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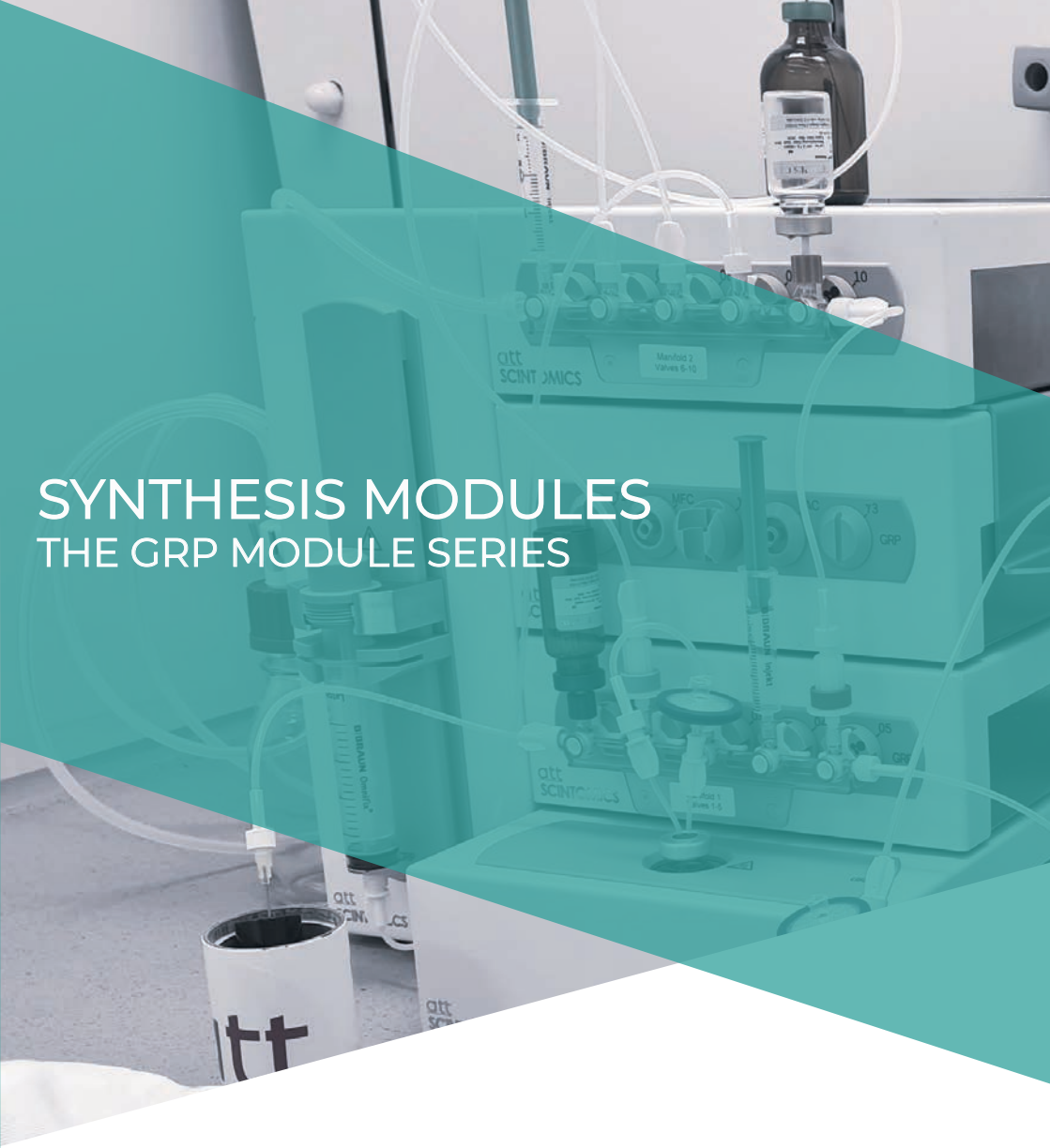


SYNTHESIS MODULES
THE GRP MODULE SERIES

SCINTOMICS MOLECULAR,
APPLIED THERANOSTICS TECHNOLOGIES GMBH

att SCINTOMICS

WELCOME TO SCINTOMICS MOLECULAR, ATT GMBH

HISTORY

In 2006, Scintomics GmbH started with the vision of combining functionality and aesthetics with quality and GMP requirements, resulting in the development of a fully automated production system for the manufacture of radiopharmaceuticals, which was produced and distributed by Scintomics GmbH until 2020.

Since then, there has been a steady development of both the fully automated production systems and the company itself.

In order to offer customers a complete service, the company SCINTOMICS Molecular, Applied Theranostics Technologies GmbH (SCI-att) was founded in 2018 with the purpose of distributing the module-related chemicals, intermediates, precursors and other consumables for radiopharmaceutical production.

To combine the module and consumables business, the whole module operations such as production and sales were transferred to SCI-att in 2020.

QUALITY POLICY

SCI-att is responsible for the development, production and distribution of automated components and system-related consumables for the production of radiopharmaceuticals.

SCI-att also distributes starting materials (chemicals, intermediates, precursors and disposable consumables) for the radiopharmaceutical production of radiotracers.

SCI-att stores and transports the starting materials according to GDP guidelines. Products manufactured on behalf of SCI-att are GMP-compliant. In addition, all products are manufactured and distributed in accordance with ethical principles and international standards.

We continuously invest into our facilities and the training of our employees to be ahead of the quality requirements and standards at all times. Furthermore, we guarantee the highest levels of quality and performance to our clients and strive to improve our services to the benefit of our customers and their patients.

CERTIFICATION

SCI-att was successfully audited in November 2022 and received the wholesale license and the GDP certificate by the German authorities.
As part of an annual GDP compliance audit, SCI-att has been certified since 2020 by fulfilling the requirements of the EU Guideline on Good Distribution Practice for Medicinal Products for Human Use (2013/C 343/01) Issue November 05, 2013.

PARTNERS

At SCI-att we are proud of the long lasting partnerships we have developed over the past years and our ambition is to provide all these partners with the highest possible level of service. We treat every single customer with diligence and care, and have the necessary flexibility to adjust our services to your necessities.

Through our network of distributors and partners we are able to maintain and guarantee the same level of service and care in various countries all around the globe.

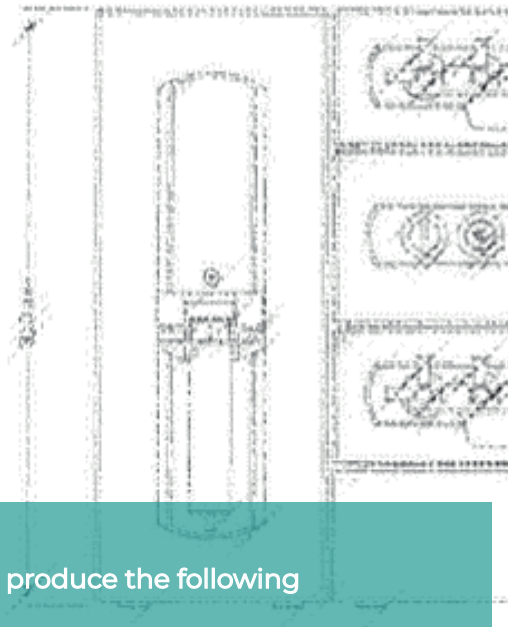
The siGRP Module is part of the GRP Module series. The GRP (Good Radiopharmaceutical Practice) Module series was developed for the production of radiopharmaceuticals in the clinical environment.

All siGRP Modules are expandable with additional Valve Units. In addition, the Modules offer the possibility to cover the research and development area as well as the routine production of radiotracers, according to the guidelines of Good Manufacturing Practice.

The siGRP Module is a fully automated Synthesis Module especially designed for the synthesis (by means of isotopic exchange reaction on SiFA = silicon-fluoride acceptor) of [^{18}F]siPSMA-14 and [^{18}F]siTATE.

This means that no heating (thus NO radioactive hydrogen fluoride is released!) and no gallium generator is needed.

The labelling is done by an isotopic exchange reaction, where the fluoride purification is done by our patented [^{18}F] drying method at room temperature instead of the conventionally used azeotropic drying.



The siGRP Module can be used to produce the following radiopharmaceuticals:

[^{18}F]siPSMA-14
[^{18}F]siTATE / [^{18}F]siFA*lin*-TATE

siGRP MODULE

All siGRP Modules include a license for the GRP Interface Software, our standard software for working in a GMP environment. This means that you can prepare the module and start and stop the synthesis via this software. Manual interaction during the synthesis is not possible and the program runs automatically.

Optionally, a license for the ControlCenter software can be included. This is a software for the individual control of GRP Modules and their components, which gives the user additional possibilities, mainly in the field of research and development.

siGRP MODULE COMPONENTS

1x siGRP Valve Module Slave (V6-10),
optionally with Vial Holder
1x siGRP Detector Unit
with 1 Radioactivity Sensor, 2 Pressure Sensors
1x Valve Module Master (V1-5)
1x siGRP Reactor Unit without Heater
with Vacuum Pump
1x Syringe Pump

DIMENSION OF THE SINGLE UNITS

Component	W x H x D [cm]
siGRP Valve Module Slave (V6-10)	21 x 7,5 x 22
siGRP Detector Unit	21 x 9,5 x 22
Valve Module Master (V1-5)	21 x 7,5 x 22
siGRP Reactor Unit	21 x 7,5 x 30,5
Syringe Pump	21 x 31 x 25,5
Entire Module Unit	33 x 39,5 x 30,5

The size of the Module equipped with Cables, Vial Holder and Cassette is approx. 40 x 40 x 40 cm.

If you have any further questions about our siGRP Module, please do not hesitate to contact us.

smartGRP MODULE

The smartGRP Module is the newest and smartest syntheziser in our GRP Module family. It was developed for the production of the most common radiopharmaceuticals in the clinical environment.

This module offers the possibility to cover all research and development areas as well as the routine production of radiotracers, according to the guidelines of Good Manufacturing Practice. Additionally all smartGRP Modules can be expanded with further valve units to increase their scope of application even more.

The smartGRP Module is a cost-effective alternative for doing standard synthesis, such as [^{68}Ga]- and [^{177}Lu]- labelling-peptides. In addition, it can also be used for the [^{18}F]-synthesis that the siGRP Module offers.

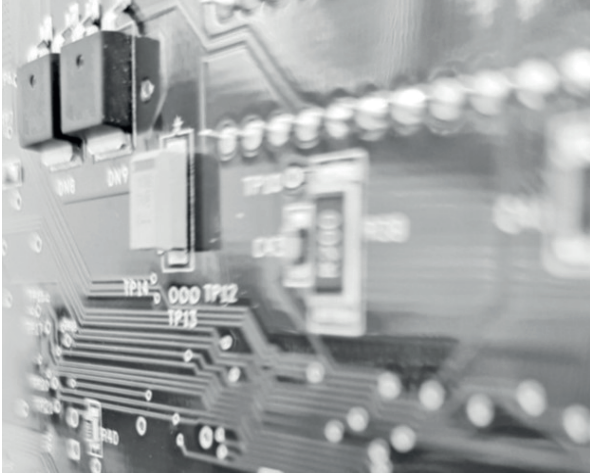
It has reduced electronic components and features compared to the normal GRP Module but contains everything that is necessary to perform all the routine productions with the well-known GRP environment.

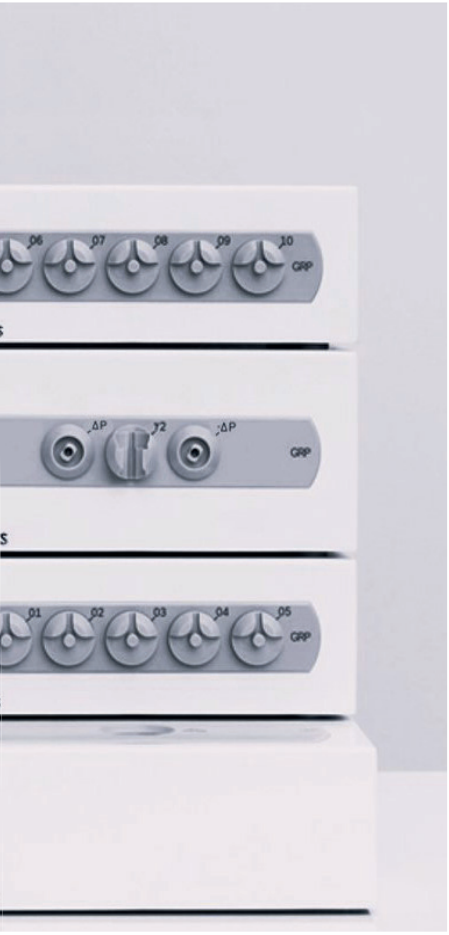
All smartGRP Modules include a license for the GRP Interface Software, our standard software for working in GMP mode.

Optionally, a license for the ControlCenter Software could be included. This is a software for the individual control of GRP Modules and their components, which gives the user additional possibilities, mainly in the field of research and development.

The smartGRP Module can be used to produce the following radiopharmaceuticals:

[^{18}F]siPSMA-14, [^{18}F]siTATE / [^{18}F]siFA*lin*-TATE,
[^{177}Lu]-Tracer,
[^{68}Ga]-Tracer (2-manifold method)





smartGRP MODULE COMPONENTS

1x Valve Module Slave (V6-10),
optionally with Vial Holder
1x smartGRP Detector Unit
with 1 Radioactivity Sensor, 1 Pressure Sensor
1x Valve Module Master (V1-5)
1x smartGRP Reactor Unit
with Heater, MFC, 1 Pressure Sensor,
Vacuum Pump
1x Syringe Pump

DIMENSION OF THE SINGLE UNITS

Component	W x H x D [cm]
Valve Module Slave (V6-10)	21 x 7,5 x 22
smartGRP Detector Unit	21 x 9,5 x 22
Valve Module Master (V1-5)	21 x 7,5 x 22
smartGRP Reactor Unit	21 x 7,5 x 30,5
Syringe Pump	21 x 31 x 25,5
Entire Module Unit	33 x 39,5 x 30,5

The size of the Module equipped with Cables, Vial Holder and Cassette is approx. 40 x 40 x 40 cm.

If you have any further questions about our smartGRP Module, please do not hesitate to contact us.

GRP 3V MODULE

The GRP 3V Module is the fully equipped flagship product in our GRP module family. It was developed for the production of various radiopharmaceuticals in the clinical environment.

All GRP Modules are expandable with additional Units up to configurations containing 6 Valve Units and 2 Syringe Pumps.

GRP Modules offer the possibility to cover the research and development area as well as the routine production of radiotracers, according to the guidelines of Good Manufacturing Practice.

Its reliable performance for the automated synthesis of [^{68}Ga]-, [^{177}Lu]- and [^{18}F]-labelled radiotracers has been proven in over >100 centers worldwide on ten thousands of successful productions.

All GRP Modules include a license for the GRP Interface Software, our standard Software for working in GMP mode.

Optionally, a license for the ControlCenter Software could be included. This is a Software for the individual control of GRP Modules and their components, which gives the user additional possibilities, mainly in the field of research and development.

GRP 3V MODULE COMPONENTS

1x Valve Module Slave (V11-15),
optionally with Vial Holder
1x Valve Module Slave (V6-10)
1x Detector Unit
with 3 Radioactivity Sensors, MFC
2 Pressure Sensors
1x Valve Module Master (V1-5)
1x Reactor Unit
with Heater, Vacuum Pump
1x Syringe Pump

DIMENSION OF THE SINGLE UNITS

Component	W x H x D [cm]
Valve Module Slave (V11-15)	21 x 7,5 x 22
Valve Module Slave (V6-10)	21 x 7,5 x 22
Detector Unit	21 x 9,5 x 22
Valve Module Master (V1-5)	21 x 7,5 x 22
Reactor Unit	21 x 7,5 x 30,5
Syringe Pump	21 x 31 x 25,5
Entire Module Unit	33 x 39,5 x 30,5

The size of the Module equipped with Cables, Vial Holder and Cassette is approx. 40 x 46 x 40 cm.

If you have any further questions about our GRP 3V Module, please do not hesitate to contact us.

The GRP 3V Module can be used to produce the following radiopharmaceuticals:

[^{18}F]siPSMA-14,
[^{18}F]siTATE / [^{18}F]siFA*lin*-TATE
[^{177}Lu]-Tracer,
[^{68}Ga]-Tracer (2-manifold],
[^{68}Ga]-Tracer (3-manifold) like
[^{68}Ga]-FAPI,
[^{99m}Tc]PSMA I&S
[^{89}Zr], [^{18}F]-NaF, [^{90}Y]
[^{18}F]FDG (3V), etc.

The GRP 4V Module can be used to produce the following radiopharmaceuticals:

[^{18}F]siPSMA-14,
[^{18}F]siTATE / [^{18}F]siFA*lin*-TATE
[^{177}Lu]-Tracer,
[^{68}Ga]-Tracer (2-manifold],
[^{68}Ga]-Tracer (3-manifold) like
[^{68}Ga]-FAPI,
[^{99m}Tc]PSMA I&S
[^{89}Zr], [^{18}F]-NaF, [^{90}Y]
[^{18}F]FDG (4V), [^{18}F]FMISO,
[^{18}F]FET, [^{18}F]FLT, [^{18}F]FMC, etc.

SOFTWARE

A comprehensive and powerful innovation environment is indispensable for the method development of new syntheses and subsequent optimization studies.
During the validation phase and routine production however, quick, safe and convenient operation is required.

Upon successful conclusion the pre-validation phase, methods can be exported from the comprehensive ControlCenter development environment into the comfortable and fast to operate GRP Interface Software.
This interface only shows what is necessary. In the background all processes are controlled, all parameters are recorded and a complete report of the synthesis is created upon completion.

Exactly what GMP requires.

OUR GRP MODULES ARE A PERFECT COMPANION AND AN OPTIMAL TOOL FOR YOUR RADIOPHARMACEUTICAL PRODUCTION.

SERVICE

We place the highest value on continuously trained personnel to provide excellent service and maintenance on-site.

Together with our GRP Modules we are happy to offer you a wide range of service agreements tailored to your requirements. We also provide you with GDP compliant documentation for our products. Our qualified service technicians will be happy to assist you at any time.

Furthermore we also offer various different training packages: on-site, in house and even online, to make sure you get the most out of your GRP Module.

If you have any further questions about SCI-att, our products and service, please do not hesitate to contact us.