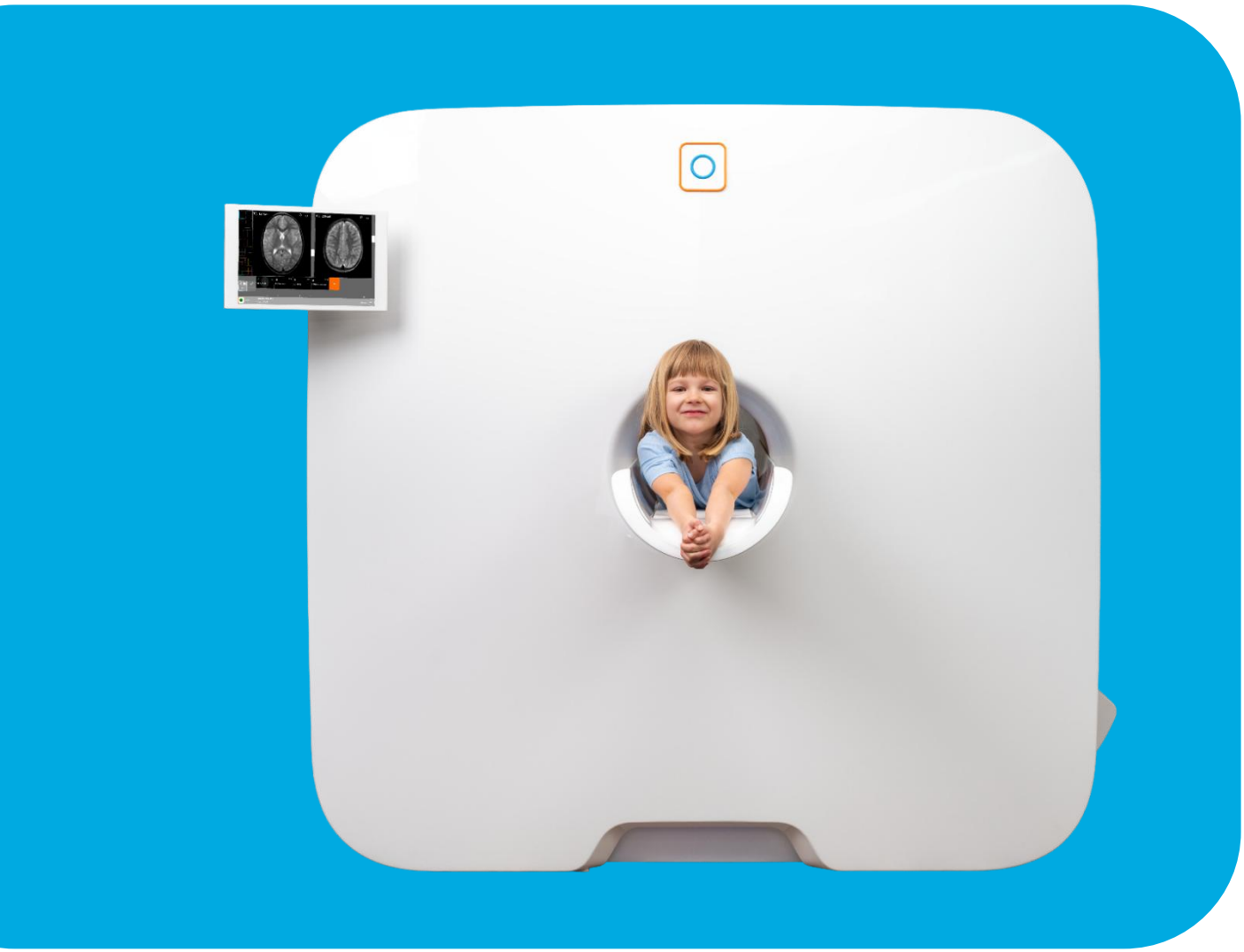
neo315

Pediatric MRI solved



Content

Source: iStock_muratkoc

Why Pediatric MRI?

Although MRI is readily available for adolescents and adults in developed countries, access for the most vulnerable patients, newborns, and infants, is not guaranteed. Ultrasound and X-ray provide the basic imaging in the pediatric ward. MRI is the gold standard for soft tissue imaging and can provide much more information, e.g. showing the status of the nervous system, the extent of a congenital cardiac malfunction, or a comprehensive characterization of the upper or lower abdomen. In many clinical settings, patients are transported to an adult MRI system located in the radiology department, some distance from the pediatric ward. This is a labor-intensive process that necessitates careful management of risks, such as temperature management. What if, instead of transporting the infant, we brought the MRI system to the infant patients, thus lowering the hurdles of accessibility, and being able to provide a complete radiation-free assessment early in life when it matters most. At the same time, a dedicated pediatric MRI system frees up time on the adult MRIs. Often, multiple adult MRI exams can be performed at the time necessary for a pediatric exam.

This brochure presents our neo315, a highly innovative system solution that brings this vision to life. Institutions operating the system will be able to develop new clinical workflows. By investing in early, comprehensive, and non-invasive diagnostics of young patients, an institution can take a leading role and help drive progress throughout the community. Developing pediatric MRI is a great cause for securing research funds and for attracting new talent. A dedicated pediatric MRI can showcase an institution's commitment to making a difference early in the life of their patients, and its commitment to ensuring long term health and disease prevention.

neo315

The neo315 is a compact yet complete pediatric MRI system, offering a 30 cm wide patient bore, and full clinical field strength of 1.5 Tesla[1]. Depending on the patient's weight and size, all organs up to approximately six years of age can be examined[2].

This six-and-a-half-year-old girl fits comfortably on the patient table. (Photo: Matthias Sasse)

The patient bore size of 30 cm has been chosen after verifying with anesthesiologists it is sufficiently large to host ventilated patients.

[1] The product name neo315 is composed from the 3 dm wide patient bore and its 15 x 0.1 T field strength.

[2] The neo315 specifically addresses the difficulties of imaging children up to six years of age. Older pediatric patients, who may be more mobile and who can cooperate, are continued to be scanned on adult MRI systems. In other words, "Pediatric MRI solved" refers to the neo315 providing a solution for the previously challenging subset of the pediatric patients.

Innovation Highlights

As the world's first MRI system using a High Temperature Superconductor (HTS), the neo315 is packed with innovations:

Zero Liquid Helium
conductively cooled, dry magnet

Local Shielding
no RF-cabin required

Light
magnet weighs 1,95 t

Easy Use
intuitive operation via Touch UI

Compact
fits through 120 cm (4ft) wide doors

Minimal Footprint
strayfield less than 10 m^2 or 100 sq ft

HTS offers a 10 times higher current density than conventional Niobium Titan superconductors, thus allowing for lighter and more compact magnets. Our HTS magnet is conductively cooled by copper lines, without using any liquid Helium. It is sufficiently light to be supported by the floors in most existing hospitals. The system has been transported to the upper levels of hospitals by patient bed elevators. Due to its strong active internal B0 shielding and minimal footprint, it fits in almost any room.

The neo315 requires no shielding of the room for electromagnetic compatibility. It is easily and intuitively operated by a touch user interface.

How the neo315 Fits in

The neo315 can be installed in places adjacent to pediatric patient rooms which were never intended to accommodate a 1.5T MRI system. The rationale for a point-of-care MRI is that the system is available *where* it is needed, thus significantly reducing the need for patient transport. Further, it is usually available *when* needed, allowing exams to be scheduled according to the patient's rhythm rather than the busy schedule of an adult MRI system. To date, most patients scanned with the neo315 have undergone MRI examinations without sedation or anesthesia and have consistently produced quality diagnostic images.

Exemplary installation of a neo315 in a former office close to the pediatric unit.

There are many reasons why a conventional 1.5T MRI system is not suitable for installation in a pediatric ward, depicted by the image on the left:

- The room would be too small to accommodate an adult MRI system.
- Since the neo315 requires no RF cabin, the large windows do not need to be blocked, which provides a daylight flooded work and patient environment.
- Since the neo315 has an extremely compact stray magnetic field, a conventional radiator next to the neo315 is not problematic and can remain in place. So, standard existing room heating can be used.
- The neo315 is conductively cooled, and no liquid Helium is used. No quench pipe is required, making siting easier and less costly.
- A patient bed and other non-MR-compatible equipment may be brought as close to the system as indicated by markings on the floor, or by an elevated floor as shown in the example installation.

Intuitive and easy usage of neo315 through its TouchUI.
(Photo: IMG/genese Werbeagentur)

The neo315 Touch UI enables simple operation at the front of the scanner. When radiologists have devised and validated complete protocols for certain indications, pediatric staff can be trained to operate the scanner. This approach will reduce staffing challenges and allow exams to be scheduled according to patient needs.

Gentle MRI

When designing the neo315, great care has been taken to keep the acoustic noise burden inside the system minimal. To date, the first patient exams have been performed successfully while the patients were asleep.

Imagine she could simply sleep during the MRI exam. (Source: Adobe Stock)

Further, it is essential to keep the acoustical noise emission of the system to the patient environment at a very low level, particularly in pediatric environments. The neo315 MRI system is inherently less noisy than adult scanner. Further noise reduction is achieved by installing a noise-insulating door to the technical room.

The shape of the patient bed cradles the patients and stabilizes them mechanically. The MRI operator moves the patient bed manually and as soon as no force is applied to the patient bed it locks in place, thus preventing the risk of detaching patient lifelines.

The patient bed enables precise, manual positioning of the young patients. (Photo: Matthias Sasse)

Patient safety is ensured by internal system monitors. The neo315 automatically tracks and limits its performance, preventing nerve stimulation and RF-induced accumulation of heat in the patient. The neo315 safety concept is tailored to its patient population – including infants:

- a mechanically operated squeeze ball for the patient to signal discomfort is not required.
- its conservatively designed heat absorption monitor makes it possible to scan neonatal patients at a higher ambient temperature.

First Installations & Results

The neo315 is currently being installed at:

- Berlin, Charité, University Medical Center
  Focus: MRI verification after surgical interventions

- Frankfurt a. M., University Clinic
  Focus: verification of the positioning of intubation equipment and imaging of the abdomen.

- Halle, University Clinic
  Focus: motion insensitive imaging of the CNS

- Hannover, Medizinische Hochschule
  Focus: lung imaging

- Magdeburg, University Clinic
  Focus: reducing anesthesia and sedations in MRI

- Oldenburg University Clinic
  Focus: neurological status of newborns

All installations will be used for routine clinical pediatric MRI exams, and every site has a focus on certain types of exams which are implemented by the site's clinical teams in collaboration with Neoscan.

Map of neo315 installation sites in Germany.

The very first patients have been examined at neo315 installations in Germany:

First case: Follow-up imaging was performed on a 7-months old infant with a known subdural hematoma. Prior MRI scans from an adult 1.5T MRI system acquired under anesthesia were available for comparison. The neo315 images were acquired of the awake and cooperative patient. The total acquisition time was 17 minutes and all images were deemed to be diagnostically adequate:

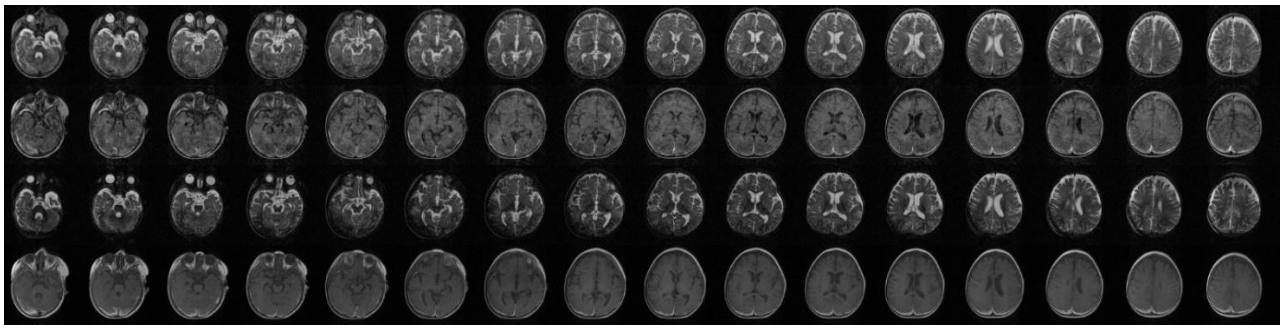


Image stacks

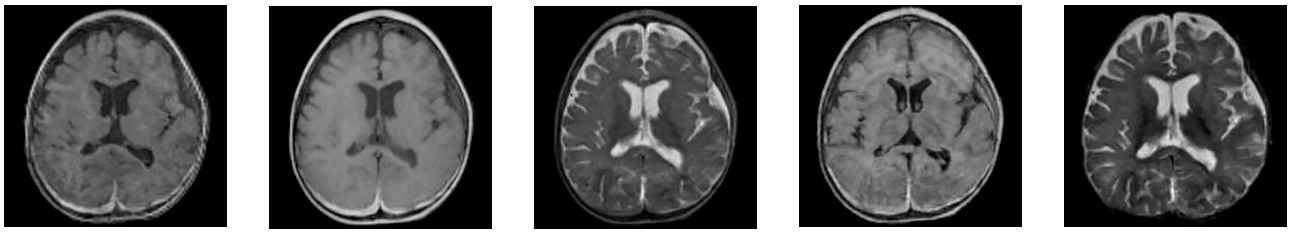
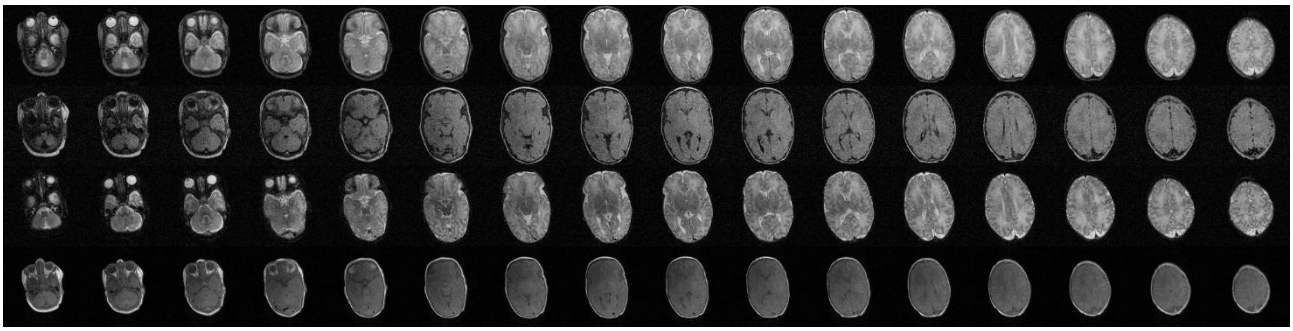


Image contrasts from left to right: MPRAGE, TSE T1, TSE T2, TSE T2 FLAIR, TSE T2 STIR

Second case: Images of a symptom free 1-month old infant. The patient fell asleep early during scanning, and remained comfortable and still during the 13-minute exam:



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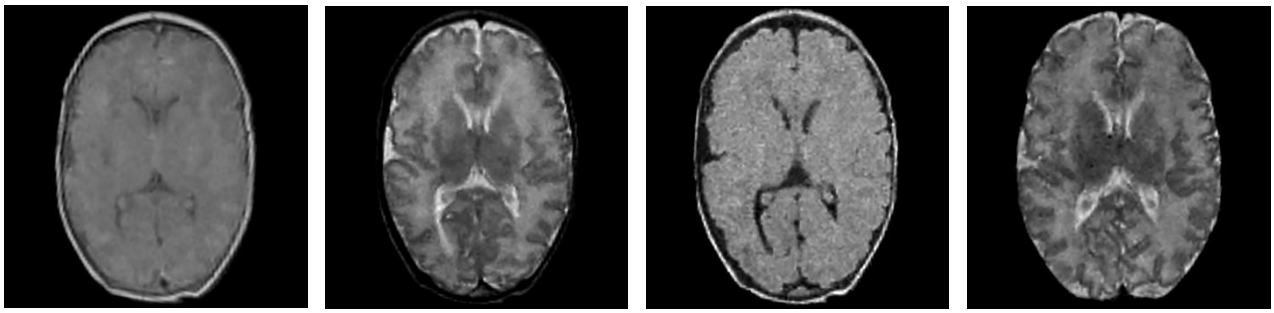


Image contrasts from left to right: TSE T1, TSE T2, TSE T2 FLAIR, TSE T2 STIR

Features

The neo315 is a compact yet complete pediatric MRI system, offering a 30 cm wide patient bore, and a state-of-the-art field strength of 1.5 Tesla. Patients can be positioned within the scanner to enable images of any organ. These are the system specifications:

The Magnet

- Superconducting Magnet
  1.5T toroid-shaped magnet with minimized stray field.
- HTS Magnet Technology
  First clinical MRI magnet using a ceramic high temperature (HTS) superconductor. The magnet is cooled conductively without any liquid helium.
- Long Lifetime Design
  Cryostat can be opened and closed for service, ensuring extended magnet life.
- Benefits
  Low siting and operating costs, lower energy consumption compared to conventional 1.5T.

Magnet	Solenoidal symmetric HTS magnet; driven magnet
Field strength	1.5 T
Working temperature	< 10 K
Patient bore diameter	30 cm
Field of view	18 cm DSV (diameter spherical volume) with typically 5 ppm peak-to-peak
Field stability	< 0.1 ppm/h
Stray field 5-Gauss line	< 1.5 m radius in radial direction, < 2.0 m radius in axial direction, from the magnet iso-center
Mass	< 2.0 t
Dimensions	170 cm in width and height, 118 cm in length; without cryocooler and without co-vers

The Gradient System

The gradient system is an insert of dynamically powered copper coils which generate additional fields for localizing the patient's anatomy.

Gradient Coil	Symmetric, actively shielded, force-compensated, water-cooled gradient coil
Gradient strength [3]	Up to 45 mT/m per axis when used in clinical mode
Slew rate [2]	Up to 100 T/m/s per axis when used in clinical mode
Passive magnet shimming	Integrated with the gradient coil
Patient specific shimming	3 linear terms and the 5 terms of second order: XY, X^2-Y^2, ZX, ZY, Z^2
Acoustic noise level for the patient	Less than 85 dB(A) when using clinical sequences

[3] The gradient system performance is intentionally limited in clinical scanning mode, to reduce acoustic noise. The gradient coil hardware is capable of more than 120 mT/m gradient strength and more than 800 T/m/s slew rate.

The RF System

The RF system is a radio-frequency coil insert for MR signal transmission and reception. The neo315 fulfills the standards of electro-magnetic compatibility (EMC) of a medical product without requiring an RF-cabin.

Body RF Coil	Whole body "birdcage" coil operating in circular polarized (CP) mode, RF shielded, diameter: 32 cm, length: 31 cm, optimized for signal transmission and signal reception
Transmit performance	~ 30 µT, depending on the load, by a 2 kW solid state RF amplifier, air-cooled
Bandwidths	Up to 800 kHz in transmit mode, up to 1 MHz in receive mode
Number of receive channels	16 independent CP receive channels are standard, up to 32 channels can be configured
EMC medical product requirements	System is self-shielded, i.e. no RF-cabin is required

The integration of multi-channel receive coils into the neo315 is currently under development[4] - this option is currently not commercially available. A multi-channel receive coil can manually be placed on the surface of the patient. This coil design has the advantage of a higher signal to noise ratio and it can support parallel imaging and thus reduce the minimum acquisition time for a desired image resolution. In the future, the user shall be able to decide whether to use the general-purpose body coil or local receive coils. Neoscan integrates already released 1.5T receive coils from established coil manufacturers. The 16 receive channel configuration of the neo315 will be sufficient for all coils under consideration.

[4] A multi-channel receive coil is not commercially available in all countries. Its future availability cannot be guaranteed.

The Digital Console

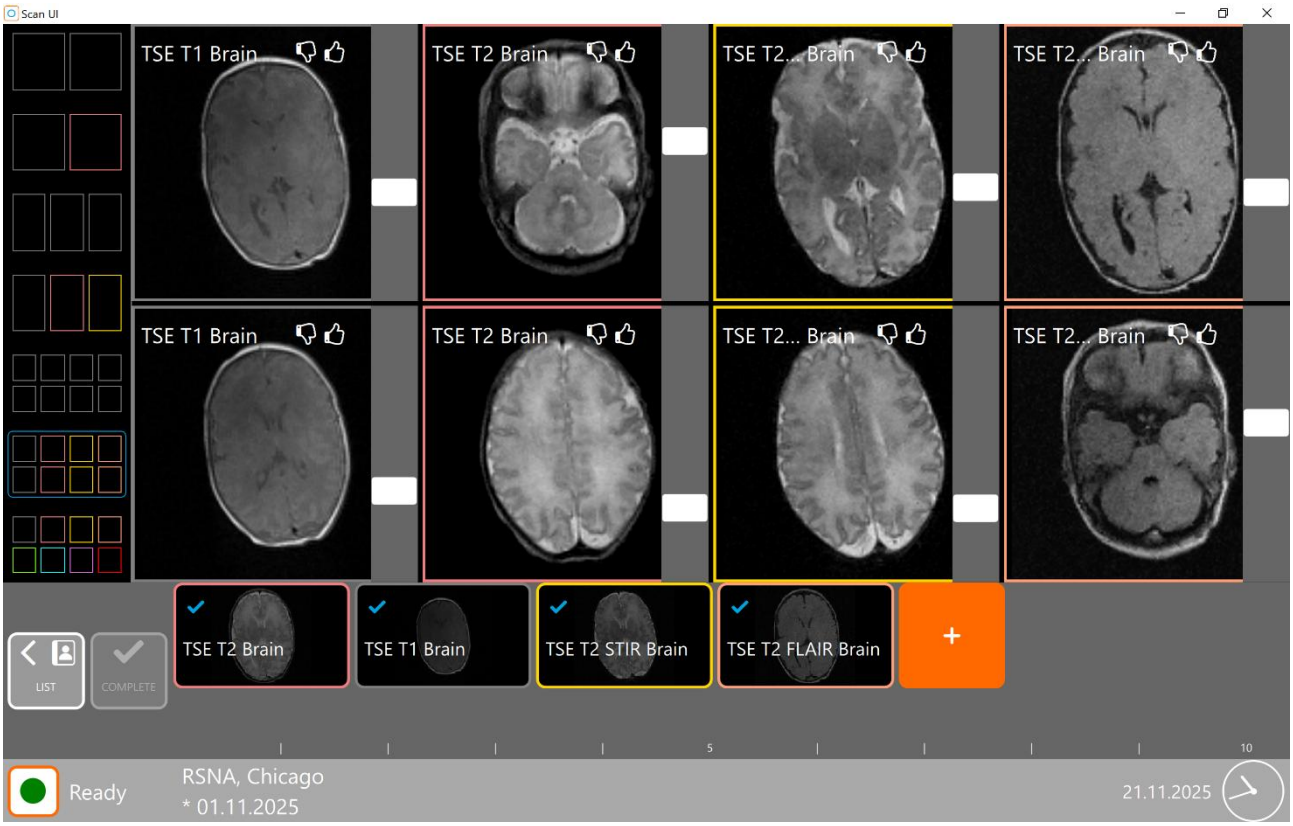
The "brain" of the neo315 is the Digital Transmit and Receive System DTRS: a multicore server which is responsible for the execution of the MR acquisition protocols, MR signal digitization and image reconstruction.

- Multicore LINUX Server
  Hosting off-the-shelf high end arbitrary waveform generators and digitizers, operated by a real-time LINUX OS.
- Direct RF
  The MR Larmor frequencies are synthetized by software and not by hardware, making the system inherently broadband.
- Nanosecond Precision
  Accurate timing of the sequence at a 2 nanosecond raster and precise re-execution of sequence elements for phase coherent accumulation of MR signals.
- Parallel Signal Processing
  Massive parallel processing of MRI signals by a high-end graphic card.

Shortest time resolution accessible by the sequence	640 ns
Internal sequence time resolution	2 ns
Dynamic range of RF and gradient pulse shapes	14 bit
ADC resolution at 125 MSamples/s receive rate	16 bit
Longest ADC duration	0.5 s seconds at 50% ADC – non-ADC duty-cycle, i.e. every second an ADC event of 0.5 seconds duration may occur, without reaching the limit of raw data throughput from the digitizers to the DTRS in the case of 32 active receive channels; the performance is higher at lower channel count

The User Interface

The TouchUI allows the user to operate the neo315 solely by touch gestures. Its functions include patient registration, scanning, verifying successful image acquisition, and sending images to the hospital PACS.



1The user interface allows for viewing the MR images during scanning.

- User friendly interface
  requiring less than a day of operator training.
- Patient centric scanning
  allowing for pausing and continuing exams according to patient needs.
- Pre-configured Exams
  Single scans and the order of scan execution are pre-set by technologists and radiologists, facilitating exam execution by the user.
- User Feedback on success
  The user has the option to note whether a scan was successful or not; in the future, this feature allows the software to evaluate and perhaps to learn how to increase the rate of successful scans.

LUMINA Software

The name of the software is derived from "Low-effort Usage of MR Imaging aNd Applications", and it is programmatic: a complete operating system for efficient point-of-care MR imaging. It includes support of the TouchUI, safe scanning of patients, image reconstruction, as well as communication with the hospital IT via the DICOM services.

LUMINA is being developed in-house, free of legacy code and it is based on a highly compact kernel. In addition to supporting the DTRS and the TouchUI as described above, it includes:

- Asynchronous Reconstruction Server LARS
  image reconstruction is initiated as early as possible, i.e. first multi-slice images are displayed while the sequence is still running.
- Patient specific adjustments
  frequency, flip-angle, shimming, and B1 profiles are adjusted to the individual patient.
- Patient Monitors
  SAR and dB/dt monitors for patient safety.
- Remote Service Capabilities
  System diagnostics, system tune-up and quality assurance tests.
- Compliant
  with the current standards on HIPAA and cybersecurity.

Sequences and Image Reconstruction

Currently, Neoscan puts a strong focus on developing and validating the MR acquisition methods. We focused on brain and neuroimaging, and this will be followed by imaging of the heart, upper and lower abdomen, as well as spine and extremities. Neoscan supports the user community in exchanging acquisition methods and scanning experience.

- Protocols run on patients[5]
  Multi-Slice Imaging: TSE-T1w, TSE T2w, STIR TSE T2w, FLAIR TSE T2w, 2D FLASH

  Volumetric Imaging: 3D MPRAGE T1w, 3D FLASH, 3D DESS

- Image reconstruction methods
  Cartesian, Radial, Parallel Imaging, Spectroscopy

- Image acquisition features under development
  Graphical slice positioning, respiratory and cardiac gating

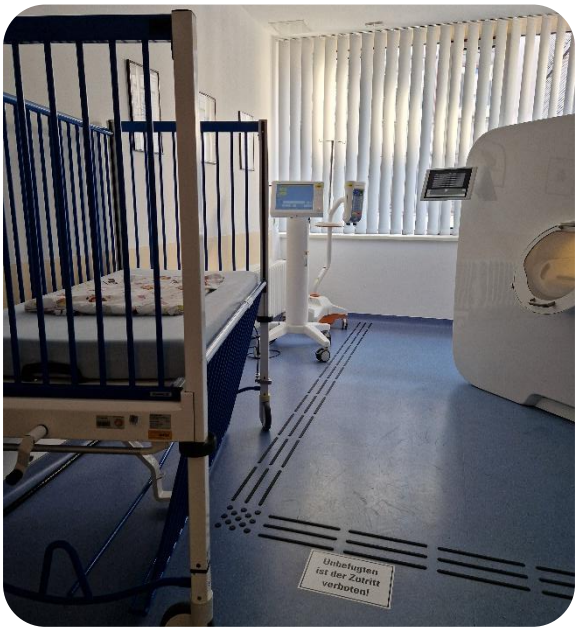
The LUMINA architecture is open in that it allows Neoscan developers and users to intuitively define new MR acquisition methods without programming. By resorting to the sequence definition language MR#, MR sequences are no longer "programmed" but rather simply configured from five elementary tokens.

A FLASH sequence composed from the 5 tokens Parameters, Operators, Shapes, TimeSlices and Iterators

The MR# sequence development framework includes timing of sequence elements in a 640 ns raster, nested sequence execution at unlimited depth, handling of slice orientation in space, handling of interdependent protocol parameters, generation of sequence-driven trigger signals, recording the k-space position and a timestamp per acquired signal, raw data access and Bloch simulation of freely defined electronic phantoms, connected with image reconstruction.

[5] Protocols before validation in patients: Diffusion-Weighted EPI, Susceptibility-Weighted Imaging, Ultra-Short-TE Imaging, Point-Resolved Spectroscopy

Compatible Products



Even non-MR-compatible equipment such as conventional patient beds can be safely used in the vicinity of the neo315.
However, all devices which enter the MRI safety zone are to be tested compatible with neo315. Neoscan is committed to increase the list of accessories that are tested as compatible and is actively performing the compatibility tests of devices required by future neo315 users. For now, the following devices have been successfully tested:

The patient bed and the other equipment are located outside of the 5 Gauss line.

Patient Ventilation

- HAMILTON-MR1 by Hamilton Medical AG

Patient Monitoring

- Expression Model MR400 MRI Patient Monitoring System by INVIVO, a division of Philips Medical Systems

- TeslaM3 MRI Patient Monitoring System by MIPM Mammendorfer Institut für Physik und Medizin GmbH

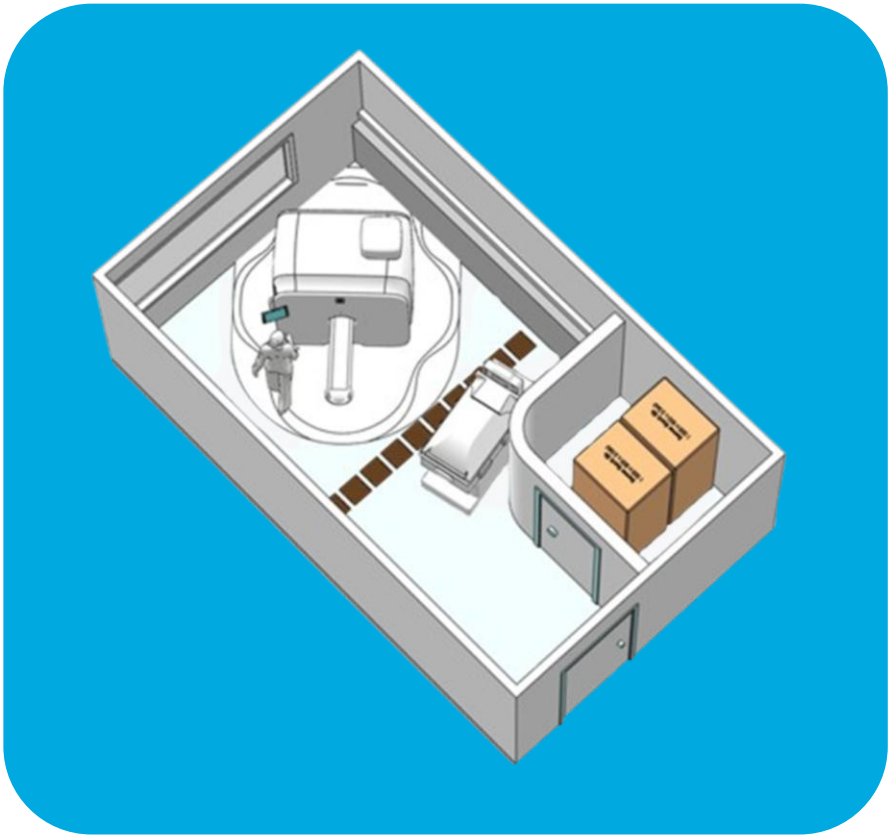
Patient Positioning and Other

- MEDRAD® MRXperion MR Injection System by Bayer Medical Care Inc.

Siting

The neo315 can be installed in locations which have not been intended to accommodate a high-field MRI system. The scanner only requires two technical cabinets (2 x 400 V 3-phase electrical power), and cooling water for operation. This is very modest when compared to conventional whole body MRI scanners.

In the above image the neo315 is sited within a former patient room, with the technical cabinets placed in an adjacent remodeled sanitary room. Unlike conventional whole body scanners, the neo315 does not require an RF cabin or a quench pipe. The magnetic stray-field is approximately a quarter of the area of an adult 1.5T system, and in most cases the floor supports the scanner weight of less than 2 tons. The neo315 Installation Guide provides further details on installation requirements.



Exemplary installation option

Costs

The neo315 is manufactured with 18 km of ceramic high temperature superconductor compared to conventional scanners which typically use lower cost wire. The neo315 can be offered at a price lower than that of a conventional full-scale adult 1.5T system.

When considering total cost of ownership, the neo315 has additional advantages, specifically when used in combination with a conventional adult MRI system:

Clinical Facts

- More critical MRI imaging will be in reach given the low hurdle patient access to non-invasive imaging.
- An available adult MRI system can be used more efficiently for adult exams if the pediatric scanning is performed on neo315.
- A focus on neonatal care attracts new patients to an institution.

Operational Advantages

- It is foreseeable that scanning of patients with well-established indications can be performed by adequately trained and qualified patient care staff.
- Reducing the efforts and risks of patient transport and using standard transport equipment to the neo315.
- Longevity of the neo315, in that the most expensive component, the magnet core, is accessible and can be repaired if needed.

Financial Benefits

- More efficient use of hospital space, lowering the operational cost.
- Lower costs to operate and service, no use of liquid helium, an affordable plan for keeping the system up-to-date, and lower energy consumption.

Please approach Neoscan for a health economics assessment optimized for your institution!

Neoscan Solutions

About Neoscan Solutions

Neoscan Solutions is a medical device manufacturer that was founded in 2017 in Magdeburg's Port of Science and now employs 50 specialists. The company focuses on the development, production, distribution and service of innovative technology in the field of magnetic resonance imaging. In addition to an MRI system for infants, the company's portfolio also includes research devices and MR software.

Team Neoscan Solutions

neo315 Distribution

The neo315 is a Class IIa medical device designed to meet the highest standards of safety and performance. It holds CE certification and is FDA-cleared, ensuring compliance with European and U.S. regulatory requirements. It is ultimately intended to become available worldwide. Neoscan also relies on logistic partners, distributors, and agents to sell, install, maintain and service neo315 around the globe. Please contact Neoscan to learn when the neo315 will be available in your country.

Legal Notice

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