ENVIRONMENTAL PRODUCT DECLARATION

MyLab™A50 (code 100661100 / 100661000)
MyLab™A500 AI (code 100661130 / 100661030)
MyLab™Fox (code 100660001 / 100660002)

Environmental performance refers to the average product produced at the plant in Via degli Olmi, 11, 50019 Sesto Fiorentino, Florence, Italy

DECLARATION NUMBER	REGISTRATION NUMBER	CPC CODE	RELEASE DATE	EXPIRATION DATE	PUBLISHER	PROGRAM OPERATOR
ESA01_A50	EPDITALY1308	481	26.02.2026	25.02.2031	EPD Italy	EPD Italy

This EPD has been developed in conformity to ISO 14025 and BS EN 50693:2019. An EPD should provide current information and may be updated if conditions change. The stated validity is, therefore, subject to the continued registration and publication at www.epditaly.it

GENERAL INFORMATION

EPD OWNER

Company	Registered Office (or Legal Headquarter)	Contact us for EPD information
ESAOTE S.p.A.	Via Enrico Melen 77 - 16152 - Genova (Ge), Italia	Sergio Paddeu - sergio.paddeu@esaote.com

PROGRAM OPERATOR

Registered Office

EPD Italy

Via Gaetano De Castillia n° 10 - 20124 Milano, Italy

EPD INFORMATION

Products

MyLab™A50 (code 100661100 / 100661000)
MyLab™A500 AI (code 100661130 / 100661030)
MyLab™Fox (code 100660001 / 100660002)

Production Site

Via degli Olmi, 11, 50019 Sesto Fiorentino FI, Italia

VERIFICATION INFORMATION

Technical standards

EPDItaly007 - Electronic and electrical products and systems REV. 3.2 (valid 2026/01/19)
BS EN 50693:2019 - Product category rules for life cycle assessments of electronic and electrical products and systems

EPD Italy Regulation

EPDItaly Regulation version 6.0 (issue date 10/30/2023)

LCA Project Report

Life Cycle Assessment Study of the MyLab™50 Diagnostic Ultrasound Scanner - Rev. 0

Responsibility Statement

The EPD Owner releases EPDItaly from any non-compliance with environmental legislation. The declaration holder will be responsible for the supporting information and evidence.
EPDItaly declines all responsibility for the information, data, and results provided by the EPD Owner for the life cycle assessment

Independent Verification/Validation Statement

Independent verification of the declaration and data performed according to ISO 14025:2010.
Third-party verification/validation performed by:
TÜV Italia srl -TÜV SÜD Group (00077), Viale Fulvio Testi 280/6, 20126 Milan - Italy

Comparability Statement

Environmental declarations published within the same product category, but from different programs, may not be comparable.
In particular, EPDs for products that do not comply with EN BS EN 50693:2019 may not be comparable

GENERAL INFORMATION

Summary description and technical information of the product

MyLab™A50 is a mid- to high-end trolley-mounted ultrasound device, designed to offer high flexibility and performance in multiple clinical areas—from radiology to angiology, from cardiology to obstetrics/gynecology. MyLab™Fox is the veterinary version of the MyLab™A50.
The MyLab™A50, manufactured by Esaote S.p.A., complies with the MDR 2017/745 and successive amendments. In accordance with this regulation, Esaote has classified it as Class IIa device.

MyLab™A50

Product scope of application – HUMAN

The Esaote MyLab™50 is a multidisciplinary ultrasound device, designed for use in multiple hospital departments and specialist practices. Its application covers a variety of clinical areas, thanks to its compatibility with over 30 probes and advanced imaging modalities:

- General radiology → evaluation of the abdomen, small organs, thyroid, and salivary glands
- Cardiology → transthoracic and transesophageal echocardiography, stress echo, strain and strain-rate analysis, AutoEF
- Angiology and vascular → vascular study with PW, CW, color, and power Doppler
- Obstetrics and gynecology → pregnancy monitoring, fetal morphology studies, 3D/4D
- Urology → renal, bladder, and prostate ultrasound (including with endocavitary probes)
- Musculoskeletal and rheumatology → joints, muscles, soft tissues, and tendons
- Pediatrics and neonatology → examinations on young patients with high-frequency probes

MyLab™FOX

Product scope of application - VETERINARY

Clever, fast, and intelligent by nature, the fox is a resourceful animal that can adapt well to various environments. With the same features, the MyLab™FOX is a multidisciplinary and adaptable scanning partner for all your diagnostic needs.
For decades, at Esaote, we have been collaborating with veterinarians to develop systems that meet clinical demands and improve the day-to-day clinic workflow, with a clear-cut focus on animal care and productivity.
Thanks to the latest technological advances and a fast and intuitive workflow, MyLab™FOX optimizes diagnostic confidence in any ultrasound examination, in a wide range of applications for all types of animals.

Product reference standards

MDR 2017/745 – Medical device regulation
ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes

CPC code

481

THE COMPANY

Esaote is one of the **world's leading manufacturers** of medical diagnostic systems.
It is a leader in the field of **Ultrasound**, **Dedicated Magnetic Resonance Imaging**, and one of the main players in **Information Technology in healthcare**, with also a presence in the interventional sector.

Since its founding in the early 1980s, Esaote has oriented its Research & Development policy towards the creation of highly innovative products, based on careful analysis of clinical needs and market trends.

The Esaote Group employs **over 1,300 people in more than 100 countries**, 20% of whom are engaged in **Research & Development**, a sector in which it has always invested 10-13% of its revenues.
The company, which boasts collaborations with clinical and scientific research centers and universities around the world, has received numerous awards for its performance in terms of **innovation**, for investments in **research**, **human capital and technology**, and extraordinary **product design**.

DISCOVER MORE

Mission
Complexity is simple.

We aim at bringing into the world our unique vision and values by combining advanced software with Ultrasound and MRI devices to take the most from images, delivering to professionals the best tools to take decisions for optimal care

Vision
More in less.

We see a future in which highly accurate diagnosis and treatment will be done with our simple but powerful medical devices as the primary choice for supporting patient care

Values
Efficiency in action.

Teamwork
Commitment
Integrity
Results
Customer focus

MyLab™A50 and MyLab™Fox

Ultrasound Devices designed for reduced footprint

The MyLab™A50 and MyLab™Fox ultrasound devices are designed for flexibility and efficiency in clinical environments. The devices offers users the ability to select from different monitor configurations, allowing adaptation to various clinical needs and space requirements. The control panel is available in both a gesture-based touch version and a conventional simplified layout, supporting diverse user preferences and workflows.

The design emphasizes minimization of production materials, with a compact and modular structure that reduces the overall material footprint. Energy consumption is limited through efficient hardware components and the availability of an optional battery, which enables operation for over an hour without mains power—supporting use at patient side and reducing energy waste during idle periods. The devices is engineered for low operating noise, contributing to a quieter clinical environment.

The keyboard is designed for durability, ease of cleaning, and resistance to corrosive agents, further supporting long-term use and hygiene. Both the MyLab™A50 and MyLab™Fox support a wide range of clinical applications, making them flexible enough to be used by many professionals across different clinical settings, limiting the need for additional systems.

GENERAL INFORMATION

Sustainable Innovation
The MyLab™A50 and MyLab™Fox ultrasound devices exemplifies Esaote's dedication to sustainable innovation through its integration of advanced diagnostic performance and responsible design and manufacturing practices. The development of the devices is guided by a strong focus on durability, modularity, and energy efficiency, ensuring reliable operation and adaptability in various clinical environments. Materials are carefully selected for their minimal environmental impact, resistance to corrosion, and the ease with which they can be disassembled, supporting efficient end-of-life recycling.

The company emphasizes the use of lightweight and compact components, which not only lower transportation emissions but also contribute to enhanced energy efficiency during daily operation.

ECO-DESIGN FOR SUSTAINABLE MANUFACTURING

Eco-design for sustainable manufacturing
Eco-friendly design lies at the heart of the MyLab™A50 and MyLab™Fox ultrasound devices, ensuring both high diagnostic performance and long-term sustainability. By prioritizing durability, modularity, and energy efficiency, Esaote crafts a product that not only meets clinical demands but also minimizes its environmental footprint. The thoughtful selection of corrosion-resistant, recyclable materials enables easier disassembly and end-of-life recycling, while the system's lightweight, compact components reduce emissions during transportation and daily use. These design choices are further validated by strict adherence to ISO 13485 and ISO 14001 certifications, reflecting a commitment to quality and environmental stewardship. Ultimately, each aspect of the MyLab™A50 and MyLab™FOX's design contributes to a reliable, adaptable, and eco-conscious medical device, demonstrating how responsible innovation shapes a sustainable future in healthcare.

GENERAL INFORMATION

OBJECTIVE OF THE STUDY

The objective of this study is to evaluate the potential environmental impacts, from a life cycle perspective, associated with some devices of the MyLab™A product family. The assessment focuses on the device itself, independently of specific clinical applications or diagnostic protocols.

In the use phase, energy consumption is determined using a reference probe in accordance with Green Public Procurement (GPP) criteria and standardized test procedures (EN 50564), providing both a reference for the energy performance of the device in a “standard” configuration and a scenario to estimate annual energy use. The life cycle of the probe itself is not included, as the study aims to evaluate the environmental performance of the device, rather than the specific application or consumables.

The LCA considers the complete life cycle of the device, from raw material extraction to end-of-life, with particular attention to manufacturing, packaging, transport, installation, use and end-of-life treatment. This average EPD aims to be representative of the MyLab™A product family, covering the following product codes:

MyLab™A50	(code 100661100 / 100661000)
MyLab™A500 AI	(code 100661130 / 100661030)
MyLab™Fox	(code 100660001 / 100660002)

These products consist of the same hardware components that can be combined in different solutions to offer users alternatives.

The products under study can be composed as shown in the following table, which shows the possible component alternatives with their respective reference codes

Components	Alternatives		
Control Panel - Full Group	STD (Standard) - 330007795	ETC (Easy to Clean) - 330007022	-
Monitor (B)	150000062	150000061	150000060
Arm (C)	330006295	330002007	330007178
Keyboard QWERTY (optional)	330006703	-	-

Finally, the product configuration always considers the Battery Assembly.
The feasible product configurations marketed by Esaote and considered in this study are presented below.

Baseline components	Monitor (B)	Arm (C)	Control Panel STD / ETC	Keyboard QWERTY
B2+C2	150000062	330002007	✓/✓	Optional
B2+C3	150000062	330007178	✓/✓	Optional
B3+C2	150000061	330002007	✓/✓	Optional
B4+C1	150000060	330006295	✓/✓	Optional
B4+C2	150000060	330002007	✓/✓	Optional

REFERENCE REGULATORY CONTEXT

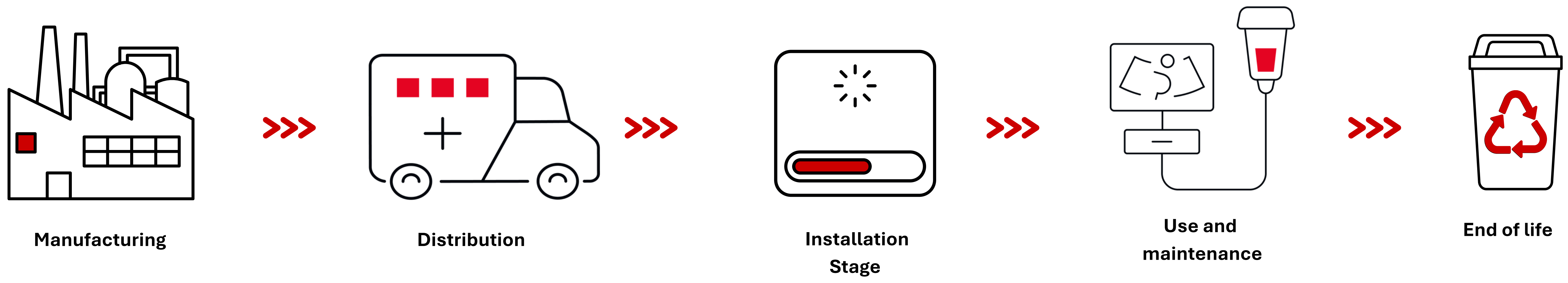
The study was conducted according to the principles and requirements of the following international standards and Product Category Rules:

- ISO 14040:2006+Amd 1:2020 Environmental management - Life cycle assessment - Principles and framework
- ISO 14044:2006+Amd 2:2020 Environmental management - Life cycle assessment - Requirements and guidelines
- BS EN 50693:2019 Product category rules for life cycle assessments of electronic and electrical products and systems
- EPDItaly007 - Electronic and electrical products and systems - REV. 3.2 (valid 2026/01/19)
- EPDItaly Regulation version 6.0 (issue date 30/10/2023)

SYSTEM BOUNDARIES AND DESCRIPTION OF PRODUCTION PROCESSES

With reference to BS EN 50693:2019, the system boundaries include the modules indicated in the following table.

	Manufacturing stage	Distribution stage	Installation Stage	Use & Maintenance stage	End of life stage	Benefit & Loads
Phases declared	✓	✓	✓	✓	✓	MND



MANUFACTURING STAGE

The Manufacturing Stage uses a cradle-to-gate approach, covering all upstream processes until the product exits the final plant. A black-box model tracks inputs like electricity and consumables, and outputs such as waste and emissions. Once shipped, the unit is sent to Esaote's logistics hub for unpacking, setup, testing, repackaging, and delivery, which begins the downstream life cycle

DISTRIBUTION STAGE

The environmental impacts of product distribution were evaluated based on logistics from the Florence manufacturing site to the destination countries' capitals. The assessment included only international transport by truck and ship. Weighted average distances were determined to be 711.97 km for trucks and 1,671.80 km for ships, and these figures were used in the LCA model to calculate transportation-related impacts

INSTALLATION STAGE

The installation phase of the device consists primarily of manual activities performed on-site and does not require significant energy or resource consumption. Therefore, the environmental impacts associated with the installation process itself are considered negligible in the context of the overall life cycle assessment. The only aspect considered in this stage is the management of the packaging materials removed during installation. Packaging waste is treated according to the appropriate waste disposal or recycling routes, and the related environmental impacts are included in the LCA

USE STAGE

The use phase was assessed based on energy consumption measured under standard operating conditions, using a reference probe in accordance with Green Public Procurement (GPP) criteria and EN 50564:2011 standardized test procedures. The probe is considered solely for characterizing the device's energy performance, and its life cycle is not included in the study. The reported energy consumption represents the average device configuration and was used to estimate annual use. The total energy consumption over a 7-year Reference Service Life (RSL) which served as the basis for calculating the device's environmental impacts during operation

EOL STAGE

The MyLab™A50 and MyLab™Fox end-of-life process follows the Recycling Passport under EU Directive 2012/19/EU (WEEE). Hazardous materials are removed, and metals, plastics, and electrical parts are recycled. The Recycling Passport provides data for accurate and traceable environmental impact management

DETAILED PRODUCT DESCRIPTION

FUNCTIONAL UNITY

The declared unit is equal to 1 product unit. Product durability has been considered equal to the product's guaranteed useful life. The selected configurations have a service life of 7 years. The results refer to an average product unit representative of the following configurations equipped with a battery assy.

Baseline components	Monitor (B)	Arm (C)	Control Panel STD / ETC	Keyboard QWERTY
B2+C2	150000062	330002007	✓/✓	Optional
B2+C3	150000062	330007178	✓/✓	Optional
B3+C2	150000061	330002007	✓/✓	Optional
B4+C1	150000060	330006295	✓/✓	Optional
B4+C2	150000060	330002007	✓/✓	Optional

The results presented in this document are based solely on the company's practices and assumptions and, as such, were not calculated for comparison with those of other companies. Differences in methodological choices, data quality assumptions, and database selection may produce incomparable results. Therefore, the analysis conducted is not intended to be a comparison.

USEFUL INFORMATION FOR THE REPRESENTATIVENESS OF THE EPD

The average product was defined as representative of Esaote S.p.A.'s manufacturing practices.

The products included in this study were selected because they belong to the same product family, share a similar manufacturing process, and use the same raw materials. The devices selected in the different possible configuration only concern the ultrasound scanner without any ultrasound probes. No specific clinical application has been targeted in the study.

Data collection refers to the year 2024, reflecting Esaote's operational and management practices. All relevant input and output flows within the system boundaries were analyzed.

The MyLab™A product family includes different component configurations, which define the product variants marketed by Esaote. Five configurations representing the main variants were analyzed, considering STD and ETC control panels and the presence or absence of a QWERTY keyboard. As far as the use and maintenance phase, the energy consumption assessment has been conducted according to the measurement setups and procedures reported in GPP Criteria and COCIR SRI (Self Regulatory Initiative).

The LCA results show that all possible configurations have highly consistent environmental impacts, with maximum variability for each environmental impact category ranging from –1.2% to +1.3% compared to the average. This deviation is well within the ±10% limit established by EPD Italy Regulation, 6th edition (§4.3.2), confirming that the average EPD is representative of the environmental performance of the individual products.

PRODUCT COMPONENTS and ECO-DESIGN

Esaote S.p.A. adopts a systematic approach to ensure that all the medical and veterinary devices comply with European regulations: REACH (EC Reg. 1907/2006), RoHS (Dir- 2011/65/EU), and WEEE (Dir. 2012/19/EU).

Compliance is enforced throughout the product's life cycle using a "Compliance by Design" philosophy. In the design phase, every component is assessed for technical and regulatory suitability, and documentation like REACH/RoHS declarations, MSDS, FMD is collected and verified. During manufacturing stage, compliance is maintained using supply chain monitoring and risk assessment.

In addition, Esaote meets mandatory communication requirements by providing SCIP notices to ECHA and informing recipients of products containing SVHC above the 0.1% (w/w) threshold.

This structured system consistently maintains regulatory compliance, minimizing environmental and public health risks from hazardous chemicals.

CONTENT OF MATERIALS

Macro-category	Material	%	Total %
Components	Electrical cables	1.60%	18%
	Liquid crystal displays (LCD)	0.80%	
	Lithium batteries	1.60%	
	Printed circuit boards (PCB)	7.80%	
	Transformers	5.90%	
Metals	Aluminum	13.90%	43%
	Steel	29.60%	
	Metals – other	< 0.1%	
Plastics	PC/ABS resin	17.50%	19%
	Polyurethane (PU)	0.10%	
	Plastics – other	1.80%	
Packaging	Cardboard	6.70%	20%
	Polyethylene (PE)	2.70%	
	Wood	10.10%	
Overall total		**100%**	

QUALITY OF DATA

In selecting the data for the LCA study, primary data collected from Esaote SpA were prioritized.
The primary data cover the period January 2024 – December 2024 and concern:

- The weight of the product's constituent materials and packaging
- The production process:
  - Energy consumption
  - Air emissions
  - Waste generated
- Distribution logistics
- Product energy consumption
- End of Life management

The overall Data Quality Requirement (DQR) calculated by combining weights and scores for all the processes considered is equal to 3.95, corresponding to a "Good" data quality level, compliant with the guidelines of the Product Environmental Footprint Category Rules Guidance 6.3. This value confirms that the data used in the study are reliable, consistent and representative of the real conditions of the processes analyzed.

Substances of concern according to the REACH Regulation - SVHC	CAS number
Dimethoxyethane	110-71-4
Dodecamethylcyclohexasiloxane	540-97-6
Decamethylcyclopentasiloxane	541-02-6
Lead	7439-92-1
6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol	119-47-1
Boric Acid	10043-35-3
2-(2H-Benzotriazol-2-yl)-4,6-di-*tert*-pentylphenol	25973-55-1

LCA RESULTS

The results refer to the declared unit equal to 1 product unit with a service life of 7 years

MANDATORY IMPACT CATEGORY INDICATORS

Damage category	u.m.	Manufacturing	Distribution	Installation	Use & Maintenance	End of life	Total
GWP-total	kg CO2 eq	2.26E+03	1.36E+01	4.28E+01	6.82E+02	1.95E-02	3.00E+03
GWP-fossil	kg CO2 eq	2.27E+03	1.35E+01	2.15E+00	6.78E+02	1.95E-02	2.96E+03
GWP-biogenic	kg CO2 eq	-1.46E+01	2.38E-03	4.06E+01	1.64E+00	4.37E-06	2.77E+01
GWP-luluc	kgCO2 eq	2.99E+00	4.85E-03	9.68E-05	2.00E+00	5.23E-06	4.99E+00
ODP	kg CFC11 eq	9.84E-05	2.59E-07	4.13E-09	1.04E-05	9.40E-11	1.09E-04
AP	mol H+ eq	1.65E+01	1.06E-01	7.20E-03	3.74E+00	3.29E-05	2.03E+01
EP-freshwater	kg P eq	2.48E+00	8.37E-04	2.45E-04	4.79E-01	1.19E-06	2.96E+00
EP-marine	kg N eq	3.11E+00	3.22E-02	1.41E-02	6.12E-01	4.33E-05	3.77E+00
EP-terrestrial	mol N eq	3.26E+01	3.54E-01	3.67E-02	5.79E+00	1.34E-04	3.87E+01
POCP	kg NMVOC eq	9.36E+00	1.15E-01	1.90E-02	1.93E+00	4.10E-05	1.14E+01
ADPE	kg Sb eq	6.34E-01	3.90E-05	7.26E-07	7.25E-03	1.43E-08	6.41E-01
ADPF	MJ	1.59E+04	1.45E+01	3.89E-01	8.61E+03	2.12E-02	2.46E+04
WDP	m3 depriv.	5.46E+02	7.23E-01	4.89E-02	1.87E+02	-4.21E-04	7.35E+02

GWP-total: Climate change – total; GWP-fossil: Climate change – fossil; GWP-biogenic: Climate change – biogenic; GWP-luluc: Climate change – land use and land use change; ODP: Depletion potential of the stratospheric ozone layer; AP: Acidification; EP-freshwater: Eutrophication – freshwater; EP-marine: Eutrophication – marine; EP-terrestrial: Eutrophication – terrestrial; POCP: Photochemical ozone formation; ADP-minerals&metals[2]: Depletion of abiotic resources – minerals and metals; ADP-fossil[2]: Depletion of abiotic resources – fossil fuels; WDP[2]: Water use

[2]The results of these environmental impact indicators should be used with caution as the uncertainties surrounding them are high and/or experience with the indicator is limited

ADDITIONAL ENVIRONMENTAL IMPACT INDICATORS

Damage category	u.m.	Manufacturing	Distribution	Installation	Use & Maintenance	End of life	Total
PM	disease inc.	1.35E-04	9.91E-07	4.43E-06	1.82E-05	6.23E-09	1.58E-04
IRP	kBq U-235 eq	2.09E+02	2.20E-01	3.27E-03	3.01E+02	3.01E-04	5.10E+02
ETP - fw	CTUe	1.04E+05	9.58E+01	1.20E+02	4.81E+03	4.21E+00	1.09E+05
HTP-c	CTUh	2.10E-05	1.79E-07	3.68E-08	2.69E-06	1.65E-10	2.39E-05
HTP-nc	CTUh	2.02E-04	2.15E-07	3.57E-06	1.81E-05	7.72E-10	2.24E-04
SQP	Pt	1.13E+04	9.87E+01	1.11E+01	2.67E+03	4.04E-02	1.40E+04

PM: Particulate Matter emissions; IRP[1]: Ionizing radiation, human health; ETP-fw: Eco-toxicity (freshwater); HTP-c: Human toxicity, cancer effects; HTP-nc[2]: Human toxicity, non-cancer effects; SQP[2]: Land use related impacts / Soil quality.

[1]This impact category mainly concerns the potential impact of low-dose ionising radiation on human health from the nuclear fuel cycle. It does not consider the effects of possible nuclear accidents, occupational exposure or the disposal of radioactive waste in underground facilities. Potential ionising radiation from soil, radon and certain building materials is also not measured by this indicator.

RESOURCE USE INDICATORS

Damage category	u.m.	Manufacturing	Distribution	Installation	Use & Maintenance	End of life	Total
PERE	MJ	3.27E+03	2.94E+00	5.37E-02	3.32E+03	3.81E-03	6.60E+03
PERM	MJ	1.90E+02	0.00E+00	0.00E+00	0.00E+00	0.00E+00	1.90E+02
PERT	MJ	3.46E+03	2.94E+00	5.37E-02	3.32E+03	3.81E-03	6.79E+03
PENRE	MJ	1.53E+04	1.45E+01	3.89E-01	8.61E+03	2.13E-02	2.39E+04
PENRM	MJ	6.94E+02	0.00E+00	0.00E+00	0.00E+00	0.00E+00	6.94E+02
PENRT	MJ	1.59E+04	1.45E+01	3.89E-01	8.61E+03	2.13E-02	2.46E+04
SM	kg	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
RSF	MJ	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
NRSF	MJ	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
FW	m3	1.91E+01	2.41E-02	1.59E-03	1.09E+01	4.01E-06	3.01E+01

PERE: Use of renewable primary energy (excluding renewable primary energy resources used as raw materials); PERM: Use of renewable primary energy resources used as raw materials; PERT: Total use of renewable primary energy resources (primary energy and resources used as raw materials); PENRE: Use of non-renewable primary energy (excluding non-renewable primary energy resources used as raw materials); PENRM: Use of non-renewable primary energy resources used as raw materials; PENRT: Total use of non-renewable primary energy resources (primary energy and resources used as raw materials); SM: Use of secondary materials; RSF: Use of renewable secondary fuels; RSF: Use of non-renewable secondary fuels; FW: Net use of fresh water; HWD: Hazardous waste disposed; NHWD: Non-hazardous waste disposed; RWD: Radioactive waste disposed

OUTPUT FLOW INDICATORS

Damage category	u.m.	Manufacturing	Distribution	Installation	Use & Maintenance	End of life	Total
CRU	kg	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
MFR	kg	0.00E+00	0.00E+00	1.66E+00	0.00E+00	6.97E+01	7.14E+01
MER	kg	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
EEE	MJ	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
EET	MJ	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00

CRU: Components for re-use; MFR: Materials for recycling; MER: Materials for energy recovery; EE: Exported energy (EEE – electrical / EET – thermal)

ENVIRONMENTAL INFORMATION DESCRIBING WASTE CATEGORIES

Damage category	u.m.	Manufacturing	Distribution	Installation	Use & Maintenance	End of life	Total
HWD	kg	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
NHWD	kg	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
RWD	kg	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00

HWD: Hazardous waste disposed; NHWD: Non-hazardous waste disposed; RWD: Radioactive waste disposed

The waste indicators were quantified using the EDIP 2003 method. Specifically, the Hazardous Waste category was used for the Hazardous Waste Disposed indicator, the sum of the Bulk Waste and Slag/Ashes categories was used for the Non-Hazardous Waste Disposed indicator, and the Radioactive Waste category was used for the Radioactive Waste Disposed indicator.
These indicators account for the resources consumed and waste generated throughout the entire life cycle of the declared product, including upstream, core, and downstream processes. They are derived from the life cycle inventory (LCI) and represent the net flows of resources and waste crossing the system boundaries.
It should be noted that waste treatment processes must be included within the system boundaries, and the waste indicators reflect only the residual waste remaining after these processes, within the predefined 100-year timeframe.
Furthermore, some aggregated generic LCI datasets—particularly those from the Ecoinvent database—typically include all waste treatment processes within the system boundaries. In contrast, other aggregated datasets, such as those from GaBi, often contain untreated waste streams extending beyond the system boundaries. For this latter type of dataset, an appropriate waste treatment process should be added to the product system, provided that waste treatment is typically performed in the represented region

CALCULATION RULES

ASSUMPTIONS

- Packaging: packaging related to the product component materials has been excluded from the analysis (cut-off); however, it has been considered as waste generated by the manufacturing plant
- Maintenance of production processes: flows associated with the maintenance of process machinery and the production plant have not been considered, unless included in the Ecoinvent datasets used
- Product configuration and testing: product configuration and testing activities are primarily manual; the associated energy consumption has been considered negligible in comparison to the overall product life cycle
- Maintenance phase: the maintenance phase has been excluded from the LCA assessment, as it represents a manual, exceptional activity that can be performed remotely, with environmental impacts negligible compared to the overall life cycle of the device
- Use phase: energy consumption during the use phase has been determined using a reference probe, in accordance with the Green Public Procurement (GPP) criteria for electrical and electronic equipment used in the healthcare sector (EU GPP – Health Care EEE) and standardized test procedures EN 50564:2011. The probe is considered solely for the purpose of characterizing the device's energy performance, and its life cycle is not included in the study. The reported values represent the device under study and are used to estimate annual energy consumption in a typical use scenario, independent of specific clinical applications or diagnostic protocols
- End-of-life of the product (EoL): the end-of-life of the device was modeled using the Recycling Passport (European Directive 2012/19/EU) as a reference for the average product composition and the breakdown of material fractions. Each output flow (metals, plastics, printed circuit boards, batteries, cables, and residual fractions) was associated with the most representative Ecoinvent dataset for the corresponding WEEE treatment processes in a global market context. The percentage allocation of the material masses was assumed to be fully representative of the device's end-of-life behavior and used to define the destinations for recovery, recycling, or disposal. The modeling therefore reflects the average efficiency of the treatment and recovery processes available in the selected datasets

CUT-OFF

The criterion adopted for the initial inclusion of input and output flows is based on a 5% cutoff, calculated in terms of both mass and primary energy. Therefore, the process was neglected only if its contribution was less than 5% of the total. However, all processes for which data were available were included in the analysis, even if they were below the 5% threshold. This approach avoids the collection of unknown data without excluding already available information and is consistent with what has been reported in similar LCA studies in the literature.

ALLOCATION

Economic allocation has been applied in the following cases:

- To allocate electricity consumption
- To allocate atmospheric emissions
- To allocate the quantities of waste leaving the plant

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