

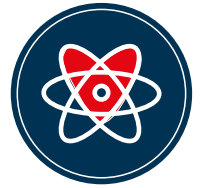
# KARL<sub>100</sub>

THE PET INFUSION EVOLUTION

DISCOVER ALL THE BENEFITS  
OF THE SMALLEST  
AND SAFEST AUTOMATED  
ADMINISTRATION SYSTEM.



MRI COMPATIBLE



MULTI-TRACER  
COMPATIBLE



CE  
0476

**TEMA** SINERGIE  
High tech, high care

# KARL<sub>100</sub>

THE PET INFUSION REVOLUTION

RADIOPROTECTION:  
IT IS THERE FOR YOU AND IT IS EVIDENT.

KARL100 is the smallest and safest Class A radiopharmaceutical dose administration system available on the international market, with 4 major benefits.

## 1] OPERATOR SAFETY

NO HAZARDOUS MANUAL OPERATIONS



Uncapping of the lead pot and perforation of the multi dose vial septum are performed automatically, as well as the dose drawing from the vial, within the fully shielded compartment for a full operator protection throughout the whole process. A specific study performed with an innovative dose rate monitor (Aegis ED3) proved a significant decrease of the staff doses using KARL100.

DOSE MAP

The highest dose received to each part of the hand is rendered in red, and the lowest in blue.



KARL100 is also equipped with a built-in GM tube for a real-time online dosimetry monitoring.

## 2] PATIENT SAFETY

KEEPS RADIOPHARMACEUTICALS STERILE

Your patient is never connected to the multi-dose mother vial: there is **no risk of patient-to-patient contamination**. Each single syringe is automatically connected to the main disposable set within an isolated vented box with a filtered and controlled atmosphere (Class A). Incoming activity from multi-dose vial is filtered through an **in-line 0.22 micron filter**.



NO RISK OF AN OVERDOSE

The injection of single dose syringes by means of **mini injectors** prevents any chance of an accidental dangerous overdose.

## 3] FLEXIBILITY

USE YOUR STANDARD SHIELDED CONTAINERS

KARL100 can handle and automatically uncap **any major lead pot and vial brand/model**: there is no need for your radiopharmacy to drop their routine.

NO LIMITS FOR SUPPLIED ACTIVITY CONCENTRATIONS

KARL100 **draws all of the source vial activity up to the last drop!** Also, it grants a clear-cut dispensing, even for an extremely high incoming activity concentration, thanks to an automatic dilution of the main activity.



## 4] MULTI-FRIENDLY

CARRY ONLY 1KG MINI-INJECTORS!

Quit carrying heavy shields each time you inject a dose: the operator may carry only light and portable mini-injectors to each injection room (**user-friendly**), allowing dose preparations and multiple infusions simultaneously (**time-friendly**) and reducing patient anxiety during dose administration by using only these very compact individual mini-injectors (**patient-friendly**). It is always possible to measure a dispensed dose into an external calibrator (ie. for quality control) without having to waste it. The dose remains sterile and can be injected right afterwards.



**NO FDG WASTE!**  
KARL100 AVOIDS ANY FDG WASTE  
EITHER FOR LINE PRIMING  
OR WRONG DOSE DISPENSING.  
FDG CAN BE RECOVERED AT ANY TIME!

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## DIMENSIONS & CHARACTERISTICS

### KARL100

Dimensions: 54(w) x 116(d) x 107(h) cm  
(21" x 45" x 42")  
Weight: 445 Kg (981 lbs)  
Power Supply: 110/220 VAC 50/60 Hz + Built-  
in Lithium Battery  
Power Requirement: Max 300 Watts  
Class Im (CE 0476) Medical Device

### Rad-Inject

Dimensions: 16.3 cm (6.4")  
Weight: 1.1 Kg (2.4 lb)  
Power Supply: Lithium Battery  
Class IIb (CE 0476) Medical Device



## TECHNICAL SUMMARY

Maximum bulk activity	Ci	2
	GBq	74
Maximum bulk vial volume	ml	50
Maximum volume saline solution (NaCl)	ml	500
Maximum patient dose	MBq	1000
Maximum dose volume	ml	10
Minimum dose volume	ml	0,5
Accuracy (Dose Dispensing Precision) calculated as Requested Dose / Dispensed Dose	%	±2
Maximum injection rate	ml/min	12
Minimum injection rate	ml/min	0,04
Maximum pharmaceutical loss	ml	0
Surface material	Type	Polyurethane HD
Working area material	Type	Anodized aluminium
Power consumption	Va	350
Frequency	Hz	50/60
Dose Repeatability	%	1
Disposable kit sterilisation	Gas	EtOH (validated process)
Disposable kit components	Grade	Medical
Disposable kit components standards	Type	European Pharmacopeia and/ or ISO 10993

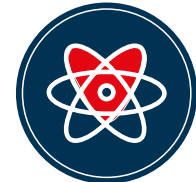
## KARL100 FEATURES

- Automatic connection of the syringe to the main disposable set within a GMP Class A, HEPA filtered atmosphere
- Incoming activity from multi dose vial filtered through an in-line 0.22 micron filter
- No risk of patient-to-patient contamination / No risk of accidental overdose
- Handling and automatic uncapping of the lead pig for any major brand pig/vial model combination
- Automatic perforation of the multi dose vial septum

## DOSIMETRY DATA AT REST (in $\mu\text{Sv/h}$ ):

Incoming PET activity	Activity in Bq	Surface	5 cms from Surface	10 cms from Surface	30 cms from Surface
700 mCi	25,90	12,00	7,11	4,72	1,0
750 mCi	27,75	12,78	7,62	5,06	1,07
800 mCi	29,60	13,63	8,13	5,40	1,14
1 Ci	37,00	16,00	8,5	6,47	1,5
1,5 Ci	55,50	25,5	15,20	10,12	3,33
2,0 Ci	74,00	34,70	20,03	13,49	4,44

- Max concentration of incoming activity: no limits
- Provided with built-in GM tube, for continuous record of dosimetry safety monitoring  
GAMP5, 21 CFR part11 compliant control software provided with:
  - User-Friendly touch-screen total control interface
  - Configurable weight based dose calculation algorithm for patient dose optimization
- Cabled / WiFi Ethernet connection for allowing efficient internet communication for trouble-shooting and (Optional) data exchange with PET/NM departmental management software
- Motorized Drive for moving the dose drawing machine easily
- Battery with 8-hours working time with 100% recharging in only 2 hours!



**MULTI-TRACER  
COMPATIBLE**

$^{18}\text{F}$  -  $^{11}\text{C}$  -  $^{177}\text{Lu}$  -  $^{90}\text{Y}$   
 $^{223}\text{Ra}$  -  $^{68}\text{Ga}$  -  $^{64}\text{Cu}$



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