New software for the TracerLab Mx

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Introduction: With almost 800 systems installed all over the world, the Coïncidence/TracerLab Mx (General Electric, USA) is still the best seller among synthesizers for [^{18}F]FDG production. This device is approved by relevant Authorities for most of the Marketing Authorizations and used in a GMP environment to produce pharmaceutical grade fluorodeoxyglucose. When FDG started to be commercialized, private laboratories were approved by the Authorities as “mono-product” producers allowed to prepare, sell and deliver only FDG. Further, following the increasing market demand for other radiopharmaceuticals, they were solicited to produce already published tracers under special license and under specific orders for approved clinical protocols. Today, more and more producers are very far in the development of new tracers and on their way to submit Marketing Authorizations.

Objective: On one hand, most of the production laboratories must adapt their license and organization to become “multi-product” and one major step of the file update is the demonstration that in one room, several different synthesis are managed at no risk for the final product (schedule, cross contamination, ….). On the other hand, most of technician teams are trained on the TracerLab Mx and the switch to any other system may easily take up to several months to recover the same reliability. Today, by using the TracerLab Mx in its original configuration, the above mentioned two points are not under control, mostly due to the inadequacy of the original software.

Features:

The purposes of a new software development were:

1) Availability of specific folders for each different produced radiopharmaceuticals
2) Use of kits commercially available from ABX (Dresden, Germany) for NaF, FLT, F-Miso, FET, F-acetate and F-choline
3) Avoidance of sequence problems, with reset of the PLC memory between each run
4) Specific kit test dedicated to the molecule
5) Display a specific flow path layout for each molecule
6) Creation of a specific report corresponding to the name of the molecule
7) Building of data base in order to manage and optimize the preventive maintenance
8) Implementation of different level of users that can log into the system (administrator, operator,...)
9) Safe and secure control of the TracerLab Mx from any computer through secured LAN (cabled and/or wifi) or secured internet connection
10) Open updatable list of compounds

Other useful features added to the software:

11) Addition of a 5th radioactivity detector
12) Possibility to connect a UV detector
13) Control of the 8 outputs still available on the back of the Mx

14) For the user willing to run synthesis including HPLC purification, dedicated screen displaying HPLC UV and radio detection, “Collect” and “Stop collect” button and the possibility to control an “Add On Reform”

Upgrade Procedure:

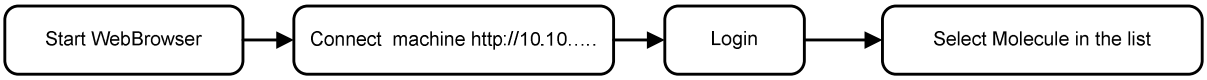
The upgrade of an existing TracerLab Mx is quite simple:

- Replacement of the RS232 cable by an RJ45 cable
- Replacement of the PLC control board
- Installation of a control server and a WIFI router

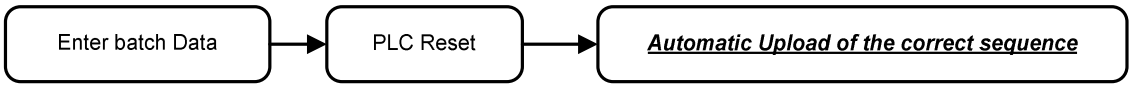
From that configuration, any computer loaded with standard browser (Firefox for example), can control the TracerLab Mx.

User Procedure:

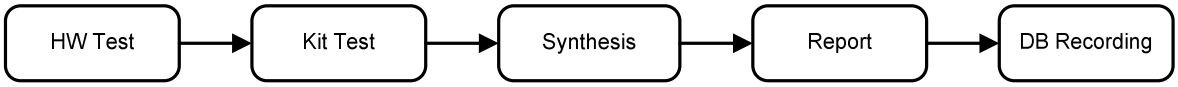
Step 1:



Step 2



Step 3 :



Results:

	Duration	Uncorrected Yield
Kit Only		
NaF	<10 min	Quantitative
FLT	54 min	21%
F-Miso	54 min	22%
F-choline	32min	17%
FET	54	17%
F acetate	42	39%
FDG	26	61%
HPLC		
MPPF	68 min	21%
FLT	40 min	39%
Fallypride	Under Progress	
Licensed 1	Under Progress	

Conclusion:

By using the new software the Tracer Mx has now become a flexible platform dedicated not only to FDG production, but also to most of the fluorinated tracers with clinical demand.