



MAGNETOM Amira – A BioMatrix System

Environmental Product Declaration

siemens-healthineers.com/amira





Transforming care delivery

Now with BioMatrix, MAGNETOM Amira transforms care delivery by providing standardized and reproducible imaging over the range of patient characteristics, reducing unwarranted variations and optimizing clinical operations.

Key product features

- New **BioMatrix Respiratory Sensor** automatically detects breathing patterns for a simplified workflow
- New **BioMatrix Tuner SliceAdjust** adapts to challenging body regions to provide excellent homogeneity
- New **BioMatrix Interface Select&GO** eases patient preparation and accelerates patient positioning by 30%¹
- **Push-button exams** and **GO technologies** powered by artificial intelligence boost patient throughput
- New accelerated applications with **Simultaneous Multi-Slice** reduce scan time of entire MSK exams by up to 46%¹
- With the **System Start Timer**, your system boots automatically and is ready for scanning on time, every day
- Cost-efficient energy management with **EcoPower** delivers energy savings of up to 30%¹, positively affecting the bottom line
- Free-breathing exams with **Compressed Sensing** improve both the patient experience and diagnostic confidence, and expand the patient population eligible for MRI

¹Data on file

MAGNETOM Amira – A BioMatrix System¹

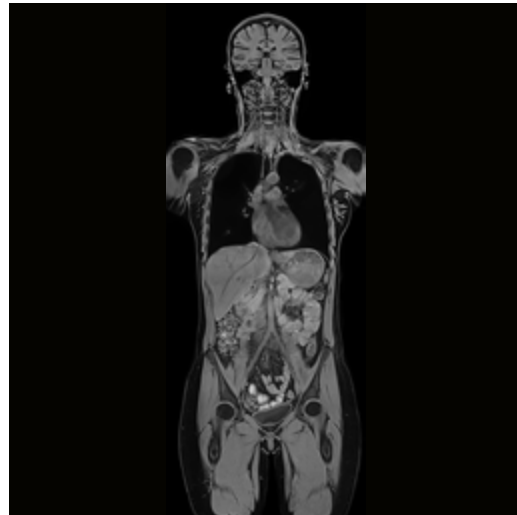
Key differentiator

MAGNETOM Amira with BioMatrix delivers consistency and efficiency in daily clinical routine. The user-friendly work environment and GO technologies enable push-button examinations and help to accelerate the entire workflow from patient positioning to result distribution. Artificial intelligence based technologies support in automating routine tasks, for robust and consistent workflows, even in a high volume environment. New speed technologies such as Simultaneous Multi-Slice TSE can dramatically reduce scan times for routine examinations. Furthermore, MAGNETOM Amira with BioMatrix also expands the patient population eligible for MRI, with free-breathing Compressed Sensing applications.

MAGNETOM Amira with BioMatrix incorporates Eco-Power for up to 30% savings in energy consumption during system stand-by and system off-modes. MAGNETOM Amira with BioMatrix is easy to site with low space requirements and low connection values enabling to use existing infrastructures and with that reduce installation costs.

Zero Helium boil-off magnet technology

MAGNETOM Amira with BioMatrix uses a super-conducting magnet. During operation, the magnet windings must be cooled below their critical temperature. That happens with liquid helium. Equipped with a Zero Helium boil-off technology, MAGNETOM Amira with BioMatrix requires no helium refill in normal use. This saves costs while maintaining a stable system performance.



Environmental benefits

- Reduction of energy consumption with Eco-Power technology
 - State-of-the-art Zero Helium boil-off technology
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Customer benefits

- Consistent high image quality with BioMatrix Technology
 - Reduced life-cycle costs by increased energy efficiency
 - Small installation area enabled by ultra-short and lightweight magnet technology
 - Increased marketability and accommodation of more patients thanks to free-breathing exams with Compressed Sensing
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¹Amira BioMatrix is 510k cleared

Environmental management system

Siemens Healthineers gives high priority to achieving excellence in Environmental Protection, Health Management and Safety (EHS).

Across the globe, Siemens Healthineers has implemented a consistent EHS management system. It lays the foundation for the continuous improvement of our performance in these areas, and regular auditing assures our conformance.

As a result of this consistent approach, Siemens Healthineers is considered one organization and is certified in accordance with ISO 14001 and OHSAS 18001.

Environmental product design



Material supply:
From natural resources to delivery of semi-finished products



Production/delivery:
From production of components to operation startup by the customer



Use/maintenance:
Includes daily use by our customers as well as maintenance



End-of-life:
From disassembly at the customer site, through material and energy recycling

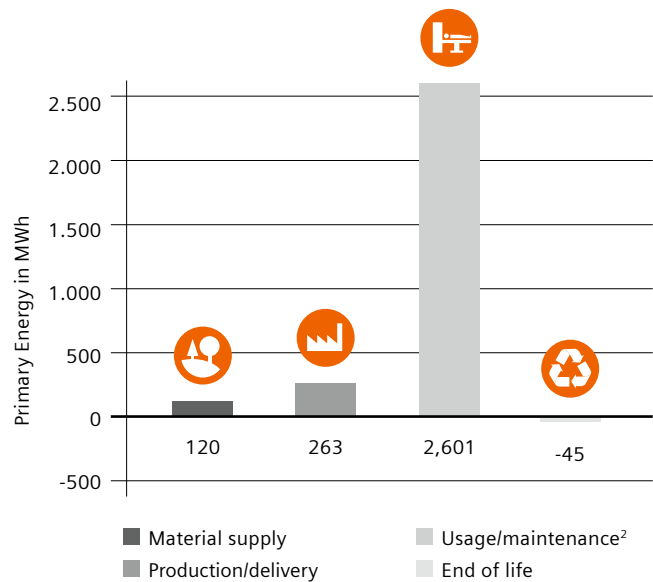
Siemens Healthineers considers environmental aspects in all phases of the product life cycle, including material supply, production/delivery, use/maintenance and end of life.

Our product design procedure fulfills the requirements of IEC60601-1-9:2007 "Environmental product design for medical electrical equipment".

This standard supports the effort to improve the environmental performance of our products.

Cumulative energy demand

Energy consumption is the most important environmental characteristic of medical devices. This is why we use the Cumulative Energy Demand to assess environmental performance. Cumulative Energy Demand is the total primary energy¹ that is necessary to produce, use and dispose of a device – including all transportation. Our medical devices can be recycled almost completely for materials or energy. With an appropriate end-of-life treatment it is possible to return up to 45 MWh in the form of secondary raw materials or thermal energy to the economic cycle.



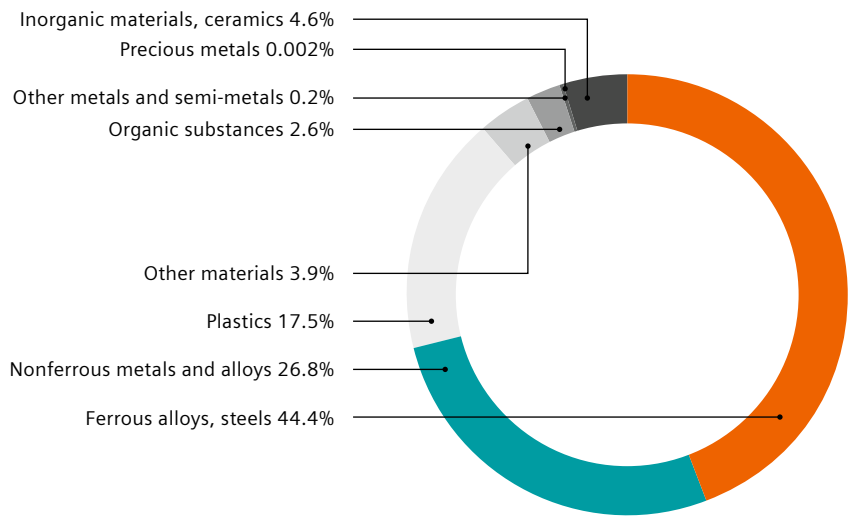
¹Primary energy is the energy contained in natural resources prior to undergoing any man made conversions (e.g. oil, solar).

²Based on 10 years usage.

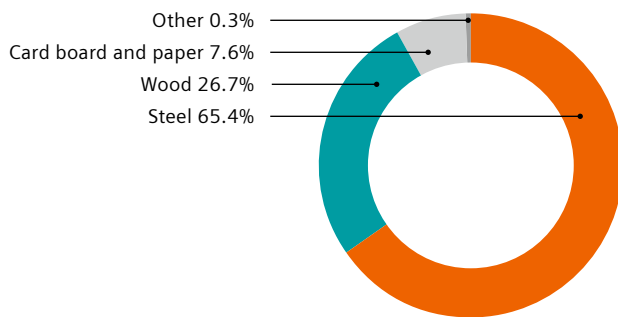
Product materials

MAGNETOM Amira is mainly built out of metals. This ensures a high degree of recyclability.

Total weight: approx. 5,865 kg



Numbers may not add up due to rounding



Packaging materials

Our MRI systems are transported by 40' flat truck for airfreight (most of carton box) and by 40' open top container for sea freight (the components packed by vacuum packing and wooden box) and domestic delivery (same as airfreight delivery). The magnet is delivered on a reusable steel pallet.

The values shown on the chart are average values from these two kinds of packaging. The packaging reuse ratio is more than 50%. The rest is supplied to material recycling. Only an insignificant amount (< 1%) has to be recycled for energy.

Total weight:
1630 kg

Numbers may not add up due to rounding

Product take back

Most of the materials used to produce MAGNETOM Amira are recyclable. 88.9% (by weight) can be recycled for material content and 11.1% for energy.

Our product take back program ensures that we address the environmental aspects of our products – even at the end of life. As part of this program, we refurbish systems

and reuse components and replacement parts whenever possible through our Refurbished Systems business.

We reuse components and subsystems for non-medical products. We also recycle for material or energy value. Disassembly instructions for disposal and recycling are available for our products.



Operating data

Heat emissions of the device ¹	
• System ready to measure ²	8.7 kW
• Scan ³	13.1 kW

Allowed ambient temperature ³	18°C–22°C
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Allowed relative humidity ⁴	40–60%
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Noise level	
• Basic load	≤ 60.7 dB (A) ⁵
• Full load	≤ 85.3 dB (A) ⁵

Power consumption ¹	
• System off	4.4 kW
• System ready to measure ²	8.7 kW
• Scan ³	13.1 kW

Power-on time ⁶	6.5 min
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Power-off time ⁶	7 min
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Technical specifications

Interface for heat recovery	No
Possible type of cooling	Water-cooling
Complete switch-off is possible	No
Device is adjustable for the user in terms of height	Not applicable
Uniform operating symbols for device families	Yes

Radiation

Measures/techniques to minimize ionizing radiation exposure	Not applicable
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Minimization of ionizing radiation compared to the limit value for patients	Not applicable
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Electromagnetic fields

Measures/techniques to minimize the exposure to electromagnetic fields	<ul style="list-style-type: none"> • actively shielded magnet • actively shielded gradients • if necessary magnetic shielding • RF-cabin with 90 dB damping
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¹All values are typical values, applicable for 400V/50Hz. The power consumption described herein is based on results that were achieved in a setting according to the COCIR methodology MRI – Measurement of the energy consumption (<http://www.cocir.org/site/index.php?id=46>). Since many variables impact power consumption (e.g. sequences used for scanning and sequence parameters, scan time), there can be no guarantee that each customer will achieve the same values.

²Device is in operation but no patient examination takes place.

³Average value for energy consumption at examination of patients.

⁴Within examination room.

⁵Measured according to NEMA in magnet room.

⁶From off-mode to operating state.

Replacement parts and consumables

Item	Life cycle ¹
• Cold head	2 years
• ECG-Electrodes	Disposable material

Disposal/Substance information

End-of-life concept	Yes
Recycling information	Yes
List of hazardous substances	Yes

Cleaning

The following classes of active agents in specific concentrations have been tested and are approved for cleaning

- Aldehydes
- Guanidine derivatives
- Peroxide compounds
- Pyridine derivatives
- Chloro derivatives
- Commercially available cleaning agents, detergent substances

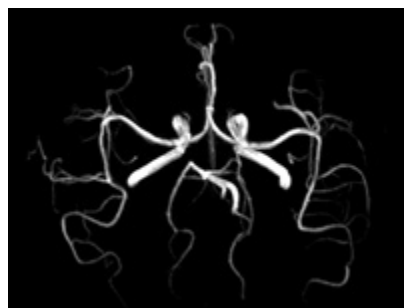
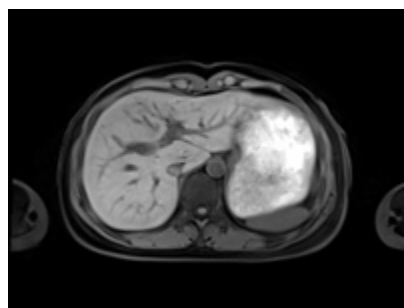
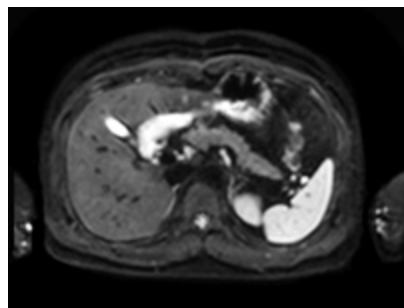
Suitability of device for sterile areas No

Please refer to the dedicated user manuals for system and components for a detailed list of approved and not approved cleaning substances and further instructions.

Further ecologically relevant information

Elements of instructions are:

- | | |
|--|-----|
| • Recommendations for saving energy | Yes |
| • Recommendations for efficient cleaning | Yes |
| • Recommendations for appropriate use of consumables | Yes |



¹Recommended exchange interval.

Not for distribution in the USA.

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The information in this document contains general technical descriptions of specifications and options as well as standard and optional features which do not always have to be present in individual cases.

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