

MultiSyn

compact multi-synthesis radiosynthesizer



www.iphase.com.au

MultiSyn

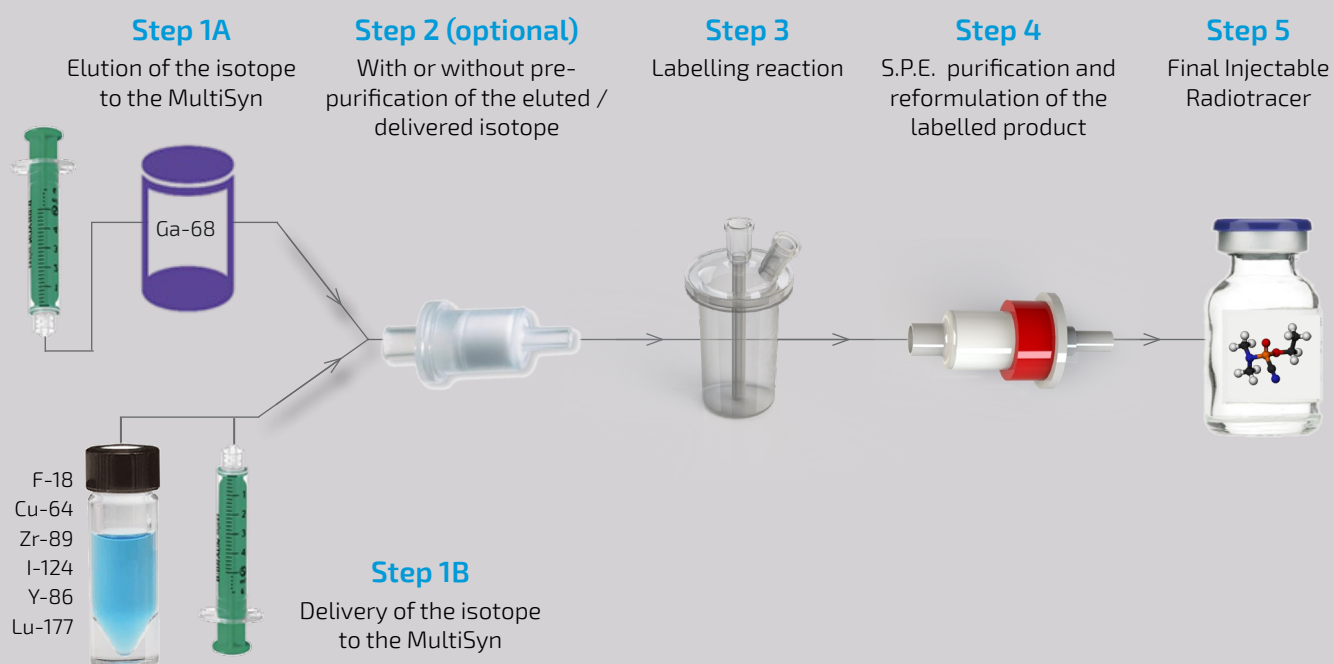
Multi-Purpose



The MultiSyn is an affordable multi-purpose, multi-chemistry compact disposable cassette radiosynthesizer

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.



Multi-Isotope

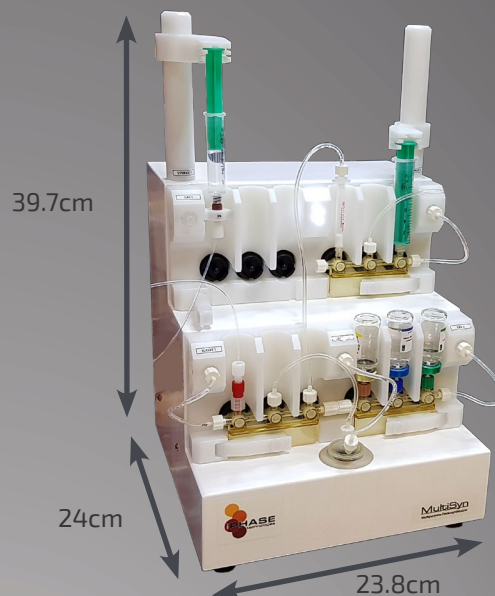
One synthesizer for all your radiochemistry needs



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.

Compact Dimensions



Easily install multiple synthesizers in the one hotcell

Low cost 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 and significantly lower your labs consumables costs.

Cassettes manufactured in Australian GMP clean rooms.

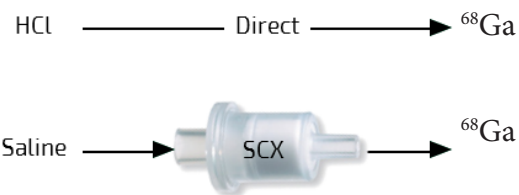
Reagents manufactured by ABX & Huayi. (Disposables purchased from iPHASE technologies)





Compatible with all ^{68}Ga generators

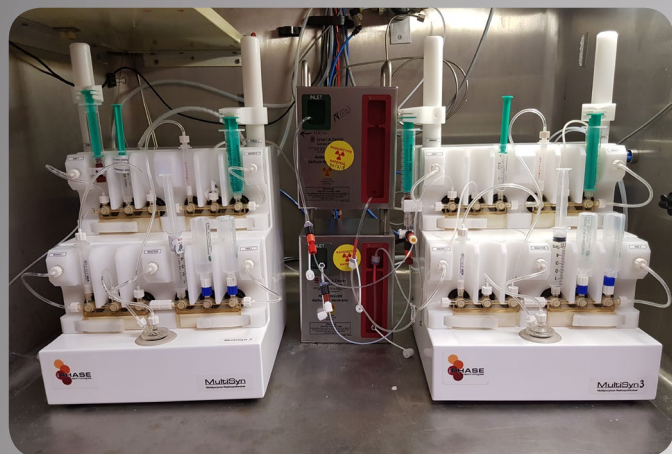
The MultiSyn is compatible with all ^{68}Ga generators. It has a built-in force limiting syringe drive for either direct generator elution or pre-purification of the generators eluate. (positive pressure elution).



Direct Elution

The simplest ^{68}Ga synthesis method involves direct labelling of the generators eluate.

This method reduces synthesis time and simplifies system setup.



Pre-purification

Certain reactions require reduction of the acid concentration of the generator eluate and/or purification of metal impurities (such as ^{68}Ge) from the eluate to improve reaction conditions.

This is easily accomplished with generator pre-purification and involves trapping the generator eluate onto a purification cartridge and subsequent elution to the reactor with a >99% trap and release efficiency of ^{68}Ga .

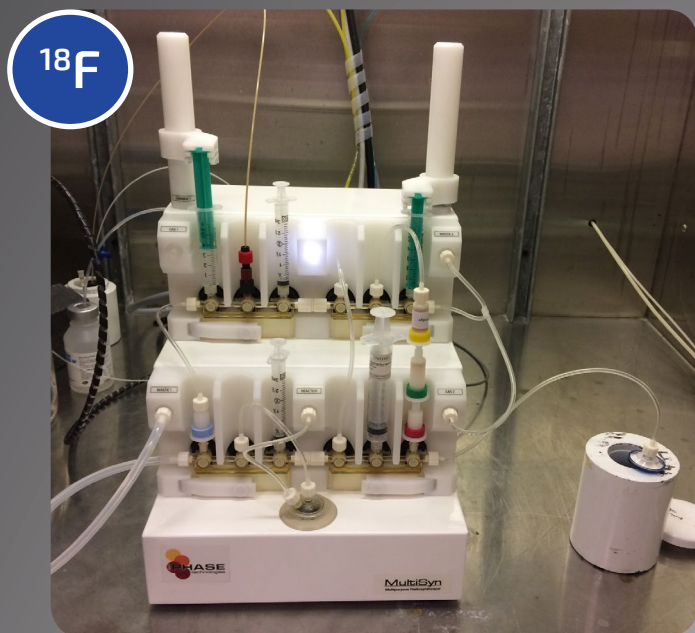


Multiple Generator Elution

The MultiSyn can be used to elute multiple generators to increase final radiotracer activity.

Radiotracer	Avg. Yield @ E.O.S.	Synthesis Time
^{68}Ga -PSMA	96%*	15 mins
^{68}Ga -DOTATATE	95%*	17 mins

*Decay corrected radiochemical yields.
Uncorrected yields: [^{68}Ga]PSMA = 82%, [^{68}Ga]DOTATATE = 78%



^{18}F -FDG

In addition to its metal radiolabelling capabilities, the MultiSyn is also ideal for the low cost radiosynthesis of ^{18}F -FDG by simply swapping the cassette. Other ^{18}F compounds that can be synthesized on the MultiSyn are ^{18}F -NaF & ^{18}F -PSMA.

Radiotracer	Avg. Yield @ E.O.S.	Synthesis Time
^{18}F -FDG	>65%	27mins

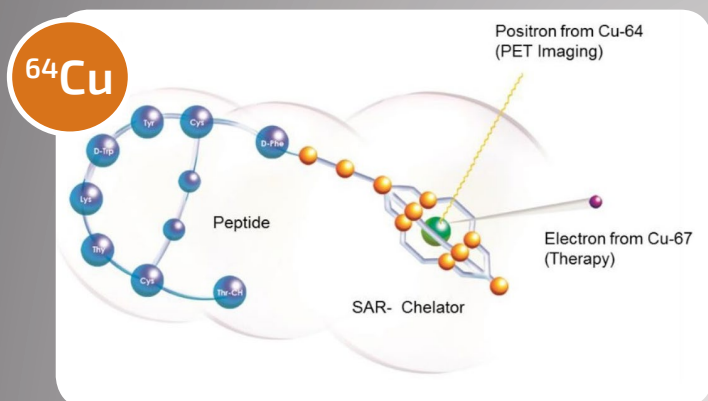


Theranostics

The MultiSyn enables the radiochemist to easily synthesize theranostic compounds using isotopes such as ^{177}Lu . Theranostic compounds that have been successfully developed on the MultiSyn for routine production are ^{177}Lu -PSMA & ^{177}Lu -DOTATATE.

Radiotracer	Avg. Yield @ E.O.S.	Synthesis Time
^{177}Lu -DOTATATE	92%	30 mins
^{177}Lu -PSMA	92%	30 mins

For latest radiotracers check www.iphase.com.au



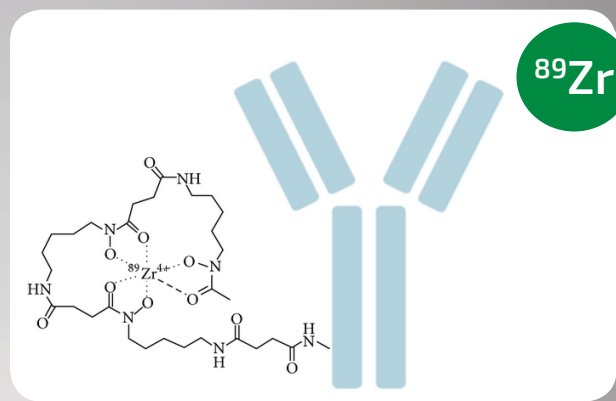
Radiometal labelling

The MultiSyn can be used for a number of different radiometals such as $^{64,67}\text{Cu}$, ^{225}Ac & $^{86,90}\text{Y}$

Image courtesy of Clarity Pharmaceuticals

Radiotracer	Avg. Yield @ E.O.S.	Synthesis Time
$^{64,67}\text{Cu}$ -SARTATE	74%	22/42 mins

Cu-64 SARTATE = 42min (room temp reaction - can be reduced to 22min with reaction at 90C)



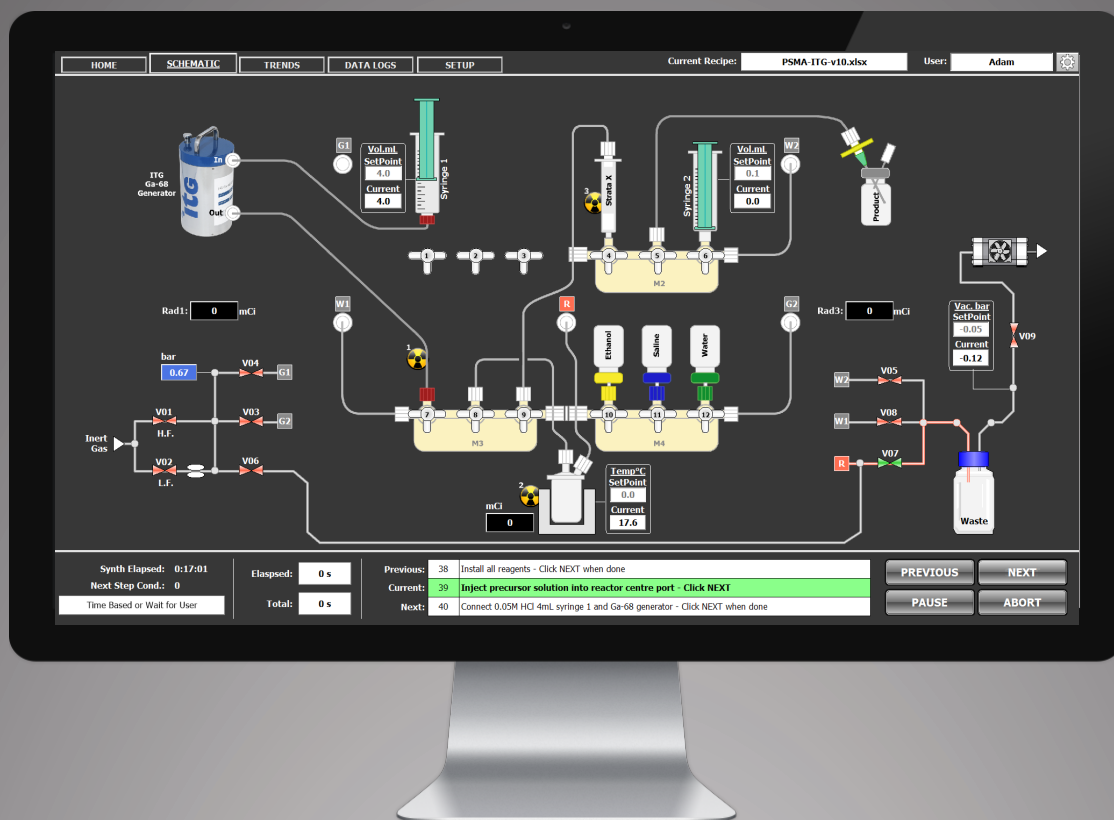
^{89}Zr Antibody Labelling

Fully automate ^{89}Zr monoclonal antibody radiolabelling using the MultiSyn. Typical fully automated synthesis process involves:

1. Automated cartridge conditioning
 2. ^{89}Zr Neutralization
 3. Radiolabelling
 4. Purification using PD-10 cartridge
- Image courtesy of Floor C. J. van de Watering

Open User Interface

System control & visual synthesis recipe development all in one platform



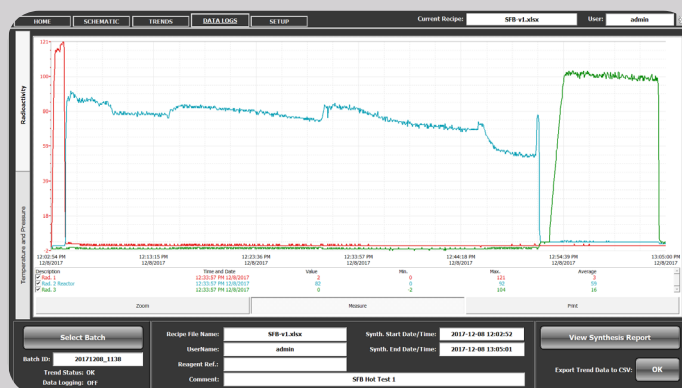
- ✓ Easy to use open software interface for easy tracer development
- ✓ Guides you step-by-step during the synthesis
- ✓ Can be installed on multiple computers for remote synthesis development

- ✓ 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.

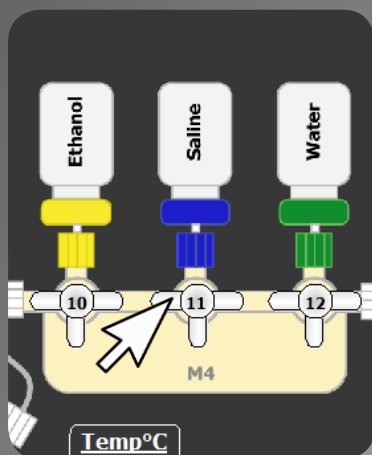


Historical Data Review

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

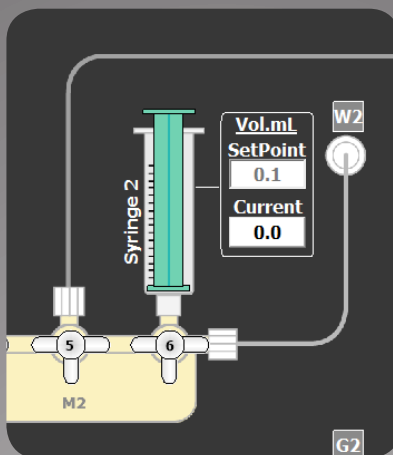
Graphical **Synthesis Recipe** Development

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).

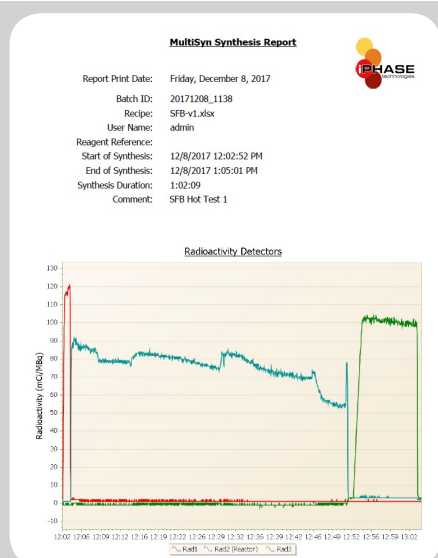


3. Save Step

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

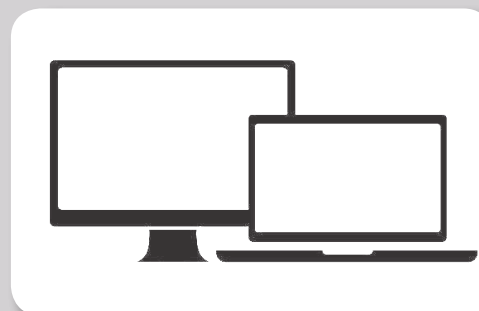
			(sec)	Manifold Rotary Tap Position (0=off, 1=left, 2=right)												(mL)	(mL)	Process Valve (0=off, 1=on)								(0-255 °C)	(-1.0-0.0 bar)				
Step	Step Message	Step Condition	Step Time	RT1	RT2	RT3	RT4	RT5	RT6	RT7	RT8	RT9	RT10	RT11	RT12	Syringe 1 Position	Syringe 2 Position	V01	V02	V03	V04	V05	V06	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	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.



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.

Technical Specifications

Hardware	
Reactor	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 12 x 3-position electric servo actuators • Can rotate all the disposable manifold stopcocks to 3 positions: left, right and off
Manifold Clamps	<ul style="list-style-type: none"> • Unique magnetically locking latches for disposable stopcock manifold clamping
Syringe Drives	<ul style="list-style-type: none"> • 2 x electrically actuated syringe drives • Multi-syringe size capable: 1mL, 5mL, & 10mL 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 ⁶⁸Ga generators with high back pressures and delivers smooth & reliable generator elutions.
Vacuum Pump	<ul style="list-style-type: none"> • Built-in chemically resistant vacuum pump, dual head • Max vacuum -0.95bar
Automation	<ul style="list-style-type: none"> • 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 enclosure via 2 multi-pin electrical cables
Sensors	
Radioactivity	<ul style="list-style-type: none"> • 3 tungsten collimated linear CsI(Tl) crystal PIN diode radioactivity detectors
Pressure	<ul style="list-style-type: none"> • 2 x pressure sensors for vacuum and inert gas pressure monitoring
Temperature	<ul style="list-style-type: none"> • PT100 sensor for reactor temperatures
Software	
Graphical Interface	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Easily generated using unique Click-&-Save graphical recipe development technology and stored as Excel® step lists
Utilities and Dimensions	
Compressed Air	<ul style="list-style-type: none"> • 6-8 bar (87-116 psi), 4mm O.D. push-in tube connection
Inert Gas	<ul style="list-style-type: none"> • Helium, Nitrogen or Argon; 2-8 bar (29-116 psi), 1/8" O.D. tube connection
Case	<ul style="list-style-type: none"> • Compact solvent resistant powder coated case
Dimensions	<ul style="list-style-type: none"> • 238 mm x 270/397 mm x 240 mm (WxHxD)

