SOMATOM X.ceed

Environmental Product Declaration

siemens-healthineers.com/somatom-xceed

SIEMENS Healthineers

Progress that is impressive – ecological advantages of SOMATOM X.ceed

- Average energy savings of 31% for standard examinations[1]
- Contactless 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 98% of the materials used can be returned to the flow of recyclable materials

[1] *Energy savings compared to SOMATOM Definition Edge according to the COCIR calculation model for power consumption over a 24h day*

SOMATOM X.ceed

Intelligent imaging. Exceeding excellence.

SOMATOM® X.ceed is a high-resolution, high-speed CT engineered specifically for the most challenging clinical situations, with the category-best imaging chain. To help teams take full advantage of its benchmark potential, it comes with the built-in guidance of two unique Companions – one for diagnostic imaging, the other for intervention. In the interventional setting, myNeedle Companion supports targeted needle path planning and guidance as well as laser-guided insertion across multiple modalities.

myExam Companion helps simplify diagnostic procedures. Even in complex, time-critical, and life-threatening situations, it offers automated guidance from door to diagnosis. Its intelligent orchestration of humans and hardware optimizes speed and image quality for every clinical challenge, at the lowest appropriate dose.

In difficult situations, SOMATOM X.ceed enables excellent clinical decisions – and elite performance of CT and personnel.

Intelligent navigation for enhanced consistency
No matter the user, patient, or throughput, our Companions guide users through even time-critical procedures, including emergencies and interventions. This helps them interact easily, naturally, and precisely with both patient and technology.

Elite performance from door to diagnosis
SOMATOM X.ceed benchmarks the category with an optimal combination of high temporal and spatial resolution, power, and scan speed designed to master the most challenging clinical situations at low dose. myExam Companion offers radiology teams automated guidance throughout.

Patient-friendly design with an 82 cm bore
More natural communication with patients and our Mobile Workflow help patients relax – in combination with the large bore and enhanced accessibility of the new multi-purpose table.

Consistent standards across your institution
myExam Companion, myNeedle Companion, and Shui® – the design system of Siemens Healthineers – provide users with common interfaces across multiple modalities. Combined with our digital solutions, they can help you redefine and standardize protocols across your institution, optimizing clinical workflow, staffing schedules, results, and productivity.

SOMATOM X.ceed: 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 X.ceed 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 X.ceed 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 unneccessary radiation is blocked from the patient. With this, dose can be reduced significantly while the image quality is maintained.[2]

Environmental product design

Manufacturing:
From natural resources to operation startup by customer

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

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

Transportation:
Transports are summarized over the life cycle

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 ISO 45001.

[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 COCIR[3], 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

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.

Siemens Healthineers's sustainability performance is consolidated reported in the group-wide Siemens Sustainability Information. 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)[4]

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 X.ceed 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] *For a description of the EU GPP criteria see: http://ec.europa.eu/environment/gpp/pdf/criteria/health/EN.pdf*

Material compliance

Within the materials compliance program at Siemens Healthineers and with the use of BOMcheck[5] – an industrywide tool pioneered by Siemens – regulated and declarable substances are monitored. Chemicals of concern as listed on the materials declaration standards IEC 62474 and IPC 1752A (including RoHS and REACH substances) are systematically identified to ensure they are not present above permitted threshold limits in our products.

SOMATOM X.ceed conforms with Directive 2011/65/EU of the European Parliament on the restriction of the user of certain hazardous substances in electrical and electronic equipment.

Management of chemicals of concern

Regulated and declarable substances are monitored through the materials compliance program at Siemens Healthineers and through BoMCheck, an industry-wide tool pioneered by Siemens Healthineers. 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.

We ensure these substances are not present above permitted threshold limits in our products and/or provide 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).

We publish the result of our regular analysis based on product ID and part number via **siemens.com/reach-svhc-md.**

SOMATOM X.ceed 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:

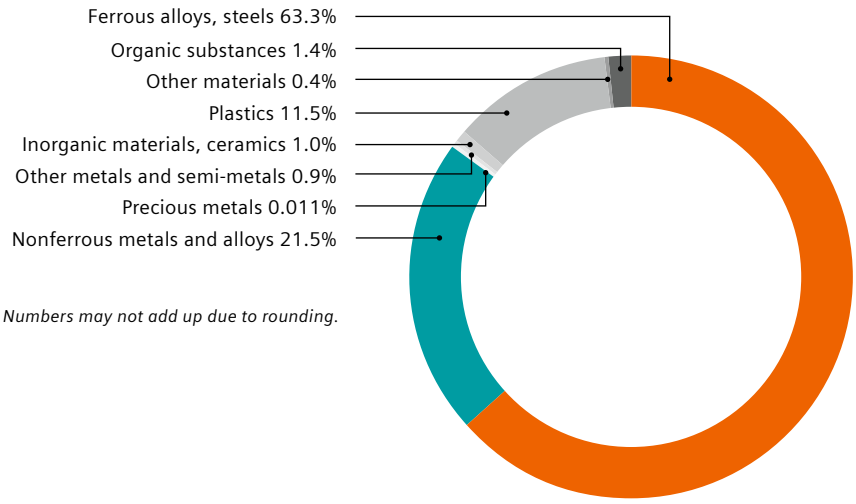
- ISO 14001:2015 (Environmental management system)
- ISO 45001:2018 (Occupational health and safety management system)
- IEC 60601-1-9:2007+A1:2013 (Environmental product design for medical electrical equipment)
- RoHS Directive 2011/65/EU (Restriction of the use of certain hazardous substances in electrical 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)

[5] *BOMcheck is a web-based declaration and regulatory compliance data base, see www.bomcheck.net.*

Product materials

SOMATOM X.ceed is mainly built out of metals. This ensures a high degree of recyclability.

Total weight: approx. 2420 kg



Numbers may not add up due to rounding.

Packaging materials

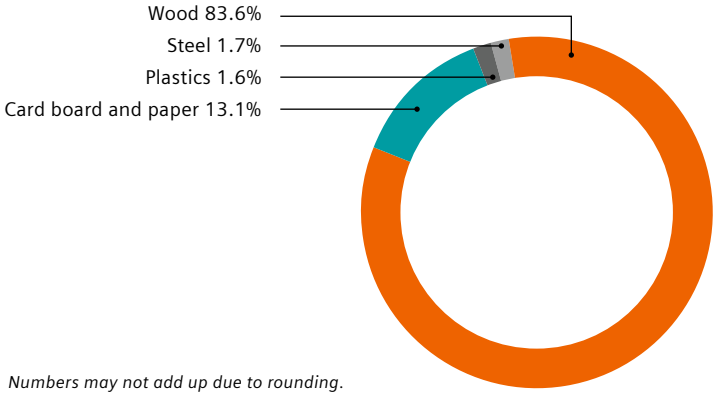
It is our goal to minimize our packaging material and reduce the packaging waste by reusing and recycling it.

The SOMATOM X.ceed 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 X.ceed. The packaging materials consist of almost entirely wood and cardboard all of which can be recycled.

Total weight:

- Open packaging: approx. 35 kg
- Closed packaging: approx. 508 kg



Numbers may not add up due to rounding.

Reduction of critical substances

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

By all these measures we progressed to achieve a rate of recyclable substances in the SOMATOM X.ceed of 98%, while the remaining 2% can be completely used for thermal energy recovery.

Sustainable use of rare earth metals

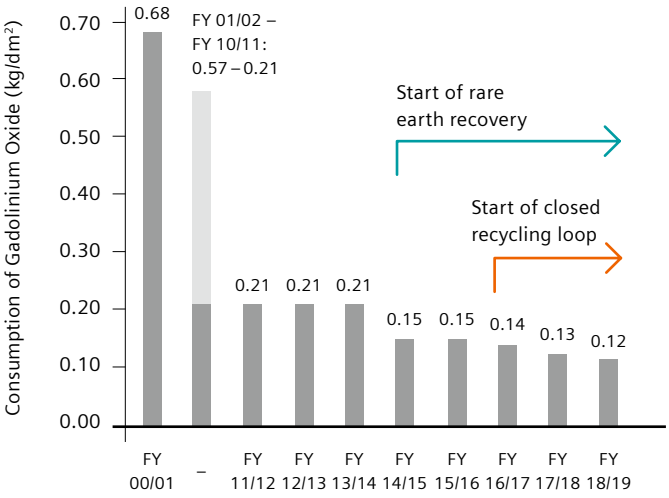
The consumption of rare earth material per unit area for CT detectors was reduced significantly. In fiscal year (FY) 18/19 we were able to reduce the supplied gadolinium oxide for production of a defined surface area of CT detector ceramics (UFC) by 82% in comparison to FY 00/01.

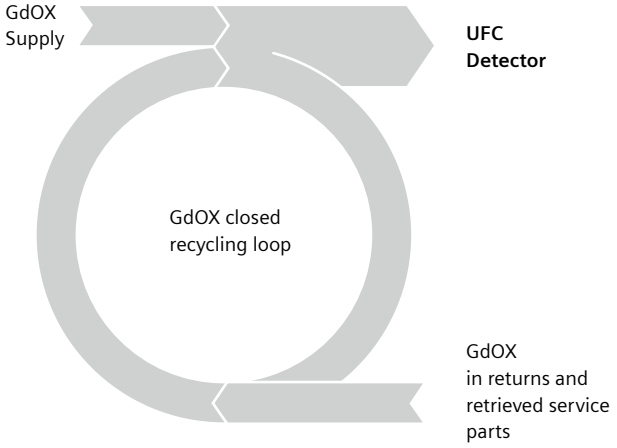
This is due to continuous improvements in our manufacturing technologies and processes.

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%[6] 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

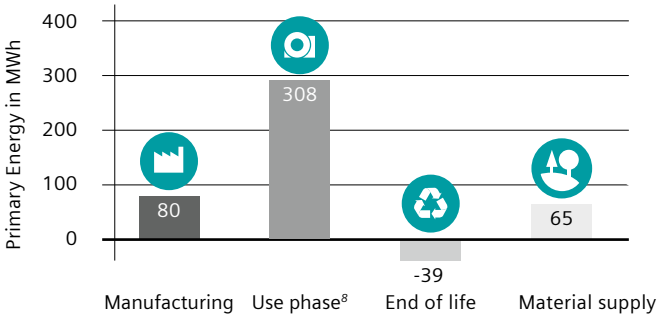




Cumulative energy demand

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 energy[7] that is necessary to produce, use and dispose 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 39 MWh in form of secondary raw materials or thermal energy to the economic cycle.



Energy values based on one production site.

[6] *Data on file*
[7] *Primary energy is the energy contained in natural resources prior to undergoing any man-made conversions (e.g. oil, solar).*
[8] *Based on COCIR definition of CT energy consumption, 10 years usage*

Product take back

The high-performance X-ray tube assemblies are designed the way that as many 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, Siemens[9] 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 Siemens[9] 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.

[9] *As part of Siemens AG Siemens Healthineers is following the Siemens requirements.*

Operating data

Heat emissions of the device	
• Basic load[10]	< 3.1 kW
• Full load[11]	< 15 kW
Allowed ambient temperature[12]	18°C–30°C
Allowed relative humidity	20–75%
Noise level[12]	≤ 68 dB (A)
Power consumption	
• Basic load[10]	< 3 kW
• Full load[11]	~ 20 kW
• Maximum load	< 125/150 kVA optional
Power-on time[13]	< 4 min
Power-off time[14]	< 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 high image quality with reduced noise. Tin Filter allows to lower the dose whilst maintaining image quality for non-contrast examinations • Vectron® X-Ray tube enables low-dose scanning and reduces scan time for all types of examinations • CARE kV allows a precise userindependent kV selection • Superfast scanning with a full rotation in only 0.25 seconds

[10] *Device is in operation but no patient examination takes place*
[11] *Average value at examination of patients (abdomen routine mode)*
[12] *Within examination room*
[13] *From off-mode to operating state*
[14] *From operating state to off-mode*

Electromagnetic fields

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

Replacement parts and consumables

Item • X-ray tube • UPS-battery	Life cycle[15] replaced when defective and non-operational[16] 24 months

Disposal/substance information

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

Cleaning

Incompatible cleaning processes: Total device	• Sprays • Chlorine releasing agents • Substituted phenols based agents • Scouring cleaning agents • Organic solvents • Ammonia releasing agents
Restrictions for particular device components	• 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

[15] *Recommended exchange interval*
[16] *Average replacement varies form system to system as it depends on tube usage and the type of performed procedures*
[17] *Gantry-tunnel (inside), patient tabel overlay, control elements, console, keypad, intercom, mouse*

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Published by Siemens Healthcare GmbH · Printed in Germany · 11061 1021 ·