GLOBAL ELECTRONICS COUNCIL

Sustainability for a Connected Future

STATE OF SUSTAINABILITY RESEARCH

Medical Imaging Equipment

Prepared for Medical Equipment Proactive Alliance

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Acronyms

5SGSC – Five-Star Green Supply Chain
BBP – benzyl butyl phthalate
BPA – bisphenol A
BPADP – bisphenol A diphosphate
CMR – carcinogenic, mutagenic, or toxic for reproduction
CT – computed tomography
DBP – dibutyl phthalate
DEHP – di (2-ethylhexyl) phthalate
DINP – diisononyl phthalate
ECHA – European Chemicals Agency
EDC – endocrine disrupting chemical
EPA – Environmental Protection Agency
EPD – environmental product declaration
EPRM – European Partnership for Responsible Minerals
FMD – full material disclosure
GCN-J – Global Compact Network Japan
GEC – Global Electronics Council
GWP – global warming potential
HVAC – heating ventilation and cooling
ICT – information and communications technology
JRMTWG – JEITA Responsible Minerals Trade Working Group
MEPA - Medical Equipment Proactive Alliance
MIE – Medical Imaging Equipment
MITA – Medical Imaging Technology Association
MRI – magnetic resonance imaging
NREL – National Renewable Energy Laboratory
OCS – Operation Clean Sweep for Zero Pellet Loss
P2PC – Plastics to Precious Chemicals
PAH – polycyclic aromatic hydrocarbons
PBB – polybrominated biphenyl
PBDE – polybrominated diphenyl ether
PBT – persistent, bioaccumulative, and toxic
PET – positron emission tomography
PFAS – poly- and perfluoroalkyl substances
PFOA – perfluorooctanoic acid
PFOS – perfluorooctane sulfonate
POP – persistent organic pollutants
PTFE – polytetrafluoroethylene

PVC – polyvinyl chloride
REACH – Regulation for Registration, Evaluation, Authorization and Restriction of Chemicals
RGA – Responsible Gold Agreement
RoHS – Restriction of Hazardous Substances
RSL – restricted substances list
SCIP – Substances of Concern In articles as such or in complex objects (Products)
SPECT – single photon emission computed tomography
SVHC – Substances of Very High Concern
TBBPA – tetrabromobisphenol-A
TSCA – Toxic Substances Control Act
U/S – ultrasound
VOC – volatile organic compound

1. Introduction

1.1 Overview

Modern healthcare depends on the capabilities of non-invasive imaging technologies to visualize the internal functions and status of the human body for the purposes of diagnosis, analysis, and monitoring. Imaging systems are used across the full spectrum of healthcare from screening and wellness to diagnosis, clinical decision support, and post-treatment monitoring, even extending to home care monitoring. By leveraging improved analytic methods and combining different imaging modalities, advances continue to be made in the capability, safety, and efficiency of medical imaging systems.

The healthcare organizations that purchase and use medical imaging equipment are broadly committed to the use of sustainable purchasing practices as a way to minimize the social and environmental impact of their operations. The development and use of sustainability criteria allow purchasers to communicate a consistent set of sustainable procurement requirements to manufacturers and monitor their own organizational impacts.

The Global Electronics Council (GEC) prepared this State of Sustainability Research at the request of the COCIR to provide a science- and data-based foundation for criteria development by the Medical Equipment Proactive Alliance (MEPA). This report describes the social and environmental impacts of medical imaging equipment, based on publicly available information and information provided by COCIR members. By analyzing medical imaging product design, composition, use, and supply chain for raw materials and components, this report identifies priority impact areas for development of environmental and social performance criteria.

1.2 About GEC

The Global Electronics Council (GEC) is a non-profit that leverages large-scale purchasing power, both public and private sector, as a demand driver for more sustainable technology. By deciding to buy sustainable technology, institutional purchasers can "move the needle" toward a more sustainable world. GEC also helps manufacturers understand the sustainability impacts of their technology, commit to address those impacts, and act to change operational, supply chain, and procurement behaviors.

GEC is the manager of the ecolabel EPEAT™, used by more purchasers of electronics than any other ecolabel worldwide. EPEAT is a comprehensive voluntary sustainability ecolabel that helps purchasers identify more sustainable electronic products that have superior environmental and social performance. EPEAT establishes criteria that address priority sustainability impacts throughout the life cycle of the product, based on an evaluation of scientific evidence and international best practices.

1.3 About MEPA

The Medical Equipment Proactive Alliance (MEPA) – a partnership of industry, healthcare purchasers and non-profit organizations -- is committed to developing sustainability criteria for medical imaging equipment that will allow healthcare purchasers to communicate a consistent set of sustainable procurement criteria to manufacturers and to track and communicate the sustainability impacts of their actions.

2. Medical Imaging Equipment Products

2.1. Scope

At a high level, medical imaging refers to the use of noninvasive technologies and techniques to visualize the interior of the human body for the purpose of diagnosing, monitoring, or analyzing medical conditions. The techniques used to produce a visualization include the use of sound waves, electromagnetic radiation, and magnetic fields.

While research into new, more advanced techniques of processing data continue to expand the types and applications of medical imaging equipment, this State of Sustainability Research focuses on the following most common modalities:

Computed Tomography (CT)	An imaging technology using X-rays that are processed by the machine's computer to generate cross-sectional images—or "slices"—of the body. These slices are called tomographic images and contain more detailed information about the internal organs than conventional X-rays. (Derived from: https://www.nibib.nih.gov/science-education/glossary/c)
Magnetic Resonance Imaging (MRI)	A non-invasive imaging technology used to investigate anatomy and function of the body using magnetic fields and radio waves. It is based on sophisticated technology that excites and detects changes in protons found in the water that makes up living tissues. (Adapted from: https://www.nibib.nih.gov/science-education/glossary/m)
Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT)	PET and SPECT scanners read the emissions of radiopharmaceuticals injected into the patient to create 3 dimensional images of their distribution. The decay of the radiotracers used with PET scans produce small particles called positrons. When positrons react with electrons in the body they annihilate each other. This annihilation produces two photons that shoot off in opposite directions. The detectors in PET/SPECT scanners measure these photons and

	use this information to create images of internal organs. (Adapted from: https://www.nibib.nih.gov/science-education/glossary/p)
Ultrasound (U/S)	A medical diagnostic technique, high frequency sound waves are used to provide real-time medical imaging image inside the body. (Adapted from: https://www.nibib.nih.gov/science-education/glossary/u)
X-Ray	A medical imaging technology using ionizing radiation that can pass through most objects, including the body. X-rays travel through the body and strike an x-ray detector (such as radiographic film, or a digital x-ray detector) on the other side of the patient, forming an image that represents the "shadows" of objects inside the body. (Adapted from: https://www.nibib.nih.gov/science-education/glossary/x)

While medical imaging equipment (MIE) may also include types of equipment that measure the interior of a body but that are not primarily used to produce visual representations, such as electroencephalography or electrocardiography, such techniques are considered outside the scope of this research.

Due to low unit sales and high complexity, combined technologies (e.g., SPECT/CT, PET/CT, PET/MRI, and imaging for radiotherapy) are excluded from the scope of this research.

3. Market Analysis

3.1. Global Market Overview

The medical imaging equipment industry (also referred to as diagnostic imaging) has demonstrated strong growth in recent years, accelerated by the increased demands on global healthcare systems resulting from the impacts of the SARS-CoV-2 (COVID-19) pandemic. Market research firm Research and Markets estimates the current global diagnostic imaging equipment market to be $43 billion in 2021, and is expected to grow at a compound annual growth rate (CAGR) of 5% to $52.2 billion in 2025[1].

Of the various modalities of medical imaging equipment, radiography accounted for more than 49% of sales in 2021[2]. Market share for this oldest imaging technology is maintained by improvements in digital radiography that enable efficient, high-contrast resolution digital images using smaller flat panel detectors[2]. In 2016, while x-ray systems accounted for 61% of the new units sold globally, CT systems made up 20.5% of the market and MRI systems %18.5[3].

In the near term, COVID-19 negatively impacted global demand for medical imaging equipment by as much as 1.3% in 2020 compared to average year-on-year growth between 2017-2019; however, the market largely has returned to pre-pandemic levels. One key dimension of this negative growth has been the reduction in the number of hospital visits and associated examinations[4].

Looking forward, a steady increase in average lifespan will be a primary driver for the demand for diagnostic imaging. Detecting and treating diseases associated with older adults such as cardiovascular, cancer, orthopedic, and diabetes will increase the demand for medical imaging equipment[4].

3.2. Overview of MIE by Region

The North American MIE market was estimated to be around $11 billion annually in 2020 with x-ray systems holding majority of the market share followed by U/S, CT, and MRI[4]. Outside of North America, the Asian/Oceanian and Western European markets are the largest buyers of MIE (Figure 1).

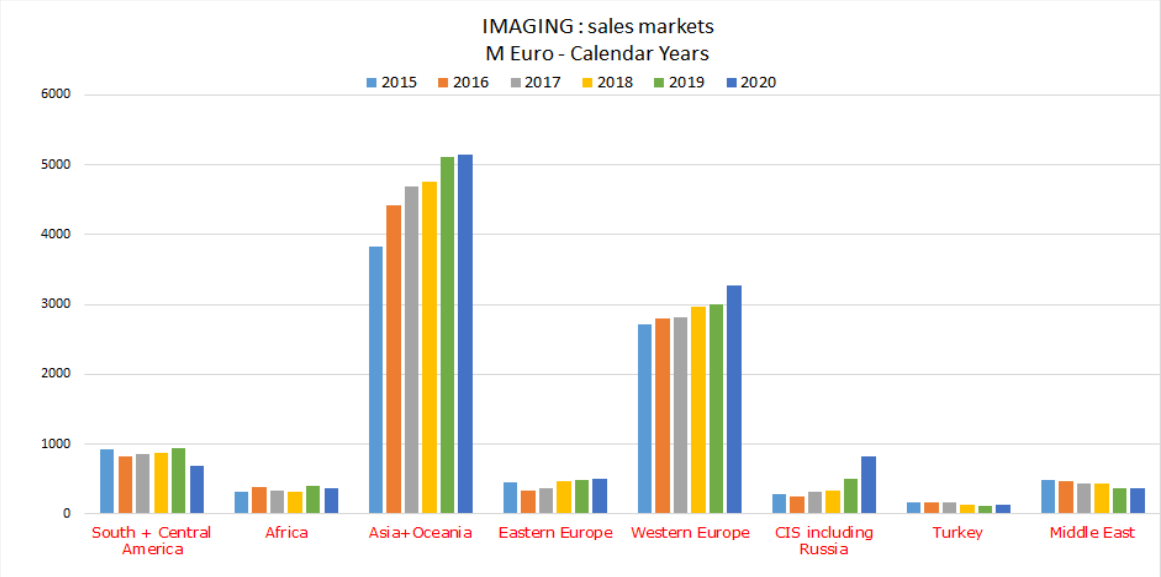
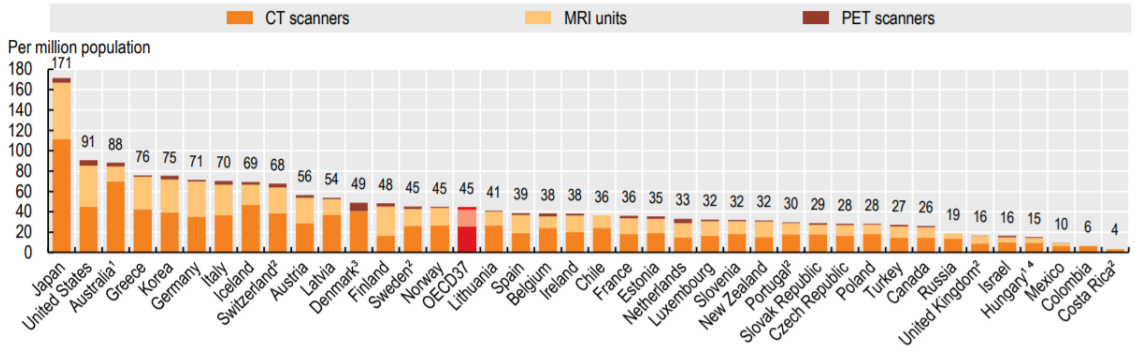


Figure 1. Medical imaging sales in million euro for non-US markets 2015-2020[5]

Although trend and unit sales information was not readily available, the World Health Organization's *Global Atlas of Medical Devices* provides extensive information about the presence and availability of medical imaging equipment globally. In the study, most countries reported that a majority of their population have at least 1 mammography, CT, and MRI unit per 1,000,000 population. Europe and the Western Pacific regions had the highest density of MIE, while Africa had the lowest density[6].

The Organisation for Economic Co-operation and Development (OECD) published information in 2021 breaking down the number of CT scanners, MRI units, and PET scanners for specific countries [7], as shown in Figure 3. Japan dominated the number of CT scanners per 1,000,000, followed by the United States, Greece, Iceland, and Denmark. Denmark also reported a high density of PET scanners. MRI scanners were most dense in Japan, the United States, Greece, Korea, and Germany.



1. Data include only equipment eligible for public reimbursement. 2. Data exclude equipment outside hospital (only for MRI units in Switzerland). 3. Data on MRI units are not available. 4. Data include only equipment outside hospitals.
Source: OECD Health Statistics 2021.

Figure 2. CT scanners, MRI units, and PET scanners, 2019 (or nearest year)[7]. CT scanners, MRI units, and PET scanners, 2019 (or nearest year)[7]

3.3. Overview of MIE Manufacturers

Historically, the medical imaging equipment industry has been dominated by a small number of companies that developed the core imaging modalities: GE Healthcare, Siemens, and Philips[8]. However, recent decades have seen a diversification of large manufacturers, particularly in the x-ray segment. Table 1 summarizes the revenue and types of product offerings by the largest medical imaging equipment manufacturers.

Table 1. Major global medical imaging manufacturers

	Modality					
Company	CT	MRI	NM	U/S	XRay	**Annual Revenue**
Agfa-Gevaert Group[9]	✔				✔	$1.93b (2020)[10][1]
Althea Group[11]	✔	✔	✔	✔		$548m[12][2]
Canon Medical Systems Corporation[13]	✔	✔	✔	✔	✔	$3.8b (2020)[14]
Carestream Health[15]					✔	$1.36b (2019)[16]
Fujifilm[17]	✔			✔	✔	$3.03b (2021)[18]
GE Healthcare[19]	✔	✔	✔	✔	✔	$17.725b (2021)[20]

[1] The radiology segment of Agfa-Gevaert's annual revenue in 2020 was $500m. [10]
[2] Althea Group is a privately held business and does not publicly release financial statements, so annual revenue information is from ZoomInfo. [12]

Company	Modality					Annual Revenue
	CT	MRI	NM	U/S	XRay	
Hologic[21]				✔	✔	$4.96b[22]
Konika Minolta[23]				✔	✔	$949m (healthcare)[23]
Koninklijke Philips[24]	✔	✔	✔	✔	✔	$9.25b[24]
Samsung Electronics[25]	✔			✔	✔	$46.7b (CE segment[3])[27]
Shenzhen Mindray Bio-Medical Electronics [28]				✔	✔	$3.3b (2020[4]) [30]
Shimadzu Corporation[31]			✔		✔	$3.54b (2021) [32][5]
Siemens Healthineers[33]	✔	✔	✔	✔	✔	$20.4b[34]

3.4 Refurbishment Market

When compared to most medical electronic devices, medical imaging products are generally large, durable, and high cost. Large, durable devices are more easily disassembled, cleaned/sterilized, and refurbished than smaller ones without creating risks to health or the functioning of the product[34]. The high-price of MIE products also makes them more cost-effective for reprocessors who can still offer high-quality products to customers at a discount[34]. Refurbished equipment prices can often be purchased at 30% - 70% of the cost of the original equipment, increasing their desirability to purchasers[37]. Expensive, durable devices are also better tracked by end users and more easily handled through manufacturer takeback programs[34]. For example, Siemens Healthineers and Philips both have active takeback and refurbishment programs for MIE[35], [36].

Globally, the market for refurbished, pre-owned, or remanufactured MIE is expected to experience strong growth of between 7% and 12.2% CAGR, rising from $10.1 billion - $11.7 billion in 2020 to around $21.4 billion in 2027[37]–[39] (Figure 3). North America is currently the largest market, followed by Europe, Asia, Central / Latin America, and Middle East[39]–[41]. In terms of modality, outside of the US, MRI makes up the largest share of the secondary market for MIE (46%), followed by CT (20%), U/S (18%), and x-ray (13%) [40].

[3] Medical equipment is part of Samsung's CE segment. [26]
[4] Medical imaging systems made up 26% of total net revenue in 2014. [29]
[5] Net sales numbers provided because revenue data is not available.

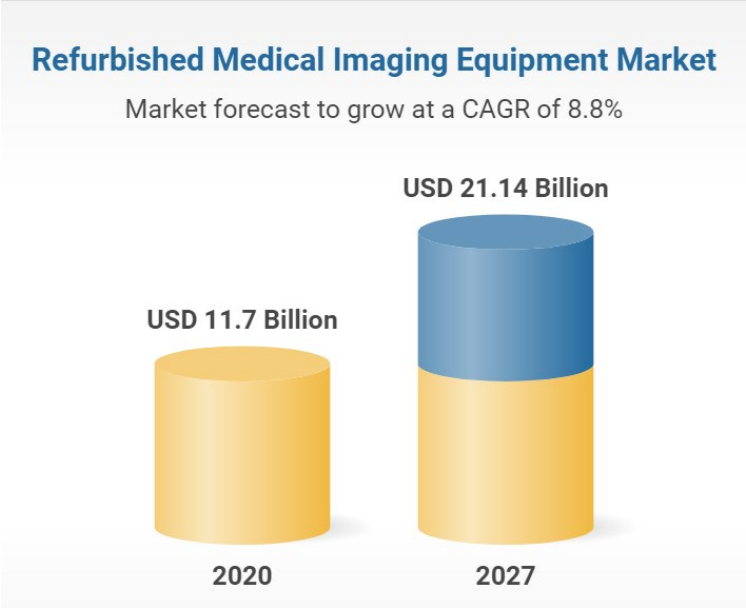


Figure 3. Refurbished Medical Imaging Equipment Market[35]

Although growth in this market is expected to be strongest in Asia and other low-income countries, some analysts expect that 40% of growth will take place in North America[38], [39]. Strong pressure to lower costs, better funding of health care providers, and the capabilities of refurbished products contribute to the continued strength of the market in North America [38], [41].

4. Components, Functionality, and Composition

4.1. Product Components and Functionality

4.1.1 Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) relies on radiofrequency and superconducting magnets to produce detailed images utilizing the natural magnetic properties of the body [36]–[38]. MRI devices run on four essential components: superconducting magnets, gradient coils, radiofrequency coils and a computer system (see Figure 4).

Superconducting magnets consist of a coil of wire that is wound on a cylindrical form within a bath of liquid helium enclosed in a device that maintains the magnets at a low temperature (cryostat). When the metals in these wires are cooled to extremely low temperatures, they enter a superconducting state, presenting no resistance to the flow of an electrical current and creating a strong magnetic field [39], [40].

Helium is used to cool the metal to achieve superconducting temperatures, which is 9.2K (-273.15°C, -443.11°F) for Niobium-titanium [37], the most widely used alloy used for super magnets [41]. Gradient coils are primarily used to spatially encode the MR signal, while radio frequency coils send RF pulses and receive signals back from the patient's body[42]. The computer system allows the control of RF and gradient pulses, data collection and processing to display the generated image[42].

To achieve its cooling performance, helium must be liquified, a process that uses large quantities of energy[39]. Superconducting joints, typically made from lead-bismuth soldered, are crucial in a superconducting magnet system to produce a stable magnetic field [37].

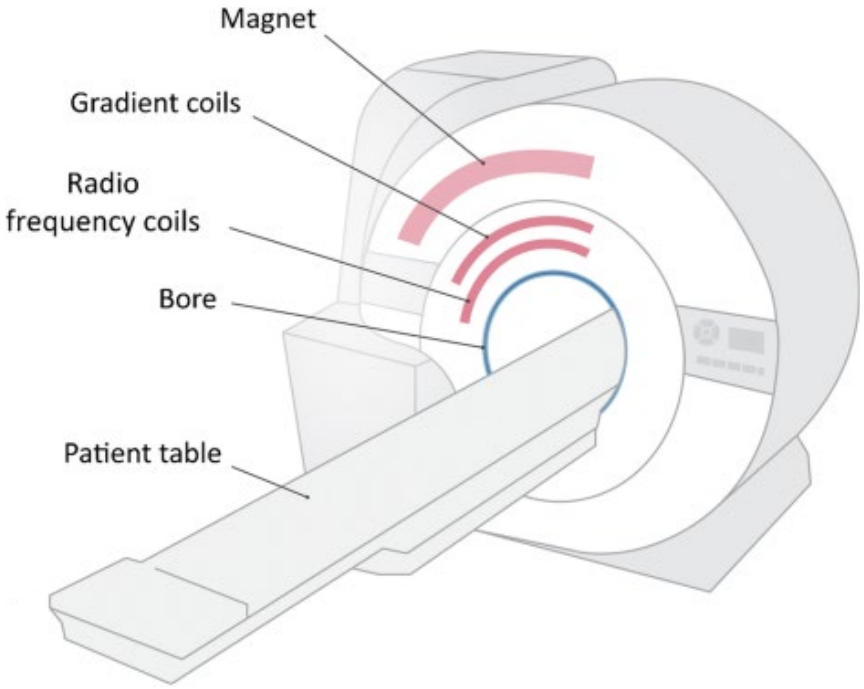


Figure 4. MRI overview[43]

4.1.2 X-ray

X-ray machines use high energy electromagnetic radiation to create a two-dimensional image of the body [5]. The main components of X-ray devices include X-ray generators and an image detection system[9], [44]. An X-ray generator system mainly consists of the tube, which includes a cathode, anode, and high voltage source to generate X-rays, and a cooling system (e.g., water or oil recirculating systems) to cool the anode (Figure 5). The image detection system includes a console that allows the technologist to regulate the tube voltage, current and exposure time[9], [44].

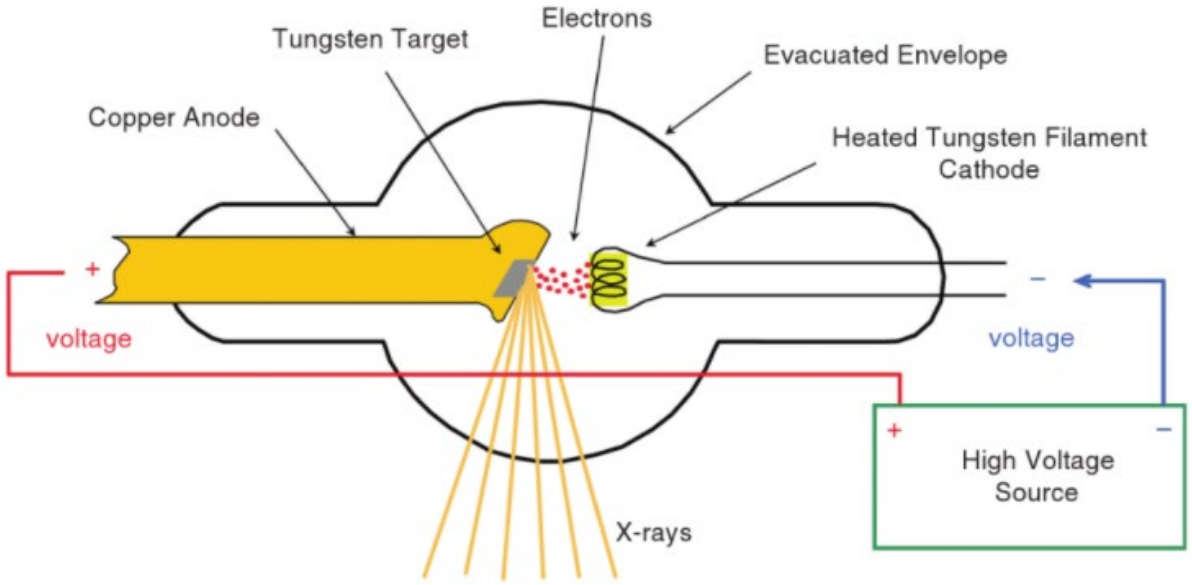


Figure 5. X-ray overview [41]

4.1.3 Computed Tomography

Unlike X-ray machines, computed tomography (CT) scanners use a rotating X-ray generator to reconstruct tomographic images of the body[45]. The main components of CT scanners include rotating X-ray tube, a gantry with a ring of X-ray sensitive detectors, and a computer (Figure 6). CT scanners work on the same principle as X-ray devices but produce 360-degree images of patient's body. To create enhanced images, CT scanners use an iodine based or critical materials based (e.g., gadolinium based) contrast medium[46]–[48].

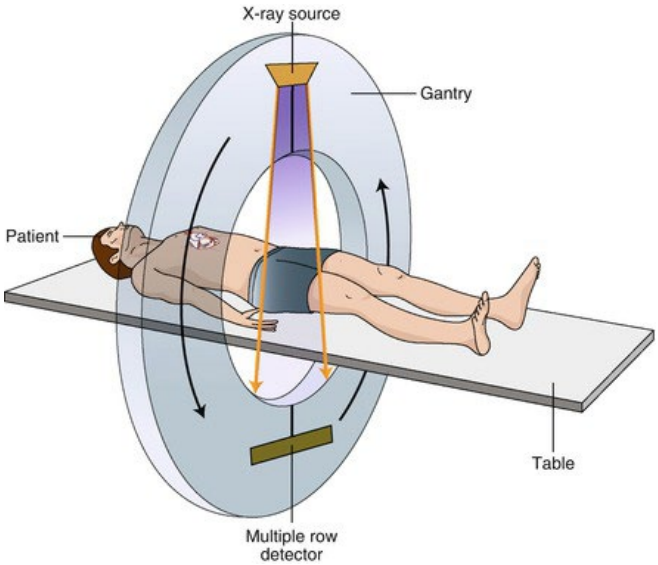


Figure 6. CT overview[49]

4.1.4 Ultrasound

U/S, as the name suggests, uses high frequency sound waves to create an image of internal body structure[50]. AU/S system consists of a transducer probe and a processing unit that includes controls and a display. The transducer probe component generates and receives sound waves using a principle called piezoelectric (pressure electricity) effect[50].The controls in the processing unit are used to manage amplitude, frequency and duration of pulses emitted by the transducer probe. The processing unit uses the waves from the transducer probe to process data and generate an image that can be viewed on the display[50].

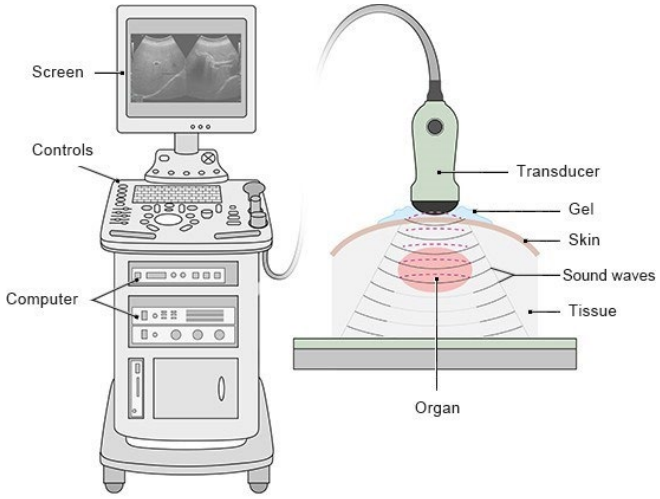


Figure 7. Ultrasound overview[51]

4.2. Equipment Material Breakdown

Table 2 summarizes the material composition of U/S, CT, and MRI systems. Medical imaging equipment mainly is comprised of metals including ferrous alloys such as steel and non-ferrous alloys (e.g., aluminum, copper, molybdenum) contributing more than 70% by weight, followed by plastics (e.g., ABS, PC, PE, PP) ranging from 9% to 23% of equipment weight. Critical substances (e.g., REEs) account for nearly 6% of weight for MRI systems and <1% by weight for U/S and CT devices. While this percentage contribution of these critical substances might seem low, the number becomes significant when scaled to mass of the device. Precious metals such as gold, silver, palladium, and platinum are also observed to be present in these modalities contributing from 0.001% to 0.03% by weight. From the data analyzed from COCIR members, depending on the modality, electronic components such as printed circuit boards (PCB) account for anywhere between 0.5% to 18% of total weight of a device. LCD displays account for less than 0.5% of the total.

Table 2. Product composition of U/S[52], MRI[53], and CT[46]–[48] equipment

Product Name	Ferrous alloys, steels	Nonferrous metals and alloys	Precious metals	Other metals and semimetals	Plastics	Critical substances	Inorganic materials, ceramic	Organic substances	Other materials	Total weight (Kg)
U/S	44%	32%			18%	<1%	5%		<1%	75
CT 1	64%	22%	0.012%	0.240%	9.80%	0.46%	2.20%	0.46%	0.43%	3500
CT 2	65%	20%	0.03%	0.33%	9.19%	0.65%	1.85%	1.60%	0.99%	4400
CT 3	52%	18%	0.004%	1.20%	23%	0.88%	3.40%	0.73%	0.38%	2190
MRI	45%	30%	0.001%	0.12%	14.40%	5.52%	3.70%	0.10%	0.96%	6195

5. Environmental Impact Analysis

5.1. Summary of Life Cycle Analyses

Environmental product declarations, data from COCIR members and publicly available environmental life cycle assessments of medical imaging devices were reviewed for this report. Very few LCAs were available, and most were limited in scope. One recent LCA study[54] compared multiple environmental impact categories for U/S, CT, and MRI modalities in the scenario of abdominal imaging. Other available LCAs only focused on a single impact category, for example, cumulative energy demand or carbon footprint for a single modality.

The comparative life cycle analysis study on U/S, CT, and MRI focused on the environmental impacts of production and use phase as illustrated in Table 3[54]. The functional unit of this study is one abdominal examination. The production phase included energy consumed by all steps in the manufacturing of a device through machine purchase (materials, component manufacturing, assembly, and transport). The use phase included energy consumption The use phase included the energy consumed by lighting and heating, ventilation, and air conditioning in the room where the devices operated, from the time of purchase through expected end of life.

Table 3. Environmental impacts of MRI, U/S and CT equipment allocated per abdominal examination [54]

		U/S		CT		MRI	
Metric	Units	Production	Use	Production	Use	Production	Use
Global warming: air	kg of CO2 eq. gases	0.5	0.6	4	2.7	6.1	13.7
Acidification: air	kg of SO2 eq. gases	2.60E-03	4.40E-03	2.00E-02	1.90E-02	3.10E-02	1.00E-01
Human health criteria: air	kg ofPM10 eq. gases (production);kg of PM2.5 eq. gases (use)	7.80E-04	2.70E-04	6.10E-03	1.10E-03	9.40E-03	6.30E-03

		U/S		CT		MRI	
Eutrophication of air	kg of N eq	7.10E-05	0	5.30E-04	6.10E-08	8.50E-04	2.50E-07
Eutrophication of water	kg of N eq	3.40E-07	2.30E-06	2.50E-06	9.70E-06	4.10E-06	5.00E-05
Ozone depletion: air	kg of CFC-11 eq	9.10E-07	2.90E-08	3.00E-06	1.20E-07	1.10E-05	6.30E-07
Smog: air	kg of O3 eq. released	3.80E-02	3.00E-02	3.00E-01	1.00E-01	5.00E-01	7.00E-01
Ecotoxicity	kg of2,4-D emitted to continental water eq. (production); kg of 2,4-D emitted to continental soil eq.(use)	4.80E-05	5.00E-12	3.90E-04	1.10E-10	5.80E-04	7.90E-10
Human health cancer	kg of benzene emitted to urban air eq.	5.20E-04	3.80E-06	4.10E-03	1.60E-05	6.30E-03	8.20E-05
Human health: non cancer	kg of toluene emitted to urban air eq.	8.00E-01	5.10E-06	6.10E+00	2.20E-05	9.80E+00	1.10E-04

In general, MRI devices have the greatest impact on the environment compared to U/S and CT devices. This is mainly because of factors, such as product weight and product life expectancy, that drive energy consumption in both production and use phases. For the U/S and MRI devices, production phase is observed to be the greatest contributor for the impact categories evaluated excluding global warming potential (GWP) and acidification. The use phase of U/S and MRI devices is the greatest contributor to GWP and acidification. On the other hand, for the CT devices, production phase is the greatest contributor toward all environmental metrics evaluated.

Priority components and materials

Data provided by COCIR members was analyzed to identify components and materials that contribute most to the total life cycle environmental impact of MIE. Printed circuit board is the largest contributor towards the environmental impacts for all the modalities despite accounting for less than 20% of the total mass of a device. This could be attributed to the energy and water consumption during the manufacturing PCB components, circuit board, and assembly[55]. Production of components made of materials including copper, steel, molybdenum, and aluminum were observed to be second greatest contributors towards the impacts. Due to energy intensiveness of the manufacturing process, LCD displays are one of the most significant contributors toward the life cycle impact [55].

The next sections examine the LCA and other data by 3 sustainability impact areas: climate change, resource use, and chemicals of concern. When data is available, the sections highlight the materials, components, and activities within the product life cycle that contribute to the impacts. Each section concludes with strategies to mitigate the identified impacts.

5.2. Climate Change Mitigation

5.2.1. Analysis of Life Cycle Impacts

The publicly available LCA study by Martin et al. [54] shows that the use phase carbon of U/S (55%) and MRI devices (70%) is the greatest contributor to life cycle greenhouse gas emissions, and upstream carbon contributing 45% and 30%, respectively. For CT devices, upstream carbon is the greatest contributor towards life cycle greenhouse gas emissions at nearly 60%, with use phase carbon at 40%. Figure 8 summarizes the percentage contribution of upstream and use phase carbon emissions of MRI, U/S, and CT devices. Use phase carbon includes greenhouse gas emissions associated with energy consumed to run the device by a customer. Upstream carbon includes greenhouse gas emissions released from all the steps from material and component manufacturing, assembly of a final device, and transportation to the purchaser of a device.

The LCA by Martin et al. includes the energy consumption of the imaging device, as well as the HVAC and lighting systems in the room where the imaging device operates[54]. Figure 9 shows the contribution of machine components, HVAC and lighting systems to the energy consumed for 3 modalities. Machine components of a device is the largest contributor (ranging from 55% to 80%) of total use phase energy followed by HVAC and lighting components for all the three modalities studied, which is consistent with a study by Esmaeili(2016) on energy consumption [56]. For MRI, analysis has shown that one third of MRI energy consumption can be attributed to magnets and cryocoolers for constant cooling and condensation of helium gas to liquid even when the device is off[57], [58].[6] For MRI devices, the power needed to counter the electrical resistance of materials greatly exceeds the power required to refrigerate a super magnet. Without super magnets MRI imaging would be an order of magnitude more expensive [need cite].

Further, Martin et al. also observed that energy consumed from fossil fuels (>75% contribution) is the main driver of upstream carbon of all the three devices[54]. Figure 10 illustrates the contribution to greenhouse gas emissions from multiple sources of combustion emissions during upstream activities.

[6] The use of helium for cooling poses additional sustainability challenges, as it is a scare resource, once deemed critical by the EU and poses potential health risks.

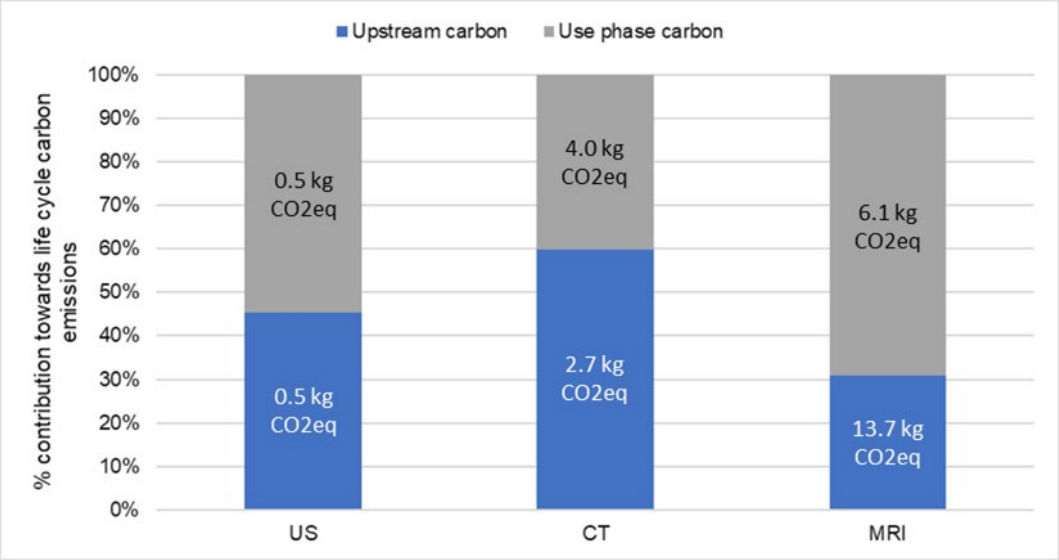


Figure 8. Percentage contribution of upstream and use phase carbon towards life cycle carbon emissions of three modalities per abdominal imaging –U/S, CT, and MRI[54]

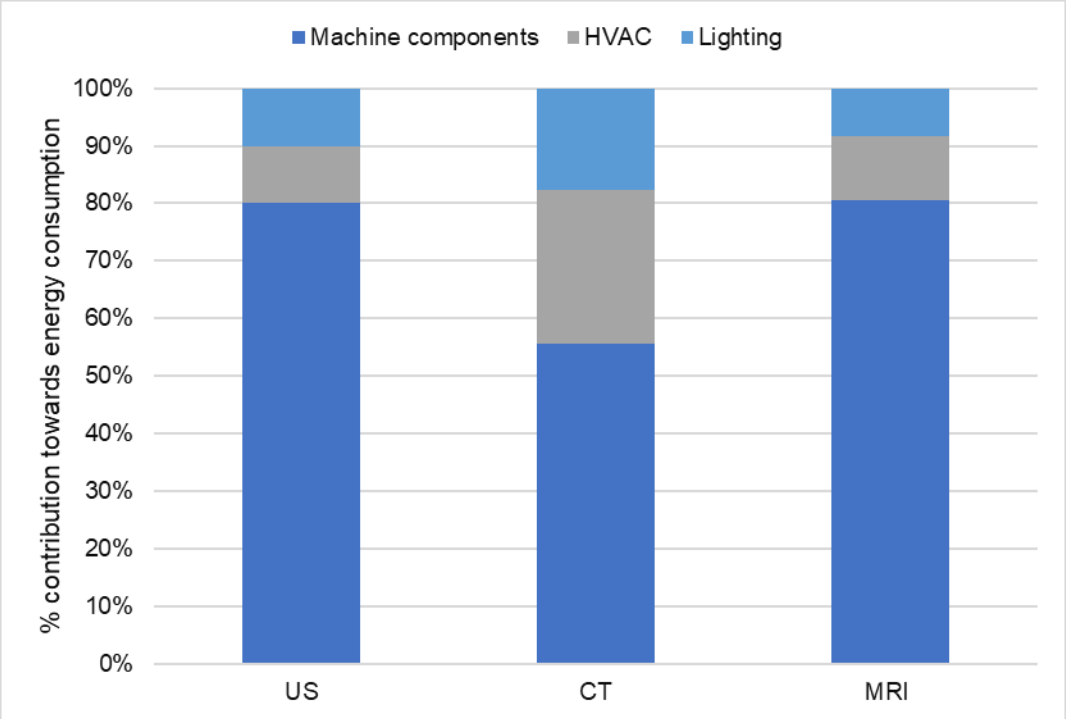


Figure 9. Percentage contribution of various factors towards use phase energy consumption per abdominal imaging using U/S, CT, and MRI[54]

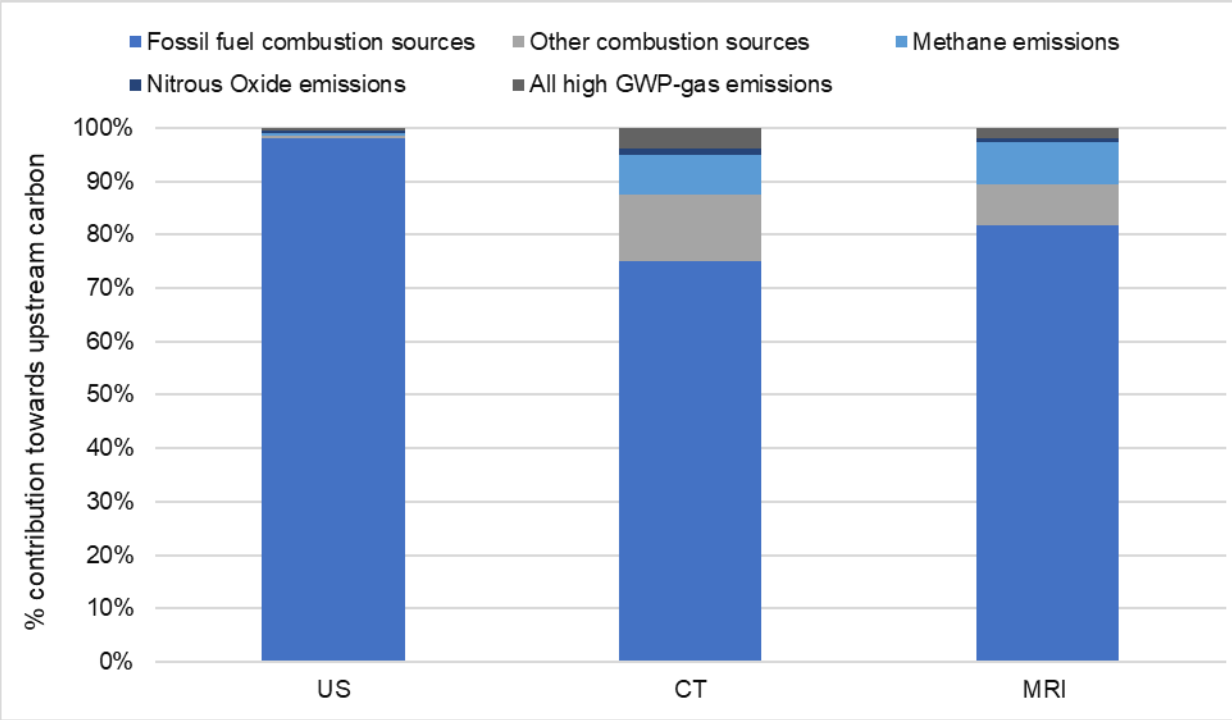


Figure 10. Percentage contribution of various sources towards upstream carbon [54]

Multiple environmental product declarations (EPDs)[46]–[48], [59] and technical report[39] were also analyzed in this report. As observed previously, energy consumption is the most significant factor, as a result, EPDs mainly focused on life cycle cumulative energy demand of medical imaging devices. Cumulative energy demand is the total primary energy required to produce, use, and dispose of a device including transportation. Figure 11 summarizes contribution of material, manufacturing, use and end of life phases to cumulative energy demand. The greenhouse gas emissions resulted from burning of sources, such as coal, natural gas, oil, biomass to produce total primary energy required (or CED) is the largest source of Global greenhouse gas emissions[60].

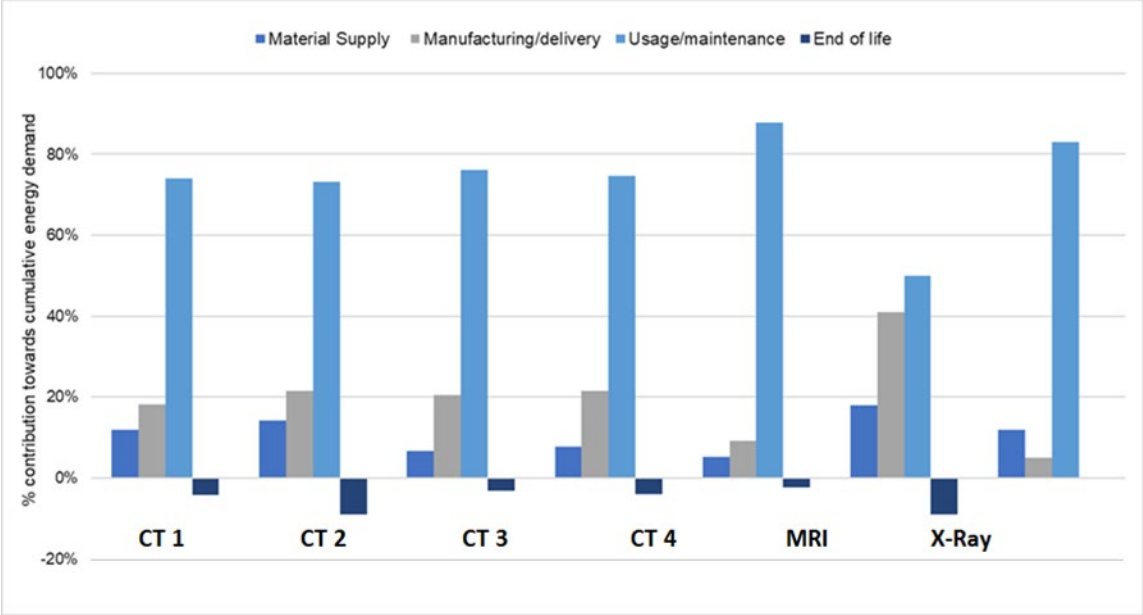


Figure 11. Percentage contribution of various life cycle activities towards cumulative energy demand for different modalities. CT[46]–[48], MRI[53], X-ray and U/S[39]

The use phase is the greatest contributor towards the life cycle cumulative energy demand. Depending on the modality, the relative contribution of use phase can range from 50% to 88% of total CED.

Except for U/S, the manufacturing of components and transportation of the device to the purchaser are the second greatest contributors, accounting from 9% to 41% depending on the modality. An imaging guided therapy equipment EPD [59] indicated that logistics accounted for nearly 5% of the total life cycle environmental impact of a device (See Figure 12). The contribution of material supply ranges from 5% to 18% of total CED. Finally, depending on the modality, equipment end-of-life can result in 2% to 9% of energy savings mainly attributed to the recovery of materials from these devices.

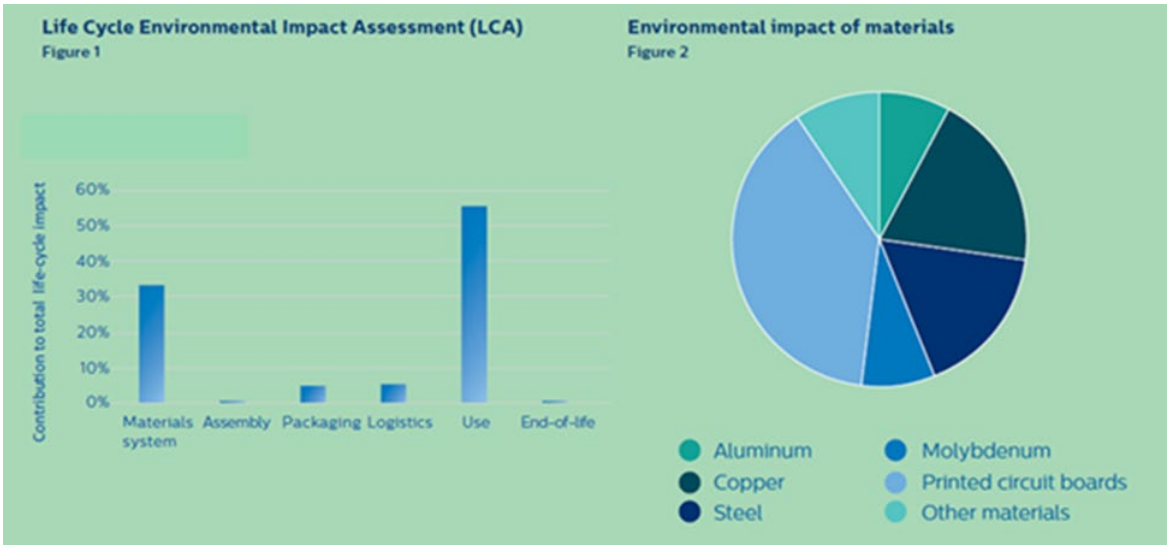


Figure 12. Contribution of life cycle phases towards the environmental impacts of an imaging guided therapy equipment. Figure also indicates the top components contributing towards materials system phase[59].

5.2.2. Mitigation Strategies

Based on the above analysis of the source of GHG/carbon emissions in the life cycle of medical imaging equipment, the following are strategies aimed at reducing the identified climate change impacts.

Product carbon footprint

Available LCA data was limited and provided mostly highly aggregated results (e.g., materials, manufacturing, use). Nonetheless, the data shows the significant contribution of upstream processing and manufacturing to total greenhouse gas emissions. Manufacturers would benefit from conducting additional LCA studies, or product carbon footprint analyses, to provide insights into which materials, components, and activities contribute to upstream carbon emissions for specific modalities, and to tailor greenhouse gas reduction strategies tailored to their supply chain.

Energy efficiency in manufacturing

Improving energy efficiency in component manufacturing could provide a significant reduction in the upstream supply chain of medical imaging equipment devices. As discussed in GEC's Climate Change Mitigation State of Sustainability Research [55], manufacturers can design energy efficiency projects based on their own requirements, or implement existing programs, such as ISO 90001 for quality management and ISO 14001 for environment management. Although not specific to medical device manufacturers, a U.S. DOE analysis found that a 4% to 5% reduction in total emissions could be achieved by integrating ISO 50001 energy management systems in manufacturing facilities [61]. Conducting a product specific LCA or product carbon footprint customized to supply chain specific data can help identify the facilities that need to be prioritized.

Use of renewable energy in manufacturing

In addition to implementing energy efficiency efforts in the upstream supply chain, the source of electricity (or grid energy mix) also plays a crucial role in increasing or decreasing GHG emissions from manufacturing facilities. Sourcing electricity generated from renewable energy sources, such as solar and hydropower, emit fewer greenhouse gases, which lowers the total carbon footprint of a product. For example, as referenced in GEC's State of Sustainability Research for Climate Change Mitigation[55], World Economic Forum estimated that 35% of GHG emissions can be reduced from electronics supply chain by using renewable energy[62].

Product energy efficiency

Reducing the energy consumed during the use phase can drive a major reduction in life cycle carbon emissions of medical imaging equipment. Power consumption of medical imaging devices is mainly driven by the mode of the devices, user behavior, and specified applications. Table 4 and Table 5 summarize the power consumption of MRI and CT modalities observed in different modes as reported by the Medical Imaging Technology Association (MITA).

The available data shows considerable energy and cost saving potential during off-mode or low-power mode. For example, COCIR conducted multiple studies in 2014 and 2015 to understand potential for energy efficiency improvements in MRI[63], CT[64], and X-ray[65]. They observed greater savings (30% to 50%) when users practice energy-saving behaviors such as turning devices to off-mode or low power mode when not in use.

COCIR analysis showed that on average, 11.200 kWh ($1650) of electricity can be saved on average per CT system per year[66], 30 MWh ($4781 euros) by MRI per year[63], and 3.45 MWh ($594) by X-ray per year [65]. While these studies state that any further savings are unlikely when it comes to efficiency improvements of these devices, GEC recommends further research and data from manufacturers to understand the potential.

Table 4. MRI energy consumption provided by MITA in 2014[67]

Mode	Average Power Consumption (kW)	Average distribution of daily energy consumption (%)
Off	9.3	34
Ready to scan	14.6	34
Scan	22.3	32

Table 5. CT energy consumption provided by MITA in 2014[67]

Mode	Typical time in mode per day (Hours)	Average energy consumption per day (kWh/d)	Estimate of % energy in use phase
Off	0	0	0%

Low power	12	12.2	25%
Idle	10.8	31.1	62%
Scan	1.2	6.1	13%

Conserving energy during use of medical imaging equipment is another approach to mitigating energy requirements. Although manufacturers may not be able to directly change user behavior, there are options for manufacturers to support energy conservation by users. A study by the National Renewable Energy Laboratory (NREL) found that users do not consistently power down medical devices or use idle modes at night when not in use[68].

A manufacturer-provided user training program could also include information on using these modes properly to lower energy consumption without degrading performance. Training or documentation provided to the user could highlight MIE energy use using the COCIR developed methodologies to measure energy consumption in each of the four modalities (MRI[69], X-ray[70], CT[71], and U/S[72]). This methodology specifically accounts for different user scenarios, protocols, parameters, and measurement procedures to allow comparison of energy consumption between different products from the same modality type.

Optimizing customer operations

In addition to reducing power consumption of a device, working with hospitals to encourage sourcing of energy from renewable sources would further help reduce overall climate change impacts of medical imaging devices.

Product transport carbon footprint

Product transport carbon emissions are influenced by a wide range of factors, including logistics, packaging weight, mode of transportation, and type of fuel source used. The first step is to conduct a detailed product life cycle assessment that can help identify the hotspots of transportation carbon emissions to help drive mitigation strategies towards these hotspot areas. Multiple tools are available for the companies to track, report, and reduce GHG emissions, improve energy and fuel efficiency, set goals, and improve overall environmental performance.

As identified in GEC Climate Change Mitigation State of Sustainability Research [55], examples of such tools include:

- Global Logistics Emissions Council (GLEC),[7]
- EPA SmartWay program,[8]
- Clean Cargo Working Group,[9]

[7] https://www.smartfreightcentre.org/en/how-to-implement-items/what-is-glec-framework/58/
[8] https://www.epa.gov/smartway
[9] https://www.clean-cargo.org/

- Green Freight Asia,[10] and
- United Nations Climate & Clean Air Coalition.[11]

5.3. Sustainable Use of Resources

5.3.1. Analysis of Life Cycle Impacts

Material supply chain impacts

As described in Section 4.2. Equipment Material Breakdown, metals including ferrous and non-ferrous alloys are the major material constituents in MIE, accounting for more than 70% of the total mass of equipment, followed by plastics accounting for 9% to 23%. Medical imaging equipment also contains critical minerals such as rare earth elements for the functioning of the device.

For example, neodymium and niobium are used in the magnets present in MRI devices. Further, critical metals are also consumed during the production of components used in MIE. For example, gadolinium oxide is used in the production of CT detector ceramics [46]–[48]. COCIR estimates that around 10 tons of niobium in EU and 40 tons globally can be recovered every year from the disposed MRI magnets[73]. Currently, there is little information that is publicly available on how many MRI magnets are sent to recycling.

Material extraction and production consume large amounts of energy and water resulting in a diverse range of sustainability impacts including climate change, water scarcity, adverse land use, ecotoxicity, and resource depletion. Material mining and refining processes also release potential toxic chemicals into the environment, polluting air, water, and land.

Production of MIE contributes nearly 99% of overall toxicity impact in the product life cycle (see Table 3). Therefore, analyzing sustainability impacts associated with materials extraction and production is essential to understand the greatest contributing materials to the environmental impacts and to identify materials at greatest supply chain risk.

To analyze these supply chain risks, additional data is needed about the types and quantities of metals used in MIE. However, for MIE, this kind of data is not readily available in the public domain. As a result, we present the summary of analysis of research summarized in GEC's State of Sustainability Research for the Sustainable Use of Resources [74]. The analysis was conducted on research related to multiple supply chain metrics of metals, including base, precious, rare-earth elements, critical elements, and hazardous elements. Findings showed that precious metals, such as gold, platinum, rhodium, and palladium have the greatest risk. This risk can be mainly attributed to low reserves and ore concentration. Additionally, critical metals such as tantalum, gallium, and REEs

[10] https://www.greenfreightasia.org/
[11] https://www.ccacoalition.org/en

are also at increased supply chain risk due to availability and concentration of ore as well as the rate at which these ores are depleting. As a result, even if these metals are in lower concentrations in a product, their contribution towards the entire life cycle of a product could be significant.

Packaging

The EPDs analyzed for this report included packaging in the scope of the life cycle analyses; however, only one EPD [59] reported the contribution of packaging (nearly 5%) relative to the entire life cycle impacts. Factors including packaging weight and material selection influence the packaging contribution towards full product life cycle impacts. In the EPDs analyzed, packaging materials and weight varied with type of medical imaging equipment. For example, packaging of U/S equipment mainly constituents of paper, carboard, plastic and wood[52]. Whereas, packaging of MRI devices mainly include steel, which is used to deliver the magnet used in MRI followed by paper, carboard, plastic and wood. [53]

End of life

Medical imaging devices are built to last 15 to 20 years. However, they are not utilized to their full potential in their first lifetime. On average, most of the MIE devices are observed to be used up to 10 years (see Table 6). This is mainly because of technological advancement and consumers (e.g., hospitals) wanting to upgrade to a newer technology to provide the best care to the people.

Table 6. References for X- ray via [75] and other products[76]

	Life Expectancy (years)			
Product	High	Mid	Low	Refurbishment Potential
U/S	9	8	7	NA
CT	12	10	8	85%
MRI	12	10	8	95%
X-ray	10	NA	8	60%
SPECT	12	10	8	NA
SPECT/CT	12	10	8	NA
PET	12	10	8	NA
PET/CT	12	10	8	NA

Opportunities to reuse, refurbish or return the used devices can extend the lifetime of the equipment. Fortunately, refurbishment is a common practice in the medical imaging industry, especially in the United States and European Union because of their high value and their design for repair and refurbishment. Nearly 75% of global refurbishment market of medical products is represented by MRI, CT, and X-ray devices[75]. Table 6 summarizes the refurbishment potential for MRI, CT, and X-ray devices.

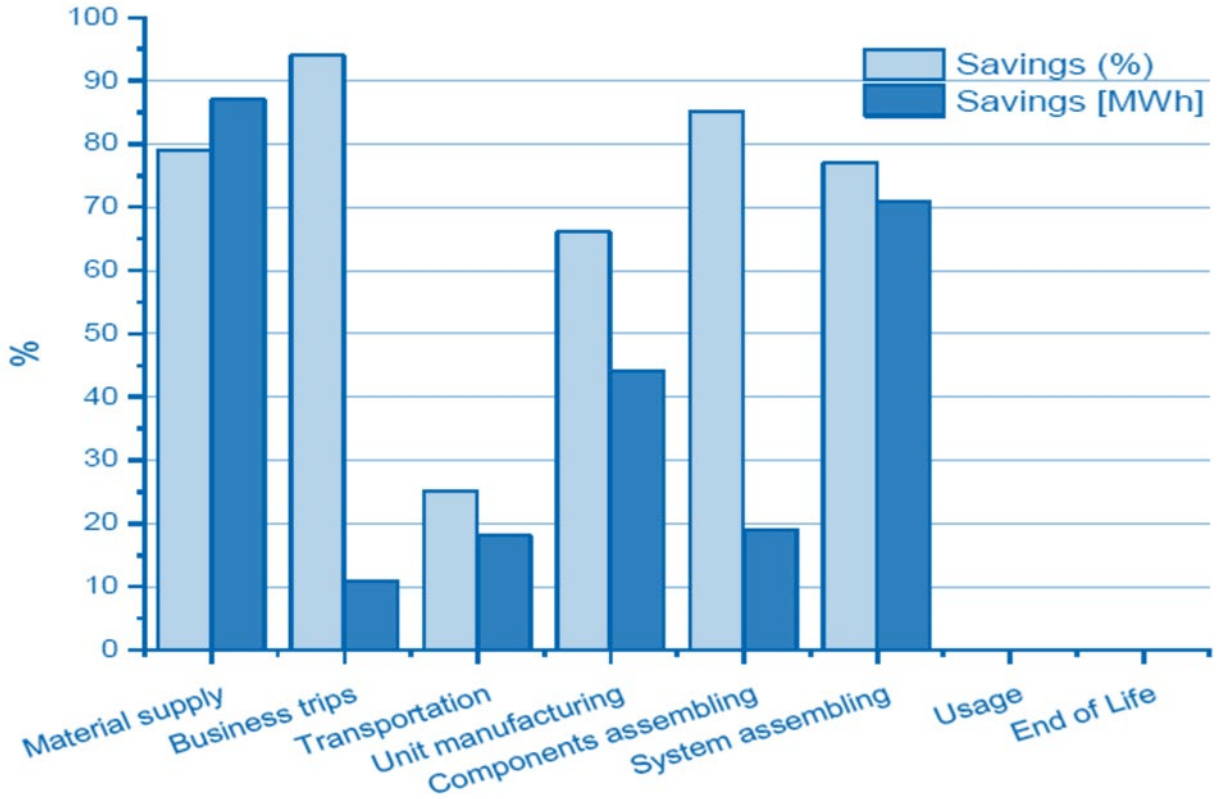


Figure 13. Comparison of energy savings (in percentage and absolute values) of refurbished and new CT devices across supply chain activities[75]

Gabriel et al. estimated cumulative energy demand of supply chain activities of a new system and refurbished CT devices. Results showed that a 32% savings can be achieved by using a refurbished device compared with a new one [75]. As illustrated in Figure 13, the savings are mainly attributed to the reduction in energy consumption in material supply, component / system assembly, transportation (including both product transport and employee business trips), and unit manufacturing [75].

While refurbishment of devices can reduce impacts associated with materials and production phases, there may be instances where energy consumption of refurbished devices during use might be higher than newer, more efficient technologies. Upgrading components of older devices during refurbishment to use newer, more efficient technologies would require regulatory approval as a new product, according to COCIR.

Given the possible energy and emissions savings associated with refurbishing devices versus those associated with newer, more efficient devices, a life cycle perspective is necessary to fully understand the impacts of various options. Currently, there is no data about these tradeoffs, so further research and analysis is required to understand the issue.

Currently, refurbishment opportunities are offered by both the original equipment manufacturers (OEMs) and third-party vendors[77]. Leading medical device manufacturing companies such as Siemens, GE and Phillips have established product take back programs enabling collection of used equipment from their users and refurbish. However, there are still barriers to refurbishing medical imaging devices, including age of the devices that are being used currently, changes in regulatory landscape as discussed in Section 5.4.2 and lack of awareness on take back programs[78], [79]. Addressing these barriers can further strengthen the refurbishment market leading to higher environmental savings.

5.3.2. Mitigation Strategies

Dematerialization and material substitution

One potential way to reduce the environmental impacts of materials in a product is to reduce the intensity of materials (dematerialization) or replacing a high impact material with a lower impact one. One example related to the medical imaging devices is reduction of gadolinium, a critical material. Over the years, with the advancement of technology, manufacturers were able to reduce the amount of gadolinium by nearly 69% needed in the production of CT detector ceramics (See Figure 14)[48].

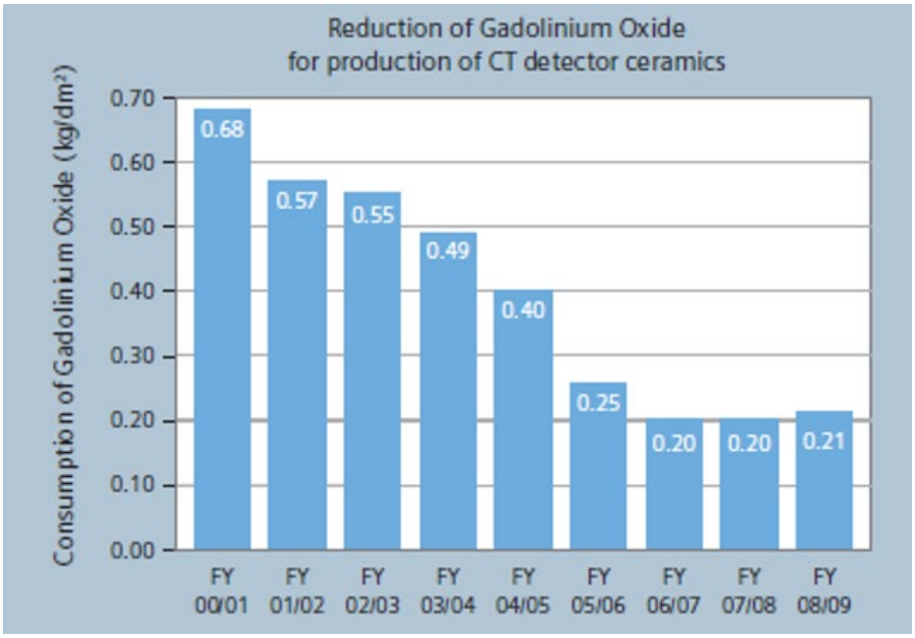


Figure 14. Consumption of gadolinium oxide over the time period of 2001 to 2009[46]

Research needs to be done to determine whether there is a possibility of implementing these product design solutions without compromising patient safety and health.

Reuse and recycling of critical substances

Using recycled critical minerals and rare earth elements reduces negative impact associated with raw material extraction and production. For example, Gabriel et al. found that reusing magnet from MRI can potentially reduce climate change impact by 73% and ozone depletion by 71% [73]. Further, incentivizing recovery and reuse of critical substances can also lead to investment in research and development and infrastructure for the responsible collection and processing of medical imaging devices. For example, Kuusakoski Recycling, Northern Europe's leading recycling services company, has developed an innovative solution to recover copper and niobium from MRI magnets [73].

Packaging

Reducing the packaging weight by eliminating unnecessary materials and improve packaging efficiency can help reduce impacts associated with packaging. However, a comprehensive life cycle approach should be taken to avoid any tradeoffs.

End of life management options

Refurbishing is aimed at keeping products in service, where feasible, as well as improving material recovery to divert products from the waste stream. Manufacturers or third-party vendors should follow the standard industry practices and ensure that the quality of refurbished devices is same as the new products.

Many manufacturers already offer a managed service or product as service business model that facilitates return, refurbishment, and recycling of medical imaging devices; however, uptake among healthcare providers is low. Manufacturers could expand efforts to educate providers about the benefits associated with this business model.

Once medical imaging devices or components reach end of life, they are treated as Electrical and Electronic Equipment (EEE) waste[77]. Manufacturers should take responsibility for recovered products and ensure they are handled by facilities that adhere to sustainability standards for processing EEE waste. These practices can ensure that valuable materials in MIE can be reused, and hazardous substances can be safely managed.

Transparent reporting of the disposition of devices including the share of equipment reused or recycled is an important metrics for understanding and improving the efficacy of a manufacturer's reuse and recycling service for medical imaging devices that have reached end of life.

5.4. Chemicals of Concern

5.4.1. Analysis of Life Cycle Impacts

"Chemicals of concern" are "chemicals which, due to their inherent hazardous properties, present a known or reasonably suspected risk to human health and/or the environment" [80]. By providing

clinicians insights into the medical conditions of their patients to better diagnose disease and improve treatment, MIE is instrumental in advancing the health of people around the world. Yet, MIE has the potential to have an additional positive impact on health when taking a life cycle perspective, by further considering opportunities to improve the wellbeing of individuals associated with its manufacturing, operation, and disposal of such devices[58]. While the health care sector works to improve the condition of patients, it often uses chemicals of concern that can harm the health of individuals and the environment.

The typical MRI is comprised of 120 thousand component parts and more than a million articles[12] [81]. MIE manufacturers source components from suppliers to assemble in end products. A small percentage of such components is made on manufacturers' design specifications, while most of the supplied articles are off-the-shelf components Identifying and prioritizing the management of chemicals of concern will require an understanding of where these chemicals are used in the supply chain.

COCIR and BOMcheck, an industry collaborative database for managing supply chain compliance to substance regulations, manage a List of Restricted and Declarable Substances for Medical Devices [82]. As of February 2022, in version (6.5) of the list, for REACH, 104 out of the current 223 Article 33 substances and 23 out of the over 76 different Article 67/Annex XVII substance restrictions—including phthalates, hazardous metals, brominated and chlorinated compounds, PAHs, and VOCs, among others—could potentially be found in materials and parts in normally supplied articles for medical devices. Additionally, of the over 900 substances on the California Safe Drinking Water and Toxic Enforcement Act of 1986 (or Proposition 65) list, 107 substances may be in MIE components, 68 of which require "safe harbour" warnings and 28 of which—largely phthalates, flame retardants, metals, and BPA—are not covered by EU RoHS, REACH or Persistent Organic Pollutants (POPs) regulations.

The following sections describe types of chemicals of known or suspected concerns with historic and current use in MIE.

Phthalate plasticizers

In MIE, and electronics in general, phthalates give polyvinyl chloride (PVC) strength and flexibility for coating cords and cables.

Common phthalates found in PVC, including diethyl hexyl phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP), are substances of high concern due to reproductive system toxicity

[12] REACH defines articles as an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition.

[83]. Ortho-phthalates, primarily those with a lower molecular weight[13], are a subset of phthalates with associated toxicity, exposure potential, and bioaccumulative ability [84].

While data is not available for all phthalates, concerns are associated with reproductive, endocrine (hormone), and nervous system toxicity [85]. Given these concerns, regulatory restrictions exist for the use of several individual phthalates (see Phthalate plasticizers below). While biomonitoring data collected in the U.S. under the National Health and Nutrition Examination Survey (NHANES) suggests exposure to these restricted phthalates has decreased since 2006, exposure to a possible alternative, diisononyl phthalate (DINP), increased between 2006 and 2014 [86].

Chlorinated and brominated flame retardants

Chlorinated and brominated flame retardants are in polymers to prevent or halt the spread of fire from device components in the event of a fault, a need for MIE including printed circuit board laminates, connectors, cables, mounts, grommets, drive belts, housing and enclosures, electronic component insulation and encapsulation, [81] power supplies, and any plastic part within proximity of a heat source [87]. Because of their exceptional stability, flame retardants typically persist in the environment, can undergo long range transport, and accumulate in the food chain [88].

More than 175 different types of flame retardants exist [89], and possible alternatives include those based on phosphorus, nitrogen (i.e., melamine), silicon, mineral, and nanometric particles [90], [91]. In terms of exposure and toxicity, two types of flame retardants are particularly concerning: polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs). Both of these chemicals are restricted for use in electronics under European Union Restriction of Hazardous Substances Directive (RoHS). Scientists from the U.S. National Institutes of Health and the International Panel on Chemical Pollution [92] note that as other chlorinated and brominated flame retardants replaced PBDEs, concerns arose regarding these chemicals, including their exposure potential [93], and persistent, bioaccumulative, carcinogenic, neurotoxicant, and endocrine disrupting properties [89], [94]. The San Antonio Statement on Brominated and Chlorinated Flame Retardants, a scientific consensus document expressing concerns for these chemicals as a class, specifically notes the potential of brominated and chlorinated chemicals to harm human health and the environment [95].

Dioxins and furans

The end of life for MIE is likely to follow the pathway of the general electronics waste stream. A common process step for the end-of-life of devices include the burning of components, changing chemicals into vapor and distributing them further distances and in greater concentrations [96].

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[13] Ortho-phthalates are phthalates produced from phthalic anhydride as a starting chemical. Other phthalates are made from different starting chemicals, such as terephthalic acid or dimethyl terephthalate. Ortho-phthalates with a low molecular weight have 3-8 carbon atoms in their chemical backbone, while those with a high molecular weight have 9-13 carbon atoms in their chemical backbone.

Poorly controlled incineration or open pit burning of plastics and additives in common for electronics and release not only the hazardous content of electronics, but also create harmful new byproducts, such as dioxins, furans, polycyclic aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs), and polychlorinated biphenyls [97], [98]. Toxic dioxins and furans and other polychlorinated biphenyls come from chlorinated and brominated compounds [99], primarily in electronic devices from flame retardants and PVC.

Concerns associated with chlorinated dioxins and furans include cancer, endocrine disruption, endometriosis, neurological damage, birth defects and impaired child development, reproductive system damage, and immune system damage [100]. Many of these various emissions, once volatilized, have the potential to travel far distances in the atmosphere, found in climates far from where these emissions occur [84], [101], [102].

Metals

The metals in MIE provide beneficial properties for which current alternatives are needed. Lead bearings are in x-ray tubes, and lead-bismuth soldered are commonly used for joints in MRI superconducting magnet system [37]. Cadmium is in and circuit boards and cadmium telluride in CT detectors [103]. Beryllium is used in x-ray filtration and for connectors, switches, springs, and clips, while beryllium oxide is integrated circuits. Specialized x-ray tubes, such as those used for mammography, employ beryllium as a metal filtration sheet to permit the transmission of low-energy photons that produce optimal images [104]. Beryllium is also used generally in electronics as an alloy for corrosion protection.

The adverse effects of metals found in electronics, including arsenic, cadmium, chromium, lead, and mercury include various forms of occupational cancers[105], as well as cardiovascular diseases, organ damage, neurologic and neurobehavioral disorders, developmental abnormalities, hematologic and immunologic disorders, diabetes, and hearing loss [106].

The extraction of metals and minerals needed for the manufacturing of electronic devices is an intensive process often involve toxic inputs and generate hazardous byproducts. Dust from metals and minerals extraction is a particular concern because of its prevalence in mining and raw materials processing combined with its association with lung diseases, such as pneumoconiosis, chronic obstructive pulmonary disease, occupational asthma, and lung cancer [107]. The impacts of metals that are toxic on their own are worsened by dust inhalation exposure.

Bisphenols

Bisphenol A (BPA) is a monomer used in the creation of epoxy resins and polycarbonate plastics. Polycarbonate is a plastic which may be incorporated in the structure and external casing of MRI [108], while epoxies are used internally in electrical components for capacitors, diodes, and printed circuit boards, and to combine circuits and transistors [109].

BPA is also an inhibitor in PVC, part of an antioxidant in some plasticizers, a precursor, and hence potential breakdown product, for the flame retardants Tetrabromobisphenol A (TBBPA) [110] and bisphenol A diphosphate (BPADP) [111]–[113]. Residual unreacted monomers of BPA can migrate out materials, but a greater exposure concern comes from uncontrolled shredding and burning of electronic waste, which can spread BPA to air, water, and soil and be inhaled or ingested[114]–[117]. BPA has negative developmental and endocrine properties [118]–[120], possibly connected to obesity [121], [122], diabetes [123], [124], heart disease [123], [125], [126], and reproductive health issues [121], [127]–[129].

BPA is also potentially mutagenic [130]–[133], leading to hormone-dependent cancers [134]–[136]. Given concerns and restrictions regarding BPA, manufacturers often use other bisphenols, such as bisphenol-S and bisphenol-F, as a replacement. These bisphenols impart similar endocrine disrupting activity as BPA [137], speaking to the need to characterize the health hazards of any BPA replacement.

Poly- and perfluoroalkyl substances

Poly- and perfluoroalkyl substances (PFAS) are a group of thousands of chemicals [138], sometimes referred to as 'forever chemicals' due their persistence and accumulative properties [139]. Fluoropolymers, polymers that are a subset of PFAS, are in cables, liquid crystal displays, light management films in flat panel displays, lithium (Li) ion batteries, [140]. In medical devices, the fluoropolymer polytetrafluoroethylene (PTFE) is used for fittings, valves, pumps, tubing [141]. PFAS are prevalent in electronics [142], used in semiconductors as antireflective coatings, photoresists, and surfactants [140] because of their ability to withstand aggressive etching chemicals and provide purity from contaminants [143].

The most well-studied of these substances, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), termed "long-chain" PFAS for the number of fluorinated carbons, are linked to a variety of health problems, including cancers, liver disease, adverse reproductive and developmental effects, and hormone and immune system issues [139]. However, given the high persistence, accumulation potential, and hazards of the PFAS studied to date [139], [144], the need to understand PFAS as a class of chemicals is increasingly being considered by regulatory agencies, such as the U.S. Environmental Protection Agency (EPA)[14] and European Chemicals Agency (ECHA).[15]

Helium

In MRI machines, helium provides the cryogenic temperature needed to create superconducting electromagnets (see Section 5.2.1 for additional information). In the instance of an emergency

[14] https://www.epa.gov/pfas

[15] https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas

shutdown–a process known as a "quench" of the superconducting electromagnet–the liquid helium from the MRI boils off and expands rapidly [145].

In MRI systems, a quench pipe is in place to vent the helium gas outside the building. However, if the helium cannot dissipate through the pipe, it can release into the scanner room and, and although not poisonous, presents the risk of asphyxiation for the occupants of the room [145], [146]. Additionally, quench pipe placement must consider the risk of exposure, as the end of the quench pipe can release high quantities of helium, pose a severe risk of frostbite and asphyxia if someone were to be exposed [147].

5.4.2. Mitigation Strategies

Safe and sustainable-by-design

In October 2020 the European Commission published its Chemicals Strategy for Sustainability (CSS) for a Toxic-Free Environment calling for an acceleration of the safe and sustainable-by-design approach to chemicals[16] [57]. This marks a nearly 20-year shift in the approach to chemicals management away from using controls to mitigate the potential risk of exposure to known harmful chemicals to the reduction and replacement of chemicals with inherit hazard characteristics, and an assumption of hazards for chemicals with insufficient data.[17] Regulatory schemes have slowly shifted away from placing responsibility on government agencies to generate chemical data on potentially hazardous chemicals towards requiring the hazard profile of chemicals be fully characterized before the chemical can enter the marketplace. While MIE manufacturers may not be responsible for the development of safer chemical alternatives, as a downstream user of chemicals, the impacts of increasing legislation, purchaser concerns, and ecolabels demands for safer products shapes the best practices for MIE chemical management.

MIE has a long history of ensuring that patients are not exposed to potentially harmful chemicals and the industry has made substantial progress in meeting a shifting regulatory landscape. However, as the organization responsible for placing the product on the market, and often designing the product, selecting materials, and engaging suppliers, manufacturers have a responsibility to consider the

[16] The European Commission defines safe and sustainable-by-design as a pre-market approach to chemicals that focuses on providing a function (or service), while avoiding volumes and chemical properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile. Overall sustainability should be ensured by minimizing the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a life cycle perspective.

[17] The precautionary principle encourages protective policies, where acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures against serious or irreversible harm to humans or the environment

potential for all possible aspects for exposure to chemicals of concern throughout the life cycle of their products.

Product substance restrictions: downstream use of chemicals of concern

Regulatory restrictions

Restricting hazardous substances provides a straightforward approach to addressing chemicals of concern, providing information to product and process designers about which substances to avoid. The baseline for chemicals management is compliance with regulations that direct the reduction, phasing out, or substitution of specific substances. Chemicals based regulations impose limits on identified substances based on hazard criteria.

The European Commission's Registration, Evaluation, Authorisation and Restriction of Chemical (REACH) is the most comprehensive chemical focused regulation based on the number of chemicals included, the types of hazards considered, as well as the impacts of alternatives assessed. REACH begins with recommendations from EU Member States ECHA for Substances of Very High Concern (SVHC), including chemicals with carcinogenic, mutagenic or toxic for reproduction (CMR), persistent, bioaccumulative, and toxic (PBT),[18] very persistent and very bioaccumulative, or endocrine disrupting chemical (EDC)[19] traits to identify and address such substances.[20] Once a substance is identified as a SVHC, manufacturers are required to communicate to purchasers about the presence of such chemicals in products[21] in concentrations above 0.1%.

As of January 2021, manufacturers communication obligations for use of SVHCs also includes reporting to the Substances of Concern In articles as such or in complex objects (Products) (SCIP) database, maintained by ECHA. On an ad-hoc basis,[22] ECHA selects priority substances from the SVHC candidate list to include in REACH Annex XIV, substances subject to authorization (REACH

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[18] CMRs have inherent properties that can cause cancer, alter DNA or damage reproductive systems, respectively. These hazards are often the basis for priority chemical regulations. PBTs are chemicals that 1) do not easily degrade, remaining in the environment (i.e., are persistent), 2) increase in concentrations in a biological organism over time, compared to the chemical's concentration in the environment, and 3) cause harmful effects to an exposed organism. PBTs include organic chemicals, such as persistent organic pollutants (POPs), as well as inorganic heavy metals. POPs are prone to atmospheric transportation by wind and water, becoming widely distributed in the environment., and given their long-range transport, and toxic properties, are a specific concern given they are "likely to cause significant adverse human health or environmental effects near to and distant from their sources," as noted by the UN Committee for Environmental Protection Convention on Long-range Transboundary Air Pollution.

[19] EDCs interfere with normal hormone function resulting in homeostatic imbalance or reproduction issues

[20] In addition to naming specific hazards, REACH allows for consideration of impacts that may have "equivalent concern" to carcinogenicity, mutagenicity, reproductive toxicity, persistence, and bioaccumulation.

[21] REACH specifies this requirement for articles, defined as an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition.

[22] REACH Annex XIV is updated approximately every two years after a process involving public consultation and review

Article 56). Manufacturers wishing to continue use of these substances after ECHA's specified sunset date must apply for authorization, a process requiring manufacturers to demonstrate that no suitable alternatives for the substance exists.[23] REACH substances subject to authorization can be restricted in full or in specific applications by determination by ECHA, ultimately included in Annex XVII, a list of REACH Article 67 restricted substances.

While the comprehensiveness of chemical-based regulations in other regions is confined by the resource availability of the regulatory bodies who conduct hazard assessments, several contain individual MIE relevant substances, not included in REACH. For instance, the U.S. Toxic Substances Control Act (TSCA) requires action to be taken to address chemicals that pose unreasonable risks to human health or the environment, and includes phenol, isopropylated phosphate (3:1), also known as PIP 3:1 or tris(4-isopropylphenyl) phosphate, a phosphorous flame retardant for PVC, high impact polystyrene (HIPS), and polycarbonate [110].

California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65) also includes hundreds of chemicals known to cause cancer or birth defects or other reproductive harm. Products sold must bear a label if the presence of one of the hundreds of chemicals listed on Proposition 65 is not within defined safety limits.

Additionally, the European Commission's regulations on medical devices (EU) 2017/745 calls for the consideration of toxicity in the selection of materials and substances in the design and manufacturing of medical devices.[24] It also bans the use of phthalates, CMR 1a/1b, and endocrine disrupting substances from parts of medical devices where exposure may arise, unless the manufacturer can provide a justification based on the methodology determined by the EC. In Canada, manufacturers of certain medical devices, including MIE, are required to inform Health Canada whether the device is manufactured from raw materials containing or derived from DEPH or BPA [148].

Problems created from ever-growing stockpiles of electronic waste spurred the creation of the European Union Restriction of Hazardous Substances Directive 2002/95/EC (RoHS) as a "start of pipe" solution to toxic waste [149]. Generally speaking, MIE have a longer expected life span and benefit from a robust secondary market for refurbished devices. While a major impetus for RoHS was

[23] Another process for application for authorization involves demonstrating that the risk of exposure is below a derived no-effect level.

[24] While the European Commission medical device regulation (EU) 2017/745 (amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC) calls for the consideration of toxicity in all relevant medical devices in Annex I, Chapter II, Section 10.1, guidance on what substances classify as toxic (CMR 1A and 1B substances and endocrine disrupting substances) only pertains to materials which have invasive contact with the patient, or any material which transports or stores fluids or gases which contact the patient.

reducing potential exposure to hazardous substances during electronics waste processing, stakeholders along the supply chain have benefited from the restriction of hazardous substances in electronics as manufacturers have successfully worked at finding innovations to replace critical chemical technologies.

Voluntary restrictions on chemicals of concern

While regulatory restrictions provide the impetus for MIE manufacturers to address chemicals of concern, regulations may not happen until years after scientific evidence demonstrates the hazardousness of a substance. Leading manufacturers extend substance management efforts to take advantage of the latest scientific information and may restrict additional priority chemicals for restriction in their own Restricted Substance Lists (RSLs).

The business drivers that may motivate these initiatives include customer demand, brand reputation, and preemptively addressing pending regulation.

In addressing the numerous challenges associated with sourcing and storing the over one thousand liters of liquid helium needed for conventional MRI scanners, several manufacturers developed alternative technologies which require less helium fully contained in a closed system. For instance, in 2018, Philips brought its Ingenia Ambition 1.5T MR scanner to market, requiring 7 liters of liquid helium for cooling [150]. In 2020 (2021 for the U.S. market), Siemens Healthineers brought its AG MAGNETOM Free.Max 0.55T MRI scanner to market, operating on 0.7 liters of liquid helium [151]. These magnet technologies reduce the health risks associated with accidental exposure to large volumes of helium as well as decreasing the use of scarce helium supply.

Effective chemical management policies require resources and leadership for continuous improvements, including organizational mission, internal champions, and organizational policy or guidelines [152]. The List of Restricted and Declarable Substances for Medical Devices managed by COCIR and BOMcheck include some voluntarily phase out substances in the industry, such as beryllium, brominated and chlorinate flame retardants, PVC, and phthalates [82].

Manufacturers have also created their own restricted or regulated substances lists. The Philips Regulated Substances List includes substances of concern, such as brominated flame retardants and PVC, deemed a priority to the manufacturer to phase out or ban before they are subject to any legal enforcement [153]. In its Green Procurement Standard, Canon includes substances targeted for reduced use [154].

The role of purchasing criteria in restricting chemicals of concern in the health care sector

Once viewed as "medical activism" [155], the goal of removing chemicals of concern from the healthcare environment by supporting the development and use of environmentally safe materials, technology, and products is increasingly a priority for many health care organizations [156]. What began as addressing specific issues related to activities in the healthcare setting, such as the use of mercury in thermometers and blood pressure devices [157], the leaching of the phthalate DEHP from

PVC devices that administer medicines or fluids into the body [158], [159] and the release of dioxins from medical waste incineration [160], [161], has expanded to comprehensive organizational procurement policies and a demand for products without chemicals of concern [162], [163].

Several standards for sustainable purchasing include criteria restricting chemicals of concern, incentivizing manufacturers to eliminate these substances to ensure that their products are eligible for procurements. Kaiser Permanente, the largest provider-owned health care organization in the U.S., restricts three categories of chemicals of concern for electronic products, shown in Table 7 [164]in their 2022 Environmentally Preferable Purchasing (EPP) Standard [165].

Table 7. Kaiser Permanente Environmentally Preferable Purchasing (EPP) standard chemical criteria relevant to electronics. Source: [164],[165]

Chemicals of concern	Restriction	Scope
Chemicals restricted in EU RoHS[25]	Cd < 0.01% All others < 0.1%	Homogenous electronic parts
Polyvinyl chloride (PVC)	< 0.1%	Homogenous materials
Bromine and chlorine-based compounds	< 0.1%	Homogenous materials for product housing

The EU 2014 GPP Criteria for Electrical and Electronic Equipment used in the Health Care Sector (Health Care EEE) calls for a chemical management system to ensure awareness of the presence of REACH Candidate List (SVHC) substances. However, a 2022 Joint Research Centre (JRC) report assessing the fitness of EU GPP criteria for four product groups notes more ambitious provisions could be the introduction of additional criteria for restrictions and the phasing out of hazardous substances that are present in Health Care EEE, including phthalates, bisphenol A (BPA) and halogenated compounds [166].

Understanding the content in products: full material disclosure

In regards to chemicals of concern in the healthcare sector, the Global Green & Healthy Hospitals, the largest sustainable healthcare network in the world, recommends [167]

[26] Examples of full material disclosure in electronics includes Seagate Technology PLC full material disclosure (FMD) system, collecting information for over 95% of chemical ingredients, Apple collecting information on 90% of product mass for their 13-inch MacBook Pro in 2020 as part of their Full Material Disclosure (FMD) initiative, HP Inc. collecting an inventory of more than 90% of the substances by weight used in 95% of HP Inc. EPEAT 2020-registered personal systems products

- Development of chemicals and materials policies and protocols to protect patient, worker, and community health and the environment, while helping drive society wide demand for alternatives.
- Address the use of chemicals of concern, including, for example, glutaraldehyde, halogenated fire retardants, PVC, DEHP and BPA, and seek safer alternatives and substitutes.
- Adopt policies that require disclosure of chemical ingredients in products and materials and seek to ensure that all ingredients have undergone at least basic toxicity testing.
- When products or materials are identified that contain Substances of Very High Concern — substances that have been identified as carcinogenic, mutagenic or toxic for reproduction, or that are persistent and bioaccumulative or warrant similar concern — hospitals should make it a high priority to replace them with safer alternatives.

Manufacturers can better prepare for and lessen their risk of supply chain interruptions and high switching costs associated with regulatory restrictions by having greater clarity into the contents of their devices to increase their agility to manage their supply chain by considering chemicals of concern. Data sharing throughout the supply chain can also improve communication and collaboration between key decision-makers to help them prioritize the innovation of safer chemicals.

The implementation of RoHS for MIE illustrates the potential benefits to manufacturers who move beyond regulatory compliance to address chemicals of concern. In general, the presence of chemicals of concern are noted as potentially problematic when considering their implications for circularity, potentially inhibiting the reuse, refurbishment and recycling of devices and their constituent parts and materials. The challenges that the presence of hazardous chemicals pose in the context of an ever-evolving regulatory landscape is well illustrated by the complexities of refurbishment of MIE devices, given the value and long lifetime of devices.

Medical devices came into the scope of RoHS in 2014, presenting several obstacles to manufacturers refurbishing or repairing devices. For instance, devices that were compliant at the time they were put on the market, may later face limitations on refurbishment or repair because there is often insufficient information about whether they containe substances covered by the newly implemented RoHS restrictions.

Obtaining information on specific substances is a straightforward task if done from the start, while investigating the potential presence of a substance with the possibly 11,000 suppliers associated with MIE after the fact requires much greater effort [168]. Manufactures have been requesting FMDs through their systems, i.e. BOMcheck since the very beginning but the response from the supply chain has been limited. Only a small percentage of declarations are FMDs [169].[]

While MIE had previously been exempted from RoHS, regulatory trends provided manufacturers with insights into potential upcoming restrictions and a lack of awareness of the presence of these

chemicals on the part of the manufacturer created additional challenges for them in achieving their business and sustainability goals. Given this challenge, having knowledge of a full inventory of content would have better prepare manufacturers to meet this required declaration.

Another aspect of the RoHS implementation was that refurbished devices sold prior to July 2016 containing newly restricted RoHS substances could only be sold again in the EU if they had initially been sold in the EU, so that the total inventory of refurbished devices could not exceed the stock that came from within the EU [168], [170], [171]. Also, while refurbished MIE devices could be sold if they meet these requirements, initially refurbished parts from devices could not if they did not comply with RoHS after July 2016, even though newly manufactured parts with the same restricted substances could be sold for repair or refurbishment [172].

Through global refurbishment practices, many of the larger medical devices are collected, refurbished and then resold to new end-users. Such practices are particularly of interest at present, in light of their contribution to the circular economy. Refurbishment prolongs the lives of products, giving added benefit to resources that have already been used, as well as to the end-users who purchase them.

According to the RoHS Directive, first-time placement on the EU market requires a device to be compliant with the substance restrictions. After this initial compliance, secondary market operations are not limited, as long as the product was compliant the first time placed on the EU market. However, in a global practice, sometimes refurbished devices are imported to the EU requiring compliance with substance restrictions that may not have been relevant at the time of production.

In some cases, parts may be harvested to be refurbished and used for the repair of other devices. When such parts are placed on the EU market, their compliance may need to be reestablished in some cases. However, refurbishment is often perceived to be a positive practice with both environmental, health, and economic benefits, and in this sense a first exemption has been granted.

Medical imaging devices are often resource intensive during the use phase, meaning that prolonging use increases the marginal benefit of resources already used. From an economic perspective, the refurbished practices allow end-users to purchase additional devices or a newer model at lower prices, allowing the provision of better services to patients. Manufacturers, who in many cases operate OEM refurbishment, do not perceive the practice as a threat to sales of new devices, as purchasing customers would usually not be able to allocate the budget needed for a new device.

In the context of the RoHS Directive, the medical device refurbishment practice is an interesting case study for learning as to aspects to be considered when developing refurbishment practices in other sub-groups of the electronics sector. Aspects shall be discussed beyond the realm of hazardous substances and their substitution, since impacts on health, on the environment and on the safety of consumers are also of importance in the context of the RoHS Directive[172].

While the implementation of policies can result in unintended consequences which possibly hinder desirable practices, manufacturers who preemptively gather information on and impose restrictions of chemicals of concern in anticipation to evolving regulation have greater agility to respond to these policies and are less vulnerable to restrictions. Given the global effort to increasingly address chemicals of concern, manufacturers will likely continue to face challenges related to the content of their products in pursuit of their other sustainability objectives.

MIE can leverage the lessons learned in the electronics industry, where full material disclosure is an evolving best practice that allows for improved management of any chemical of concern.[26] Transparency provides product designers and purchasers with the information they need to make sound choices to better manage chemicals of concern in products, creating a benchmark against which to measure progress towards safer chemical solutions [173].

While any effort aimed at transparency need to protect confidential commercial and industrial information and knowledge in accordance with laws or regulations, the United Nations Environment Programme (UNEP)'s Strategic Approach to International Chemicals Management—a mandated policy framework for international action on chemical hazards—notes that "information on chemicals relating to the health and safety of humans and the environment should not be regarded as confidential" [174].

Using Alternatives Assessment to address the issue of regrettable substitutes

Regulations restricting chemicals primarily address individual substances, so manufacturers may find the easiest path to remove a banned substance from the life cycle of electronic products is to replace it with a structurally similar one which performs the same function. Over time, however, these replacements can prove equally as problematic as the phased-out chemical, posing the same exposure risk and potential health impacts to workers, end-users, and recyclers. This phenomenon, which researchers have dubbed "regrettable substitution" results from insufficient toxicological information on replacement chemicals, a lack of readily available alternatives, as well as the cost, especially when requiring a change in industrial processes.

Most policies aimed at eliminating chemicals of concern pay little attention to potentially regrettable substitutes, as evidenced by ongoing restrictions for multiple chemicals that provide the same function. Chemsec (2019) notes that understanding the hazard properties of a new chemical is a multi-year process, creating a lag for regulators trying to understand which harmful chemicals to

[26] Examples of full material disclosure in electronics includes Seagate Technology PLC full material disclosure (FMD) system, collecting information for over 95% of chemical ingredients, Apple collecting information on 90% of product mass for their 13-inch MacBook Pro in 2020 as part of their Full Material Disclosure (FMD) initiative, HP Inc. collecting an inventory of more than 90% of the substances by weight used in 95% of HP Inc. EPEAT 2020-registered personal systems products

restrict and a cycle of replacing newly restricted substances with regrettable substitutes until they too are restricted[85].

Several organizations provide alternative assessment methodologies and will conduct alternative assessments for IT manufacturers, including:

- ChemFORWARD Chemical Hazard Assessment (CHA) [27]
- Clean Production Action GreenScreen for Safer Chemicals[28]
- Cradle to Cradle Products Innovation Institute Cradle-to-Cradle Certified™ (C2CC)[29], and
- Scivera GHS+ Chemical Hazard Assessment [30].

Each of these methodologies has a distinct assessment framework. While primarily based on the Globally Harmonized System for Classification and Labeling of Chemicals (GHS) physical and health hazards[31], the four methodologies each considers additional endpoints for assessments, with its own unique set of endpoints.

In addition to the third-party verified assessment methodologies previously mentioned, the following resources provide comprehensive frameworks for assessing safer alternatives [175], inclusive of potential adverse impacts on human health and the environment, societal impacts, performance, and cost considerations.

- National Academy of Sciences (NAS) Framework to Guide Selection of Chemical Alternatives[32],
- Interstate Chemicals Clearinghouse (IC2) Alternatives Assessment Guide[33],
- California Department of Toxic Substances Control (DTSC) Alternatives Analysis Guide[34]
- The Clean Electronics Production Network Alternatives Assessment Guide[35] and Process Chemicals Data Collection Tool[36] Organisation for Economic Cooperation and

[27] ChemFORWARD presents Cradle to Cradle Certified chemical hazard assessments and chemical rating methodology in a globally harmonized repository - https://www.chemforward.org/safer-alternatives
[28] Clean Production Action. 1310 Broadway, Suite 101, Somerville, MA 02144. www.greenscreenchemicals.org
[29] Cradle to Cradle Certified - https://www.c2ccertified.org/get-certified/product-certification
[30] Scivera, https://www.scivera.com/, acquired by Enhesa in October 2021
[31] https://www.un-ilibrary.org/content/books/9789210040839
[32] https://www.nap.edu/catalog/18872/a-framework-to-guide-selection-of-chemical-alternatives
[33] http://theic2.org/alternatives_assessment_guide#gsc.tab=0
[34] https://dtsc.ca.gov/scp/alternatives-analysis-resources/
[35] https://static1.squarespace.com/static/558b1fe4e4b00725460da07a/t/5d4c8d196544cd0001a9b0e6/1565297948283/CEPN+Alternatives+Assessment+Guide+August+2019.pdf
[36] http://www.centerforsustainabilitysolutions.org/pcdctool

Development (OECD) Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives[37]

- OECD Substitution and Alternatives Assessment Toolbox[38]

[37] https://www.oecd.org/chemicalsafety/risk-management/guidance-on-key-considerations-for-the-identification-and-selection-of-safer-chemical-alternatives.pdf
[38] http://www.oecdsaatoolbox.org/

6. Social Impacts

6.1. Description of Impacts, Considerations, and Risks

6.1.1. Corporate Social Performance

Table 8 summarizes the analysis of Corporate Social Responsibility (CSR) reports and commitments for socially and environmentally sustainable strategies of top manufacturers in the medical imaging equipment market. There is significant variation among manufactures in terms of performance and reporting. Philips, Samsung, and Shimadzu report across the full spectrum of social performance indicators, including Scope 1,2, and 3 emissions. Siemens, Canon, Fujifilm, GE, and Konika Minolta had only a single factor gap. However, Shenzen, and Althea reported very little or no information about the sustainability of their operations.

Table 8. Summary of corporate social performance measures for major MIE manufacturers

Company	Carbon Footprint Reporting	3rd Party Verified Env Impacts	CDP CC Score[176]	CDP Water Score[176]	Sustainability in Business Mgmt	Support for Sustainability R&D	DEI Program	GRI Use	SDG Use	Responsible Supply Chain	Sourcing
Agfa-Gevaert	Scope 1, 2	✔	✘	✘	✔	✔ (5.5%)	✔	✔	✔	P2PC, OCS	[10]
Althea Group	N/A	N/A	✘	✘	✘	✘	✘	✘	✘	✘	[12], [177]
Canon Medical Systems	N/A	✔	✔ (2021)	✔ (2021)	✔	✘	✔	✔ (2018)	✔	RBA, 5SGSC, RMI	[14], [178], [179]
Carestream Health	Mfg only	✔	✘	✘	✔	✔	✘	✔ (2019)	✔	RMI	[16], [180], [181]

Company	Carbon Footprint Reporting	3rd Party Verified Env Impacts	CDP CC Score[176]	CDP Water Score[176]	Sustainability in Business Mgmt	Support for Sustainability R&D	DEI Program	GRI Use	SDG Use	Responsible Supply Chain	Sourcing
FUJIFILM	Scope 1, 2	✔	✔ (2021)	✔ (2021)	✔	✔	✔ *	✔	✔	CDP, RMI, RBA	[18], [182] – [184]
GE Healthcare	Scope 1, 2	✔	✔ (2021)	✔ (2021)	✔	✔	✔	✔ (2019)	✔	RMI	[185] – [188]
Hologic Inc.	Overall emissions	✔	✔ (2021)	✕	✔	✕	✔	✔	✔	RMI	[22], [182], [189] – [191]
Konica Minolta	Scope 1	✔	✔ (2021)	✔ (2021)	✔	✕	✔ **	✔ (2018)	✔	RMI, JRMTWC, UNGC, RBA	[23], [192] – [196]
Koninklijke Phillips	Scope 1, 2, 3	✔	✔ (2021)	✔ (2021)	✔	✔	✔	✔ (2019)	✔	UNGC, RBA, RMI, EPRM, RGA	[24], [197]
Samsung Medison	Scope 1, 2, 3	✔	✔ (2021)	✔ (2021)	✔	✔	✔	✔	✔	RMI, RBA, EPRM, BSR	[26], [27]
Shenzen Mindray	✕	✕	✔ (2017)	✕	✕	✕	✕	✕	✕	✕	[29], [30]
Shimadzu Corporation	Scope 1, 2, 3	✔	✔ (2021)	✔ (2021)	✔	✔	✔	✔ (2016)	✔	RMI, GCN-J	[32], [198] – [201]
Siemens Healthineers	Scope 1, 2, 3	✔	✔ (2021)	✕	✔	✔	✔	✔ (2021)	✔	RMI	[34]

Key: * = for gender and nationality only, ** = for gender, disability, and international experience only, 5SGSC = Five-Star Green Supply Chain, EPRM = European Partnership for Responsible Minerals, GCN-J = Global Compact Network Japan, JRMTWG = JEITA Responsible Minerals Trade Working Group, P2PC = Plastics to Precious Chemicals, OCS = Operation Clean Sweep for Zero Pellet Loss, RGA = Responsible Gold Agreement

6.1.2. Supply Chain Risk

Looking at product composition by mass for MIE, electronic components may seem insignificant at only 5% of the total by weight. However, in terms of CO2eq emissions and when upstream supply chain is considered, electronic components have the most impact from a supply chain perspective. Therefore, this section focuses on the electronics component supply chain risks, which GEC recently studied [74], [202].

The supply chain for electronics creates a variety of risks from a social perspective, including forced labor, low wages, excessive worker hours, and poor working conditions [203]. These impacts appear during mining and production of raw materials, manufacturing of components, and during the end-of-life management of e-waste[202].

Working conditions and human rights

Working conditions for the electronics industry continue to be a source of risk for human rights violations[202]. China continues to dominate the electronic manufacturing market followed by Asia Pacific countries and developing markets[204], [205]. These manufacturers employ significant numbers of at risk populations such as migrant workers, child workers, student/interns, and women[206]. For example:

- Nearly one third of migrant workers in Malaysia's had been coerced into work [207].
- Chinese electronics manufacturers have been found to coerce students into irrelevant, underpaid internships in electronics factories and forced to work 10-12 hours a day, six days a week [208]
- Workers in Brazil faced widespread violations of the UN Guiding Principles and OECD Guidelines in the electronics industry; elevated risk of musculoskeletal disease, stress, or injury; and faced reprisal when attempting to unionize[209].
- Women, who comprise 60% to 90% of workers in electronics factories in Southeast Asia face risks of cancer and reproductive damage due to exposure to hazardous chemicals [210].
- 25% of global mica production originates in parts of India where child labor and hazardous working conditions are pervasive[211].

The raw material extraction and manufacturing processes for electronics components create high risk of exposure to heavy metals and toxic chemicals as described in Section 5.4.1 above, by exposure to dust, mercury, or other chemicals has been reported. Prolonged exposure to these hazardous substances can lead to serious health issues, such as cancer, respiratory illnesses, disruption of hormone systems, and infertility [212]. This risk is exacerbated in informal artisanal and small-scale mining operations [213].

Conflict minerals

Electronic components contain a variety of metals classified as conflict and/or critical raw materials, such as gold in PCBs, indium as indium tin oxide in displays, cobalt in batteries, tantalum in

capacitors on PCBs, and gallium and germanium in ICs. Approaches to managing these risks differ by region. In the United States, conflict minerals are defined as minerals extracted from specified conflict areas which are known for human rights abuses: DRC and adjoining countries.[202]

By contrast, the EU lays out a set of general governance and conflict criteria that, when met by a country or region, activates conflict mineral regulations. These EU criteria apply to areas whose natural resources are in high local, regional, or international demand and are experiencing armed conflict, suffer from weak governance, or evidence systematic violation of international law. Minerals covered under this EU regulation include cassiterite (tin), wolframite (tungsten), coltan (tantalum), and gold ore (together referred to as "3TGs").[74]

Critical minerals and critical raw materials

Both the US and the EU have identified certain minerals and raw materials as "critical." Although the definition and material specified in this category differ between the US and EU, the purpose behind each designation is to identify and reduce foreign dependence on important minerals. Both regulations direct governments to identify supply chain dependencies and enhance independence through a variety of policy, funding, or other mechanisms. Both the EU and US lists include several substances that are relevant to the electronics industry and potentially HWWEDs including cobalt, indium, gallium, germanium, lithium, rare earth elements, tantalum, and tungsten [214], [215]. Table 9 summarizes the EU and US approaches to critical minerals.

Table 9. Summary of US and EU critical minerals designations

United States	A critical mineral is "any non-fuel mineral or mineral material that is essential to the economic or national security of the United States, the supply chain of which is vulnerable to disruption ... and that serves an essential function in the manufacturing of a product ... the absence of which would have significant consequences for ... national security" [216].
European Union	Critical minerals are defined by two parameters: 1. Economic Importance. Assesses the end-use application and value of a mineral relative to the cost and performance of substitutes 2. Supply Risk. Measures the risk of a disruption of the supply of the mineral to the EU.[217]

6.2. Mitigation Strategies

6.2.1. Social Responsibility

The primary strategy for mitigating social impacts is through the implementation of strong supply chain surveillance policies and processes. The World Health Organization (WHO) and International Labor Organization (ILO) both provide international standards that assist manufacturers in identifying

and mitigating supply chain risks. Risks in the supply chain include worker health and safety, collective bargaining, discrimination, forced labor, poor wages, excessive working hours, equality of opportunity, and child labor.

The following conventions of the ILO's Declaration on Fundamental Principles and Rights at Work are considered core labor standards for mitigating these risks:

- Freedom of Association and Protection of the Right to Organize Convention, 1948 (No. 87)
- Right to Organize and Collective Bargaining Convention,1949 (No. 98)
- Forced Labor Convention, 1930 (No. 29)
- Abolition of Forced Labor Convention, 1957 (No. 105)
- Minimum Age Convention, 1973 (No. 138)
- Worst Forms of Child Labor Convention, 1999 (No. 182)
- Equal Remuneration Convention, 1951 (No. 100)
- Discrimination (Employment and Occupation) Convention, 1958 (No. 110)

6.2.2. Responsible Sourcing of Minerals

Medical imaging equipment manufacturers depend on mineral supply chains that are at high risk for human rights violations and are subject to legal and regulatory restrictions and oversight. The United States *Dodd–Frank Wall Street Reform and Consumer Protection* Act Section 1502 mandates due diligence investigation and reporting on minerals sourced from designated conflict regions such as the Democratic Republic of the Congo (DRC) by publicly traded companies that file reports with the US Securities Exchange Commission. Similarly, in Europe, Regulation 2017/821 regulates the import of minerals from high-risk regions like the DRC.

6.3. Regulation / Standardization

Table 10 summarizes the relevant regulatory frameworks and standards related to social impacts.

Table 10. Overview of relevant regulation for medical imaging equipment manufacturing from a social perspective

US	Dodd-Frank Act (Section 1502). This section, as implemented, requires companies that are publicly listed on the US stock exchanges and required to file an investor report, to conduct a "reasonable country of origin inquiry" to identify all conflict minerals in their supply chain and report on whether the minerals used in their products are not "DNC conflict-free."[218].
EU	Regulation (EU) 2017/821 of the European Parliament and of the Council of 17 May 2017 specifies supply chain due diligence obligations for importers of tin, tantalum, and tungsten; their ores; and gold originating from conflict-affected and high-risk areas that exceed a threshold amount. It is intended to regulate at least 95% of the EU's 3TG imports [219].

ILO	International Labor Standards (ILO) Declaration on Fundamental Principles and Rights at work such as those defined in the following Conventions: 1. Freedom of Association and Protection of the Right to Organize Convention, 1948 (No. 87) 2. Right to Organize and Collective Bargaining Convention,1949 (No. 98) 3. Forced Labor Convention, 1930 (No. 29) 4. Abolition of Forced Labor Convention, 1957 (No. 105) 5. Minimum Age Convention, 1973 (No. 138) 6. Worst Forms of Child Labor Convention, 1999 (No. 182) 7. Equal Remuneration Convention, 1951 (No. 100) 8. Discrimination (Employment and Occupation) Convention, 1958 (No. 110)

7.1 Proposed Draft Criteria

This State of Sustainability Research identified priority sustainability impacts across the life cycle of medical imaging equipment and potential mitigation strategies to address them. It serves as a scientific foundation for diverse stakeholders to understand the environmental and social impacts of these products.

Based on the above research and analysis, this section summarizes recommendations for criteria that mitigate the environmental and social impacts of these products.

Sustainability Impact Area	Mitigation Strategy	Criterion Focus
Climate Change	Conduct product carbon footprint or full LCA to identify product specific hotspots	Product, Manufacturer, Supply Chain
	Increase energy efficiency in component and manufacturing facilities to reduce upstream embodied carbon / supply chain carbon emissions	Manufacturer, Supply Chain
	Source electricity generated from renewable energy sources in component and manufacturing facilities to reduce embodied carbon	Manufacturer, Supply Chain
	Assess product transport GHG emissions and identify opportunities for reduction	Supply Chain
	Improve product energy efficiency	Product
Sustainable use of resources	Use less material (dematerialization)	Product
	Replace high impact materials with lower impact materials (not including use of recycled content)	Product
	Reuse and recycle critical substances	Product
	Design for reuse, repair, and recycling to enable product repairability	Product, Manufacturer
	Ensure that processing facilities for recycling MIE devices adhere to sustainability standards	Manufacturer
	Report on disposition of recovered products	Manufacturer
	Improve packaging efficiency	Product

Sustainability Impact Area	Mitigation Strategy	Criterion Focus
Chemicals of Concern	Reduce the use of European Union Restriction of Hazardous Substances (EU RoHS)	Product
	Restrict substance of the European Union Battery Directive	Product
	Reduce use of European Union REACH Directive Candidate List of substances of very high concern (SVHC) for Authorization	Product
	Restrict use of bromine and chlorine in plastic parts	Product
	Restrict use of Bisphenol A structural analogues in plastic parts	Product
	Reduce use of PFAS	Product
	Reduce use of Beryllium	Product
	Reduce use of Helium	Product
	Request and obtain inventory data from suppliers	Product, Manufacturer, Supply Chain
	Evaluate priority chemicals of concern, such as phthalates and flame retardants, to identify and replace high hazard chemicals with safer alternatives	Product
Corporate ESG	Increase surveillance and improvement in environment, labor, and worker safety at manufacturing and supplier facilities	Supply Chain
	Responsibly source minerals	Product, Manufacturer

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