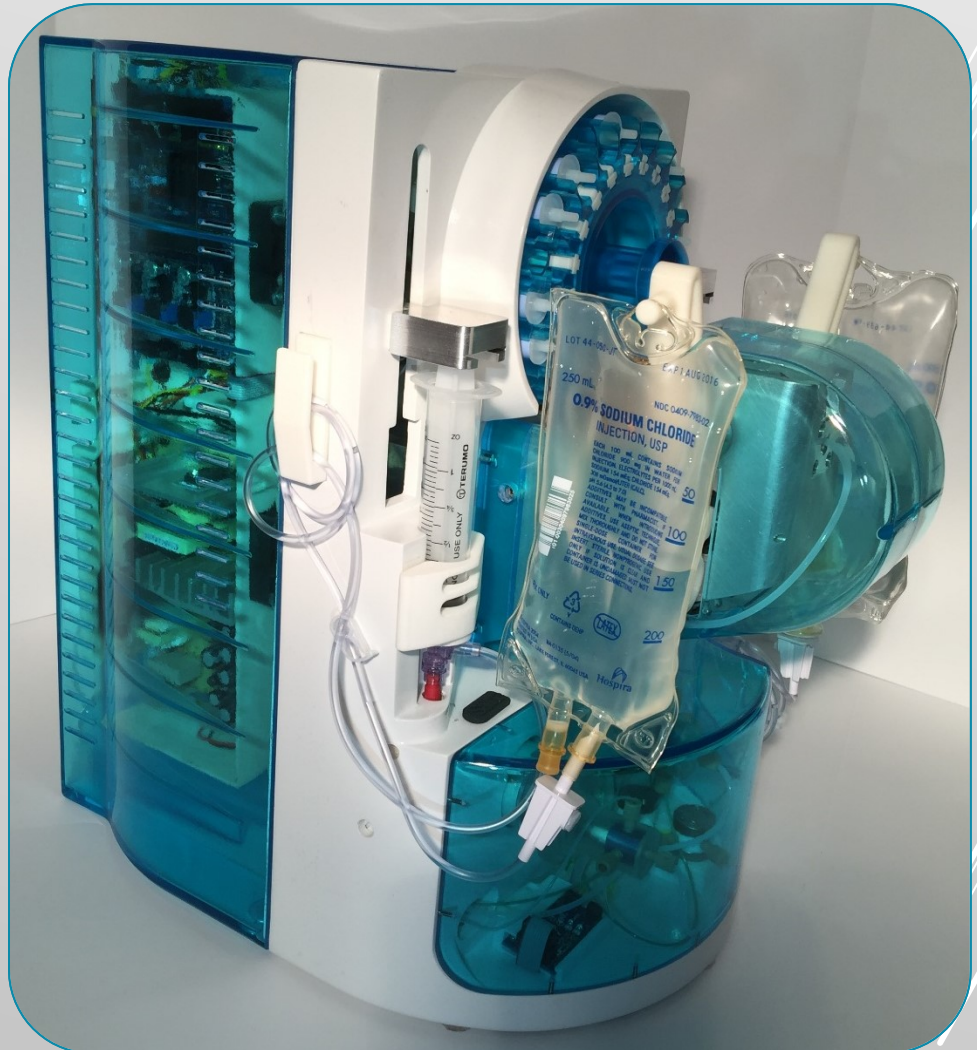




Ammonia ^{13}N production

“More Cardiac Scans for unscheduled Patients”

Ammonex20

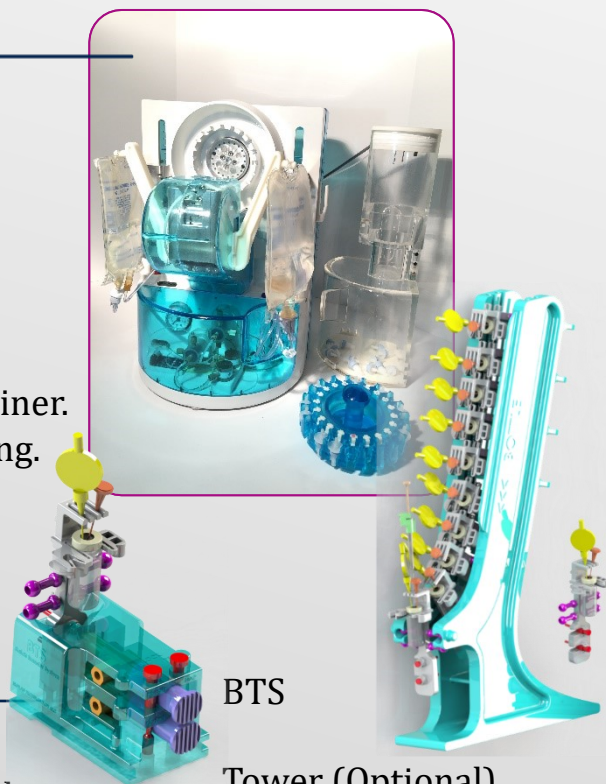


Automated process
20+ doses in 1 setup!

Patent pending USA, CANADA, EUROPE

Hardware Specifications

- Easy components loading.
- Single point waste container, up to 100+ runs.
- Easy valves and lines maintenance access.
- Ergonomic design.
- Easy mechanical and electronic diagnostics.
- Module prep in minutes.
- Module wash up in minutes.
- Auto ejection of used cartridges to waste container.
- Batch Transfer System (BTS) for dose dispensing.
- Reduced of gaseous radioactive emissions.
- All consumables are available off shelf.
- Module size: 12" x 18" x 19" (w * h * d)



Control Electronics

- Sensors feed back and records.
- Embedded OEM microprocessor controls board.
- USB connectivity.
- Dual pressures reports.
- OEM valves control system for off shelf valves used.
- Low maintenance required.

Software Methods & Master File Records

- Fully programmable methods with audit trails.
- Included cGMP batch records log (Optional complete FDA documents ready submission)
- Report Data Entry from multi LAB location.
- Final report encrypted.
- Report saved in Local hard drive, Thumb Drive or SQL server.
- Routine production from one button operation.
- SOP driving run steps for beginners.
- Multi user level control.
- Automatic filter test integrity with logged report.
- Print labels.

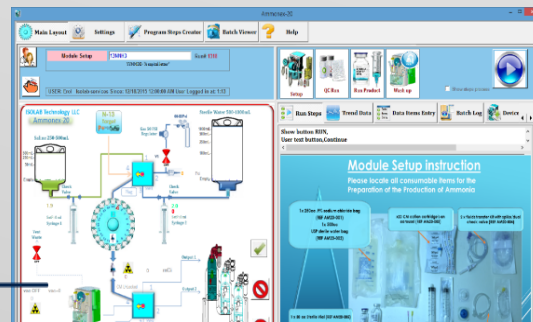
For more information Please

Contact Dan Conatser

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Run Steps Trend Data Data Items Entry Batch Log Device

Brigham and Women's Hospital
75 Francis Street
Boston MA 02115

Originator: Name1
Reviewed By: Name2
Approved By: Name3

SOP#: M009
Version #: 12.0
Effective: 1/1/2016

Cyclotron Param. Sampling Process Items Production QC Process Biological QC Sterility

Manufacturing Date (EOS): MMADDYY Batch #: 13NNH3-1320

This Batch Records is completed in compliance with the manufacturing SOP for [13N]-Ammonia, SOP#: M009

ITN#	ITEMS	QUANTITY	SPEC.	INITIAL
na	5 mL BOH/H2O (Target water)	3mL +/- 1%	S0011	na
na	na	na	na	na

For Ammonia Production: Click the setup button and follow the guided procedure followed by a QC run, follow the guided procedure followed by the Run 13 production, follow the guided procedure. When bags are empty, proceed for a washup.

The Beam current need to be set at 35uA
At 14 minutes inform production personnel that the product will be ready for delivery.
Confirm that production personnel are ready to receive product. The module should be ready at the prompt "waiting for target delivery".
At 15 minutes click the delivery icon and follow the prompt on the Ammonex220 OS to continue.
The following step will be to click continue after the target delivery is completed, take QC or Batch sample to delivery.
The following step will run the filter test integrity than prompt you to final complete ALL data entry to be logged.
For a new production run Click on the Run 13 button again, a new run will get ready automatically.
After the production is complete dry the target from the target maintenance icon.

Start of Beam: 12:00:00 AM Now
End of Beam (Auto recorded from Ammonex OS): 12:00:00 AM Now

Beam Current: 35 uA Beam Energy: 16.5 MeV
Beam Integrator: 0 uA/h or Beam Duration: 15 min Cyclotron Type: Pet.Trace

Target Bombardment was performed by: _____

Shipping Val Syringe

Feb Sat 27 2016 1:27:56 PM