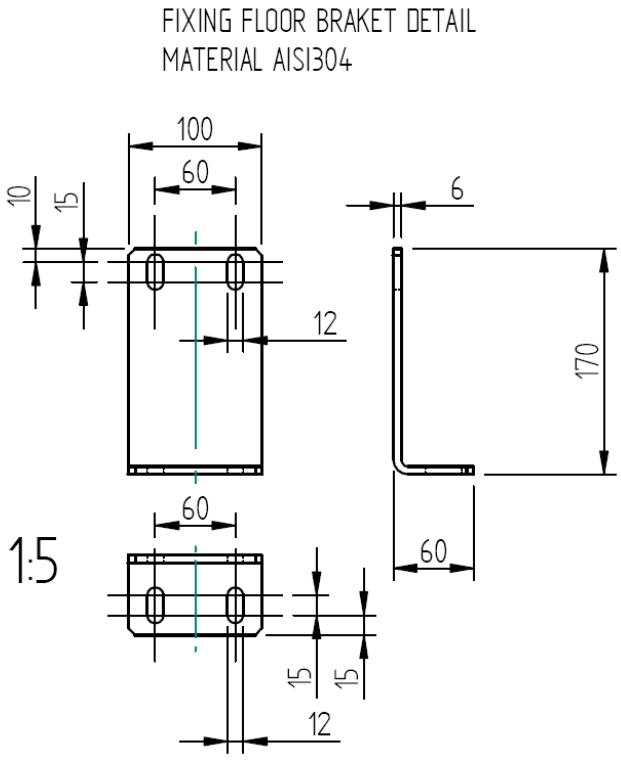


Figure 10 - Fixed bracket details

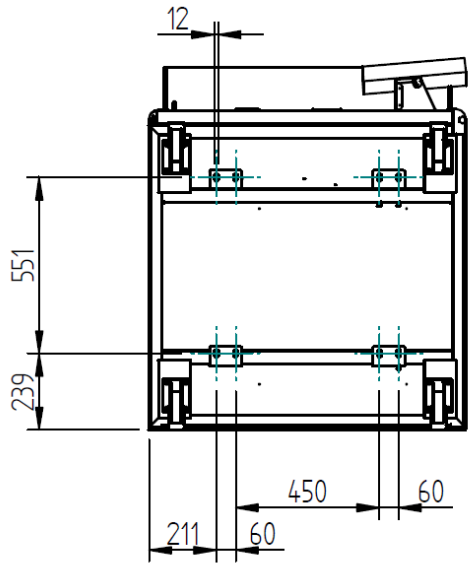


Figure 11- Fixing point, bottom view

8.4.3 Clearances for preventive and corrective maintenance areas

In this section we provide specifications for the minimum space clearance that should be allocated in areas where the i.v.STATION™ will be moved to perform the preventive and corrective maintenance tasks. The same specifications apply for installation where the i.v.STATION™ cannot be moved from its location, such as installation sites in seismic areas, where the i.v.STATION™ will be bolted to the ground. In these regions the unit cannot be unanchored from the ground at any time and the minimum clearances specified for a regular site are not applicable as these values assume the ability to move the machine for maintenance activities.

 **NOTE**	**Respect of the following specifications will guarantee that all unit doors can be fully opened, and will grant technical staff access to the back of the machine itself. Should the following specifications not be respected, technical staff may have to remove the unit from its anchoring to address technical issues.**

Device dimensions see 8.4.1(Clearances).

Clearance lengths (W x D x H): (2600 x 2600 x 2570) [mm] - (102.4 x 102.4 x 101.2) [inch].

8.5 Floor load specifications

The dynamic component of load for the i.v.STATION device, estimated at full load, is equal to 2 kN for each of its four supports, located at a distance of 820 mm along the front side and 745 mm along the lateral side of the device, as per the layout below.

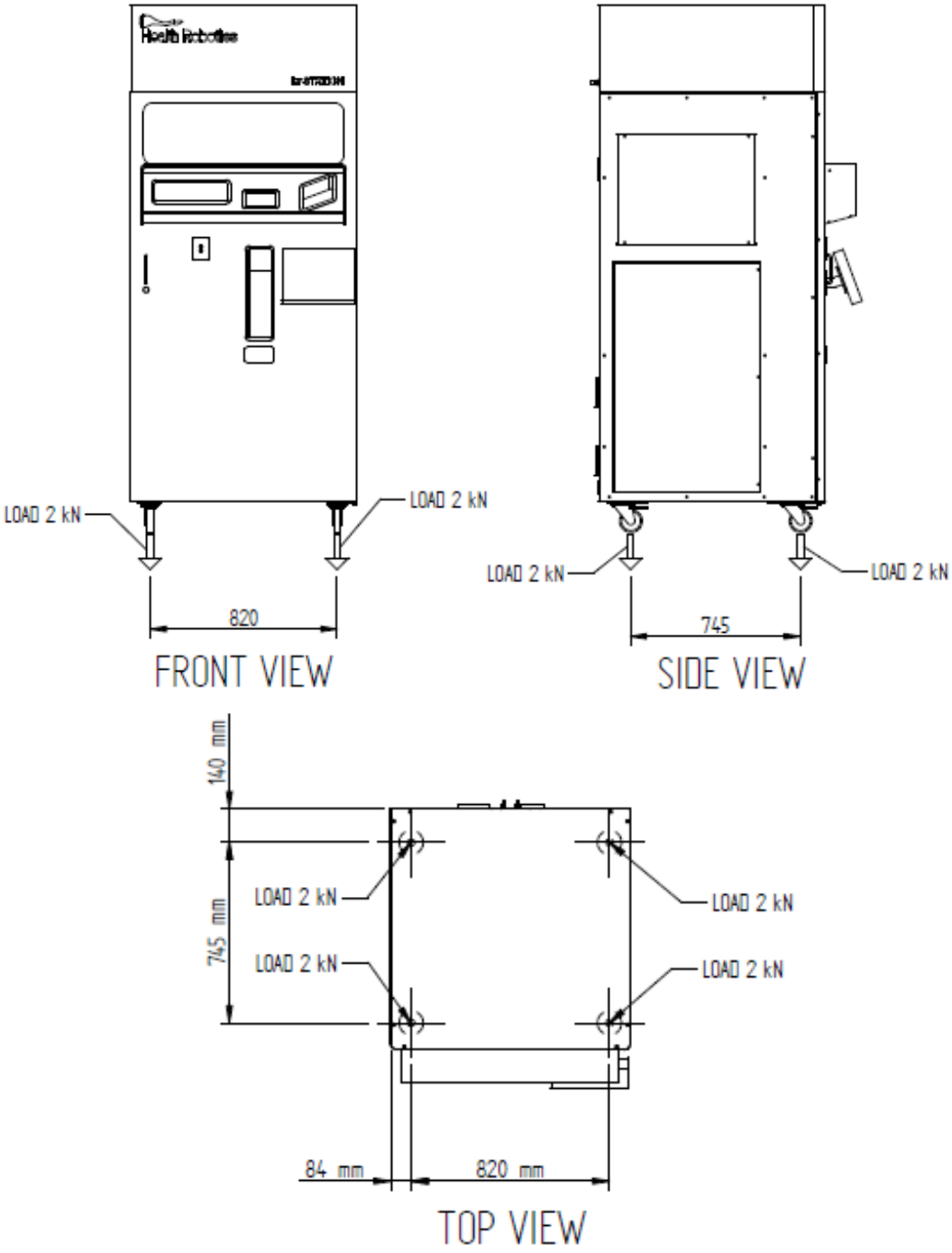


Figure 12 - i.v.STATION Floor Load specifications – metric system

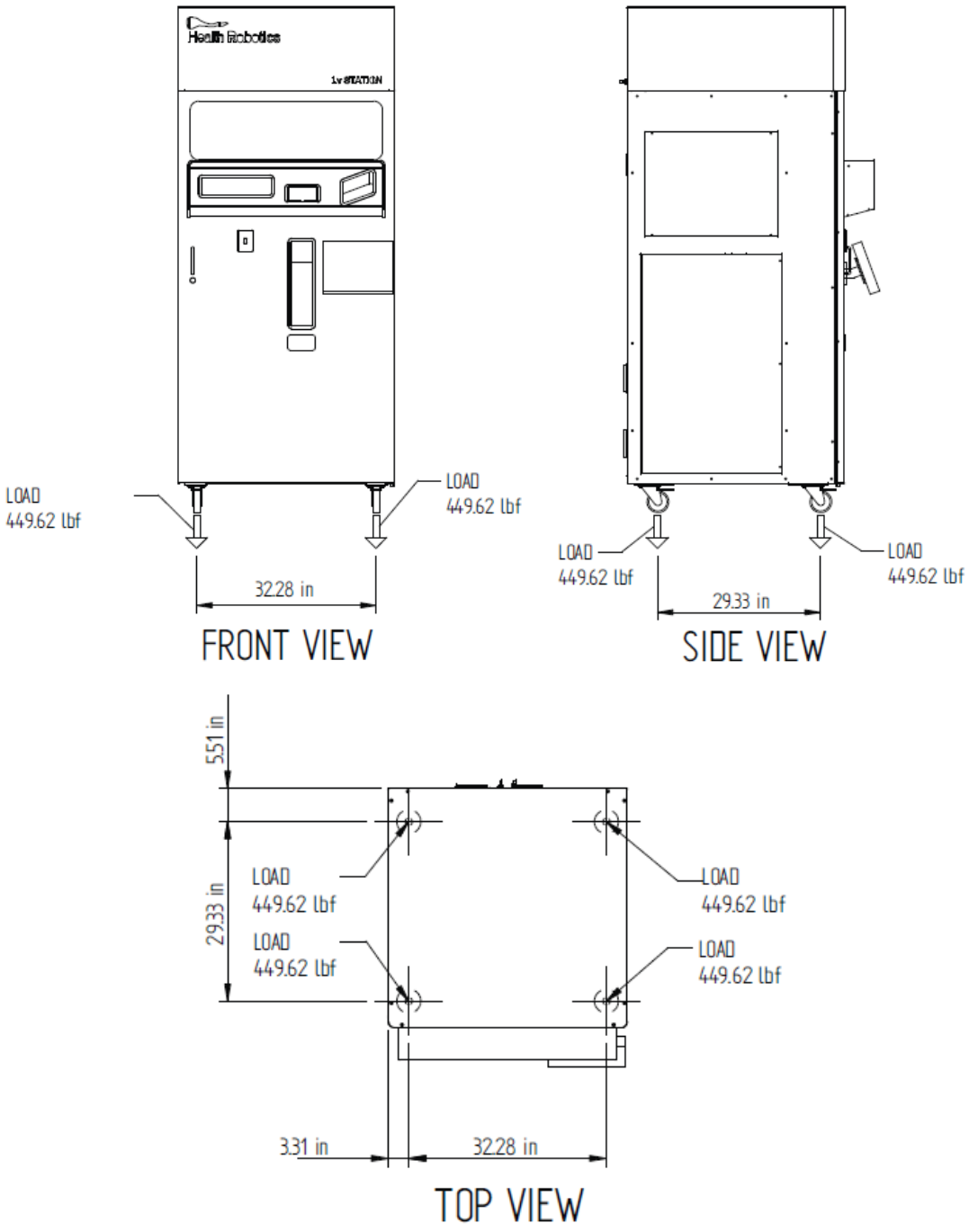


Figure 13 - i.v.STATION Floor Load specifications – imperial system

9 TECHNICAL SPECIFICATIONS

Machine Identification	
Model name	i.v.STATION™
Description	AUTOMATED INJECTABLE DRUGS COMPOUNDING SYSTEM
Operating Width X Depth X Height	1000 X 1000 (1131front shelf included) X 2310 [mm] (39.4 X 39.4 (44.5 shelf included) X 91 [inch])
Standard transportation Width X Depth X Height (foam insulation 30 [mm] (1,2 [inch])	Crate 1 (MU): 1095 X 1095 X 1995 [mm] (43.1 X 43.1X 78.5 [inch]) Crate 2 (ATU): 1095 X 1095 X 1095 [mm] (43.1X 43.1 X 43.1 [inch])
Maximum floor load (not including the estimated weight of up to 50kg, of the materials loaded for a generic compounding task).	661 [kg/m^2] @ 135 [lbs/sq ft] Dynamic component of load at full load equal to 2kN (449.62 pounds-force [lbf] for each of the four supports, located at a distance of 820mm [32.28 inches] along the front side and 745 mm [29.33 inches] along the lateral side of the device. Please refer to the Floor load specifications paragraph 8.5
Clearance	• Top: minimum 100 [mm] (4 [inch]) – Recommended 250 [mm] (10 inch]) • Left: minimum 100 [mm](4[inch]) – recommended 750 [mm] (30[inch]) • Right: minimum and recommended 750 [mm] (30 [inch]) • Front: minimum and recommended 1100 [mm] (43 [inch]) • Rear: minimum 250 [mm] (10 [inch]) and recommended 800 [mm] (32 [inch])
Clearance - Areas with Anchoring Requirements	• Top: 250 [mm] - (10 [inch]) • Left: 800 [mm] - (32 [inch]) • Right: 800 [mm] - (32 [inch]) • Front: 1100 [mm] - (43 [inch]) • Rear: 800 [mm] - (32 [inch])

Electrical		
Phase	1P + N + PE	
Market area	NA and Japan	CE
Power supply voltage	single phase [VAC] 100 - 10% to 110 [VAC] + 10%	single phase [VAC] 230 ± 10%
Circuit Breaker Size	20 [A]	10 [A]
Frequency	60 [Hz] or 50 [Hz]	
Maximum electrical power load	1,5 [kVA]	
Average power demand (standard version)	1,3 [kVA]	
Over current protection of the branch line	Delayed fuses 20 [A] or equivalent protection with overload circuit breaker.	Delayed fuses 10 [A] or equivalent protection with overload circuit breaker.
Mains plug type, with Protective Earth contact, integral with the power supply cord of the machine	North America: NEMA L5-20P	Europe: CEE 7/7 hybrid (Schuko/French)
Ground connection (supplementary conductor to be connected between the Protective Earth Terminal and an external protective earthing system) Required to meet 60601	Protective Earth cord or strap	Protective Earth conductor

Environmental and climatic conditions		
Environmental temperature limits (T)[2]	transportation	from -10°C = 14 [°F] to +55 [°C] = 131 [°F] (during not more than 16 hours)] Max change rate = 20 [K/h]
	storage	from 0°C = 32[°F] to +55°C = 131[°F]] Max change rate = 20 [K/h]
	operational use	from +15 [°C] = 59 [°F] to +27 [°C] = 80.6 [°F] Max change rate = 10 [K/h]
Relative humidity (RH) [3]	transportation	from 5% to 85% at +55 [°C] = 131 [°F] – non condensing
	storage	from 5% to 85% at +55 [°C] = 131 [°F] – non condensing
	operational use	from 20% to 75% at +30 [°C] = 86 [°F] – non condensing
Atmospheric pressure	operating	from 800 to 1060 [hPa]
Airflow		
Internal compartments	front loading panel with overpressure airflow protection and sliding doors operated automatically.	
Unidirectional airflow	Unidirectional airflow confined into the internal preparation chamber.	
Nominal airflow recirculation rate	0% / no recirculation (top airflow inlet from the ambient - down flow outlet into the ambient)	
Circulated airflow capacity	600 [m^3/h]	
Environmental classing of the preparation chamber (segregated area)	Equivalent to Class 5 [UNI EN ISO 14644-1], "at rest" state	

[2] Compliance standard DIN EN 60068-2-1, DIN EN 60068-2-2, DIN EN 60068-2-14.

[3] Compliance standard DIN EN 60068-2-78, DIN EN 60068-2-30.

Recovery time for Class 5 [UNI EN ISO 14644-1] operational conditions after a worst case fault	Less than 15 minutes.
Airflow circulation and filtering	HEPA class H14 filter.
Airflow protection	Overpressure in the internal spaces of the plenum, relative to the environment, to avoid the adulteration of the materials under preparation due to air leakage through the frame sealing.
Diameter of the exhausted air duct	No connection required
Build Materials	
Frame structure, panels and doors	Stainless steel AISI 304, UV resistant PC (polycarbonate)
Internal elements	Stainless steel AISI 304, POM (polyoxymethylene), anodized aluminum.
Sealing and isolation devices	Silicon rubber, FPM (elastomeric fluorurate)
Recommended cleaners, detergents, sanitizers, and disinfectants	• 70% alcohol spray – Sterile denatured 70% ethanol/isopropyl alcohol spray. • Alcohol wipes – Sterile wipes impregnated with 70% ethanol/isopropyl alcohol • Klercide A wipes – Sterile wipes impregnated with a biocidal quaternary ammonium/biguanide combination • soap (Marsille) or poliphenolic solutions only with appropriate rinsing; • sterile distilled water.
Recommended sterilizers [4], [5]	None [6] (HPV deprecated).

[4] To protect from corrosion the exposed surfaces and reduce other obsolescence effects, it is recommended to avoid hydrogen peroxide as sterilizing agent.

[5] All the sterilizing agents have to be completely removed from the surfaces after the end of the daily or weekly sterilizing procedure.

[6] The machine was not designed to be sterilized by fumigation using agents containing formaldehyde (methylene oxide) in any state of aggregation.

Internal Router		
Internal router with separate connections; one external LAN port used for remote terminal (RT) maintenance and 4-port Ethernet switch for the internal LAN.	LAN ext interface - 10/100 Mbit/s full/half duplex auto sense; automatic detection of "crossover" or "patch" wiring. 4-port Ethernet switch - 10/100 Mbit/s full/half duplex auto sense; automatic detection of "crossover" or "patch" wiring.	
Information System Integration Protocols		
CPOE / MAR /ADT / Pharmacy Information System interfaces	HL7, ODBC	
Internal storage for process materials		
Storage racks	Drug vials	28 sloped carrier slots
	I.V.bags	25 suspended carousel slots
	Syringes	42 shaped carrier slots
Waste management process		
Diversified waste collection	Non hazardous materials	Regulated Hospital Waste (RHW) bin container
	Sharps	
	Liquid	Tank container for excess liquid drainage
Substitution of the containers	Hinged door for operator access from the side panel	
Electronic weighing module with automatic scale (EWM)		
Type	Weigh Cell with built in motorized calibration weight.	