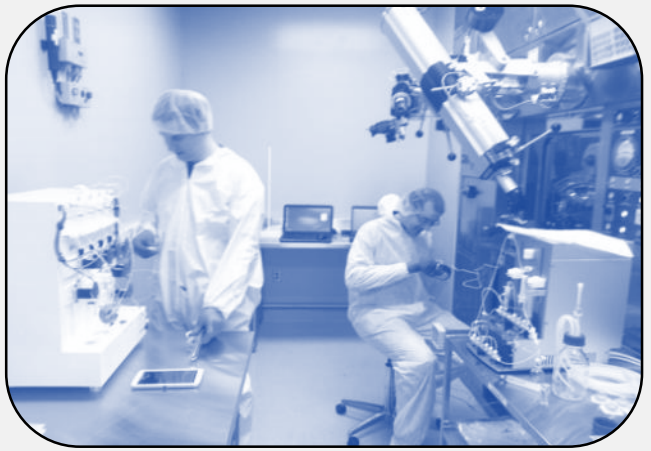


Updates on Implementation of Cyclotron-Produced Tc-99m

Joel O. Kumlin[1], F. Bénard[2], K.R. Buckley[1,2], M. Dodd[2], V. Hanemaayer[2], B. Hook[1] M. Kovacs[2], S. McDiarmid[1,2], F.S. Prato[2], T. Ruth[2], J.F. Valliant[2], M. Vuckovic[2], S. Zeisler[1,2]

M. Cross[1,2], S. Foster[1,2], F. Gleeson[1,2], K. Hayashi[1,2], J. Schlosser[1,2], K. Wilson[1], P. Schaffer[1,2]

[1]ARTMS Products

[2]ITAP Consortium

ARTMS Products

Founding Institutions

TRIUMF

TRIUMF INNOVATIONS

LAWSON HEALTH RESEARCH INSTITUTE

cpdc

BC CANCER Provincial Health Services Authority

Venture Capital

$3 Million

Quark venture

Strategic Partners

GE Healthcare

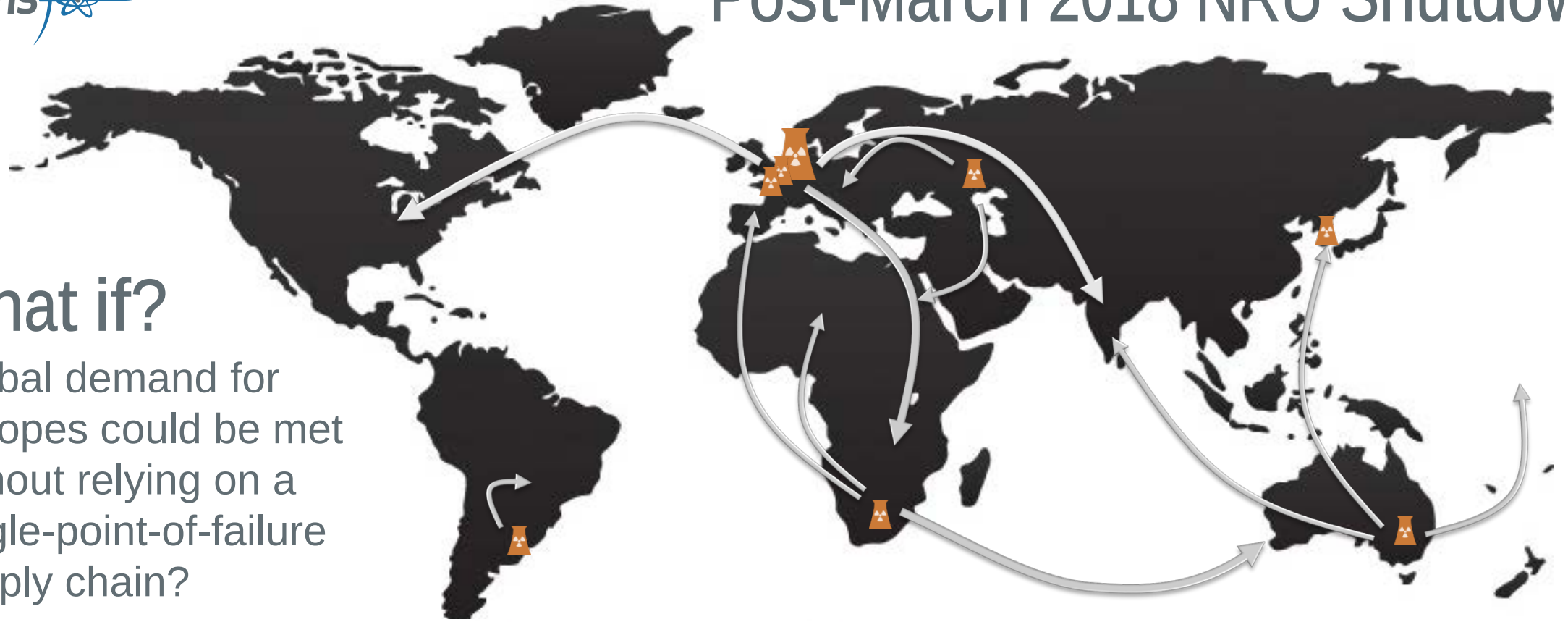
Alliance Medical

Pre-2016 Supply Model

What if?

Global demand for isotopes could be met without relying on a single-point-of-failure supply chain?

Post-March 2018 NRU Shutdown



What if?

Global demand for isotopes could be met without relying on a single-point-of-failure supply chain?

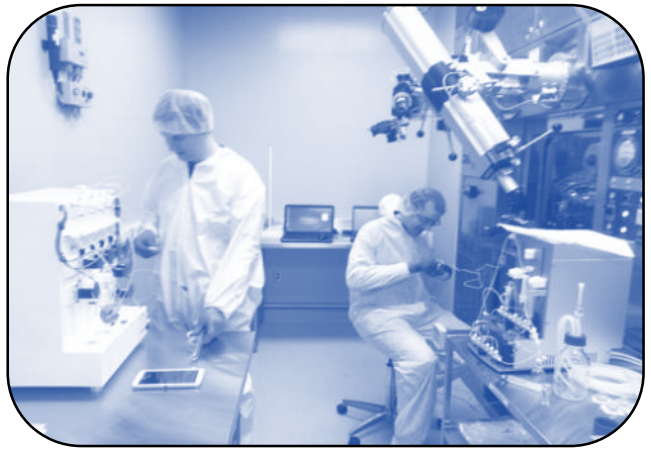
ARTMS Supply Model

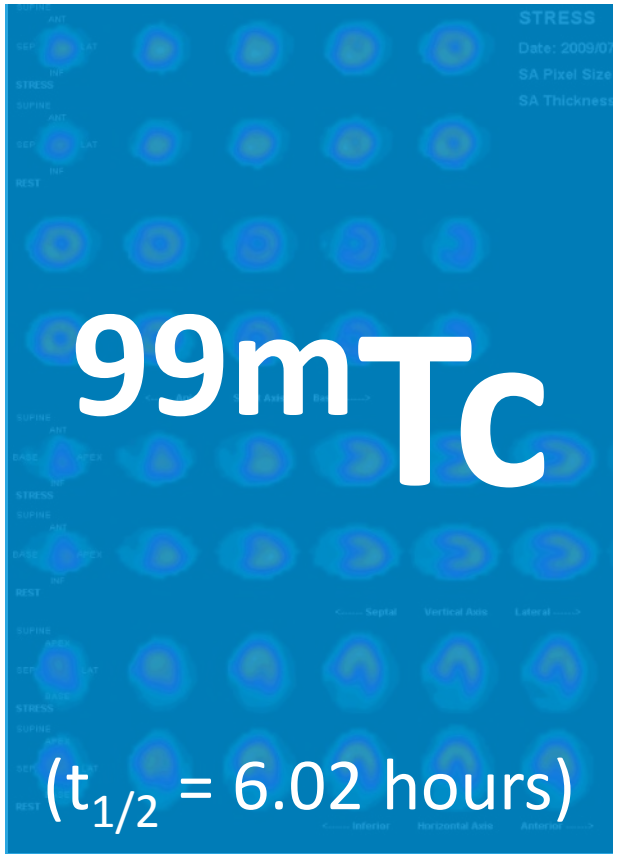
Solution:

Develop a method to produce Tc-99m, Ga-68 (and other isotopes) using hospital-based medical cyclotrons

Cyclotron + ARTMS Technology → Radiopharmacy → Clinic

Cyclotron Production: $^{100}Mo(p,2n)^{99m}Tc$

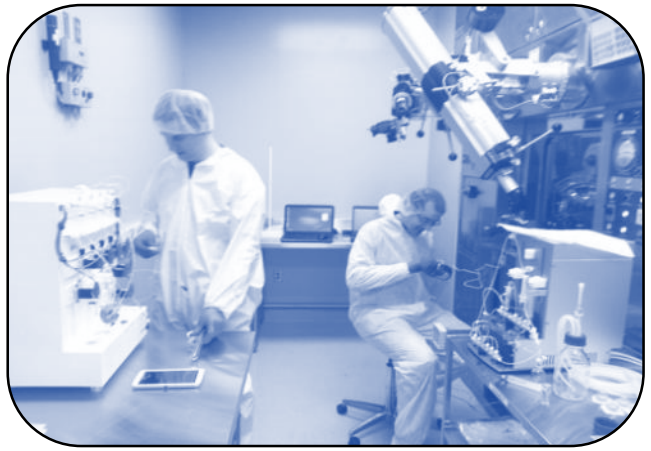




Method

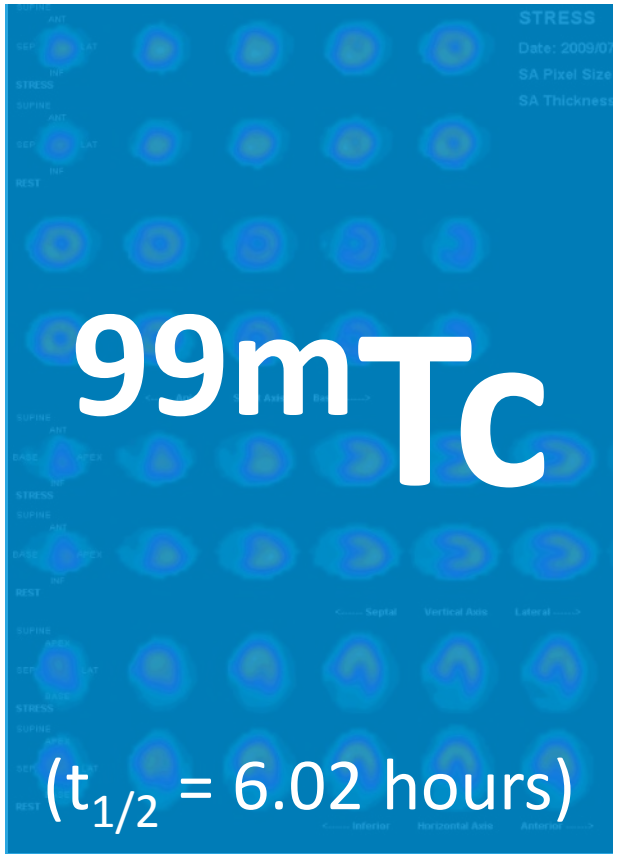
- Proton irradiation of isotopically enriched Mo-100 at 16-24 MeV
- Automated Mo-100 dissolution with H_2O_2
- Automated Tc-99m purification
- Final Tc-99m form: Injectable Sodium Pertechnetate

Cyclotron Production Yields



GE **PETTrace** (16.5 MeV, 130 µA): 4.7 Ci in 6 hrs
ACSI **TR19** (18 MeV, 240 µA): 13.9 Ci in 6 hrs
ACSI **TR30** (24 MeV, 450 µA): ~39 Ci in 6 hrs

^{99m}Tc purification efficiency: >93%
^{100}Mo recycling efficiency: >95%

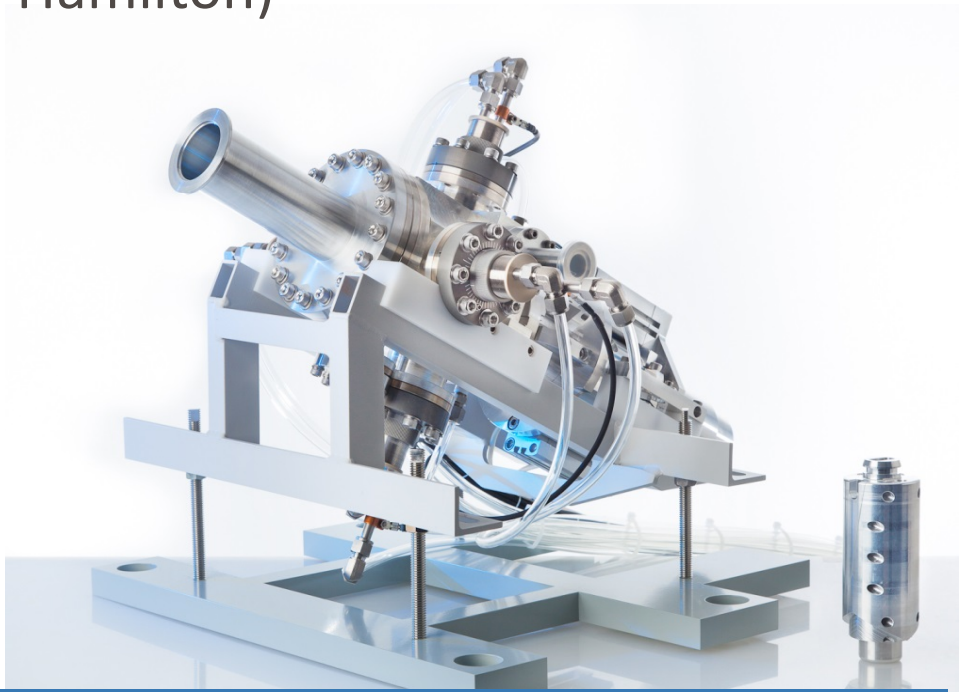


QUANTM Waste Management

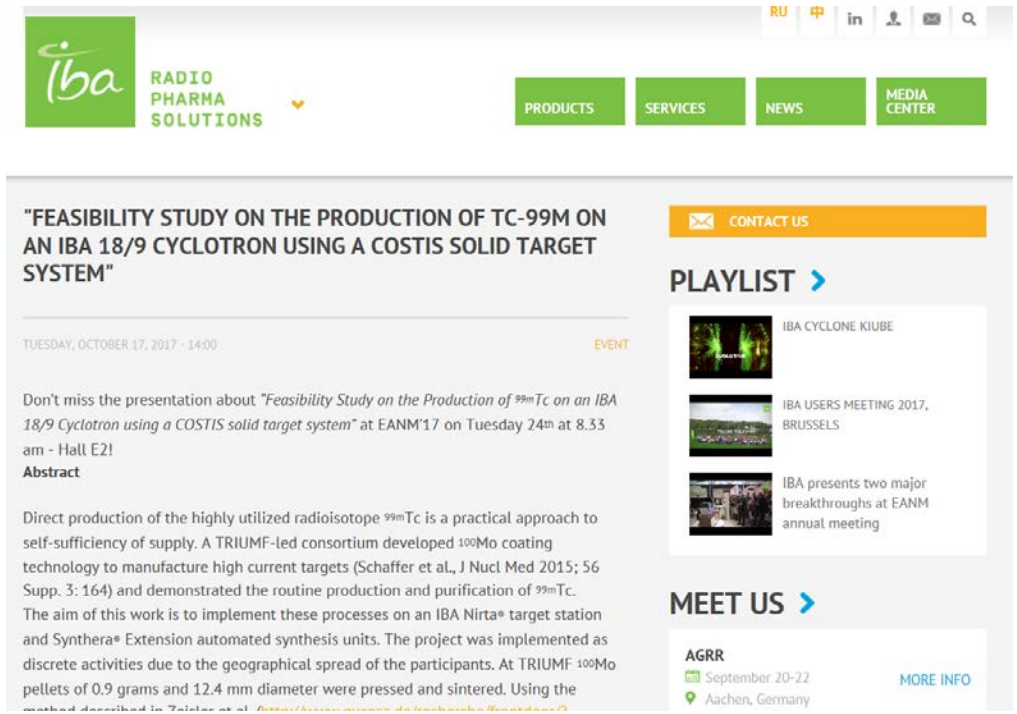
- No uranium feedstock, no fissile by-products
- Feedstock materials all stable, non-radioactive:
  - Tc-99m: Ta or Cu plate backings, Mo-100 substrate
  - Ga-68: Ag and/or Al plate backings, Zn-68 substrate
  - Zr-89: Ta plate backing, Y-89 substrate
  - Cu-64: Rh plate backing, Ni-64 substrate
- Irradiation process results in minimal by-products
  - Primary irradiation products are desired medical isotope
- Waste stream includes: isotope byproducts; activated target plates
  - All low-level/short-lived
  - Handled manually
  - Short term (weeks/months), on-site storage before disposal

Recap: 2017 Status

- Solutions developed for GE (16.5 MeV), ACSI 19 and 24 machines
- **Clinical Trial Completed!**
  - 30/30 bone patients scanned (Vancouver)
  - 30/30 thyroid patients scanned (Vancouver, London, Hamilton)
  - ‘kit study’ underway
- NDS submission (bone + kit) **Q4 2017**
- Rollout into UK – **2018** (TR24 cyclotron)
- 1 orders for ARTMS QIS system completed
  - Additional orders being filled
- Discussions with Province of BC – ongoing



Tc-99m Demonstration on IBA Cyclotron

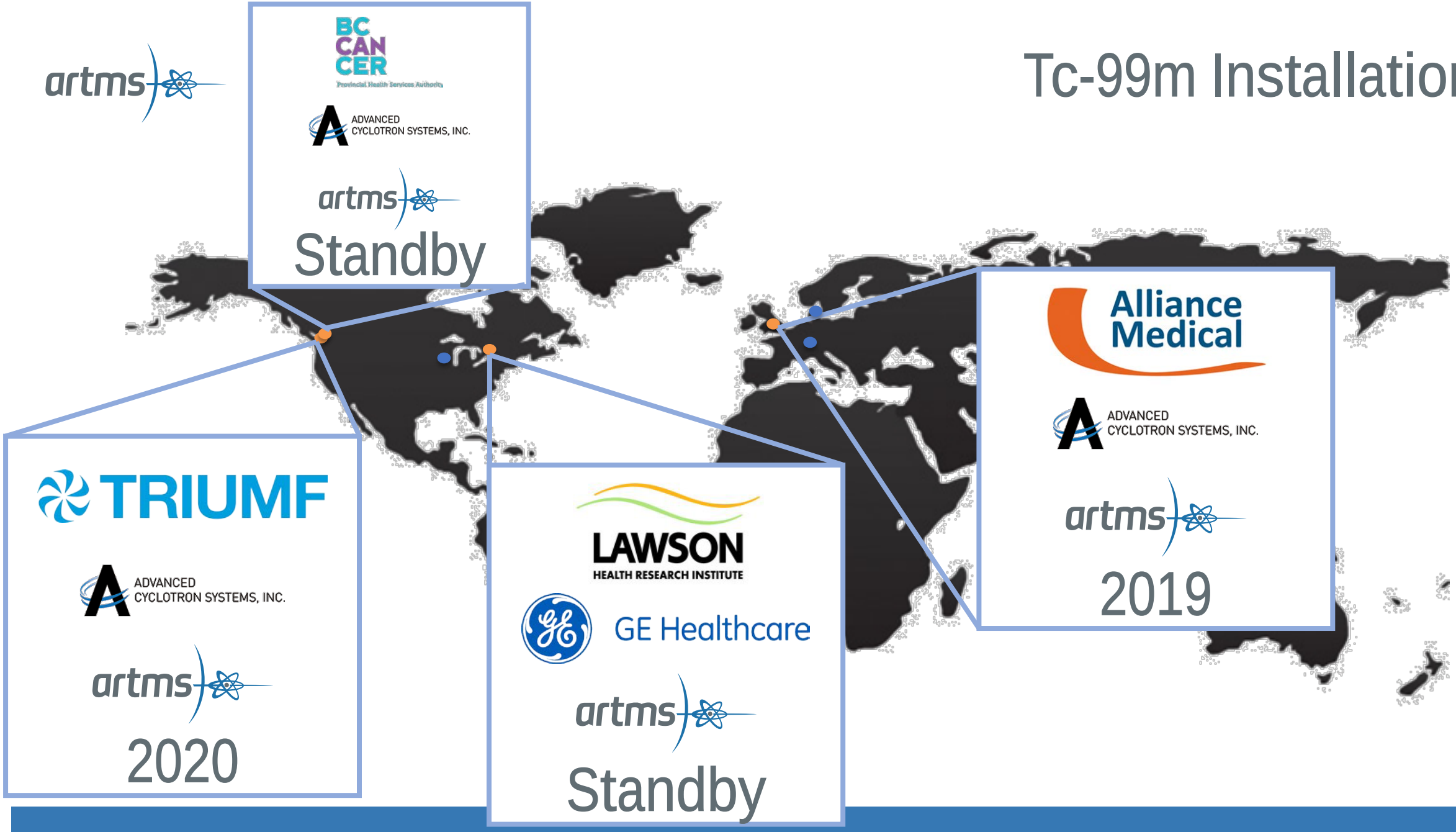


- Developed 24 mm diameter coin target (13 mm diameter Mo-100); using Press-Sinter-Braze
- Demonstrated Tc-99m production on IBA cyclotrons (18 MeV)
- Demonstration of Tc-99m purification on IBA Synthera Extension and integration with

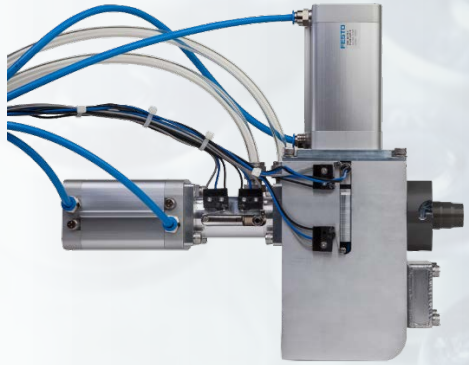
Tc-99m Installations - Dinnington

Tc-99m Installations – TRIUMF (IAMI)

Tc-99m Installations



Target Capsules



Cyclotron Target Station

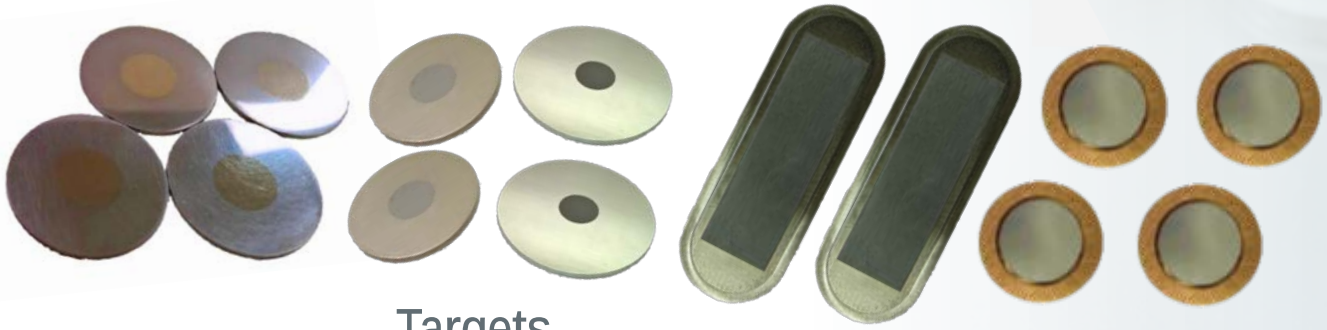
2-way Target Transfer

QUANTM Irradiation System™

CE

CSA c UL us

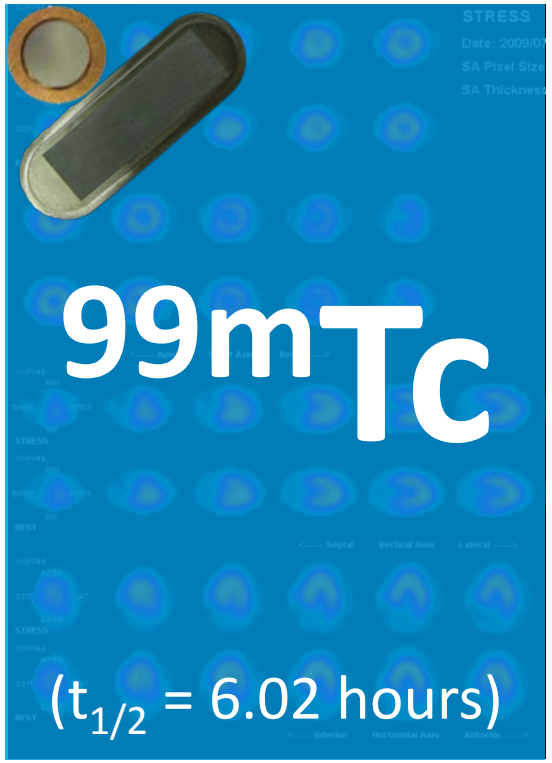
Q4 2018

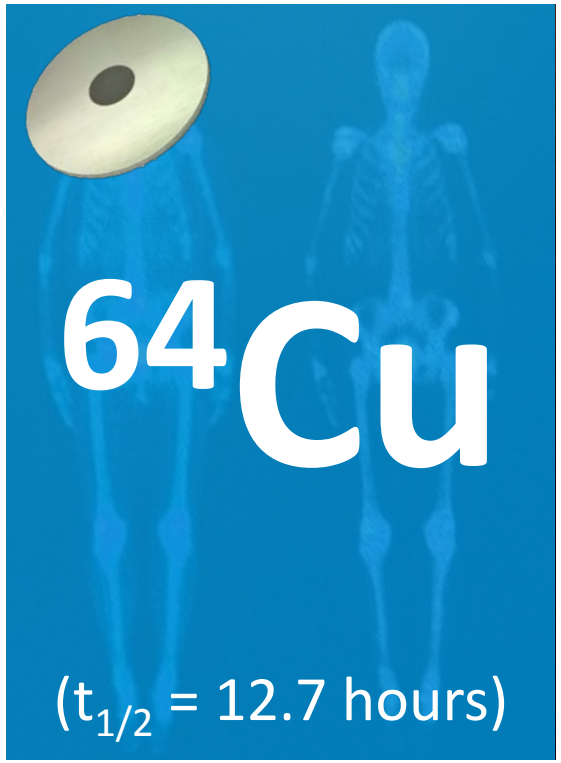


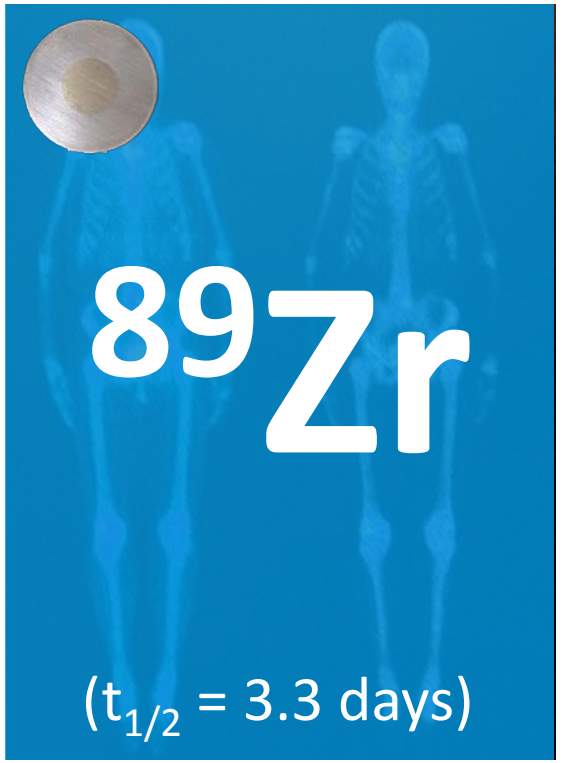
Targets

Automated Dissolution and Purification

ARTMS Products Target Line







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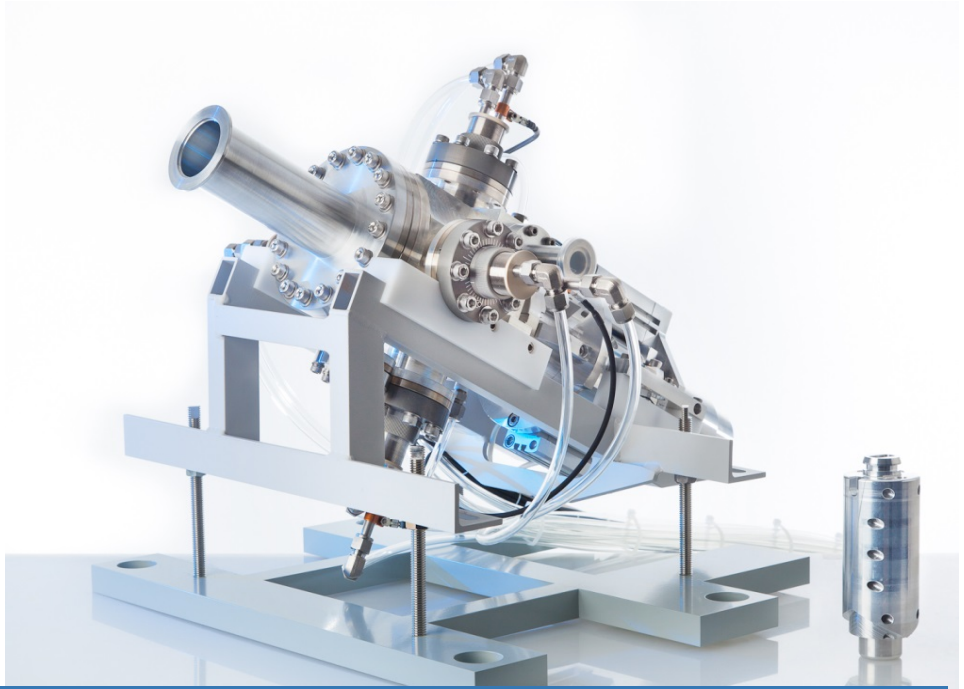
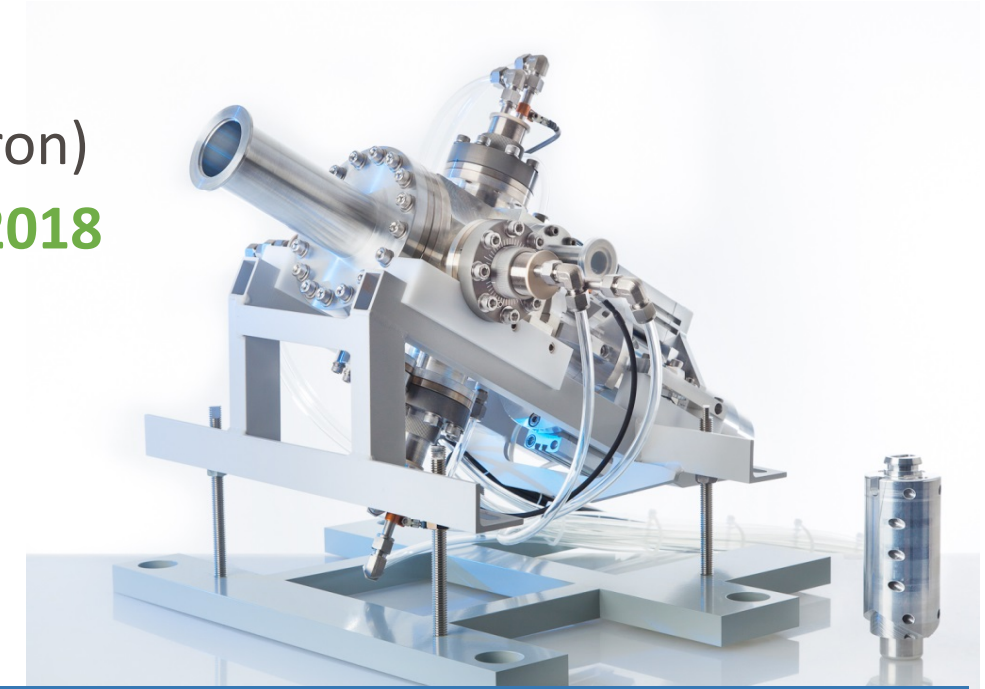


2018 Status

- Solutions developed for GE (16.5 MeV), **IBA (18 MeV),** ACSI 19 and 24 MeV machines
- **Clinical Trial Completed!**
  - 30/30 bone patients scanned (Vancouver)
  - 30/30 thyroid patients scanned (Vancouver, London, Hamilton)
  - ‘kit study’ underway
- NDS submission (bone + kit) **Q4 2018**
- Rollout into UK – Commissioning in **2019** (TR24 cyclotron)
- ARTMS QIS now CE Marked **Q2 2018**, CSA and UL **Q4 2018**
- 3 orders for ARTMS QIS system fulfilled
  - Additional orders being filled
- **IAMI initiative at TRIUMF**



Acknowledgements

L. Admans[3], F. Bénard[2], K.R. Buckley[1,2], S. Creasey[3], M. Dodd[2], V. Hanemaayer[2], B. Hook[1],
M. Jenkins[3], M. Kovacs[2], S. McDiarmid[1,2] F.S. Prato[2], T. Ruth[2], J.F. Valliant[2], M. Vuckovic[2],
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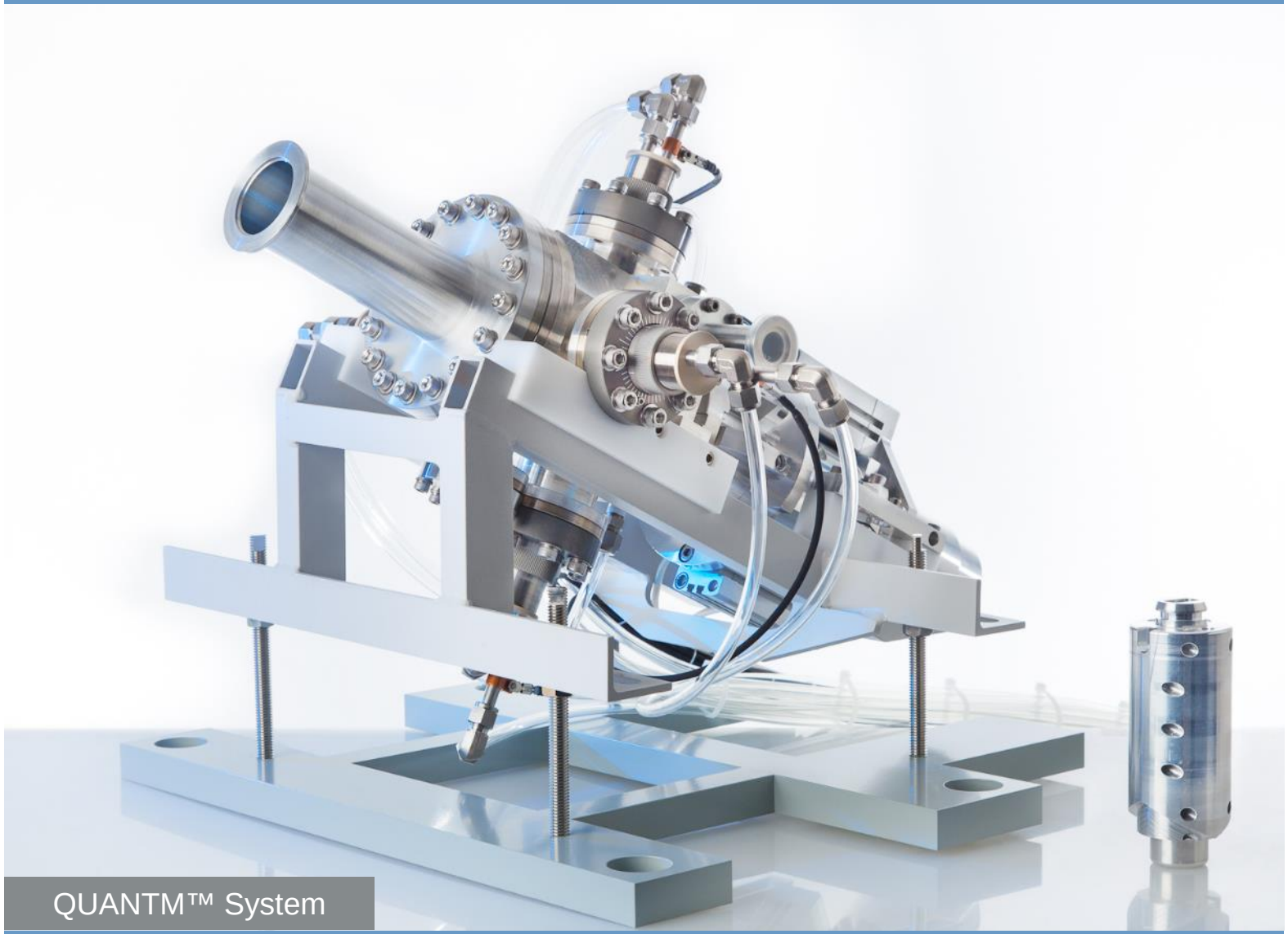
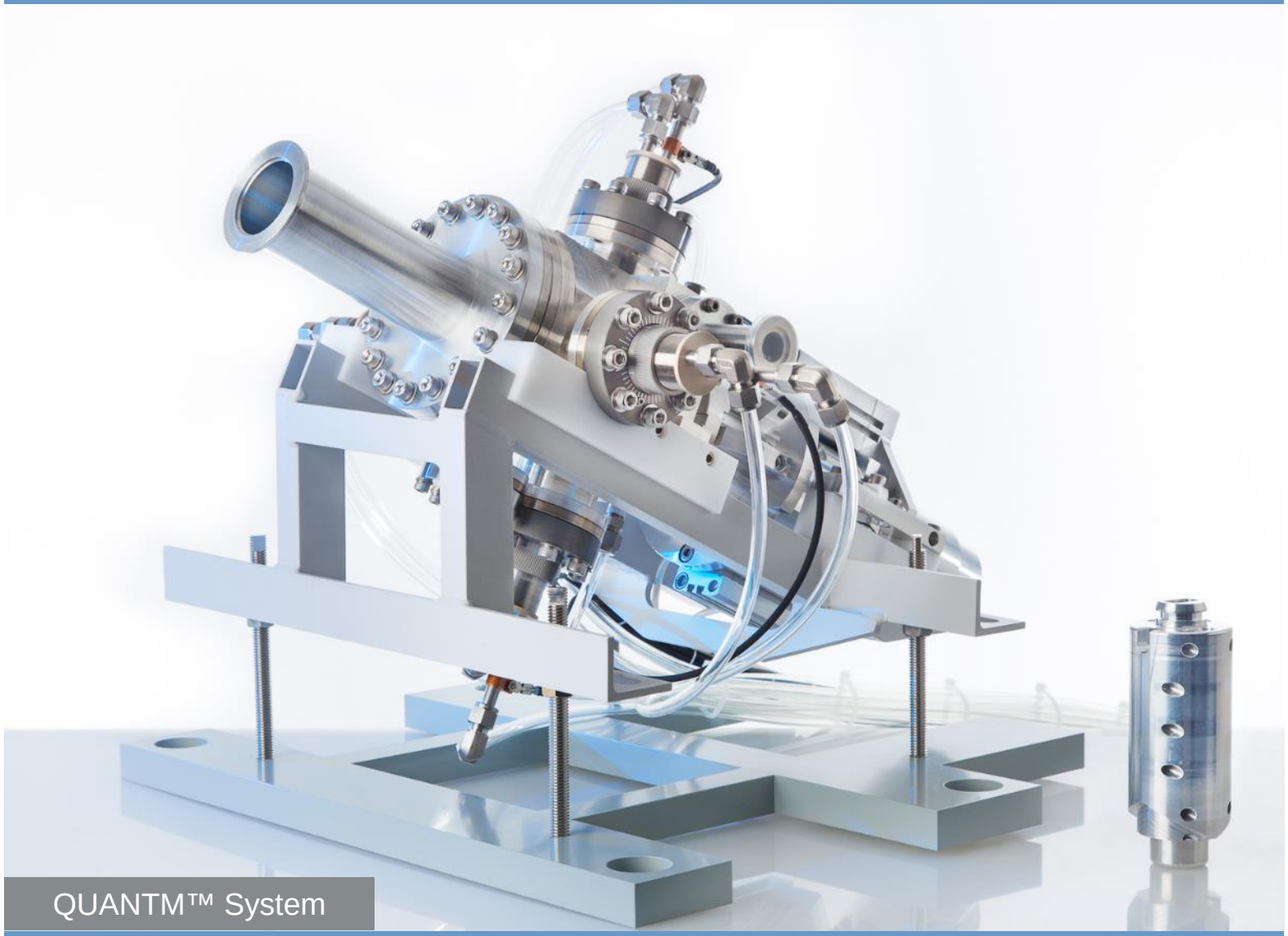
[2]ITAP Consortium
[3]Alliance Medical



QUANTM™ System

Thank You

Contact: Joel Kumlin
kumlin@artms.ca



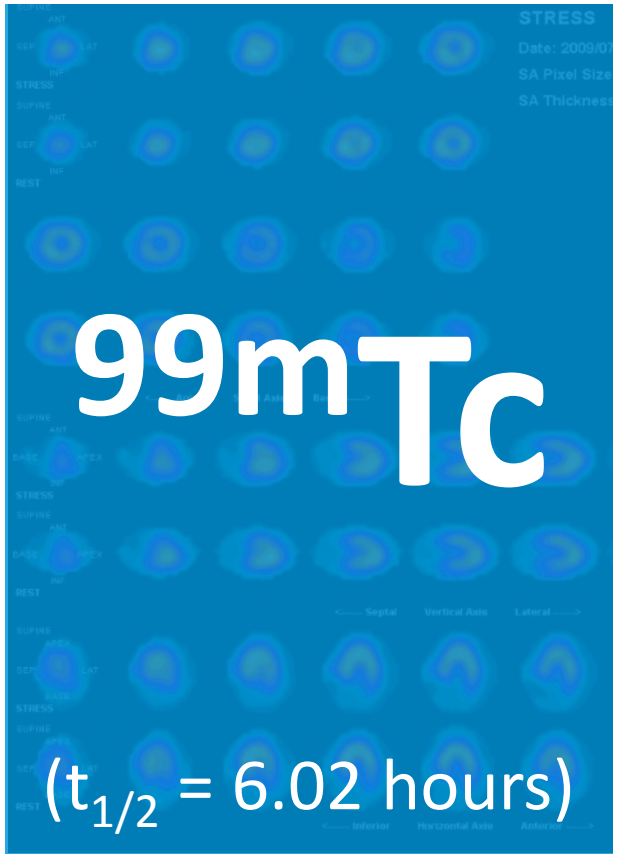
QUANTM™ System

artms

Backup Slide

Tc-99m Purity

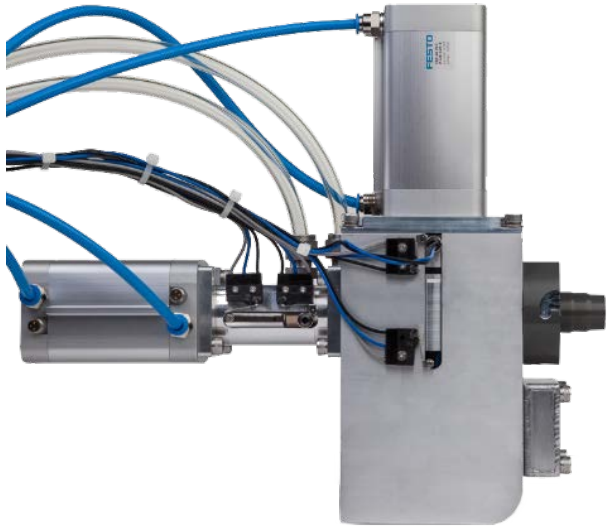
Process Validation Batch No.		1509011	1509025	1510005
Batch Size (EOS) (GBq)		35.3	51.7	37.0
Final Product Amount at EOB (GBq)		41.2	61.1	43.5
Estimated Yield (%) (decay-corrected)		100	135	89
Membrane filter integrity (≥ 50 psi)		62	61	65
Specification	**Acceptance Criteria**	**Results**		
Visual Appearance	Clear, colorless solution, free from visible particulates	Conforms	Conforms	Conforms
pH	4.5 to 7.5	7.5	7.0	7.5
Radionuclidic purity	Isotopes other than ^{99m}Tc contribute an emission rate < 6,000 emissions/ sec/MBq of ^{99m}Tc	**34**	**52**	**53**
Radionuclidic identity	Half-life between 5.72 and 6.32 hours	5.81	5.84	5.83
Radiochemical purity	≥ 95%	100	100	100
Radiochemical identity	Rf = 0.8 – 1.0	1.0	1.0	1.0
Aluminum content	≤ 10 µg/mL of solution (10 ppm)	<10	<10	<10
Hydrogen peroxide content	≤ 50 mg/L of solution (50 ppm)	0	0	0
Molybdenum content	≤ 30 µg/mL of solution (30 ppm)	0	0	0
Radioactivity concentration	(≤ 27.8 GBq/mL)	1.83	2.58	1.84
Bacterial endotoxins[2]	≤ 17.5 EU/mL	<2.5	<2.5	<2.5
Sterility[2]	No growth	No growth	No growth	No growth



ARTMS Products

The QUANTM Irradiation System™ includes hardware and disposable targets to enable the local, de-centralized cyclotron production of medical isotopes

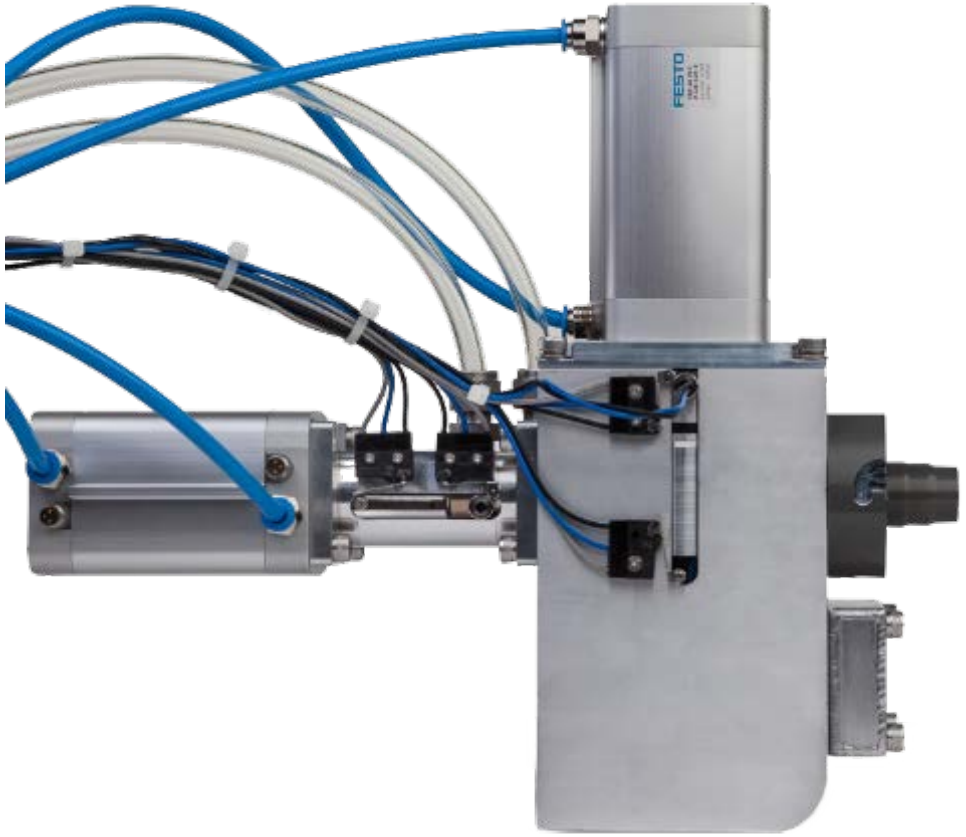
- QIS™ is compatible with all major OEM cyclotrons



- Proprietary target plates for production of ^{99m}Tc, ^{68}Ga, ^{89}Zr, ^{64}Cu

Value Proposition

- Reliable daily production
  - Avoids single point of failure supply chain
- Supply independence and logistical compatibility
  - Local control, responsive to market needs
  - Well-suited for geographically concentrated patient populations
- Multiple revenue sources enabled by multiple isotope production capabilities
  - ^{99m}Tc product line established, CTA completed
  - Next isotopes developed: ^{68}Ga, ^{89}Zr, ^{64}Cu
  - Under investigation: ^{44}Sc, ^{55}Co, ^{119}Sb, ^{124}I, ^{165}Er



QUANTM Irradiation System™

- Fitment to new and existing cyclotron systems
  - Available for all major cyclotron OEMs
- Cost competitive to existing production methods: reactor, generator
- Established target processing methods
  - Novel purification and formulation processes
- Global intellectual property protection
  - Unique, proven design and manufacturing techniques
- Environmentally benign
  - No long-lived, highly radioactive waste
  - Recycling of raw materials established

Not secure https://www.anzsnm.org.au/news-item/1378/tc-99m-generator-advisory-wednesday-sep-12-2018-0900hrs

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Back to list

Tc-99m Generator Advisory - Wednesday Sep 12, 2018 09:00hrs

Wednesday 12, Sep 2018

Tc-99m Generator Advisory
Wednesday Sep 12, 2018 09:00hrs

The Working Group held a scheduled Tcon yesterday afternoon. The outlook for next week is for much the same as this week, except that some metro sites that normally receive an ANSTO generator may have run short of Tc99m this week waiting for Thursday / Friday delivery. This is the by-product of trying to catch up with fresh generators taking over from last week's stretched supply. Sites (usual ANSTO generator sites and GMS) should get regular supplies now and we should be close to full capacity next week.

The plan is for this situation to repeat each week including the day of your generator delivery. Concurrently, ANSTO will increase generator production locally and progressively move larger proportions of sites to local supply. This will not be a fast transition. Currently about 50% of departments are on locally produced generators and the remaining 50% plus GMS will be progressively supplied locally. Once local production is at or near 100%, plans will be made to migrate departments back to preferred delivery days and preferred generator sizes. Patience is requested until this is feasible.

The Working Group will continue to meet regularly and monitor the situation and provide updates as required.