



**SOMATOM Definition Edge**

# Environmental Product Declaration

[siemens-healthineers.com/somatom-definition-edge](https://siemens-healthineers.com/somatom-definition-edge)





## Progress that is impressive – ecological advantages of SOMATOM Definition Edge

- Average energy savings of 30% for standard examinations<sup>1</sup>
- 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
- Ca. 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

<sup>1</sup> Compared to SOMATOM Sensation 64

# SOMATOM Definition Edge

Confronted with increasingly complex clinical requirements and rising numbers of patients, medical institutions are expected to perform at the limits of their capacity every day. Healthcare innovation leader Siemens Healthineers invites them to expand their clinical capabilities – and not only meet, but exceed those expectations.

SOMATOM® Definition Edge expands your clinical capabilities and helps you and your institution perform to your full potential. Because when it comes to your patient's well-being, second best is not an option.

## Exceeding expectations in Cardiology

You will be able to expand your clinical capabilities – not only by catching the bolus, but also by improving contrast media efficiency when performing TAVI planning, introducing highly precise plaque differentiation, and enabling reliable, high-speed triple rule-out scanning.

## SOMATOM Definition Edge: 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 Definition Edge 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 Definition Edge 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:

## Exceeding expectations in Emergency Medicine

You will be able to optimize process efficiency with solutions that let you not only improve emergency workflow, but also substantially reduce door-to-image time, whether for pediatric or obese patients.

## Exceeding expectations in Oncology

You will be able to improve patient outcomes not only by precisely identifying tumors, but also by reliably evaluating therapy response and implementing improved low-dose therapy control and early detection.

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.<sup>2</sup>

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.

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

## 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, 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.

## 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<sup>3</sup>, 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.

<sup>3</sup> COCIR = Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

## 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 Definition Edge. 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 Index<sup>4</sup> 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)<sup>5</sup>

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 Definition Edge 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

## Management of chemicals of concern

Within the materials compliance program at Siemens Healthineers and with the use of BOMcheck<sup>6</sup>, 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 Definition Edge 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

<sup>4</sup> in category "Industrial Conglomerates"

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

<sup>6</sup> BOMcheck is a web-based declaration and regulatory compliance data base, see [www.bomcheck.net](http://www.bomcheck.net)

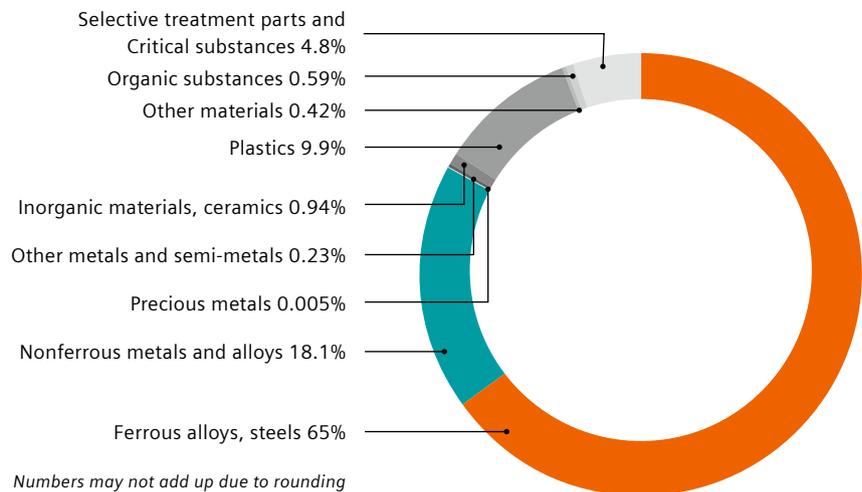
## For developing and placing on the market the following environmentally related standards and laws were taken into account:

- 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 Definition Edge is mainly built out of metals. This allows for a high degree of recyclability, moreover most of the materials used in the SOMATOM Definition Edge 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)



## Packaging materials

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

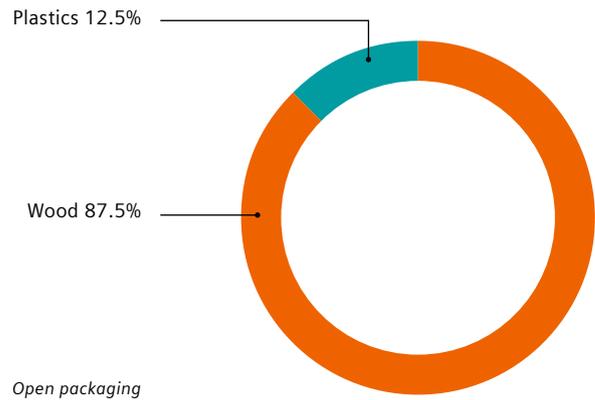
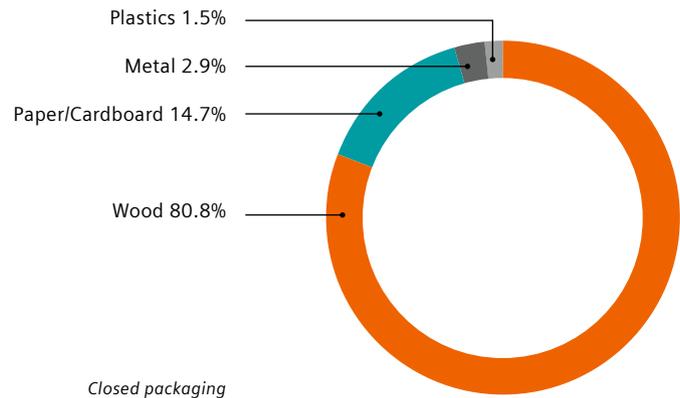
The SOMATOM Definition Edge system is transported within Europe in open packaging, the CT Gantry is only protected by a light dust protective cover. A closed packaging is required for e.g. oversea transports.

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

The values shown on the chart are average values of these kinds of packaging.

### Total weight:

- Open packaging: approx. 200 kg
- Closed packaging: approx. 1,500 kg



## Reduction of critical substances

We made strides to reduce materials in our SOMATOM Definition Edge 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 Definition Edge of 99%, while the remaining 1% can be completely used for thermal energy recovery.

## Sustainable use of rare earth metals

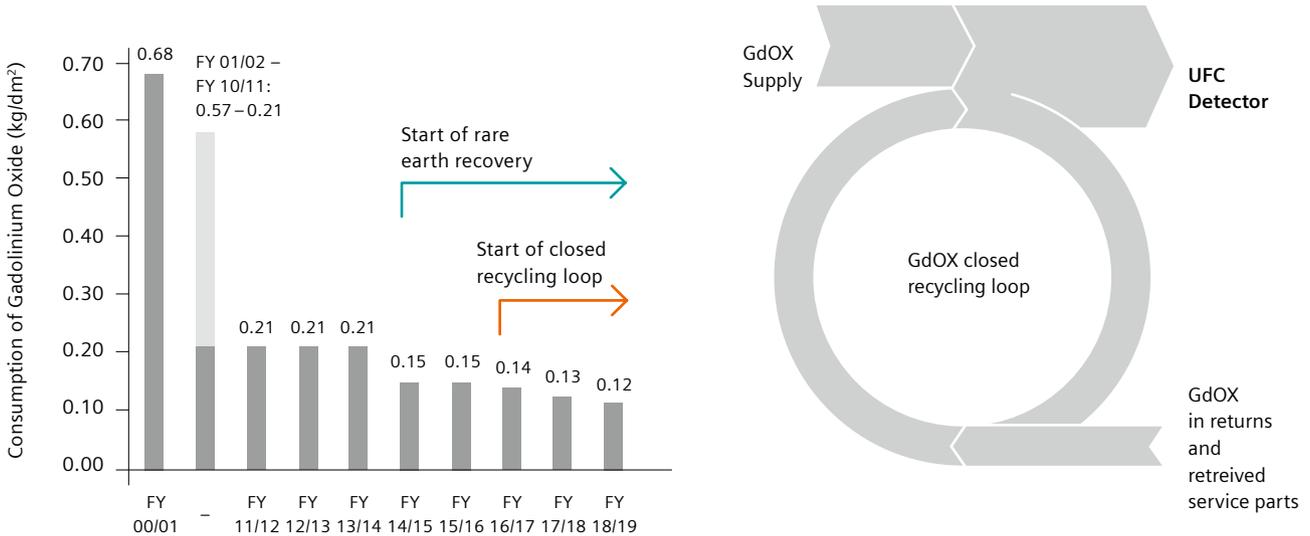
The consumption of rare earth material per unit area for CT detectors was reduced significantly. In fiscal year (FY) 18/19 we were able to reduce the supplied gadolinium oxide for production of a defined surface area of CT detector ceramics (UFC) by 82% in comparison to FY 00/01.

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%<sup>7</sup> 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



## 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.

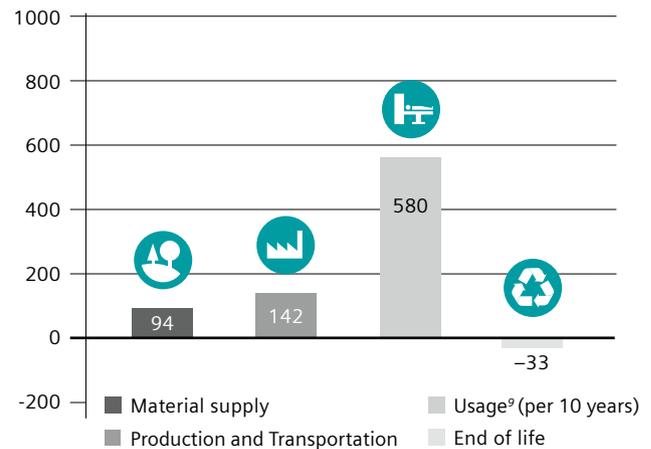
<sup>7</sup> Data on file

## 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<sup>8</sup> 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.

Primary Energy in MWh



Based on one production site.

## 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<sup>10</sup> 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<sup>10</sup> 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.

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

<sup>9</sup> Based on COCIR definition of CT energy consumption, 10 years usage.

<sup>10</sup> As part of Siemens AG Siemens Healthineers is following the Siemens requirements



## Operating data

### Heat emissions of the device

- Basic load<sup>11</sup> < 3.1 kW
- Scanning < 15 kW

Allowed ambient temperature<sup>12</sup> 18° C–28° C

Allowed relative humidity 20–75%

### Noise level

- Basic load ≤ 68 dB (A)

### Power consumption

- Basic load<sup>11</sup> < 3.1 kW
- Full load<sup>13</sup> ~ 20 kW
- Maximum load 125/140 kVA optional

Power-on time<sup>14</sup> < 4 min

Power-off time<sup>15</sup> < 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

<sup>11</sup> Device is in operation but no patient examination takes place

<sup>12</sup> Within examination room

<sup>13</sup> Average value at examination of patients (abdomen routine mode)

<sup>14</sup> From off-mode to operating state

<sup>15</sup> From operating state to off-mode

## Electromagnetic fields

Measures/techniques to minimize the exposure to electromagnetic fields	Not applicable
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## Replacement parts and consumables

Item	Life cycle <sup>16</sup>
• 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"> <li>• Sprays</li> <li>• Chlorine releasing agents</li> <li>• Substituted phenols based agents</li> <li>• Scouring cleaning agents</li> <li>• Organic solvents</li> <li>• Ammonia releasing agents</li> </ul>
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Restrictions for particular device components	• Not applicable
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Suitability of device for sterile areas	Not applicable
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Size of the surface to be cleaned <sup>17</sup>	Approx. 3 m <sup>2</sup>
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*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



<sup>16</sup> Recommended exchange interval

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

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