

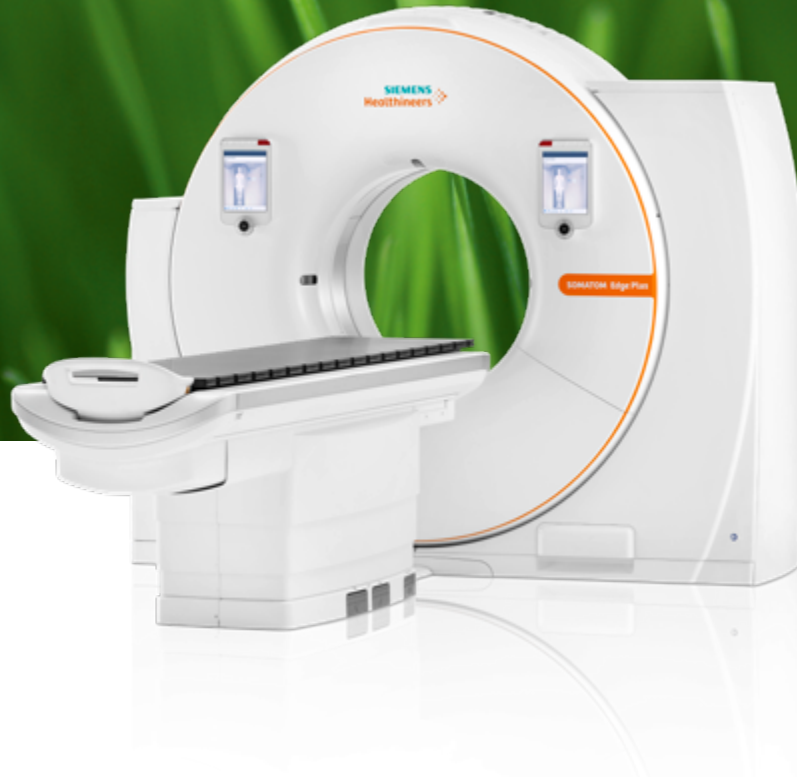


SOMATOM Edge Plus

Environmental Product Declaration

siemens-healthineers.com/somatom-edge-plus





Progress that is impressive – ecological advantages of SOMATOM Edge Plus

- Average energy savings of 30% for standard examinations¹
- 70% less detector power consumption (down to 450W) with Stellar detectors
- Contactless power and data transmission prevents abrasion and dust
- No more lead used for counterweights
- All substances contained in the product and its packaging are documented
- Plastic parts are labeled for recycling
- Disassembly instructions for high-quality recycling are available
- Complete CT systems and their components are taken back and refurbished
- Product take-back according to strict EU directives
- More than 99% of the materials used can be returned to the flow of recyclable materials
- Environmental product declaration is available for download via internet
- Tin Filter allows to lower the dose whilst maintaining image quality for non-contrast scans
- Fast scanning with a full rotation in only 0.28 seconds.

¹ Compared to SOMATOM Sensation 64

SOMATOM Edge Plus

Changing views in CT

Today Computed Tomography is one of the most established modalities in diagnostic imaging. However, the pressure to reduce expenses remains high, resulting in an ever-increasing need for standardization and accuracy. At the same time, obesity and an aging patient population pose growing challenges to image quality and efficiency. So how can radiologists routinely get accurate images and – whenever possible – additional information in order to make confident decisions?

With SOMATOM® Edge Plus, you can scan all patients at the appropriate dose and reproducible precision – based on fine tuned automation, combined with exceptional power reserves and speed. You can also leverage richer and more accurate information with technologies that bring tin-filtered scanning, 4D, and quantitative imaging to your clinical routine. Plus you can rely on consistent image quality: Game-changing workflow automation simplifies scan preparation and helps you achieve new levels of precision.

Are you ready to change views?

Changing views on patient diversity with personalized scanning

Increase your referral offerings by examining virtually all patients. Safeguard excellent image quality at an appropriate dose, without compromising operational efficiency. SOMATOM Edge Plus not only has the necessary speed, power reserves, and sensitivity – it also automatically adjusts scan parameters to each individual patient's size and shape.

Changing views on clinical paradigm with advanced imaging

Make the most of your capabilities and strengthen your reputation as a trusted advisor to referrers – every day. SOMATOM Edge Plus lets you acquire more in-depth insights and utilize advanced imaging at dose levels unthinkable just a few years ago.

Changing views on patient positioning with automated workflows

SOMATOM Edge Plus offers uniquely automated workflows to safeguard precision and consistency in patient positioning – enabling high efficiency, increased image quality, and a lower dose regardless of individual skills.

SOMATOM Edge Plus: Reduction of Lead Content

Rotating components of CT systems have to be balanced for quiet operation. The easiest way is the use of lead as counter balance. But lead is a toxic element. Therefore we abandoned the usage of lead as counter balance at the SOMATOM Edge Plus completely. A minor amount of lead is only necessary for shielding and shaping of radiation. There is no technically and economically feasible alternative at present.

Our predecessor models of the SOMATOM Edge Plus were already operating with low-energy consumption and were already equipped with effective low-dose technologies.

Even though there seemed to be limited potential for further optimizations, the following innovations led to further success: An adaptive dose shield mounted at the x-ray tube controls, that all unnecessary radiation is blocked from the patient. With this, dose can be reduced significantly while the image quality is maintained.²

Detectors of modern CT systems consist of many rows. X-rays can be utilized better and absorbed radiation doses can be reduced. Increasing the number of detector rows generates average energy savings of 30% in comparison to SOMATOM Sensation 64-slice configuration.

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, component manufacturing and assembly (which is summarized in manufacturing), use/maintenance, and end of life.

Our product design procedure fulfills the requirements of IEC 60601-1-9:2007+A1:2013 "Environmental product design for medical electrical equipment".

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

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.

² Deak PD et al. Effects of adaptive section collimation on patient radiation dose in multisection spiral CT. Radiology. 2009 Jul;252(1):140-7

Ecodesign improvements

Siemens Healthineers is committed to contribute to the challenges for a greener and more sustainable world economy by developing new environmentally conscious technologies and concepts, while at the same time improving the clinical value of medical imaging and in-vitro diagnostic devices.

As a member of COCIR³, Siemens Healthineers has proactively committed to the targets and objectives of the COCIR self-regulatory initiative (SRI) with the

European Commission to reduce the environmental impact of medical imaging equipment, following the framework set by the Ecodesign Directive (2009/125/EC). A strong focus in the last years was on reducing the energy demand of our products. The results of the eco-design initiative are published by COCIR and regularly reviewed by the EU commission.

Sustainability – the Siemens Environmental Portfolio

The Siemens Environmental Portfolio comprises of selected sustainable products characterized by i.a. outstanding energy efficiency – so does the SOMATOM Edge Plus. With our Environmental Portfolio, we make an important contribution to resource and climate protection and strengthen the competitiveness of our customers.

Siemens Healthineers respects society around the world. As a globally active company with innovation and investment competency, Siemens Healthineers holds itself to a high standard for sustainable development worldwide and makes a variety of contributions to this development. In addition, Siemens Healthineers is voluntarily and purposefully committed to advancing social issues and meeting needs.

As part of Siemens, we are proud to be top ranked within our peer group of the Dow Jones Sustainability Index⁴ for our sustainability strategy and performance, especially in the environmental area.

The latest report as well as current rating results (e.g. Dow Jones Sustainability Index, Carbon Disclosure Project, Oekom, EcoVadis, MSCI) are available under: <https://new.siemens.com/global/en/company/sustainability.html>

Green public procurement (GPP)⁵

The Green Public Procurement (GPP) initiative within the EU established environmental criteria for certain product categories, including for imaging devices. As it's a focus of Siemens Healthineers to drive energy efficiency and performance criteria for its products we have proactively evaluated the GPP requirements relevant for our imaging products, and have included requirements of GPP in our product development processes.

The relevant criteria addressed with SOMATOM Edge Plus include:

- ✓ Chemicals management system
- ✓ User instruction for green performance management
- ✓ Product longevity
- ✓ Training for energy efficiency and optimization
- ✓ Installation with energy efficiency optimization
- ✓ Energy performance

³ COCIR = Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

⁴ in category "Industrial Conglomerates"

⁵ For a description of the EU GPP criteria see: <http://ec.europa.eu/environment/gpp/pdf/criteria/health/EN.pdf>

Management of chemicals of concern

Within the materials compliance program at Siemens Healthineers and with the use of BOMcheck⁶, an industry-wide tool pioneered by Siemens Healthineers, regulated and declarable substances are monitored.

Chemicals of concern (carcinogenic, mutagenic and/or endocrine disrupting) as listed on the materials declaration standards IEC 62474 and IPC 1752A (including RoHS, REACH and California Proposition 65 substances) are systematically identified.

With this procedure we ensure those substances are not present above permitted threshold limits in our products and/or deliver information on how the product can be used in a safe way (e.g. lead for radiation shielding for which no technical and/or environmental sound alternative is available).

SOMATOM Edge Plus conforms:



RoHS

with Directive 2011/65/EU of the European Parliament on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)



REACH

with EC 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)



Calif Prop65

with California Proposition 65 administered by the California Environmental Protection Agency

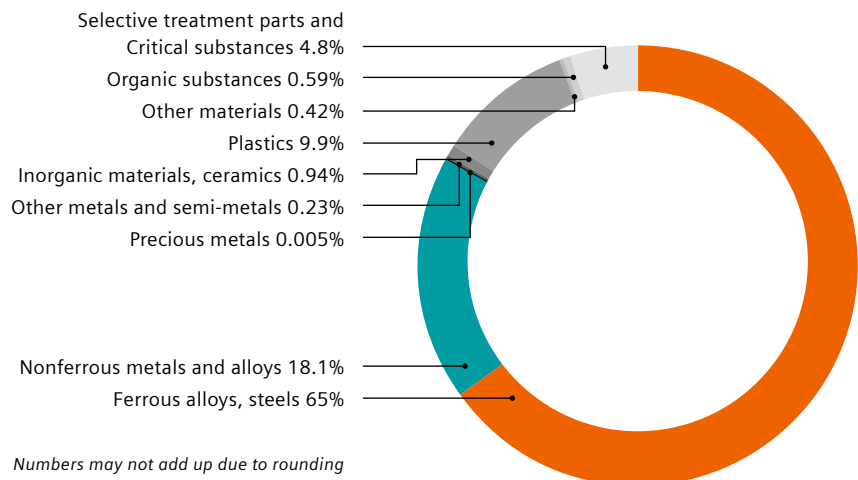
For developing and placing on the market the following environmentally related standards and laws were taken into account:

- ISO 14001:2015 (Environmental management system)
- ISO 45001:2018 (Occupational health and safety management system)
- IEC 60601-1-9:2007+A1:2013 (Environmental product design for medical electrical equipment)
- RoHS Directive 2011/65/EU (Restriction of the use of certain hazardous substances in electrical and electronic equipment)
- REACH Regulation EC 1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals)
- California Prop 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986)
- IEC 62474:2018 (Material Declaration for Products of and for the Electrotechnical Industry)
- IPC 1752A (Materials Declaration Management)
- EN50581:2012 and IEC63000:2018 (Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances)
- Ecodesign Directive (2009/125/EC)

Product materials

SOMATOM Edge Plus is mainly built out of metals. This allows for a high degree of recyclability, moreover most of the materials used in the SOMATOM Edge Plus are recyclable. 99% (by weight) can be recycled for material content and 1% for energy.

Total weight: approx. 3,340 kg (including gantry, patient table, operators console, image reconstruction system)



⁶ BOMcheck is a web-based declaration and regulatory compliance data base, see www.bomcheck.net

Packaging Materials

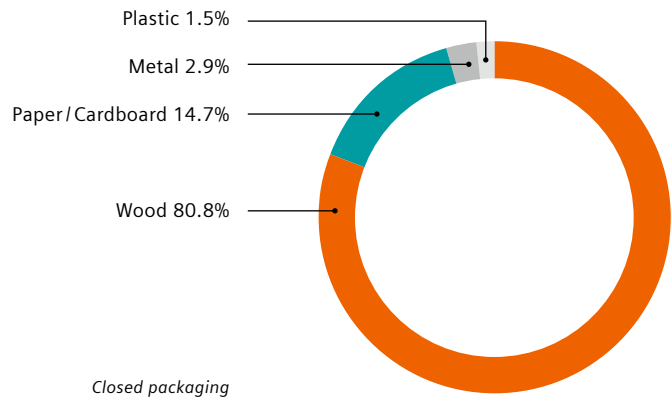
It is our goal to minimize our packaging material and reduce the packaging waste by reusing and recycling it.

The SOMATOM Edge Plus system is transported within Europe in open packaging, the CT Gantry is only protected by a light dust protective cover. A closed packaging is required for e.g. oversea transports.

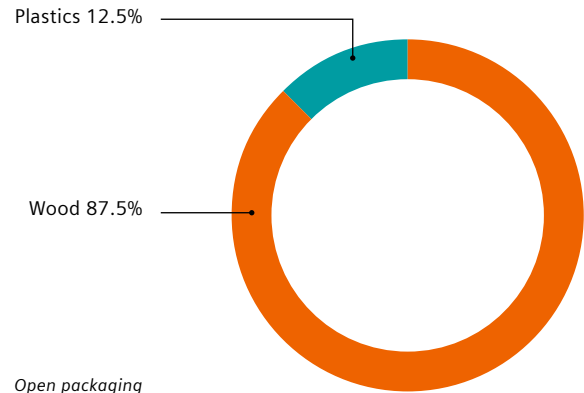
The values shown on the chart are average values from the different kinds of packaging types of the SOMATOM Edge Plus. The packaging materials consist of almost entirely wood and cardboard all of which can be recycled.

Total weight:

- Open packaging: approx. 40 kg
- Closed packaging: approx. 678 kg



Closed packaging



Open packaging

Reduction of critical substances

We made strides to reduce materials in our SOMATOM Edge Plus which are environmentally harmful and are not easily recyclable. As a first step we eliminated the usage of lead counterweights and even for radiation shielding, where lead is still commonly used in medical engineering industry, we were able to reduce further by substitution with alternative shielding materials.

By all these measures we progressed to achieve a rate of recyclable substances in the SOMATOM Edge Plus of 99%, while the remaining 1% can be completely used for thermal energy recovery.

Sustainable use of rare earth metals

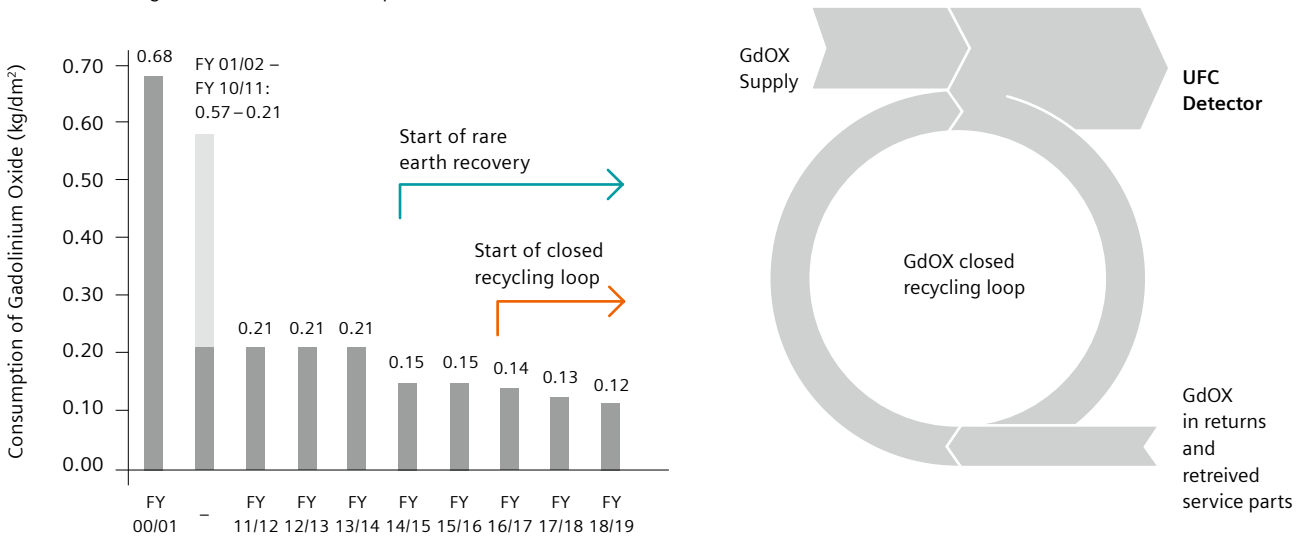
The consumption of rare earth material per unit area for CT detectors was reduced significantly. In fiscal year (FY) 18/19 we were able to reduce the supplied gadolinium oxide for production of a defined surface area of CT detector ceramics (UFC) by 82% in comparison to FY 00/01.

This is due to continuous improvements in our manufacturing technologies and processes.

Especially our measures in rare earth recovery which started in FY15 allowed for a further reduction. This could be even enhanced by introducing a closed recycling loop for the gadolinium oxide processing, which is unique in CT detector manufacturing worldwide.

Today, about 25%⁷ of the annually processed gadolinium oxide is utilized out of this closed and sustainable recycling loop.

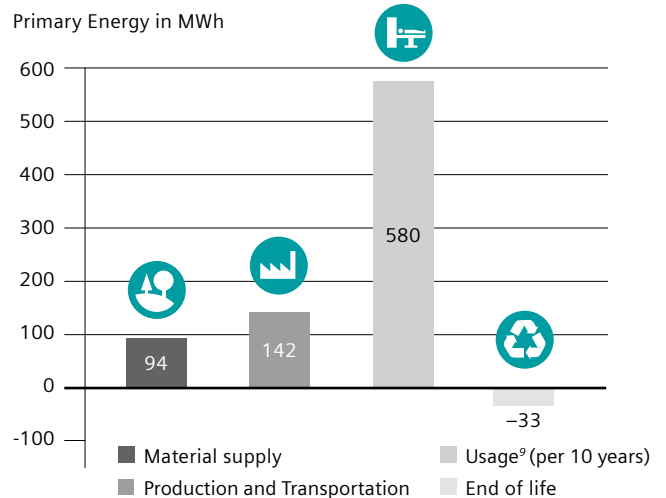
Reduction of virgin Gadolinium Oxide for production of CT detector ceramics



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 energy⁸ that is necessary to produce, use, and dispose of a device – including all transportations.

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 33 MWh in form of secondary raw materials or thermal energy to the economic cycle.



Based on one production site.

⁷ Data on file

⁸ Primary energy is the energy contained in natural resources prior to undergoing any man-made conversions (e.g. oil, solar).

⁹ Based on COC/R definition of CT energy consumption, 10 years usage.

Product take back

The high-performance X-ray tube assemblies are designed the way that as much parts as possible may be reused. At the end of life the tube assemblies are taken back and are refurbished. Quality is guaranteed by compliance to standard IEC 62309.

Under optimal conditions up to 40% of a tube assembly may consist of reused parts. 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.

Sustainability in the supply chain

Purchased products and services account for almost half the value of our total revenue. As our suppliers play a critical role in our sustainability-oriented value chain, Siemens¹⁰ expects them also to demonstrate their commitment towards these standards and principles which are summarized in the Code of Conduct.

Code of Conduct is based to a great extent on the principles of the UN Global Compact relating to human rights, labor standards, environmental protection and anticorruption initiatives. These principles are derived from the Universal Declaration of Human Rights, the Declaration on Fundamental Principles and Rights at Work of the International Labor Organization (ILO) and the principles of the Rio Declaration on Environment and Development.

We ensure sustainability in the supply chain with various programs, such as:

- **External Sustainability Audits**

External Sustainability Audits are extensive on-site inspections to check generally accepted sustainability standards. They are conducted on a risk-based approach by external specialists. The audits refer solely to the supplier's conformance and performance in relation to the six categories of the Code of Conduct for Siemens¹⁰ Suppliers. The assessments will be further tailored to the type of facility under assessment and only relevant sections are covered.

- **Responsible Minerals Sourcing Initiative**

We have rolled out a uniform and enterprise-wide process to determine the use, source and origin of the relevant minerals in our supply chain ("Supply Chain Due Diligence") including "Responsible Minerals Assurance Process" (RMAP) as part of the "Responsible Minerals Initiative" (former "Conflict Free Sourcing Initiative"). We work closely with our direct suppliers to support us in carrying out these steps.

¹⁰ As part of Siemens AG Siemens Healthineers is following the Siemens requirements



Operating Data

Heat emissions of the device

- Basic load¹¹ < 3.1 kW
- Scanning < 15 kW

Allowed ambient temperature¹² 18° C–28° C

Allowed relative humidity 20–75%

Noise level¹²

- Basic load¹¹ ≤ 68 dB (A)

Energy consumption

- Basic load¹¹ < 3.1 kW
- Full load¹³ ~ 20 kW
- Maximum load 125/140 kVA optional

Power-on time¹⁴ < 4 min

Power-off time¹⁵ < 2 min

Technical Specifications

Interface for heat recovery Yes

Possible type of cooling
Standard: water/water
Optional: water/air

Complete switch-off is possible Yes

Device is adjustable for the user
in terms of height Yes

Uniform operating symbols for
device families Yes

Radiation

Measures/techniques to
minimize ionizing radiation
exposure

- Stellar detectors and iterative reconstruction create excellent image quality with reduced noise. Tin Filter allow to lower the dose whilst maintaining image quality for non-contrast examinations
- Straton® MX tubes enable low dose scanning and reduce scan time for all types of examinations
- CAREkV allows a precise user independent kV selection
- Superfast Scanning with a full rotation in only 0.28 seconds

¹¹ Device is in operation but no patient examination takes place

¹² Within examination room

¹³ Average value at examination of patients (abdomen routine mode)

¹⁴ From off-mode to operating state

¹⁵ From operating state to off-mode

Electromagnetic fields

Measures/techniques to minimize the exposure to electromagnetic fields	Not applicable
Reduction compared to the limitvalue for users	Not applicable

Replacement Parts and Consumables

Item	Life cycle ¹⁶
• X-ray tube	1 year warranty
• UPS-battery	24 months

Disposal/Substance Information

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

Cleaning

Incompatible cleaning processes: Total device	<ul style="list-style-type: none"> • Sprays • Chlorine releasing agents • Substituted phenols based agents • Scouring cleaning agents • Organic solvents • Ammonia releasing agents
Restrictions for particular device components	<ul style="list-style-type: none"> • Not applicable
Suitability of device for sterile areas	Not applicable
Size of the surface to be cleaned ¹⁷	Approx. 3 m ²

Please refer to the dedicated operator 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	Not applicable
• Recommendations for appropriate use of consumables	Yes



¹⁶ Recommended exchange interval

¹⁷ Gantry-tunnel (inside), patient table overlay, control elements, console, keypad, intercom, mouse

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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 may not always be present in individual cases.

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The statements by Siemens Healthineers' customers described herein are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, level of IT adoption) the results shown in this brochure are not a guarantee that other customers will achieve the same results.

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