

ISMRM

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ISMRM 2023 - Toronto

NEWSLETTER & PRODUCT INFORMATION

NUKEM Isotopes GmbH

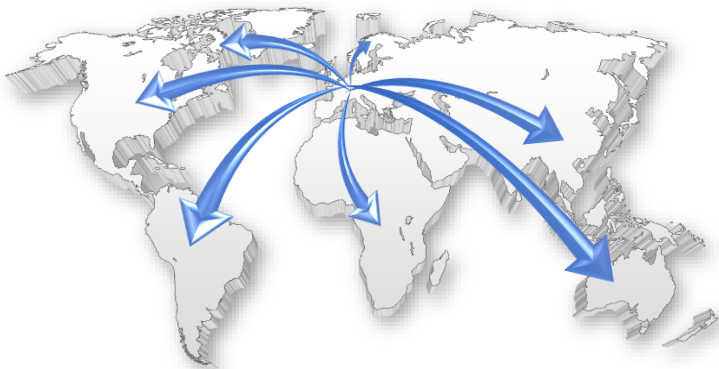
Vol. # 5



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Company Information

NUKEM Isotopes GmbH based in Alzenau, Germany, is a global leader in providing enriched isotopes in the form of ultra-pure substances for industry, agriculture and medical applications. We have been a reliable partner for long term demands of stable isotopes for more than two decades. We maintain our partnership with the major enrichment enterprises in Europe, the Peoples Republic of China and the Republic of Georgia. With our warehouses at Frankfurt Airport, Hamburg seaport and cooperation partners in the USA, we are able to ship our isotopes within 48 hours to our clients **worldwide**. With our quality management (ISO 9001-2015, 10 CFR50 App. B + 10CFR21) as well as third party analysis of our products, we guarantee our customers reliable services and high-quality isotopes.



In addition, we are proud to work with major research institutes that are leaders in their field (especially in the field of MRI). Among many others, the German Cancer Research Center (DKFZ, Heidelberg), the University Hospital in Freiburg and the University Medical Center Groningen (UMCG) in the Netherlands should be mentioned here.

This cooperation resulted, for example, in the first $^{17}\text{O}_2$ study with 10 glioma patients, published in RSNA Radiology Journal (see page 10).

If you need more information about our company, please do not hesitate to contact us anytime at info@nukemisotopes.de.

History of NUKEM ...

- 1960** Foundation of NUKEM as one of the first commercial nuclear fuel companies in the world.

- 1995** Diversification of NUKEM's Research Reactor Group by adding stable isotopes for water chemistry of nuclear power stations to the trading portfolio.

- 2000** Exclusive Sales Contract between CPH (Institute of Stable Isotopes, Tbilisi, Georgia) and NUKEM for the supply of B-10/B-11, O-17/O-18 and N-15 isotopes.

- 2011** Foundation of **NUKEM Isotopes GmbH** on November 1st for further growth of Isotopes business.

- 2015** Foundation of **NUKEM Isotopes Imaging GmbH**, a 100% subsidiary of NUKEM Isotopes GmbH.

- 2019** Merger of the activities of NUKEM Isotopes Imaging GmbH with those of NUKEM Isotopes GmbH.

- 2021** 10 years anniversary of NUKEM Isotopes GmbH.

- 2022** Change in the management of NUKEM Isotopes GmbH.



Change in the management

On **November 1st, 2022** the management of NUKEM Isotopes GmbH has changed. Mr. Wilhelm Plumpe has resigned as the companies CEO and take his well-deserved retirement. He was instrumental in the foundation of NUKEM Isotopes GmbH and we would like to thank Wilhelm for his many years of active commitment. Furthermore, we are pleased to announce that we were able to convince Wilhelm, as the company's main shareholder, to join the advisory board in future.

By shareholder resolution, **Mr. Michael Kievel** (upper photo) and **Mr. Daniel Plumpe** (lower photo) were appointed as the new managing directors of NUKEM Isotopes GmbH.



With more than 20 years of professional experience in the field of stable isotopes, **Michael** has a very strong network in the industry. Since the foundation of NUKEM Isotopes, he has been supporting our business partners in all matters as authorized signatory and Chief Sales Officer.



Daniel has been with the company since April 2020. After studying business administration and years of experience in the areas of finance and controlling in various companies in different sectors, his future focus will be on the entire commercial area and the strategic orientation of the company.

Our main isotopes

Oxygen-17 enriched gas

The developments with Oxygen-17 in the form of O₂ gas in the recent years could clearly show the big advantages of the Oxygen-17 application. The enhance in quality of information about living tissue can improve the practice of medicine in the fields of cardiology, oncology, neurology and many other fields.

The magnetic properties of O-17 make it a promising “tool” for assessment of in vivo metabolic tissue information and processes at high fields (≥3T).

If you are interested in our ¹⁷O-labeled molecules, please do not hesitate to contact us. In cooperation with our synthesis partners, we will be able to provide you with a tailor-made offer.

Oxygen-17 gas specification

Purity	≥ 99.9%	CO	≤ 10 ppm
Enrichment	≥ 70at%	CO ₂	≤ 100 ppm
		H ₂	≤ 50 ppm
		N ₂	≤ 500 ppm

Packing

1 L and 2 L ¹⁷O₂



Seamless stainless-steel cylinder with **50ml water volume** and a **¼" NPT valve**

5 L, 10 L and 20 L ¹⁷O₂



Aluminum cylinder with **400 ml water volume** and a **CGA 540 valve**

Our Oxygen-17 products are manufactured in accordance with cGMP regulations and with the requirements of 21 Code of Federal Regulations: PARTS 210 and 211.

Oxygen-17 enriched water

Oxygen-17 (^{17}O) in the form of water can be used in many fields of research. One example is the use as an MRI contrast agent for analysis of the brain cerebrospinal fluid (CSF). In addition, H_2^{17}O is the perfect precursor for the synthesis of NMR active molecules.

Oxygen-17 water specification

Purity	$\geq 99.9\%$	pH	5.5 - 8
Enrichment	$\geq 10\text{at}\%, 20\text{at}\%, 40\text{at}\%, 50\text{at}\%, 60\text{at}\%, 70\text{at}\%, 90\text{at}\%$		

Impurities*

Al	$\leq 0.05 \text{ ppm}$	Mn	$\leq 0.01 \text{ ppm}$
Br	$\leq 0.5 \text{ ppm}$	Na	$\leq 1 \text{ ppm}$
Ca	$\leq 0.1 \text{ ppm}$	Ni	$\leq 0.01 \text{ ppm}$
Cl	$\leq 0.5 \text{ ppm}$	NO_2, SO_4	$\leq 0.1 \text{ ppm}$
Co, Cr, Cu	$\leq 0.01 \text{ ppm}$	NO_3, PO_4	$\leq 0.05 \text{ ppm}$
F	$\leq 0.05 \text{ ppm}$	Si	$\leq 1 \text{ ppm}$
Fe	$\leq 0.01 \text{ ppm}$	Pb	$\leq 0.01 \text{ ppm}$
K	$\leq 0.1 \text{ ppm}$	Zn	$\leq 0.05 \text{ ppm}$
Mg	$\leq 0.05 \text{ ppm}$		

** applicable for 10at% enriched and 20at% enriched ^{17}O water only!*

Packing

1 ml, 2 ml, 5 ml, 10 ml, 20 ml, 50ml (depending on the enrichment)



Our Oxygen-17 products are manufactured in accordance with cGMP regulations and with the requirements of 21 Code of Federal Regulations: PARTS 210 and 211.

Nitrogen-15 enriched salts and gas

Nitrogen-15 (^{15}N) is mainly used for the synthesis of ^{15}N -labelled chemical compounds. These ^{15}N -labelled compounds are used for medical and biomedical applications as well as improving the harvest in agriculture.

In recent years, great progress has also been made in the hyperpolarization of small ^{15}N -labelled molecules, which can open up many new areas of research.

Nitrogen-15 specifications

Gas

Purity $\geq 99.9\%$
Enrichment $\geq 99\text{at}\%$

Compound

Nitrogen gas

Packing

Various cylinders



Salts

Purity $\geq 99\%$
Enrichment $\geq 99\text{at}\%$

Compounds

Ammonium Chloride,
Ammonium Sulphate,
Potassium Nitrate,
Ammonium Nitrate,
Sodium Nitrate

Packing

400 g or 500 g PE bottles



Oxygen-18 enriched water

Oxygen-18 is used to synthesize radiopharmaceuticals labelled with Fluorine-18 (for example 2-fluoro-2-deoxy glucose [^{18}F FDG]), whereby Fluorine-18 is obtained by the irradiating of Oxygen-18 with Hydrogen ions.

The resulting radio-labeled ^{18}F FDG can then be detected in Positron Emission Tomography (PET), a nuclear medicine imaging technique, using low radioactive isotopes.

^{18}F FDG is still one of the most common cancer diagnostic techniques.

Oxygen-18 specification

Purity	$\geq 99.9\%$
Enrichment	$\geq 98.0\text{at}\%$
Pyrogenicity	$\leq 0.25 \text{ EU/ml}$
Conductivity	$\leq 2 \mu\text{S/cm}$
pH	6-8



Packing

Our standard packing size is **50 g per glass vial**, however, upon request we can also fill 25 g or 10 g glass vials.

Impurities

Al	$\leq 0.05 \text{ ppm}$	Mg	$\leq 0.05 \text{ ppm}$
Br	$\leq 0.5 \text{ ppm}$	Na	$\leq 1 \text{ ppm}$
Ca	$\leq 0.1 \text{ ppm}$	NO_2 ,	$\leq 0.1 \text{ ppm}$
Cl	$\leq 0.5 \text{ ppm}$	NO_3 ,	$\leq 0.01 \text{ ppm}$
Cu	$\leq 0.01 \text{ ppm}$	SO_4	$\leq 0.1 \text{ ppm}$
F	$\leq 0.05 \text{ ppm}$	PO_4	$\leq 0.05 \text{ ppm}$
Fe	$\leq 0.01 \text{ ppm}$	Zn	$\leq 0.05 \text{ ppm}$
K	$\leq 0.1 \text{ ppm}$		

Our Oxygen-18 products are manufactured in accordance with cGMP regulations and with the requirements of 21 Code of Federal Regulations: PARTS 210 and 211.

Xenon-129 enriched gas

Xenon-129 (Xe-129) in the hyperpolarized state is a revolutionary novel MRI contrast agent. Xe-129 facilitates the taking of high-resolution 3D lung ventilation images by using a conventional MRI scanner.

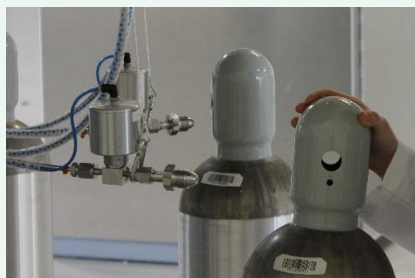
Our cooperation partner Polarean Imaging plc. designs and manufactures equipment for production of hyperpolarized Xenon-129. Further information about Polarean can be found in this Newsletter on the following pages.

Xenon-129 specifications

Purity	≥ 99.9%
Enrichment	≥ 80.0at%

Impurities

CO	≤ 10 ppm
CO ₂	≤ 10 ppm
H ₂ O	≤ 10 ppm
O ₂	≤ 10 ppm
THC (CH ₄)	≤ 1 ppm
THF (CF ₄)	≤ 5 ppm



Packing

1,000 liter per gas cylinder (with CGA 580 valve).

Other gas volumes can be filled on request, please contact us (info@nukemisotopes.de)

Important Safety Information WARNINGS AND PRECAUTIONS

Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVUE inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVUE inhalation, and resume oxygen inhalation immediately following the imaging breath hold.

Please see additional Important Safety Information on the following pages.

POLAREAN

1. On December 23, 2022, the FDA granted approval for Polarean's first drug-device combination product, XENOVIEW™ (xenon Xe 129 hyperpolarized). XENOVIEW, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarized contrast agent indicated for use with magnetic resonance imaging ("MRI") for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. XENOVIEW has not been evaluated for use with lung perfusion imaging.

More than 30 million Americans suffer from chronic lung disease, and there is a significant unmet need for non-invasive diagnostic technology. XENOVIEW expands the opportunity for pulmonary medicine to utilize the first and only inhaled MRI hyperpolarized contrast agent for novel visualization of lung ventilation without exposing patients to any ionizing radiation and its associated risks. The dose of XENOVIEW, created through the Polarean HPX hyperpolarization system, is administered in a single 10-15 second breath hold MRI procedure.

XENOVIEW™ (xenon Xe 129 hyperpolarized) for oral inhalation



Provides direct measure of regional lung ventilation



Spatially distributes to image the smallest airways



Avoids radiation exposure to patient



Non-invasive approach (10-15 second breath hold)



XENOVIEW Chest Coil

**not an actual patient*

Important Safety Information WARNINGS AND PRECAUTIONS

Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW inhalation, and resume oxygen inhalation immediately following the imaging breath hold. **Please see additional Important Safety Information on the following pages.**

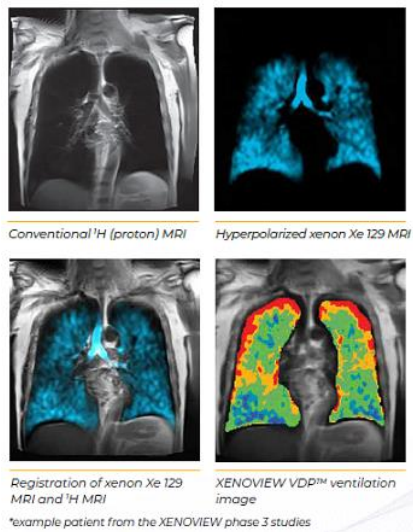
2. Simultaneously, with the approval of the XENOVIEW NDA, two 510(k) devices were cleared by the FDA that will further support a successful launch of the technology into the clinical marketplace:

XENOVIEW Chest Coil - The Polarean XENOVIEW 3.0T Chest Coil is a flexible, single channel, transmit-receive (T/R) RF coil tuned to xenon Xe 129 frequency on a 3.0T MRI magnetic field of a compatible MRI scanner. The Chest Coil is intended to be worn by a patient who inhales hyperpolarized xenon Xe 129 (XENOVIEW) to obtain an MR image of the regional distribution of hyperpolarized xenon Xe 129 in the lungs.

The Polarean XENOVIEW 3.0T Chest Coil is indicated to be used in conjunction with compatible 3.0T MRI scanners and approved xenon Xe 129 hyperpolarized for oral inhalation for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

XENOVIEW VDP - Image processing software that analyzes a pulmonary hyperpolarized xenon Xe 129 MR image and a proton chest MR image to provide visualization and evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

This image analysis platform quantifies normalized xenon intensity of a ventilated space using a pulmonary hyperpolarized xenon Xe 129 ventilation MR image and accompanying proton chest MR image. The software will be used by clinicians to assist in the interpretation and numerical classification of hyperpolarized xenon Xe 129 ventilation MR images.



Important Safety Information (continued) WARNINGS AND PRECAUTIONS (continued)

Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVIEW may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen saturation and symptoms of hypoxemia and treat as clinically indicated. **Please see additional Important Safety Information on the following pages.**

3. In February 2023, the U.S. Food and Drug Administration (“FDA”) **granted Polarean the New Chemical Entity (“NCE”) designation** for XENOVIEW, with a designated five-year market exclusivity period.

4. In 2023, the company is focused on commercial sales of XENOVIEW™ (xenon Xe 129 hyperpolarized), the first and only FDA-approved hyperpolarized MRI contrast agent, and the pursuit of corporate partnering opportunities.

Opportunities of interest include: Collaborations with pharmaceutical companies, magnetic resonance imaging (“MRI”) companies, Contract Research Organizations (“CRO”), and other strategic partners to expand the future commercial applications of the Company’s technology. The Company will focus primarily on securing new installations in leading Centers of Excellence in academic medical institutions specializing in Pulmonary and Radiology diagnostics and therapeutics distributed across North America. In addition, the Company will continue to develop a plan for seeking regulatory approval of the next indications for the XENOVIEW technology.



XENOVIEW can provide pulmonologists, surgeons, and other respiratory specialists with regional maps of ventilation in their patients’ lungs to assist them in managing their disease.

Important Safety Information (continued)

ADVERSE REACTIONS

Adverse Reactions in Adult Patients: The adverse reactions (> one patient) in efficacy trials were oropharyngeal pain, headache, and dizziness.

Please see additional Important Safety Information on the following pages.

Richard Hullihen, Chief Executive Officer of Polarean said: *"FDA approval represents achievement of a major milestone for Polarean's technology. This was only possible in close collaboration with multiple research clinicians and scientists globally, who we thank for their tireless and enthusiastic work. Approval of XENOVIEW represents a major step forward in modern respiratory imaging, and we are proud to have pioneered this exciting new technology for clinical use. The commercial team at Polarean is prepared to rapidly launch XENOVIEW for clinical application."*

Dr. Jason Woods, Director of Research in Pulmonary Medicine at the Cincinnati Children's Medical Center added: *"My colleagues and I in the Xenon MRI research community are thrilled that this technology is now available to reach both adolescent and adult patients. With the availability of XENOVIEW in the clinical setting, we will have the ability to evaluate regional lung ventilation, delivered with a benign safety profile, which has been a major unmet need for the patients that look to us to better understand their lung disease."*

Important Safety Information WARNINGS AND PRECAUTIONS

Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW inhalation, and resume oxygen inhalation immediately following the imaging breath hold. **Please see additional Important Safety Information on the following pages.**

Important Safety Information

Indication

XENOVIEW™, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarized contrast agent indicated for use with magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

Limitations of Use

XENOVIEW has not been evaluated for use with lung perfusion imaging.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Risk of Decreased Image Quality from Supplemental

Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW inhalation, and resume oxygen inhalation immediately following the imaging breath hold.

Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVIEW may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen saturation and symptoms of hypoxemia and treat as clinically indicated.

ADVERSE REACTIONS

Adverse Reactions in Adult Patients: The adverse reactions (> one patient) in efficacy trials were oropharyngeal pain, headache, and dizziness.

Adverse Reactions in Pediatric Patients: In published literature in pediatric patients aged 6 to 18 years, the following transient adverse reactions were reported: blood oxygen desaturation, heart rate elevation, numbness, tingling, dizziness, and euphoria. In at least one published study of pediatric patients aged 6 to 18 years, transient decrease in SpO2% and transient increase in heart rate were reported following hyperpolarized xenon Xe 129 administration. XENOVIEW is not approved for use in pediatric patients less than 12 years of age.

Please see full [Prescribing Information](#).

Oxygen-17 research abstracts

Magnetic resonance imaging of renal oxygen metabolism by means of ^{17}O administration during ex vivo organ perfusion

Pamplona CC¹, Castelein J², Hamelink TL¹, Lantinga V¹, Ogurlu B¹, Potze JH², Bock M³, Leuvenink HGD¹, Borra RJH², Moers C¹

¹Department of Surgery – Organ Donation and Transplantation, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands, ²Department of Radiology, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands, ³Department of Radiology, University Medical Center Freiburg, Freiburg, Germany

BACKGROUND

Renal normothermic machine perfusion (NMP) is a novel strategy to assess pretransplant renal function and injury, but it remains unclear which markers can provide information about renal viability during NMP. Magnetic resonance imaging (MRI) is commonly used to evaluate tissue morphology, metabolism, and function, and recently it has been applied to study ex vivo renal viability. The oxygen-17 (^{17}O) isotope (NUKEM Isotopes) offers a unique tool for the assessment of metabolic rate. By administering ^{17}O to the organ, H_2^{17}O is produced and the occurrence of this immediate end product of oxidative metabolism can be selectively imaged and quantified by functional MRI sequences. This project aimed to perform direct ^{17}O MRI sequences on porcine kidneys during NMP to assess the feasibility of ^{17}O imaging over time.

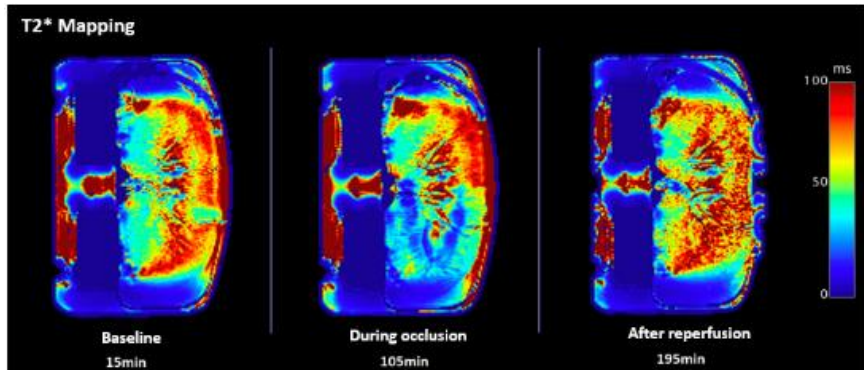
METHODS

Viable porcine kidneys were retrieved at a local slaughterhouse, subjected to 30min of warm ischemia (WI), and preserved by hypothermia. Kidneys were subsequently perfused for 3h at 37°C. Initially, oxygenation was administered with 95% O_2 / 5% CO_2 . After 1h of NMP, perfusion to the inferior pole of one of the kidneys was blocked for 75min using a balloon catheter and then reperused for 30min before ^{17}O delivery. ^{17}O was then supplied to the organ and anatomic and dynamic radial H_2^{17}O MR images were acquired before, during, and after ^{17}O administration.

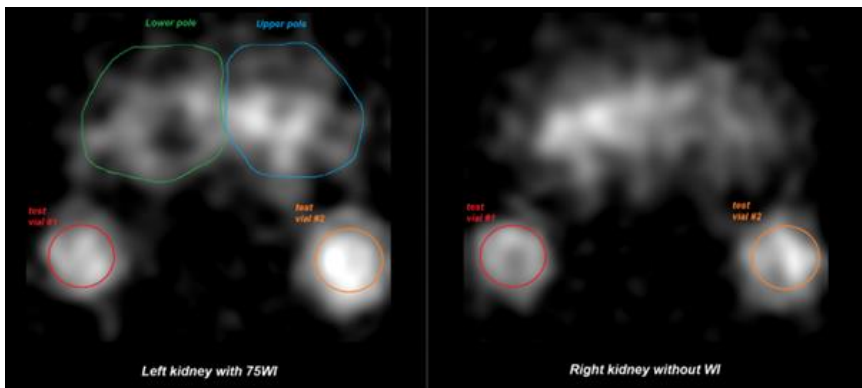
RESULTS

H_2^{17}O -magnitude imaging displayed that kidney with partial ischemia had decreased signal intensity in the inferior pole after reperfusion, while kidneys without any additional WI displayed a well distributed signal intensity over the whole organ. This signal shift after reperfusion could not

be visualized with other functional MRI sequences such as T2* mapping, a surrogate to assess tissue oxygenation.



T2 mapping images of renal perfusion showing the absence of perfusion during balloon occlusion of one segmental artery and subsequent homogeneous reperfusion.*



Transversal view of the time-averaged ^{17}O -magnitude images of the left kidney with 75 minutes of partial segmental artery occlusion and the right kidney without segmental occlusion

CONCLUSION

This pilot study showed the first evidence of the quantification of regional production of H_2^{17}O in isolated perfused porcine kidneys. With this novel MRI method, we were able to image the impact of ischemic injury on the rate of oxidative metabolism in renal tissue, which could not be visualized by any other functional MRI sequence after reperfusion. This suggests that ^{17}O imaging during NMP could offer a valuable new tool for the assessment of renal metabolism and injury.

Information about our booth wall

Your global supplier for stable isotopes

A photograph of a booth wall display for NUKEM Isotopes. The display features a central teal hexagon with the text "Stable Isotopes for medical application". Surrounding this central hexagon are five other teal hexagons, each containing information about a specific isotope:

- $^{17}\text{Oxygen}$** : "is the only non-radioactive isotope to measure oxygen consumption and metabolism in real-time by using MRI systems for diagnostic applications and medical research." It includes two small images of brain MRI scans.
- ^{13}C in the form of water, gas and D-Glucose**: Includes an image of several glass vials.
- $^{129}\text{Xenon}$** : "in the hyperpolarized state is a revolutionary novel MRI contrast agent. ^{129}Xe makes it possible to take high-resolution 3D lung ventilation images by using a conventional MRI scanner." It includes an image of a person's lungs.
- ^{129}Xe in the form of pure gas and mixtures**: Includes an image of laboratory glassware.
- Realization of a clinical study**: Includes an image of a person in a medical setting.

 At the bottom right of the display, there is a section titled "Important Safety Information WARNINGS AND PRECAUTIONS" with text about the risk of decreased image quality from supplemental oxygen. The bottom of the display has a teal banner with the text "Realizing ideas with isotopes" and the website "nukem-isotopes.com".

The $^1\text{H}/^{17}\text{O}$ -MRI images and diagrams on our wall (top, left side) were, thankfully, provided by the German Cancer Research Center (DKFZ), Heidelberg, Germany and University Hospital Erlangen, Erlangen, Germany.

The displayed images and diagrams are part of the study Quantitative Dynamic Oxygen-17 MRI at 7.0 T for the Cerebral Oxygen Metabolism in Glioma (see ISMRM Newsletter from 2022 for further information).

In addition, the MRI lung images (on the right side) were, thankfully, provided by Duke University, Durham, NC (Bastiaan Driehuys) and the image of the Xe-129 Polarizer was gratefully provided to us by our business partner Polarean.

Our ISMRM rubber duck family

*Come and visit us at our ISMRM booth H17 to pick up your **2023 duck**.*

The ducks are not for sale and only available at our booth.



Surgeon Jay
ISMRM Toronto 2023

Due to the great interest in our rubber ducks, we are pleased to present our ducks from the previous ISMRM conferences.



Paramedic Ben

London 2022



Dr. Jacques

Montreal
2019



Dr. Amy

Paris 2018



Nurse Xenia

Hawaii 2017



Nurse Gudrun

Singapore
2016



Dr. Willy

Toronto 2015



Nurse Alberta

Salt Lake City
2013



Nurse Roberta

Melbourne 2012



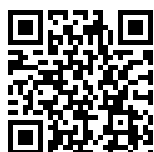
**Dr. Bob
(Robert)**

Montreal 2011

[illegible]

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Contact us



Company Video



NUKEM Isotopes GmbH

Rodenbacher Straße 47
63755 Alzenau, Germany

T +49 (0) 6023 9474 800

E info@nukemisotopes.de

www.nukemisotopes.de