

INTEGRALAB[®] PLUS

YOUR CUSTOMIZED GMP RADIOPHARMACY

EXPERTISE MAKES IT HAPPEN



Dr. med. Konrade von Bremen
Director at SWAN Isotopen AG, Bern,
Switzerland

Eng. Vincent Petry
Process and facility engineer
at IBA RadioPharma Solutions

INTEGRALAB®PLUS
CUSTOMIZED
RADIOPHARMACY
PRODUCTION

INTEGRALAB® SOLUTION,
ADAPTED TO YOUR NEEDS

INTEGRALAB®PLUS is a fully integrated solution, combining equipment and services for establishing a radiopharmaceutical GMP production center, tailored to your precise needs.

Our approach is truly comprehensive, taking your project from building design to production, with full regulatory compliance and the selection, integration, installation and qualification of equipment that meets your radioisotope production goals.

EXPERT TO
EXPERT, ALL THE
WAY

IBA works with you and supports you right through the whole process, from our first meeting through design, setting-up and operation. More than that, your IBA expert will support you throughout the lifetime of your radio-pharmacy with training, updates and

maintenance, to ensure the success of your project, for a sustainable future.

DIRECT ACCESS
TO THE EXPERT
WHO KNOWS

This is a long-lasting relationship, a partnership based on trust and

respect, from expert to expert. The big advantage for you is that a single point of contact will manage the establishment of your radiopharmacy, but at the same time, you can call directly on all IBA in-house experts to support you. This approach, unique in the market, speeds up workflow and ensures that you're always talking to the person with the answers.

EXPERT TO EXPERT,
WE SUPPORT YOU
RIGHT THROUGH THE
PRODUCT LIFETIME

REDUCE YOUR
PROJECT TIME



INCREASE YOUR
PRODUCTION UPTIME



STAY AHEAD
OF TIME



PROJECT
CONCEPTION

EQUIPMENT
INTEGRATION

PROCESS
VALIDATION

NUCLEAR
MEDICINE
DEPARTMENT
INTEGRATION

PRODUCTION
EQUIPMENT
OPERATION

IBA
ACADEMY

MAINTENANCE
SERVICES

SPECIALIST
ADVICE

EXTENDED
EQUIPMENT
SERVICES

ENDLESS
INNOVATION

UPGRADE
SUPPORT

USERS
MEETINGS

1. DEVELOP YOUR PROJECT

2. MAXIMIZE YOUR PERFORMANCE

3. BUILD YOUR FUTURE

Dr. med. Konrade von Bremen
Director at SWAN Isotopen AG, Bern,
Switzerland

Eng. Vincent Petry
Process and facility engineer at IBA
RadioPharma Solutions

*Since the project
conception of the
radiopharmacy at
SWAN Isotopen AG,
Vincent Petry has been
providing his expertise
with a customized
and optimized facility
layout, compliant with
GMP standards.*

Producing PET radiopharmaceuticals in a GMP¹ environment is complex; you need specialised facilities, with a range of advanced techniques equipment and **experts with hands-on experience** of establishing radiopharmacy centers. IBA has successfully installed almost one hundred IntegraLab[®] radiopharmacies around the world; this track record is a demonstration of IBA's **experience and expertise**.

IBA's team of experts will help you design and build a **radiopharmaceutical production facility, fully customized** to meet your needs and your production output requirements. You will work with our in-house experts covering all areas: from the process development, through the business plan and project management, all the way to the validation and regulatory compliance.

By working in partnership this way - **expert to expert** - we can get the job done on budget and on time, with a solution that complies with GMP and produces your radiotracers efficiently.

1. DEVELOP YOUR PROJECT

REDUCE YOUR PROJECT TIME

“ I thank you for your efforts with respect to the qualification of the facility and the installations and for the example SOP²'s. The protocols and SOP's were very helpful and made great impression on the inspectors. ”

*Dr Adrie P. de Jong, Head of Radiopharmacy
Medisch Centrum Alkmaar, The Netherlands*



- 1. Good Manufacturing Practice
- 2. Standard Operating Procedure

1. DEVELOP YOUR PROJECT



SUPPORT IN ALL ASPECTS OF PROJECT DEVELOPMENT

PROJECT CONCEPTION

EQUIPMENT INTEGRATION

PROCESS VALIDATION



WHAT'S THE ADVANTAGE WITH IBA?

You have direct access to IBA in-house experts on all aspects of your radiopharmacy, from the building design to the GMP and risk assessment specialist.

BUSINESS PLAN

- Support to define the radiopharmaceuticals production scope
- Build your business plan
- Supporting investment/financing, via our network of financial partners

GMP FACILITY DESIGN

- Customized and optimized facility layout, compliant with GMP standards
- Facility architectural design and engineering services

CLEAN ROOM EXPERTISE

- Integration of radiopharmaceutical laboratories requirements, including special techniques (air classification and ventilation)

SAFETY

- Risk Analysis
- Monte Carlo shielding simulation report
- Radiation monitoring and radiation protection equipment

ENVIRONMENTAL IMPACT

- Support for radioactive waste management strategy
- Decommissioning guidelines

PRODUCTION SOLUTIONS FOR PET & SPECT

- High capacity cyclotron (from 3 MeV to 70 MeV) and targetry systems
- Full range of chemistry systems for radiopharmaceutical production

PROCESS EQUIPMENT

- User requirements for specific radiopharmaceutical processes premises and equipment
- Supply of production and quality control equipment for Pharmacopeial testing

PROJECT MANAGEMENT

- Set-up your PET center on time and on budget
- One single point of contact

EQUIPMENT QUALIFICATION

- Protocols for:
- Installation Qualification (IQ)
 - Operational Qualification (OQ)
 - Performance Qualification (PQ)

GMP MASTER DOCUMENTATION

- GMP risk management
- Development of customized validation master plan (VMP)

GMP VALIDATION

- Quality management system
- Batch records for production of ¹⁸F-FDG & other radiopharmaceuticals
- Customized manufacturing equipment, operation and maintenance procedures
- Standard operating procedures

FDG MARKET AUTHORIZATION

- Deliverables based on IBA MA dossier
- Guidance to obtain market authorization

CONSULTANCY

- Technical support from IBA experts in GMP and/or regulatory affairs
- Process validation support



1. DEVELOP YOUR PROJECT

NUCLEAR MEDICINE DEPARTMENT INTEGRATION REACH HIGHER LEVELS OF PATIENT CARE

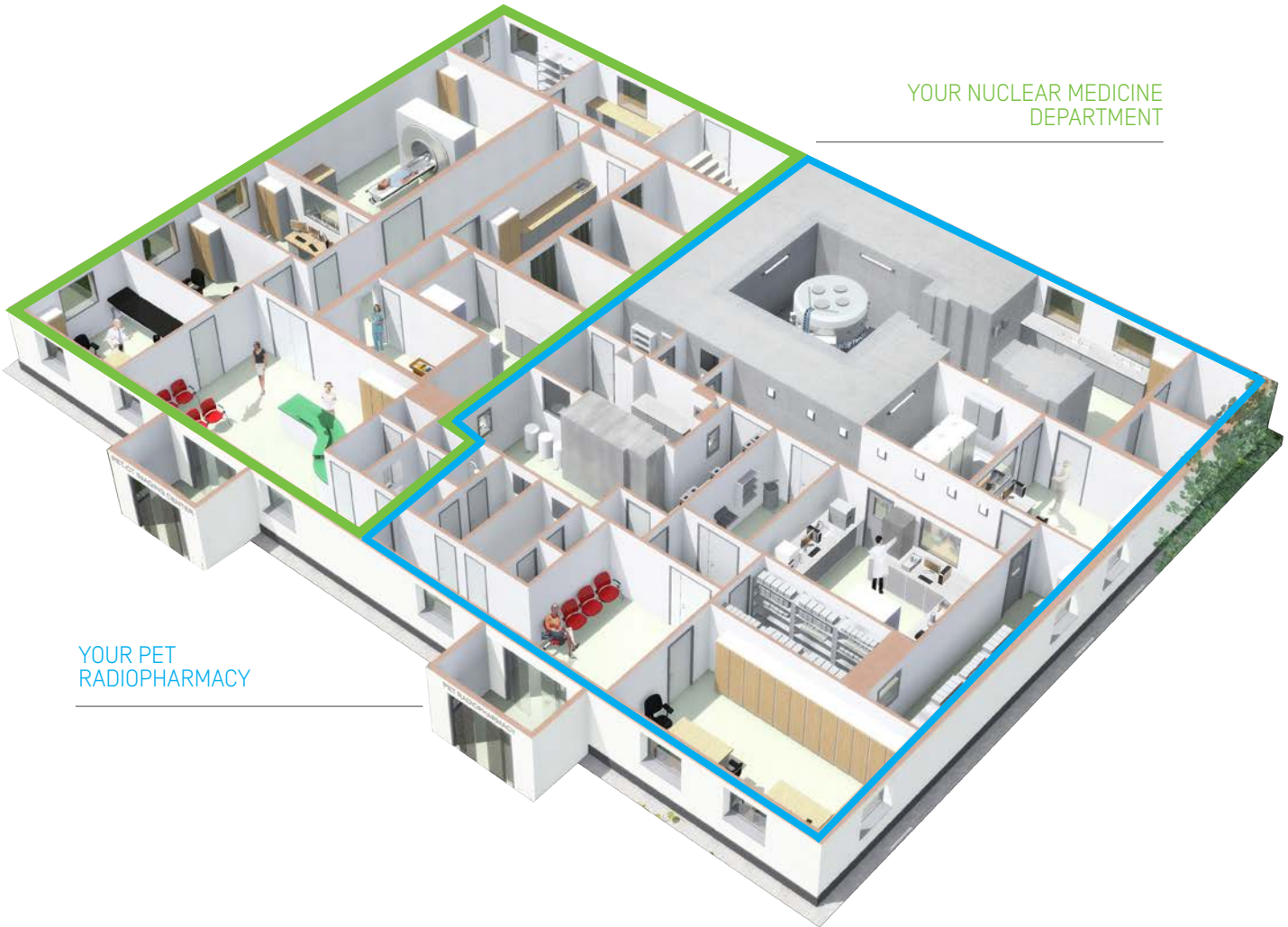
Through the successful completion of many projects around the world, IBA has built up invaluable experience in integrating nuclear medicine departments in healthcare centers. We can now bring this expertise to your hospital, helping you achieve sustainable, market-leading results in patient care, cost efficiency and staff satisfaction.

A single IBA project manager coordinates your project, but you have access to the best technology in terms of radiopharmaceutical production tools, as well as imaging equipment.

From design and installation, through full regulatory compliance, we take an integrated approach to patient care optimization, customized to your particular requirements.

" We have an IBA Cyclone® 18/9 Cyclotron and I have no hesitation recommending IBA. From initial enquiry, through the installation phase, to day to day running, your services are extraordinary. I am very impressed with your professionalism and willingness to help. I thank you so much; especially for the dedication that, despite being a small center, made us feel very important. I can't thank you enough! "

Walid I. Al Khalidi , Managing Director
Al Khalidi Medical Center Amman, Jordan



YOUR NUCLEAR MEDICINE
DEPARTMENT

YOUR PET
RADIOPHARMACY

EXAMPLES OF OUR PROVEN EXPERIENCE IN BUILDING NUCLEAR MEDICINE DEPARTMENTS

- Gliwice, Poland
Construction, building design, lab equipment, Cyclone® 18, PET/CT, GMP support & Market Authorization
- EMC Elsméd, Moscow
Building design, lab equipment, Cyclone® 18 and PET/CT
- Hanoi, Vietnam
Building design, lab equipment, Cyclone® 30 and PET/CT
- Tripoli Medical Center, Tripoli, Libya
Building design, lab equipment, Cyclone® 11 and PET/CT
- Yerevan, Armenia
Building design, lab equipment, Cyclone® 18 and PET/CT & GMP support
- Yangon, Myanmar
Building design, lab equipment, Cyclone® 18 and PET/CT

WHAT'S THE ADVANTAGE WITH IBA?

A totally integrated approach to patient care. IntegraLab® offers you highly-efficient workflows thanks to our seamless integration of all imaging equipment and software.



Dr. Ferid Haddad Ph.D
Director of the GIP Arronax in
Nantes, France

Eng. Jean-Michel Geets
IntegraLab® business
Developer at IBA RadioPhar-
ma solutions

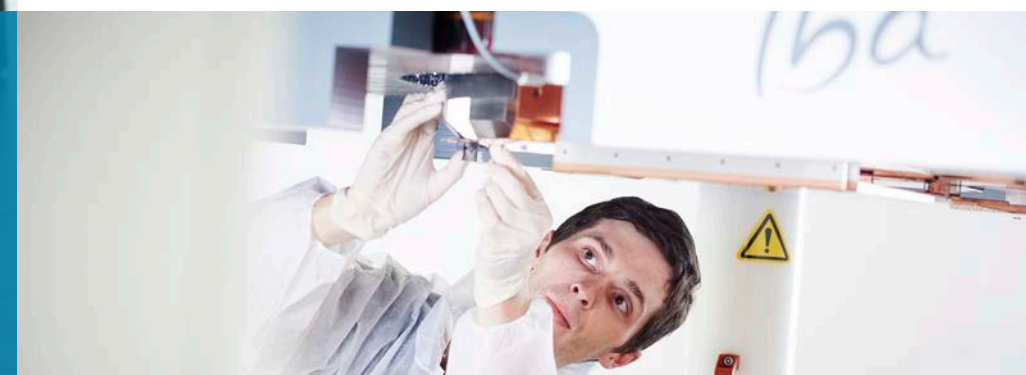
As a cyclotron expert, Jean-Michel Geets has been the key contact person for the Arronax project since its conception. He has been supporting Dr. Ferid Haddad who is managing the operation of a high energy (70 MeV) and high intensity multi-particle Cyclone® 70 cyclotron for the production of non-conventional radioisotopes since 2008.

When your new production facility is up and running, IBA continues to offer you support and expertise, to optimize uptime and maximize your return on investment.

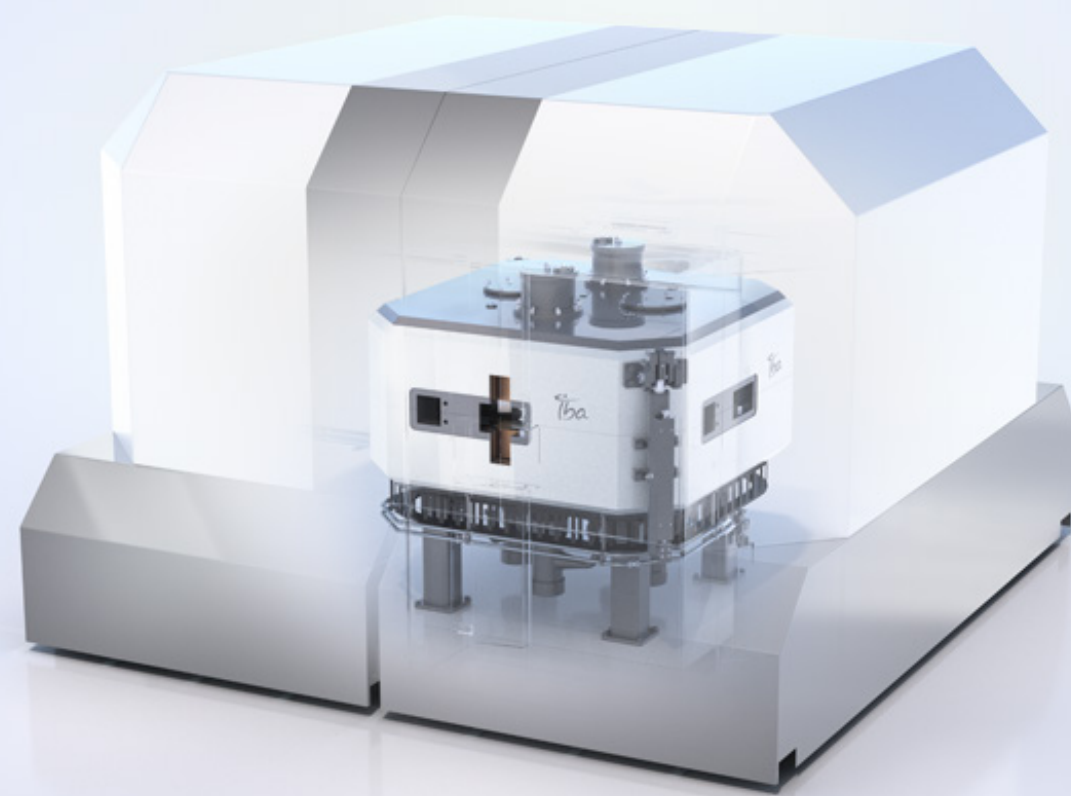
In-house IBA RadioPharma Solutions experts provide you with the latest product innovations, updates, skills and applications to ensure you maintain leading-edge performance throughout the lifetime of your PET center.

2. MAXIMIZE YOUR PRODUCTION UPTIME

SUPPORT FOR YOUR PERFORMANCE



2. MAXIMIZE YOUR PRODUCTION UPTIME



EXPERT SUPPORT TO MAXIMIZE YOUR UPTIME

HIGHEST PRODUCTION CAPACITY EQUIPMENT

- Up to 30 Ci of ^{18}F per run with the Cyclone® KIUBE cyclotron
- Up to 12 synthesis runs per day without opening the hotcell, thanks to the Synthera®+ automatic IFP™ ejection system and loader.
- The average down-time is less than 4 days per year with IBA equipment.
- Full redundancy to maximize your equipment reliability : Ion source, extraction, targetry, synthesis

IBA ACADEMY

- Comprehensive training program for equipment operation and maintenance, quality control, quality assurance, ...
- Train at IBA centers, at your site or via internship

SPECIALIST ADVICE

- Regulatory affairs changes
- Changes to GMP guidance
- Impact assessment of changing technology

MAINTENANCE SERVICES

- Technical support 24/7
- Online access to spare parts services
- System upgrades and updates
- Preventive maintenance
- Technical audit of your system



WHAT'S THE ADVANTAGE WITH IBA?

Unique training with the IBA Academy. Only a well-trained staff can maximize the uptime of your PET center. The IBA Academy provides the comprehensive training required.



Our IBA Cyclone® 18/9 was installed in 1999 and is still running to cover all our clinical and research needs. A series of upgrades and the outstanding support from IBA has allowed us to maintain over the years the reliability, efficiency and productivity of our cyclotron with an uptime better than 98%.



*Dr. Yann Seimbille
Head of the Cyclotron & Radiopharmaceutical Chemistry Unit
and Mr. Elie Eid
Cyclotron operator
University Hospital of Geneva, Switzerland*

Dr Vasko Kramer has been a Synthera® user for several years. Starting with FDG, NaF and FCH, PositronPharma has been able to include a wide range of clinically relevant tumor tracers for hypoxia (F-MISO), cell proliferation (FLT), protein biosynthesis (FET) and tumor specific receptors ⁶⁸Ga-DOTA-peptides). As a chemistry expert, Dr Gameiro closely collaborates with Dr Kramer for new developments.

Dr. Vasko Kramer Ph.D
Director of Research & Development
at PositronPharma, Chile

For as long as you operate an IBA facility we will work with you and help you secure your future by offering improvements that lead to higher performance and productivity, enabling you to produce new radioisotopes and radiopharmaceuticals.

Because technology never stands still, IBA will develop upgrade possibilities tailored to your configuration. Our engineers and researchers constantly monitor the latest technological developments and updates, integrating them into existing systems. Through R&D partnership opportunities and access to a large user's base, IBA RadioPharma Solutions will help you stay ahead of time.



Dr. Cristiana Gameiro Ph.D
Product Manager at IBA
RadioPharma Solutions

3. STAY AHEAD OF TIME

BUILD YOUR FUTURE,
IT'S ABOUT ENDLESS INNOVATION

3. STAY AHEAD OF TIME



WHAT'S THE ADVANTAGE WITH IBA?

IBA will help you stay one step ahead in reliability and technology, offering you constant improvement possibilities, backed by extended service offered by experts in all fields of radiopharmaceuticals production.

I am a two IBA Cyclone® 18/9's installations veteran! Because of that, and throughout more than 12 years hands-on, I have experienced that the kind of professional, expertise and personal relationships can only be formed through our active presence and participation at IBA user meetings events. This is also the place where we learn from other IBA user's know-how.

Dr. Mario Avila M.Sc., Ph.D.,
Technologies and Production Manager
Positron Pharma, Chile



EXPERT SUPPORT TO STAY AHEAD OF TIME

EXTENDED EQUIPMENT SERVICES

- Extended service contracts post-warranty, including preventive maintenance for all the equipment to ensure maximum uptime year after year.

ENDLESS INNOVATION

- Open collaboration opportunities
- Delivery of new tracers and automated production systems to cover your R&D needs.

UPGRADE SUPPORT

- Upgrade support for new molecules, including equipment and consumable selection, documentation and regulatory compliance
- Upgrade-ready Cyclotron configuration to offer an easy and cost-effective upgrade at a later stage, if required.

USERS MEETINGS

- IBA holds worldwide customer meetings
- Opportunity to meet other IBA users, exchange ideas and share experiences regarding operational issues and new developments in the fields of cyclotrons, targetry and chemistry.
- Learn about the current & future trends in the radiopharmacy world.

EXPERT TO EXPERT, WORLDWIDE



The CAREprogram provides continuous support in furthering your skills and applications, boosting your uptime and maximizing the return on your investment with all the latest innovations, services and training.

Our products and services have been designed from the experience we have gathered in helping our clients to improve their business performance through customer satisfaction and loyalty.

● INTEGRALAB® ACHIEVEMENTS

IBA has accomplished a large number of IntegraLab® projects worldwide.

Alkmaar, Almaty, Amman, Ankara, Astana, Baku, Bandar Enstek, Bangalore, Beijing, Beirut, Bern, Brisbane, Brunei, Brussels, Caracas, Coimbra, Dammam, Delhi, Dinnington, Fleurus, Ghent, Gilroy, Gliwice, Guilford, Guilin, Hanoi, Harvehill, Helsinki, Hengyang, Herlev, Jakarta, Kansas City, Karachi, Krasnoyarsk, Kien Giang, Kuala Lumpur, La Habana, Lahore, Memphis, Mexico, Minsk, Montreal, Moscow, Mount Pearl, Paris, Philadelphia, Porto Allegre, Rabat, Recife, Riga, Rio Negro, Río Gallegos, Riyadh, Romeoville, Rostov, Sandford, Santiago, Santo Domingo, Sevilla, Somerset, Sterling, Sydney, Teneriffe, Toronto, Tripoli, Tunis, Waghodia, Xiamen, Yangon, Yerevan, Zagreb...



ABOUT IBA

IBA (Ion Beam Applications S.A.), is a cancer diagnostics and treatment company and the worldwide technology leader in the field of proton therapy. The company's expertise lies in the development of next-generation proton therapy technologies and radiopharmaceuticals that provide oncology care providers with premium quality services and equipment, including IBA's leading fully-integrated IntegraLab® system.

ABOUT IBA RADIOPHARMA SOLUTIONS

Based on longstanding expertise, IBA RadioPharma Solutions supports hospitals and radiopharmaceutical distribution centers with their in-house radioisotopes production by providing them global solutions, from project design to the operation of their facility. In addition to high-quality technology production equipment, IBA has developed in-depth experience in setting up GMP radiopharmaceuticals production centers.

ABOUT INTEGRALAB® AND SYNThERA®+

IntegraLab® is a fully integrated solution combining equipment and services for the development of Radiopharmaceutical Production Centers. IntegraLab® includes the building designed with full regulatory compliance and the selection, integration, supply and installation of suitable high-technology equipment to match your radioisotope production goals.

SynThera®+ is a multi-purpose automated synthesizer for the production of ¹⁸F₂FDG, other compounds [¹⁸FCH₃, ¹⁸F₂FLT, Na¹⁸F, ⁶⁸Ga peptides ...]. This smallest available module on the market is designed to accommodate a wide range of radiochemistry processes.

CONTACT US:

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