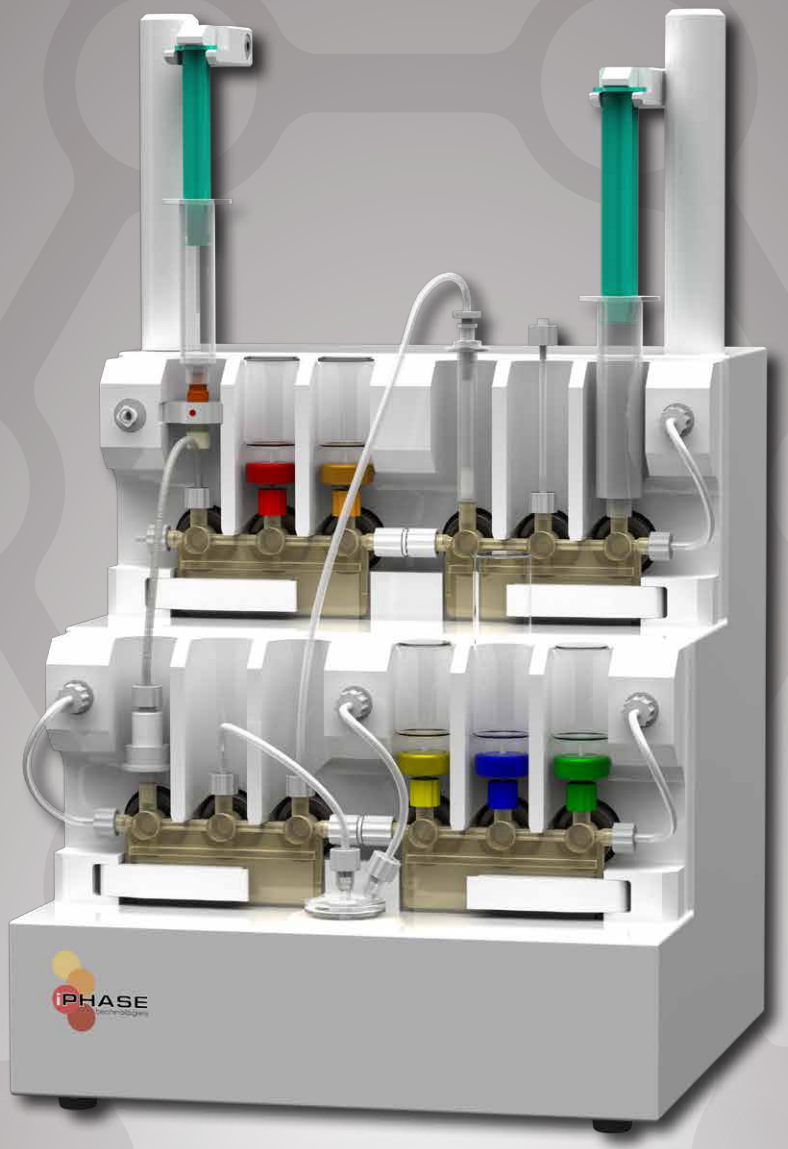
MultiSyn

compact multi-synthesis radiosynthesizer

^{177}Lu ^{18}F ^{64}Cu ^{68}Ga ^{89}Zr ^{86}Y ^{124}I



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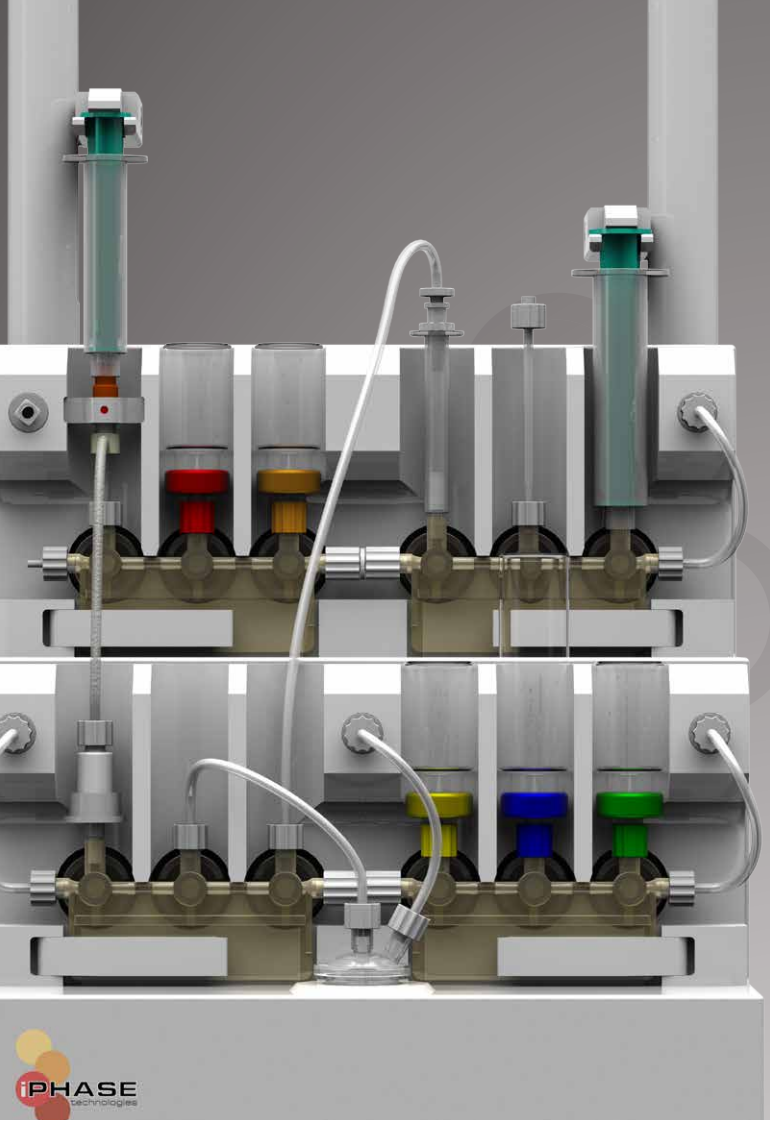


MultiSyn

Multi-Purpose. Powerful.

With the MultiSyn, we have developed the most compact, versatile and easy to use disposable cassette radiosynthesizer suitable for both R&D and routine production.

Typical Synthesis

The MultiSyn can perform the following synthetic steps, or you can setup your own by simply modifying the non-proprietary hardware cassette and graphically generating a new synthesis recipe method using our open software interface.

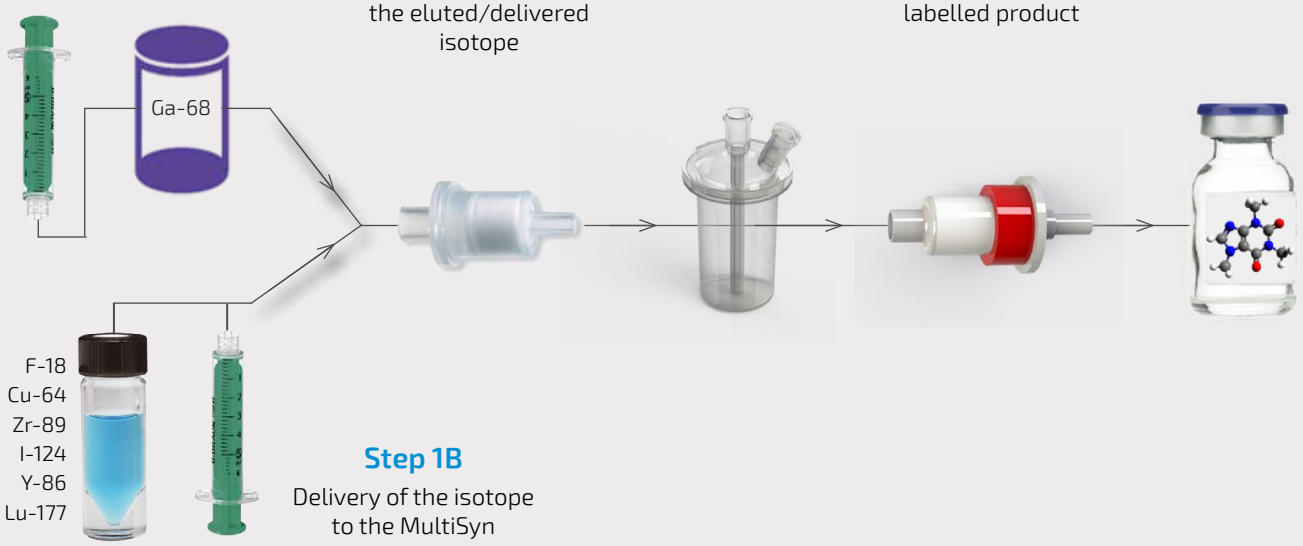
Step 1A
Elution of the isotope to the MultiSyn

Step 2
With or without pre-purification of the eluted/delivered isotope

Step 3
Labelling reaction

Step 4
S.P.E. purification and reformulation of the labelled product

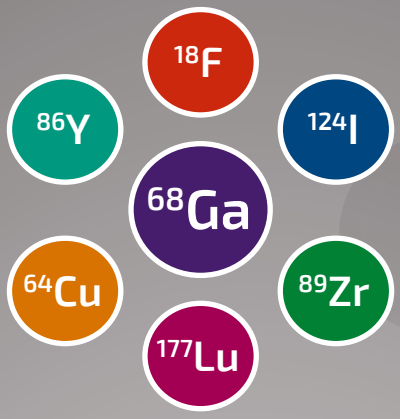
Step 5
Final Injectable Radiotracer



Step 1B
Delivery of the isotope to the MultiSyn

Multi-Isotope

One synthesizer for all your radiochemistry needs



Standardize and simplify your labs radiochemistry requirements with one versatile synthesizer. By simply changing the hardware cassette, you can easily switch to another radiosynthesis without any cross-contamination.

Disposable
Cassette & Reagents

The sterile disposable synthesis cassette and reagent set helps avoid cross-contamination and ensures reproducible results.

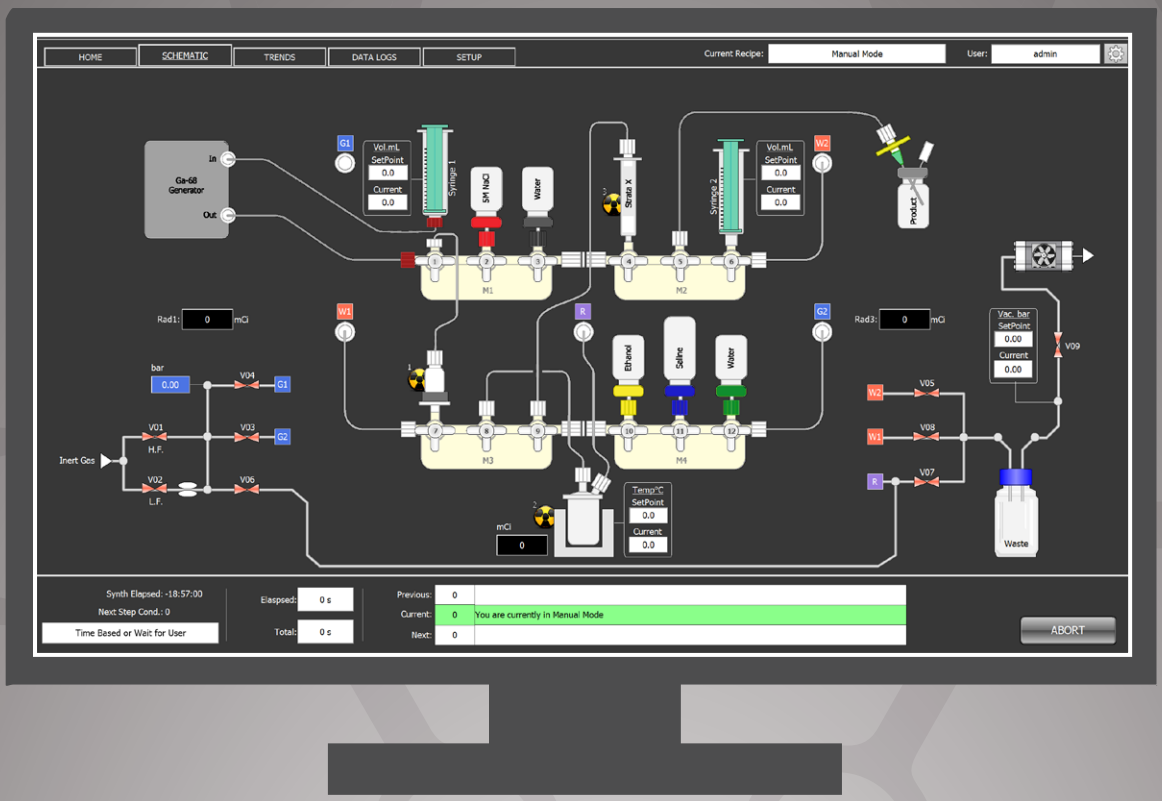
This enables you to effortlessly meet the most stringent quality control GMP compliance standards.

By using non-proprietary components, the user can modify and develop their own cassettes.

Low metal contaminant materials are used.

Open User Interface

System control & visual synthesis recipe development all in one platform



- Easy to use open software interface for easy tracer development
- Guides you step-by-step during the synthesis
- Can be installed on multiple computers for remote synthesis
- Recording of all process variables and report generation (21 CFR Part 11 & GMP compliant)
- Traditional PC or Touch Screen Tablet Control
- Built-in remote diagnostics enabling simplified troubleshooting

Real-Time Sensor Trends

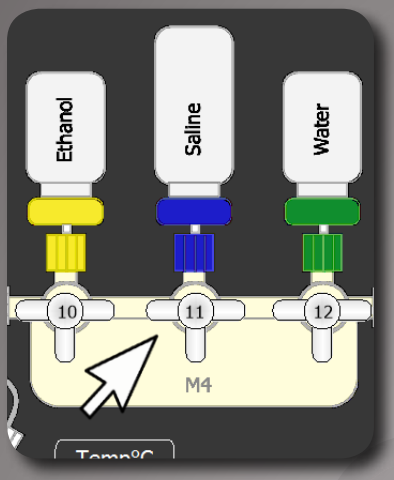
All sensor information can be displayed graphically in real-time trends.

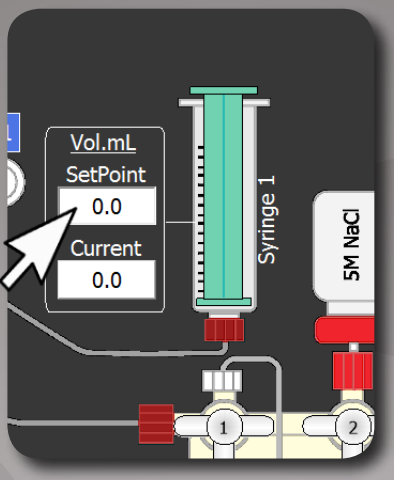
Historical Data Review

Review previous synthesis results as trend graphs with data analysis functions.

Graphical Synthesis Recipe Development

Click • Define • Save





1. Click a schematic

Click a schematic element such as solenoid valves and rotary actuators to turn them on/off or to set positions.

2. Define a parameter

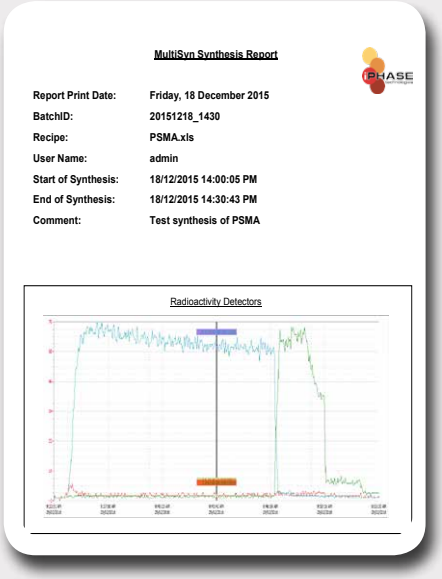
Define parameters such as reactor temperatures, syringe volumes & step parameters (description, time, condition).

3. Save Step

Click the Save Step button and the software will automatically fill-in the Excel® recipe step list automatically.

			(sec)	Manifold Rotary Tap Position (0=off, 1=left, 2=right)												(mL)	(mL)	Process Valve (0=off, 1=on)								(0-255 °C)	(-1.0-0.0 bar)			
Step	Step Message	Step Condition	Step Time	RT1	RT2	RT3	RT4	RT5	RT6	RT7	RT8	RT9	RT10	RT11	RT12	Syringe 1 Position	Syringe 2 Position	V01	V02	V03	V04	V05	V06	V07	V08	Reactor Temp	Vacuum Setpoint	PO 1	PO 2	PO 3
61	Eluting generator to reactor	0	5	0	0	0	0	0	0	2	1	0	0	0	0	0.5	0.0	0	0	0	0	0	0	1	0	0	0.0	0	0	0
62	Eluting generator to reactor	42	30	0	0	0	0	0	0	2	1	0	0	0	0	0.0	0.0	0	0	0	0	0	0	1	0	0	0.0	0	0	0
63	Eluting generator to reactor	0	10	0	0	0	0	0	0	2	1	0	0	0	0	0.0	0.0	0	0	0	0	0	0	1	0	0	0.0	0	0	0
64	Flushing HCL to reactor	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0.0	0.0	0	1	1	1	0	0	1	0	0	0.0	0	0	0
65	Flushing HCL to reactor	0	3	0	0	0	0	0	0	0	2	0	0	0	0	0.0	0.0	0	1	1	1	0	0	1	0	0	0.0	0	0	0
66	Labelling reaction - Heat up phase	11	360	0	0	0	0	0	0	0	0	0	0	0	0	0.0	0.0	0	0	0	0	0	0	0	0	120	0.0	0	0	0
67	Labelling reaction - Heat up phase	0	60	0	0	0	0	0	0	0	0	0	0	0	0	0.0	0.0	0	0	0	0	0	0	0	0	120	0.0	0	0	0
68	Labelling reaction - Cool to reaction temp	15	360	0	0	0	0	0	0	0	0	0	0	0	0	0.0	0.0	0	0	0	0	0	0	0	0	95	0.0	0	0	0

Synthesis recipes are stored as easily editable Excel® step list files.



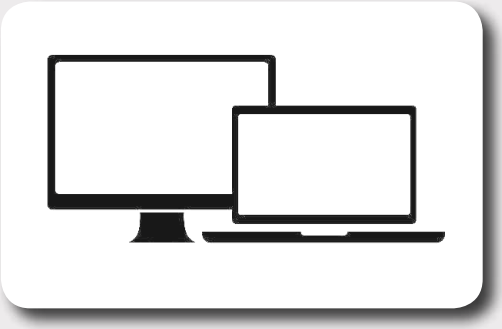
MultiSyn Synthesis Report

Report Print Date:	Friday, 18 December 2015
BatchID:	20151218_1430
Recipe:	PSMA.xls
User Name:	admin
Start of Synthesis:	18/12/2015 14:00:05 PM
End of Synthesis:	18/12/2015 14:30:43 PM
Comment:	Test synthesis of PSMA

Radioactivity Detectors

Synthesis Reports

Generate and print synthesis reports to satisfy your labs documentation and GMP requirements.

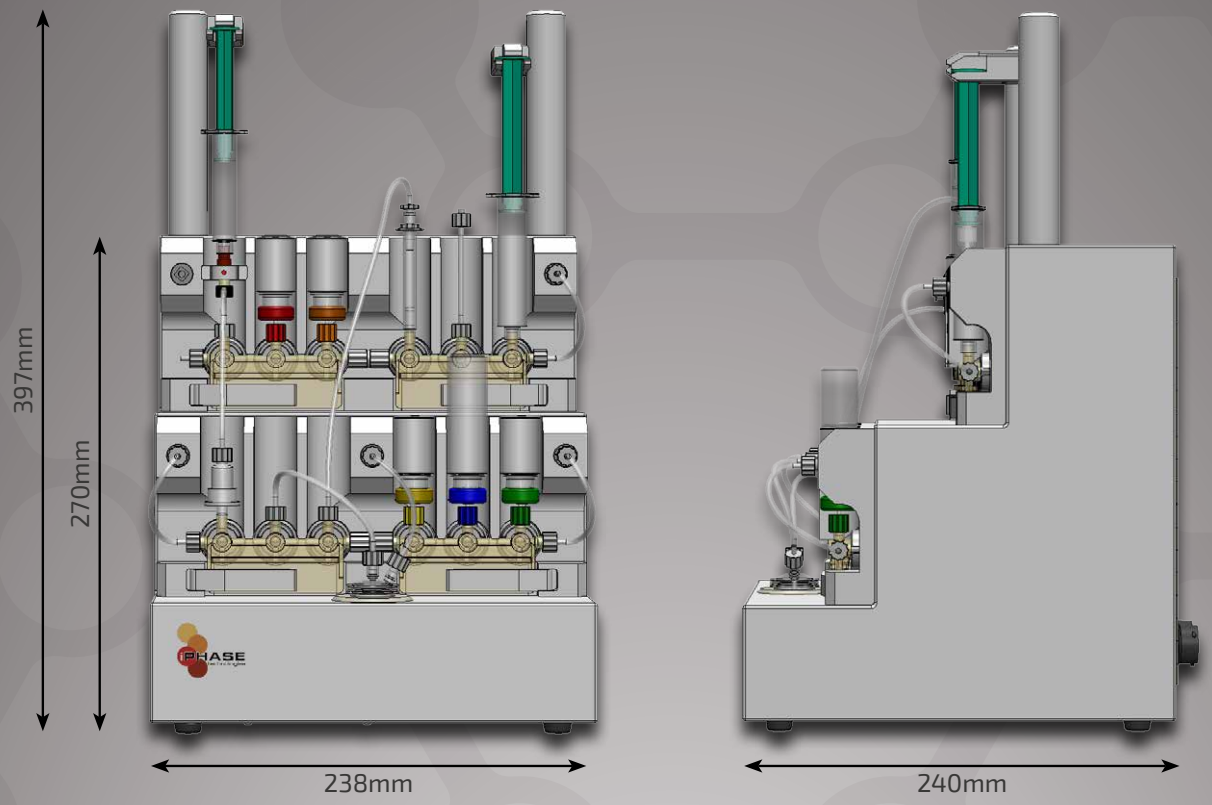


Install on Multiple Computers

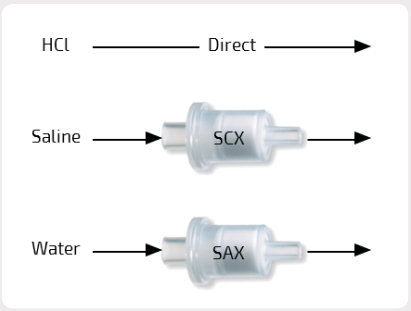
Develop the synthesis recipe in your office and test the recipe in the lab.

Compact Dimensons

Easily install multiple synthesizers in the one hotcell



Compatible With All ^{68}Ga Generators



The MultiSyn is compatible with all commercially available ^{68}Ga generators.

The MultiSyn has a built-in force limiting syringe drive for generator elution and can perform no pre-purification, as well as cationic or anionic pre-purification of the generators eluate.

External Control Electronics

By locating the control PLC components outside of the hotcell eliminates the posibility of damage to the electronic components due to high radiation fields thereby significantly increasing system reliability.

Exceptional Performance

..... more isotopes and tracers to come!

*Decay corrected radiochemical yields.
Uncorrected yields: [^{68}Ga]PSMA = 80.5%, [^{68}Ga]DOTATATE = 74.7%

iPHASE Support

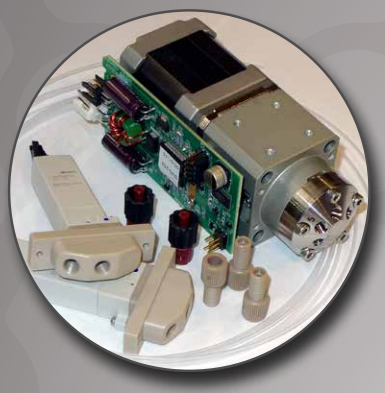
Key aspects of our support structure

Technical Support

You are always a phone call or an email away from an experienced iPHASE engineer or staff member to assist with any queries. Achieving customer satisfaction is our primary objective.

Spare Parts

Complete stock of spare parts for all synthesizers are available and can be expressed shipped to you to minimise downtime.



Remote Diagnostics

Remote diagnostics are built into every system we make. This enables our experienced engineers to diagnose, test and guide the user to the quickest solution to an issue should it arise.

iPHASE technologies

Continuing Education

The field of radiochemistry is ever changing and our continuing education program is there to ensure your team is fully up to date with our latest developments.

Hands on Training

Personalized hands on training will ensure your staff will easily learn and master all aspects of our automated technology.

Upgrades

Due to the ever evolving nature of technology, we are continually following the trends and applying the latest technologies to our systems to increase performance, productivity and reliability.

Technical Specifications

Hardware	
Reactor	• 10mL low metal contaminant Topas COC reactor or 10mL glass reactors • Heating to 150°C when using a Topas COC reactor and 220°C when using glass reactors • Contained compressed air cooling to ambient temperatures (all exhaust compressed air can be piped outside of the hotcell to eliminate contamination or pressurizing of the hotcell environment by the compressed air used to cool the reactor) • Optional Vortex Tube compressed air cooling to approx. 8°C
Stopcock Actuators	• 12 x 3-position electric servo actuators • Can rotate all the disposable manifold stopcocks to 3 positions: left, right and off
Manifold Clamps	• Unique magnetically locking latches for disposable stopcock manifold clamping
Syringe Drives	• 2 x electrically actuated syringe drives • Multi-syringe size capable: 1mL, 5mL, 10mL & 20mL sizes • Force limiting drive control circuit stops driving the syringes plunger if the back-pressure is too high, and automatically resumes drive once the back pressure is reduced. This specialized circuit is especially usefully when eluting ^{68}Ga generators with high back pressures and delivers smooth & reliable generator elutions.
Vacuum Pump	• Built-in chemically resistant vacuum pump, dual head • Max vacuum -0.95bar
Automation	• Industrial PLC (Programmable Logic Controller) with wired or wireless communications to the interface laptop or tablet PC • PLC is housed in an external compact enclosure which is located outside of the hotcell to eliminate radiation damage to the electronics. This ensures reliable operation even in high radiation fields. • Synthesizer is connected to the PLC enclousure via 2 multi-pin electrical cables

Sensors	
Radioactivity	• 3 tungsten collimated linear CsI(TI) crystal PIN diode radioactivity detectors
Pressure	• 2 x pressure sensors for vacuum and inert gas pressure monitoring
Temperature	• Thermocouple sensor for reactor temperatures

Software	
Graphical Interface	• Easy to use open platform operator interface, with sensor trends, historical data logging & analysis, synthesis reports, multi-level password protected user access, CFR 21 CFR Part 11 & GMP compliant
Synthesis Recipes	• Easily generated using unique Click-&-Save graphical recipe development technology and stored as Excel® step lists

Utilities and Dimensions	
Compressed Air	• 6-8 bar (87-116 psi), 6mm O.D. push-in tube connection
Inert Gas	• Helium, Nitrogen or Argon; 2-8 bar (29-116 psi), 1/8" O.D. tube compression connection
Case	• Compact solvent resistant powder coated case
Dimensions	• 238 mm x 270/397 mm x 240 mm (WxHxD)

iPHASE technologies Pty Ltd
Melbourne, Australia
Tel/Fax: +61 (0)3 9884 7596
info@iphase.com.au
www.iphase.com.au