

SOMATOM Definition Flash

Environmental Product Declaration

Answers for life.

SIEMENS

Progress that is Impressive – Ecological Advantages of SOMATOM Definition Flash

- Dose reduction to less than 1 mSv for cardiac examinations
- Average energy savings of 45% during standard thorax examinations*
- Average energy savings of 85% during cardiac examinations*
- 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 are refurbished
- Product take-back according to strict EU directives
- More than 97% of the materials used can be returned to the flow of recyclable materials
- Environmental product declaration is available for download via internet



*Compared to SOMATOM Definition

SOMATOM Definition Flash



Validated information according to EMAS is marked by a gray background and the statement "EMAS: validated information".

Reduction of Lead

The use of lead for balancing weight has been completely eliminated. Lead is now used only when necessary to protect patients from unnecessary radiation. And the amount of lead required in the radiation shield for this purpose has been reduced by 70% (from 5.26 to 1.45 kilograms) compared to the previous SOMATOM Definition.

Progress that is impressive

Compared to the previous SOMATOM Definition model, the SOMATOM Definition Flash uses (depending on the type of examination required) 45%* to 85%** less energy during scanning.

An additional success is the significant reduction of radiation dose in heart examinations by about 70% (< 1 mSv at 100 kV and <1.5 mSv at 120 kV) compared to the previous SOMATOM Definition. Competitive systems generally utilize from 9 to 30 mSv for equivalent examinations.***

- * Standard thorax examinations
- ** Heart examinations
- *** Jörg Hausleiter, et al, JAMA 02/2009

EMAS: validated information –
Updated environmental statement 2009



SOMATOM Definition Flash

With the introduction of the SOMATOM Definition Flash, we took on CT's most pressing challenge and made dose reduction the centerpiece of our research. Its core innovation – the revolutionary Flash Spiral – can be summarized in four words: Flash speed. Lowest dose.

The SOMATOM Definition Flash opens a door to new levels of patient friendliness with the speed to cover the entire thorax in less than a second – if necessary even without a breath hold. Now, even demanding patients, i.e. obese and trauma patients, restless children, etc. will hardly cause a ripple in your daily routine. All can be scanned quickly and efficiently.

Maybe even more important – and impressive – is the incredible reduction in dose for all scans, resulting, e.g. in dose down to sub-mSv for cardiac imaging. In its second generation, Dual Energy automatically provides a second contrast for the best possible diagnosis without extra dose. At the same time, X-CARE allows protecting individual organs and the most radiation-sensitive body regions – for example, female breasts – by accurately and efficiently minimizing exposure. After IRIS (Image Reconstruction in Image Space) Siemens now introduces with SAFIRE* the first available raw-data-based iterative reconstruction that is a unique approach allowing for up to 60% dose savings in a wide range of daily clinical applications. Each of the multiple iteration steps further eliminates image noise and artifacts.

* The information about this product is being provided for planning purposes. The product is pending 510(k) review, and is not yet commercially available in the U.S.

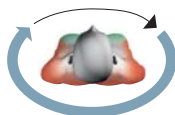
Organ-sensitive dose protection

X-CARE

Previous attempts at dose reduction were very successful but did not specifically take into consideration highly dose sensitive areas such as women's breasts. Now, the SOMATOM Definition Flash can selectively reduce sensitive-area exposure up to 40% without loss of image quality. This is accomplished by turning down the X-ray tube during those parts of the rotation that would result in the most direct exposure for these areas.



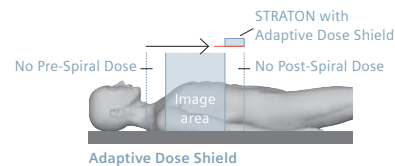
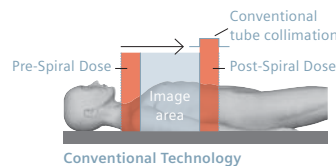
Conventional scanning applies radiation permanently during the full rotation, thus resulting in direct exposure e.g. for the breasts.



X-CARE reduces the tube current within a certain range of projections, minimizing direct exposure for highly dose-sensitive body regions.

Adaptive Dose Shield

The SOMATOM Definition Flash eliminates pre- and post-spiral over-radiation (marked in red). The Adaptive Dose Shield, which is unique in the CT industry, is part of the innovative STRATON® X-ray tube design. It automatically moves shields into place to block unnecessary dose. The Adaptive Dose Shield dynamically opens at the beginning of a spiral range and then dynamically closes at the end. Now all clinically irrelevant dose is eliminated, not only for dedicated applications, but for all standard spiral acquisitions. Giving you the ability to save up to an additional 25% of dose in routine exams.



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 through material and energy recycling

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

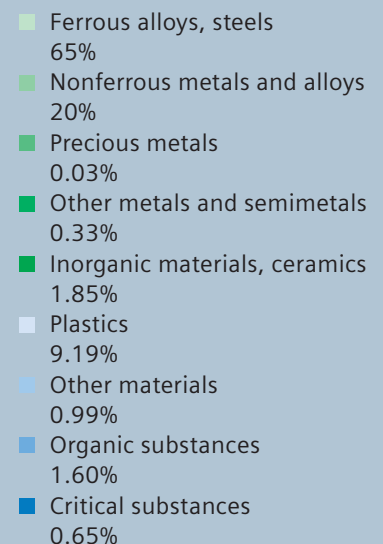
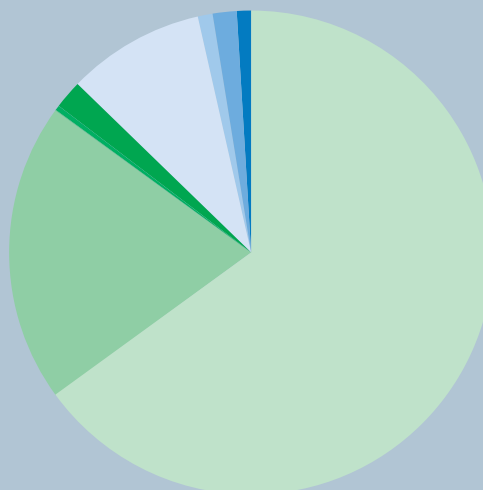
Our product design procedure fulfills the requirements of IEC60601-1-9:2007 "Environmental product design for medical electrical equipment".

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

Identification of Product Materials

SOMATOM Definition Flash is mainly built out of metals. This ensures a high degree of recyclability.

Total weight: approx. 4,400 kg



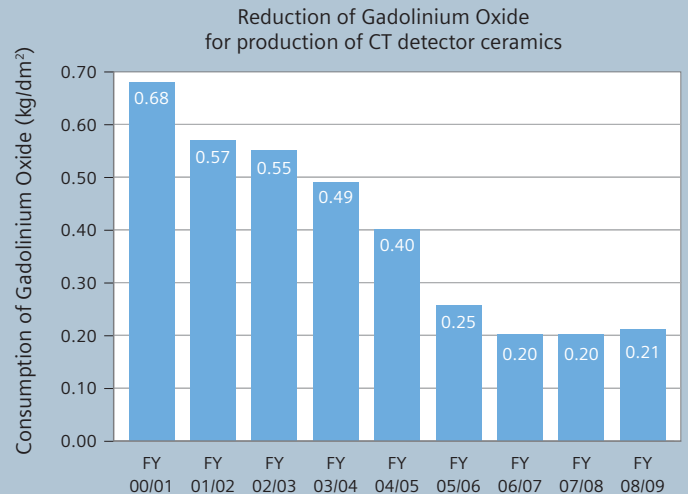
EMAS: validated information –
Updated environmental statement 2010

Reduction of Critical Substances

The consumption of material per unit area for CT detectors was reduced significantly. In FY 08/09 we were able to reduce Gadoliniumoxide consumption for production of a defined surface area of CT detector ceramics by 69% in comparison to FY00/01.

* Since FY 04/05, deliveries to our factory in China (Shanghai) have been included.

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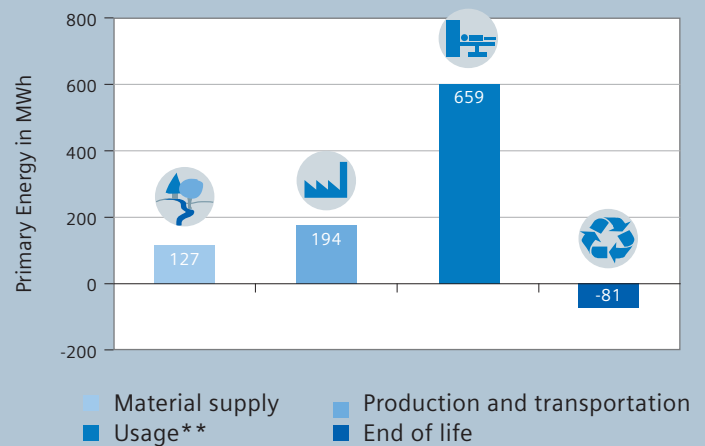


Cumulative Energy Demand

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* that is necessary to produce, use and dispose 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 81 MWh in form of secondary raw materials or thermal energy to the economic cycle.

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

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** Based on 70 patients per day, 10 sec scan time, 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.

EMAS: validated information – Updated environmental statement 2006 and environmental statement 2008



Operating Data	
Heat emissions of the device	
• Basic load ¹	< 4.5 kW
• Scanning	< 20 kW
Allowed ambient temperature³	18°C–28°
Allowed relative humidity	20–75%
Noise level	≤ 70 dB(A)
Energy consumption:	
• Basic load ¹	<4.5 kW
• Full load ²	~20 kW
• Maximum load	250 kW
Power-on time⁴	< 5 min
Power-off time⁵	< 5 min

¹ Device is in operation but no patient examination takes place

² Average value at examination of patients (abdomen routine mode)

³ Within examination room

⁴ From off-mode to operating state

⁵ From operating state to off-mode

syngo®, the ergonomic and user-friendly user interface supports the clinical workflow. The intelligent automation functions accelerate your examination and make a smooth, efficient workflow for all modalities, departments and people possible. With *syngo* your workplace is prepared for your mode of operation perfectly.

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	<ul style="list-style-type: none"> • Ultra Fast Ceramic (UFC) detectors • CARE Dose4D™ • Shaped Filter & Adaptive Dose Shield • Selective Photon Shield • X-CARE & HandCARE • Iterative Reconstruction in Image Space (IRIS)
Reduction compared to the limit value for patients	Reduction in %: ¹ Organ: Head - 0.7% Sinus - 67.8% Thorax - 66.3% Abdomen - 41.0% Upper Abdomen - 43.3% Pelvis - 48.2% Spine - 52.6%
Measures/techniques to minimize the exposure to electromagnetic radiation	Not applicable
Reduction compared to the limit value for users	Not applicable

¹ Further reduction possible when using IRIS protocols

Replacement Parts and Consumables	
Item	Life cycle ¹
X-ray tube	1 year warranty
UPS-battery	36 months

¹ Recommended exchange interval

Disposal / Substance Information	
End of life concept	Yes
Recycling information	Yes
List of hazardous substances (not contained in the device)	Yes

Cleaning	
Incompatible cleaning processes	
• Total device	Not applicable
• Restrictions for particular device components	Not applicable
List of incompatible substance classes	
• 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 the device for sterile areas	Not applicable
Size of the surface to be cleaned ¹ user in terms of height	Approx. 3 m ²

¹ Gantry-tunnel (inside), patient tabel overlay, control elements, console, keypad, intercom, mouse



Further Ecologically Relevant Information	
Elements of instruction are:	
• Recommendations for saving energy	Yes
• Recommendations for efficient cleaning	Not applicable
• Recommendations for appropriate use of consumables	Yes

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www.siemens.com/healthcare-ehs-mgmtsys

Global Business Unit

Siemens AG
Medical Solutions
Computed Tomography & Radiation Oncology
Siemensstr. 1
DE-91301 Forchheim
Germany
Phone: +49 9191 18-0
Fax: +49 9191 18-9998

Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
www.siemens.com/healthcare

Legal Manufacturer

Siemens AG
Wittelsbacherplatz 2
DE-80333 Muenchen
Germany

www.siemens.com/healthcare