

Life Cycle Assessment of Sterilis Remediator and Hazardous Medical Waste Treatment and Disposal Methods

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References

Autoclave operational data is derived from literature: Chantelle Rizan, Mahmood F. Bhutta, Malcom Reed, Rob Lillywhite, The carbon footprint of waste streams in a UK hospital, Journal of Cleaner Production, Volume 286, 2021, 125446, ISSN 0959-6526, <https://doi.org/10.1016/j.jclepro.2020.125446>

Cumulative energy demand v1.11 was used to calculate total energy demand.

DATASMART is a life cycle inventory package developed and maintained by Long Trail Sustainability to be a more accurate representation of US operations. DATASMART data can be identified by “US – EI” at the end of the process name and has been used for US energy grids and truck transport. More information is available here <https://longtrailsustainability.com/software/datasmart-life-cycle-inventory/>.

Ecoinvent v3.7.1 was used to generate the LCA model and results in SimaPro 9.4. Ecoinvent data is compiled from peer reviewed life cycle assessments and peer reviewed data sets. Most ecoinvent data is collected in Sweden and Europe and represents the industry average in these countries. Select data points, such as the average energy mix, have been collected for the United States and are included in the database. Ecoinvent data is one of the most complete datasets of all life cycle databases commercially available. Ecoinvent 3.7.1 data was compiled in April 2018 and is the most recent life cycle inventory data available at the time of the analysis.

IPCC 2021 GWP 100yrs available in SimaPro 9.4 was used to calculate carbon impact.

ISO 14040:2006(E) Environmental management – life cycle assessment – principles and framework and ISO 14044:2006(E) Environmental management – life cycle assessment – requirements and guidelines are international standards that describe the framework and principles for life cycle assessment.

ISO 14067:2018(E) Greenhouse Gases - Carbon Footprint of Products - Requirements and Guidelines for Quantification is an international standard that describes the framework and principles for product carbon footprint. ISO 14067 aligns with ISO 14040 & 14044.

Medical waste incineration air emissions are derived from literature: Załuska, M., Werner-Juszczuk, A.J., Gładyszewska-Fiedoruk, K. (2022). Impact of COVID-19 Case Numbers on the Emission of Pollutants from a Medical Waste Incineration Plant. Aerosol Air Qual. Res. 22, 210399. <https://doi.org/10.4209/aaqr.210399>

SimaPro 9.4 was used to translate the life cycle inventory data provided into environmental impact. SimaPro is a commercially available life cycle assessment tool that integrates peer reviewed data and environmental impact methodologies to assist with modeling the environmental impact of a life cycle.

Executive Summary

MilliporeSigma, the Life Science business of Merck KGaA, Darmstadt, Germany in the United States and Canada, is taking initiative to help customers in healthcare, clinical, and pharmaceutical research labs to reduce their environmental impacts by addressing single-use plastic. Through its collaboration with Sterilis Solutions, MilliporeSigma offers a way to convert biohazardous waste into non-hazardous, plastic shred that has the potential to be recycled using a device called the Remediator.

MilliporeSigma enlisted Pure Strategies to complete life cycle assessments (LCA) of processing and disposing of red bag medical waste via the Remediator and other typical methods. The scope includes eight waste treatment and disposal scenarios, namely autoclave on and offsite followed by landfill and waste to energy, regulated medical waste incineration, and treatment via the Remediator followed by landfill, recycling, and waste to energy. The functional unit is twelve pounds of red bag medical waste with the waste composition representing customers' typical mix (see *Table 1. Mix of waste processed in the study* for the specific waste makeup).

The global warming potential and cumulative energy demand of the treatment + disposal scenarios are calculated for seven geographies covering the US and Europe. The goal of the study is to calculate the product carbon footprint (PCF) of operating the Remediator, compare the carbon footprint and energy demand across treatment and disposal scenarios, and understand how geography can affect scenario carbon emissions and energy demand.

Autoclave and regulated medical waste incineration (RMWI) operational and emissions data is from literature while Remediator operational data is provided by Sterilis Solutions, based on real world data. Landfill, recycling, and waste to energy incineration emissions are from ecoinvent 3.7.1, an LCA database, and the amount of energy created via waste to energy is based on the energy content of the waste mix. The emissions savings from waste to energy is based on the geography-specific carbon emissions and energy demand of the energy grid.

Avoided burden allocation is used to characterize the impact and potential benefit of recycling and waste to energy. In the recycling scenario, it is assumed that recycling waste materials offsets the production of virgin material. Specifically, the amount of polyethylene and polypropylene recycled in the waste mix receives a credit equal to the impact of producing the same mass of virgin resin. Similarly, in the waste to energy scenario, the amount of energy generated by burning the waste is assumed to offset the same amount of grid energy.

LCA results form the basis of MilliporeSigma & Sterilis Solutions' Environmental Impact Calculator Tool. The excel based tool allows the user to select their waste mix, local energy grid, and end of life treatment and disposal options from those included in the study. The Tool is used internally by both parties to estimate the impact of waste treatment + disposal scenarios. Tool results are for internal decision making only and are not to be included as part of a carbon or GHG inventory or disclosed externally.

Key findings

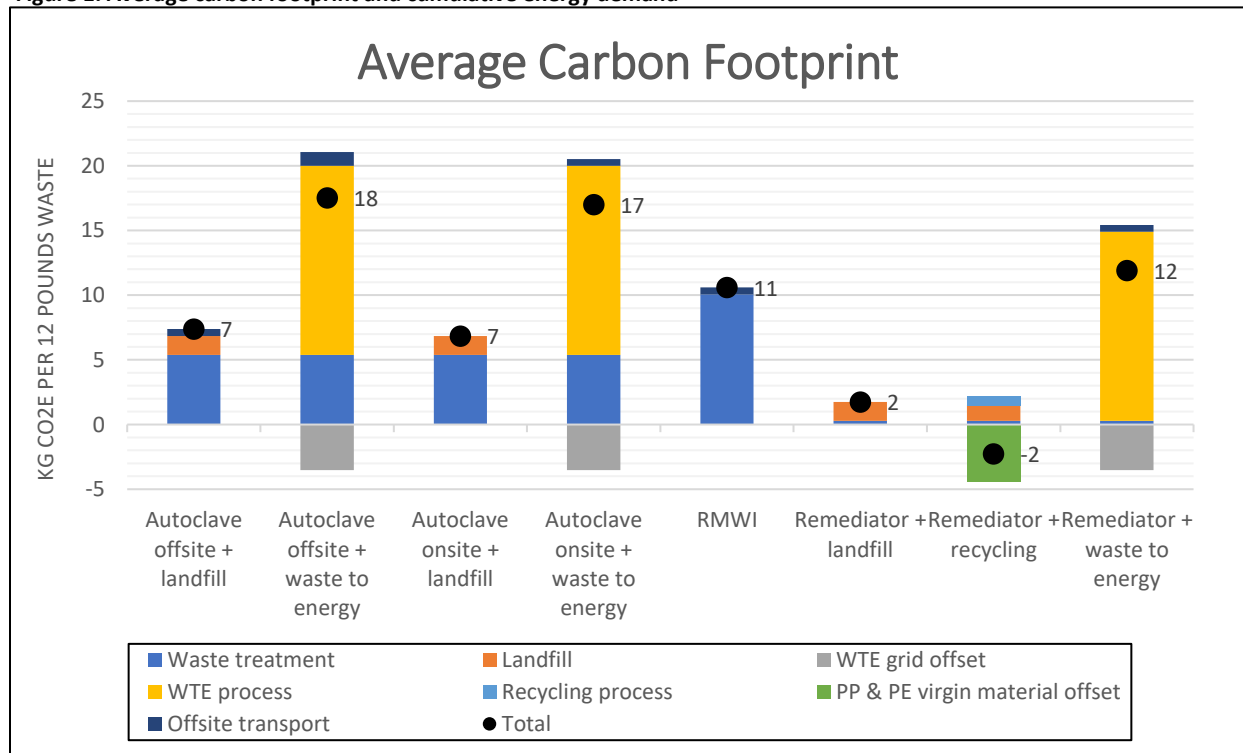
Results represent an average across all geographies unless otherwise noted.

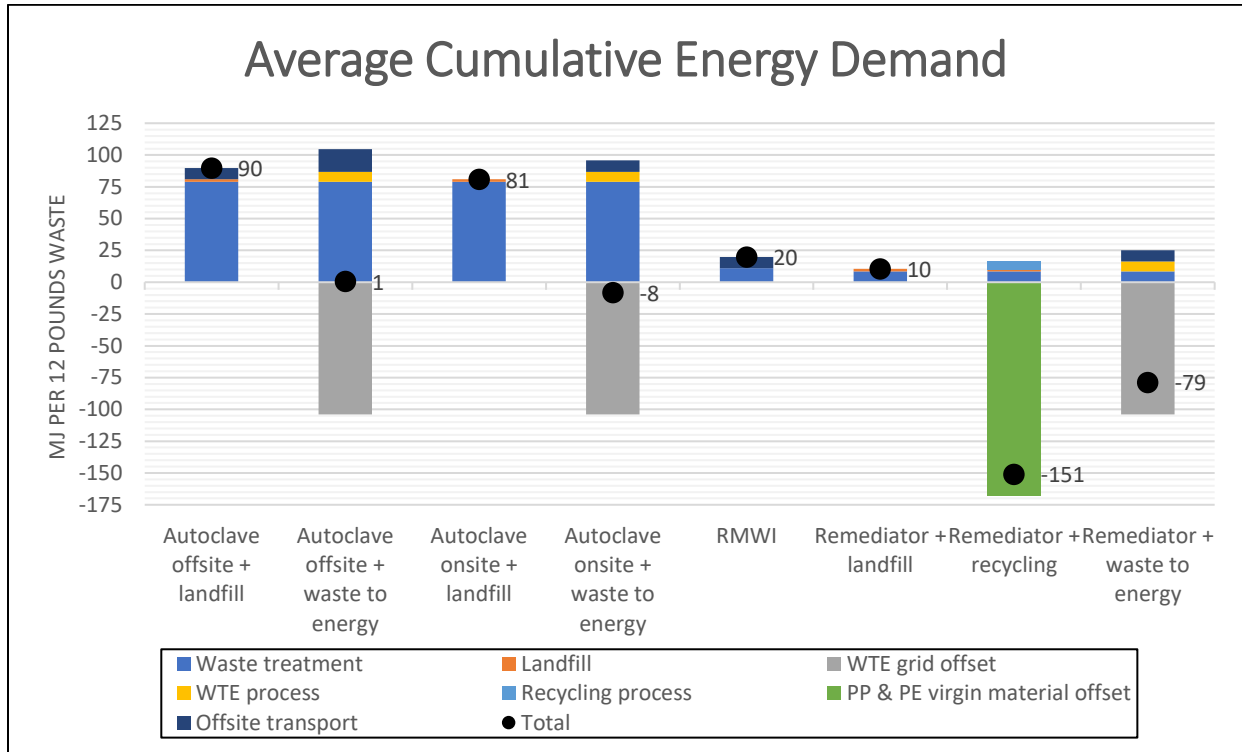
The average carbon footprint of processing waste via the Remediator is 0.3kg CO₂e per 12 pounds waste treated, or 0.05 kg CO₂ per kg waste treated. The carbon footprint is based on the mass of waste treated and the waste mix does not affect the impact of operating the Remediator. The carbon footprint varies from 0.1 to 0.5 kg CO₂e per 12 pounds waste processed based on the geography. Geographies with higher portions of fossil fuels in their grid mix, such as the UK and the US Midwest, have higher carbon footprints.

Waste treatment via the Remediator has 95% less carbon footprint and 89% less cumulative energy demand than autoclave. The difference is due to the Remediator using 95% less energy to process waste. The carbon footprint of processing waste via autoclave is 5.4 kg CO₂e per 12 pounds waste.

Processing waste via the Remediator and recycling results in a negative carbon footprint and energy savings. The carbon emissions and energy saved from using recycled polyethylene and polypropylene and avoiding the production of virgin resins is significantly more than the emissions and energy resulting from the recycling process, resulting in a net carbon and energy savings. The recycling scenario is unique, as all other waste treatment and disposal scenarios result in carbon emissions.

Figure 1. Average carbon footprint and cumulative energy demand





There are tradeoffs with waste to energy as its carbon footprint is significantly higher than landfill and recycling while saving energy by offsetting grid energy production. WTE carbon footprint is high as emissions produced from incinerating plastic are more than the emissions saved by offsetting grid energy production. WTE has significant energy savings, as the amount of grid energy offset is ten times the energy needed for incineration.

Grid mix accounts for the impact difference between geographies. WTE energy savings is higher in geographies with a fossil fuel heavy grid mix. Autoclave + landfill, RMWI, and Remediator + landfill and recycling scenarios have low variability and WTE scenarios have the highest variability among geographies. WTE in geographies with a high portion of hard coal in their grid mix (Great Britain and US Midwest) have a lower carbon footprint because the amount of grid energy offset by the WTE process has a higher reduction effect than in areas with a low carbon footprint grid mix. Geographies with a high portion of renewables (Switzerland and France) have the lowest WTE energy savings, as energy production is offsetting a low carbon emission and energy demand grid.

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1. Background

It is estimated that the life science industry produces over 5.5 million tons of plastic every year¹. Plastics are used in many medical supplies, ranging from personal protection equipment, pipettes, tubes, test kits, toxicology screening items, sharps, and others. Because medical waste is highly regulated, plastic components cannot be easily recycled. Instead, they are typically autoclaved and landfilled, burned for energy production (called waste-to-energy, or WTE), or incinerated without energy capture.

MilliporeSigma, the Life Science business of Merck KGaA, Darmstadt Germany, recognizes their responsibility to help customers in healthcare, clinical and research labs, hospitals, and pharmaceuticals to reduce their environmental impacts by addressing single use plastic.

To that end, the company committed to creating circular plastic recycling solutions that reduce the overall volume of plastic in the life science value chain. Through its collaboration with Sterilis Solutions, MilliporeSigma offers customers a way to convert biohazardous waste into non-hazardous, smaller confetti-like material that can be recycled, avoiding the impacts of autoclaving and incineration, using a device called the Remediator.

Developed by Sterilis Solutions, the Remediator is a low-profile instrument that safely sterilizes and processes red bag waste and sharps using superheated, high-pressure steam. After the mixed-material waste has been sterilized at the temperature and duration required to comply with waste regulations, the device's two-stage, rotational grinder shreds the contents into 9mm² pieces, ready to be sorted and recycled or diverted to the landfill.

Pure Strategies worked with MilliporeSigma and Sterilis Solutions to conduct a life cycle assessment of the Remediator and traditional hazardous medical waste treatment and disposal scenarios to quantify the impact of the scenarios. Three treatment methods (autoclave on and offsite, regulated medical waste incineration, and Remediator) and three disposal methods (landfill, waste to energy, and recycling) result in eight unique treatment + disposal combinations. The carbon footprint and cumulative energy demand are calculated for all eight combinations at seven geographic regions – Switzerland, Great Britain, France, Nordic countries, Midwest US, Northeast US, and Western US.

This analysis is limited to waste treatment and disposal and excludes any upstream impacts. The functional unit is twelve pounds of red bag medical waste, consisting of multiple resins, with the mix representing typical customer waste mix.

Pure Strategies calculated the carbon emissions and energy demand of the eight treatment + disposal scenarios at all seven geographies, for a total of fifty six scenarios. Carbon emissions are represented by global warming potential (GWP), expressed as kilograms carbon dioxide equivalent (kg CO₂e). Energy demand is expressed as megajoules (MJ) of energy.

¹ Urbina, M., Watts, A. & Reardon, E. Labs should cut plastic waste too. *Nature* 528, 479 (2015).
<https://doi.org/10.1038/528479c>

LCA results form the basis of MilliporeSigma & Sterilis Solutions' Environmental Impact Calculator Tool. The tool allows the user to select their waste mix, local energy grid, and end of life treatment and disposal options from those included in the study. The Tool is used internally by both parties to calculate the estimated impact of waste treatment + disposal scenarios based on location and waste composition. Calculator Tool results are for internal decision making only and not to be included as part of a carbon or GHG inventory or otherwise disclosed externally.

Life cycle assessment is a tool used to quantify the carbon impacts of a product, holistically, throughout the entire life cycle; from material extraction, manufacturing and assembly, packaging, transportation, use, and end of life. The impacts associated with the product are assessed by compiling an inventory of relevant energy and material inputs and environmental releases, evaluating the potential environmental impacts associated with identified inputs and releases, and interpreting the results to help make a more informed decision. This LCA was conducted using product specific primary data provided by Sterilis Solutions for the Remediator, literature data for autoclave and regulated medical waste incineration process inputs, and secondary material and process inputs and outputs from the ecoinvent 3.7.1 database. SimaPro 9.4 LCA software was used to model the life cycle.

The most widely recognized standardized guidelines for LCA have been developed by the International Organization of Standardization (ISO). This report contains the full LCA background, methodology, and results documentation for the Remediator as required by ISO 14040:2006(E) Environmental management – life cycle assessment – principles and framework and ISO 14044:2006(E) Environmental management – life cycle assessment – requirements and guidelines.

2. Goal

This study was prepared for MilliporeSigma and Sterilis Solutions. The overall goal of the LCA is to calculate the impacts of hazardous medical waste processed using Sterilis Solutions' Remediator and traditional methods of autoclaving, medical waste incineration, landfill, recycling, and waste to energy. Global warming potential, expressed as carbon dioxide equivalents, and cumulative energy demand, expressed as megajoules of energy, are calculated for the scenarios in the analysis.

The study aims to (1) calculate the carbon and energy impact of hazardous medical waste processing options and (2) identify hot spots with treating waste via the Remediator. The study results form the backbone of the Environmental Impact Calculator Tool, allowing users to calculate the impact of waste treatment + disposal scenarios based on their waste mix and location from those included in the study.

Product Carbon Footprint (PCF) is a tool used to quantify the global warming potential of a product throughout the entire life cycle, from material extraction, processing, transportation, and end of life. This report contains the full PCF background, methodology, and results documentation for operating the Remediator as required by *ISO 14067:2018(E) Greenhouse Gases - Carbon Footprint of Products - Requirements and Guidelines for Quantification*.

Life cycle assessment (LCA) is a tool used to quantify environmental impact of a product throughout the entire life cycle, from material extraction, manufacturing, transportation, and end of life. This life cycle assessment has been performed in accordance with *ISO 14040:2006(E) Environmental management –*

Life cycle assessment – Principles and framework and ISO 14044:2006(E) Environmental management – Life cycle assessment – Requirements and guidelines.

The practitioners are not aware of any product category rules (PCR) for waste treatment processes. Therefore, this study has not been designed to comply with any specific PCR.

This report is compliant with ISO standards 14040, 14044, and 14067, the standards for life cycle assessment and product carbon footprint and aims to objectively present results and conclusions of the PCF with transparency, outlining the methodology, assumptions, and limitations accordingly. The PCF of hazardous waste treatment and disposal methods and the Remediator is intended to be used by Millipore Sigma and Sterilis Solutions for business purposes and customer communication, in alignment with ISO 14026 Environmental Labels and Declarations. A product carbon footprint is one of many environmental indicators and does not reflect overall environmental preferability.

The product carbon footprints of the individual waste management and disposal processes as well as that of the Remediator are representative until significant changes in any of the processes occur or more relevant data is available that may significantly change the study results. For example, any redesign of the Remediator will require an update to the CFP as well as significant changes to energy grid mixes.

This report is intended to be disclosed business to business with Millipore Sigma and Sterilis Solutions' current and prospective customers. The report has gone through critical review both to verify the carbon and energy life cycle impacts of the Remediator and to ensure the methodology and data sources are appropriate to estimate potential impact of waste treatment and disposal scenarios in the Environmental Impact Calculator Tool. Critical review details are in *3.3 Critical review*.

3. Scope

This section defines the products included in the study, the system boundaries, and modeling methodology.

3.1.Functions and functional unit

The functional unit is twelve pounds of red bag medical waste containing eleven different materials as shown in in Table 1. Sterilis Solutions provided the material and mass of each material in 2022 as it represents a typical waste profile processed in the Sterilis Remediator. The Remediator can process up to twenty five pounds of waste. Typical red bags – biohazardous waste that has been contaminated with blood or other potentially infectious materials – cannot hold twenty five pounds. On average, Remediator customers are processing 12 pounds of red bag waste during a 90 minute cycle.

Eight different waste treatment and disposal scenarios are included in the study, and include combinations of autoclaving waste on and offsite, treating waste via the Remediator, traditional regulated medical waste incineration, disposing of waste via landfill, recycling, or waste to energy.

Table 1. Mix of waste processed in the study

Material	Mass (pounds)	Percent of total mass
High density polyethylene (HDPE)	1.8	15%
Polyisoprene	1.8	15%
Polypropylene (PP)	1.8	15%
Low density polyethylene (LDPE)	1.2	10%
Polycarbonate (PC)	1.2	10%
Polystyrene (PS)	1.2	10%
Polyvinyl chloride (PVC)	1.2	10%
Acrylonitrile butadiene styrene (ABS)	0.6	5%
Acrylic	0.36	3%
Silicone	0.36	3%
Miscellaneous	0.48	4%

Results are calculated for seven geographies, as shown in Table 2. Different waste treatment and disposal options are more prevalent in different areas.

Table 2. Geographic regions included in the analysis

Geographic Region	Abbreviation	Energy grid	Hard coal in grid mix	Natural gas in grid mix	Renewables & nuclear in grid mix
Switzerland	EU – CH	Electricity, medium voltage, production CH, at grid/CH	0%	0%	97%
France	EU – FR	Electricity, medium voltage, production FR, at grid/FR	4%	4%	92%
Great Britain	EU – GB	Electricity, medium voltage, production GB, at grid/GB	33%	42%	23%
NORDEL is the previous name of the Nordic regional group & covers Norway, Sweden, Finland, and eastern Denmark	EU – NORDEL	Electricity, medium voltage, production NORDEL, at grid/NORDEL	9%	6%	83%

Geographic Region	Abbreviation	Energy grid	Hard coal in grid mix	Natural gas in grid mix	Renewables & nuclear in grid mix
Midwest Reliability Organization egrid covers the midwest states - ND, SD, NE, MN, IA, northwest WI	US – MRO	Electricity, medium voltage, at grid, NERC, MRO/US US-EI	36%	22%	42%
Northeast Power Coordinating Council, Inc egrid - covers NY & New England	US – NPCC	Electricity, medium voltage, at grid, NERC, NPCC/US US-EI	0%	42%	57%
Western Electricity Coordinating Council egrid covers the western states – CA, OR, WA, ID, MT, WY, NV, UT, AZ, NM, CO	US – WECC	Electricity, medium voltage, at grid, NERC, WECC/US US-EI	20%	32%	47%

3.2. System boundary

The study is waste processing to grave and the system boundary includes processing the waste, transporting waste offsite for processing (for “offsite” scenarios), transporting waste offsite for disposal (for landfill and waste to energy scenarios), and final disposal.

Additional information on the specific boundaries for each scenario is included in section 5. Scenario life cycle inventories.

3.3. Critical review

This life cycle assessment has been performed in accordance with ISO 14040 and 14044 standards for life cycle assessment and ISO 14067 for Product Carbon Footprint.

A critical review of this report was chaired by Nathan Ayer, EarthShift Global and carried out by Nathan and two additional panelists:

- Cassandra Thiel, PhD, Clinically Sustainable Consulting; Cassandra has extensive experience performing LCAs for healthcare and medicine, including waste
- Terrie Boguski, President at Harmony Environmental, LLC; Terrie is experienced in conducting and reviewing LCAs

The panel was provide with all required information used in this analysis. The letter of compliance is in Appendix D: Critical Review Statement and all panel comments are in Appendix E: Critical Review Comments and Responses. None of the reviewers are affiliated with or endorse products included in this study.

3.4. Limitations

As with any LCA, there are limitations on how the results should be used. Results should not be considered the only source of environmental information relating to a product or process. There are limits to data quality, especially for production of upstream materials, where information may vary widely.

This LCA only considers carbon footprint and cumulative energy demand. Including additional impacts with the potential to affect the environment in a different manner would enhance the study.

The life cycle impact assessment results are relative expressions and do not predict impacts on category endpoints, the exceeding of thresholds, safety margins, or risks. This LCA is only representative of red bag medical waste with the specific mix of materials stated; treated via autoclave, regulated medical waste incineration, or the Remediator; and landfilled, recycled, or waste to energy for the geographies included in the study.

At the time of the study, the most recent grid data available was used. On September 30, 2024 the UK's last coal fired station closed² and the UK's grid mix shifted to a higher portion of renewable energy. Therefore, the UK's impact is expected to mimic NORDEL or Switzerland's, as they have a higher portion of renewables.

3.5.Data uncertainty

Data for the Remediator was collected in 2022 and represents the current version of the Remediator to process twelve pounds of red bag medical waste. Inventory data for autoclave and regulated medical waste incineration is based on literature data and is expected to vary slightly, depending on size and efficiency of the systems.

A sensitivity analysis considering increases and decreases in autoclave energy use through efficiency fluctuations is included in *6.5 Sensitivity analysis*.

3.6.Assumptions

Not all data was available to complete the analysis; therefore, some assumptions and surrogate data were required. Details of assumptions are found in section 5 *Scenario life cycle inventories* and their impact on the results are discussed in section 6.5.3 *Assumptions and surrogate data*.

Table 3. LCA assumptions

Treatment/disposal method	Assumption	Reasoning
All methods	"Synthetic rubber" material used to represent polyisoprene in the waste mix	Material, landfill, and incineration data is not available for polyisoprene. Polyisoprene is a type of synthetic rubber.
Autoclave offsite, RWMI, and WTE	200km transport distance to offsite autoclave, RMWI, and WTE	Discussions with MilliporeSigma and Sterilis Solutions determined 200km to be a reasonable and realistic distance to travel to an offsite autoclave and incinerators.
WTE	Direct emissions equivalent to emissions from municipal incineration of the same materials	It is not expected that the makeup and amount of emissions from a waste to energy incinerator will differ from those of a municipal waste incinerator.
WTE	Mass burn consumption system efficiency is assumed 17.8% for all materials	Mass burn consumption system efficiency data was not available for all materials in the waste mix. It is assumed that the same efficiency would apply to all waste, regardless of waste type.

² <https://grid.iamkate.com/>

3.7.Sensitivity analysis

Sensitivity analyses were performed for the results in order to determine if data assumptions significantly impact the results. Analyses include a range of autoclave energy use, uncertainty analysis, evaluation of assumptions and surrogate data, and cut off allocation results. Detailed results of the sensitivity analyses are included in 6.5 *Sensitivity analysis*.

3.8.Cut-off criteria

The system boundary includes all life cycle stages and materials included in the scope that contribute more than 2% of impact. It is not expected that any of the excluded materials or processes will contribute significant impact.

Table 4. Data excluded from the study

Treatment/disposal method	Data excluded	Reasoning and anticipated effect on results
Autoclave, RMWI, Remediator	Waste treatment equipment itself, including any maintenance	All three devices – autoclave, incinerator, and Remediator – are expected to process thousands of pounds of waste and require minimal maintenance. It is expected that including the devices would include minimal impact across all waste treatment scenarios.
Remediator	Water end of life – 210mL direct release during operation + 140mL remains with the waste (to landfill, recycling, or WTE)	Virtually zero impact on carbon emissions and energy demand from excluding direct release; it is expected that of the water remaining with the waste, some will evaporate naturally during transport and handling, and any water remaining at the time of disposal will have little to no impact.
Landfill	Transport from waste treatment to landfill	Transport distance is expected to be minimal and significantly less than the 200km transport distance to autoclave & WTE. Transport could vary among geographies, though it is expected that transport would either be consistently less than 200km or around 200km. The 200km transport contributes 3-8% of the autoclave, RMWI, and WTE scenarios. It is expected that landfill transport is significantly less than 200km and will contribute less than 1% of landfill scenario impacts.

3.9.Allocation procedures

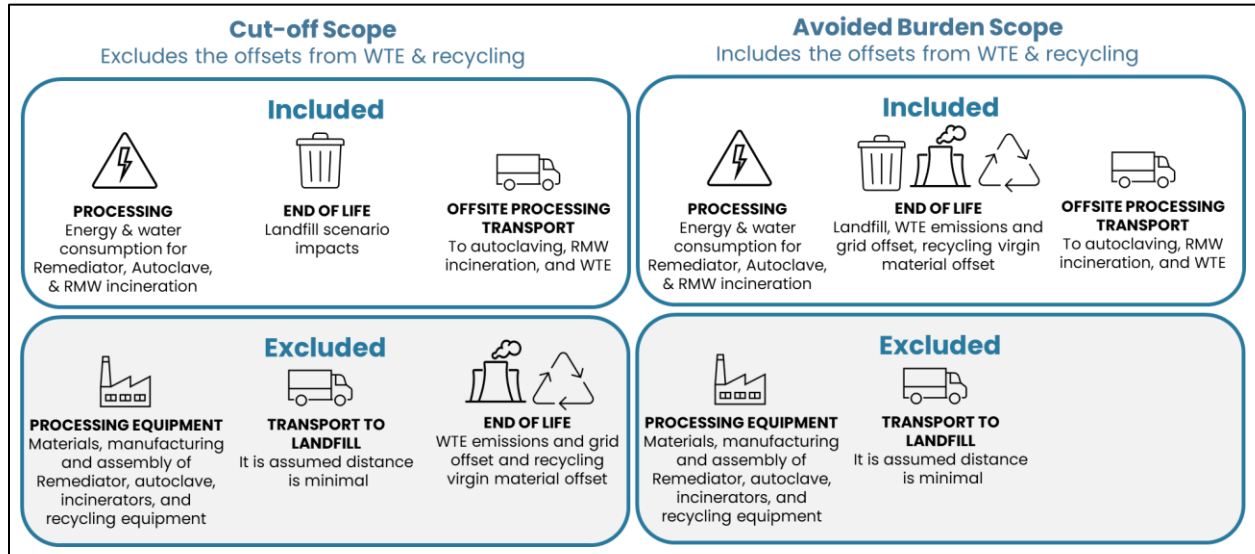
Allocation is required when a product system produces multiple products or where inputs are used across product lines and processes. Two allocation methods are used to divide impact between processes or materials.

In the cut-off method, the generator of a material sent to recycling or waste to energy receives zero impact and zero benefit at end of life. The future user of recycled materials receives the impact of collection, sorting, and pelletizing waste into usable form and the benefit of using a recycled material over virgin. Similarly, the future user of the energy generated in waste to energy receives the impact from burning the waste material and the benefit of offsetting the energy source (typically grid energy) with the waste material.

In the avoided burden method, the generator of a material sent to recycling or waste to energy receives the impact of processing that waste (collecting, sorting, and pelletizing recycled materials to get it into usable form and burning waste in waste to energy) and the benefit from the recycled

material or energy production. The benefit of the recycled material is equal to the impact of virgin material production as the recycled material is offsetting the use of virgin material. Similarly, the benefit of waste to energy is equal to the impact of the energy source that is replaced with the energy production.

Figure 2. Cut-off and avoided burden scopes for this study; Avoided Burden is the baseline study & Cut-off is used in a sensitivity analysis



In this analysis, using the cut-off method means that waste sent to recycling and waste to energy have the same end of life impacts. Millipore Sigma and Sterilis Solutions are interested in understanding the difference between the two technologies, specifically how recycling process impacts are offset by avoiding virgin resin production and how the energy generated with waste to energy offsets the incineration impacts from burning waste. While results using both the cut-off and avoided burden methods are provided, the avoided burden method is the baseline for this analysis. It is assumed that the market is underutilized and the availability of recycled material will offset the production of virgin material and the energy created in waste to energy will offset grid energy. Both Millipore Sigma and Sterilis Solutions are actively working to establish markets for the waste material. Table 5 includes the scope of all eight scenarios in the analysis.

Table 5. Scenarios and scope of the study

Abbreviation	Waste treatment + disposal	Avoided Burden impacts included	Avoided Burden credits included
ACoff+LF	Autoclave offsite + landfill	200km transport offsite to Autoclave Autoclave processing water & energy Landfilling waste after autoclaving	None
ACoff+WTE	Autoclave offsite + waste to energy	200km transport offsite to Autoclave Autoclave processing water & energy Emissions from burning waste	Amount of grid energy offset from WTE
ACon+LF	Autoclave onsite + landfill	Autoclave processing water & energy Landfilling waste after autoclaving	None
ACon+WTE	Autoclave onsite + waste to energy	Autoclave processing water & energy 200km transport offsite to WTE incinerator	Amount of grid energy offset from

Abbreviation	Waste treatment + disposal	Avoided Burden impacts included	Avoided Burden credits included
		Emissions from burning waste	WTE
RMWI	Regulated medical waste incineration	200km transport offsite to RMW incinerator Energy, water, and air emissions from burning waste	None
Rem+LF	Remediator + landfill	Remediator processing water & energy Landfilling waste after Remediator processing	None
Rem+R	Remediator + recycled	Remediator processing water & energy Energy to collect and sort all 12lbs of waste Energy, water, and waste to recycle PE and PP (assume PP & PE are recycled) Landfilling remaining non-PE & PP waste at recycler (assume remaining waste sent to landfill)	Amount of virgin plastic offset by recycling PP & PE
Rem+WTE	Remediator + waste to energy	200km transport offsite to WTE incinerator Remediator processing water & energy Emissions from burning waste	Amount of grid energy offset from WTE

3.10. Data quality

This section outlines the data quality requirements, as specified by ISO 14044 section 4.2.3.6.2.

Time related coverage

Requirement: data should be as recent as possible, and no more than 10 years old. Collected data shall represent at least one year’s worth of data.

Assessment: excellent

Time related coverage describes the age of data and the minimum length of time which data was collected. The most relevant recently available datasets are used in the analysis. It is not expected that current operations will vary significantly, if at all, from the time period of the data to now.

- The red bag medical waste proportions of material represent current customer waste profiles.
- Energy grid mix is from the ecoinvent 3.7.1 database and the newest available.
- Autoclave and RMWI operational data is from January – December 2018 actual energy and water use of a hospital based autoclave in the UK.
- RMWI direct air emissions are based on measured air emissions at a RMW incinerator from March 2020 through July 2021.
- Remediator operational energy and water demand is based on the operation of the current Remediator model.
- Landfill and recycling process data is from the ecoinvent 3.7.1 database and is the most recent available.
- Waste to energy offset is calculated using the newest version of EPA’s WARM Model, v15, November 2020.

Geographical coverage

Requirement: data should be relevant to the geographic area of study. Where geographic specific data is not available, data should be used for an area with similar technology and infrastructure.

Assessment: good

Geographical coverage describes the geographic area from which unit process data is collected for the study. While data is from European and US sources, it is expected that operations in those regions are representative of the other as treatment and disposal scenarios will operate under similar conditions; for example, the amount of energy used to autoclave waste in Europe is expected to be the same among all regions of Europe and the US.

- Geographically representative ecoinvent 3.7.1 datasets are used where available; European datasets are used when US data is not available. The most up to date country and region specific energy grid datasets are used.
- Autoclave and RMWI operational data is from one study of one UK hospital.
- RMWI direct air emissions data is from one study of a RMW incinerator in Poland.
- Remediator inputs, the amount of energy offset created with WTE, and energy required for recycling do not vary by geography; therefore the data provided is appropriate.
- Landfill waste data is not available for specific US or European regions. Therefore only two landfill waste scenarios are included; one for the US and one for Europe.

Technology coverage

Requirement: data should represent actual operations and not derived from equations or models.

Assessment: excellent

Technology coverage describes how well the data set used to develop the LCA model represents the true technological characteristics of the system. Autoclave, RMWI, and Remediator operational data are based on real world studies and data.

Completeness

Requirement: primary data should be used to represent materials and processes where possible. Ecoinvent 3.7.1 data will be used to calculate the impact of recycling, landfill, and incineration of waste materials, as this data is somewhat standardized and this study is not expected to differ substantially from those datasets.

Assessment: excellent

Completeness measures the percent of primary data collected and used for each category in a unit process. The mix of red bag medical waste is based on a typical mix generated by MilliporeSigma and Sterilis Solutions' customers. Autoclave, RMWI, and Remediator data are primary data based on real world studies of medical waste treatment by the different technologies. Ecoinvent 3.7.1 datasets are used to calculate landfill impact and the emissions of waste to energy.

Representativeness

Requirement: data should represent the geography which the operation occurs, be as recent as possible, and representative of the actual technology and systems in use.

Assessment: excellent

Representativeness is the assessment of how the data set used in the LCA model reflects the true system. All data reflects actual waste treatment and disposal scenarios during the study period and is considered representative.

Precision

Requirements: data should be as accurate as possible. For autoclave operations, it is preferred to have primary data from more than one operation, though this may not be possible, depending on the quality and representativeness of the primary data available through literature.

Assessment: cannot be measured as only one dataset is available for many data points

Precision is the measure of the variability of the data values for each data category. Precision cannot be measured as only one data set was provided for Autoclave, RMWI, and Remediator treatment methods and landfill, recycling, and waste to energy disposal methods. Sensitivity analyses consider variability in the treatment method data.

Consistency

Requirement: study methodology is applied consistently across all waste treatment and end of life techniques

Assessment: excellent

Consistency considers how uniformly the study methodology is applied to the various components of the analysis. The methodology was applied to all waste treatment and disposal consistently, in terms of modeling and assumptions.

Reproducibility

Requirement: the study is documented such that the LCA could be reproduced

Assessment: excellent

The LCA modeling has been performed and described such that this LCA could be reproduced by another LCA practitioner. This report contains all life cycle inventory data and all assumptions used to calculate the environmental impact of the waste treatment and disposal scenarios during the study period.

4. Life cycle impact assessment methodologies

This section describes the emissions included in the LCA, methodologies used to calculate emissions, and emission factor data sources.

4.1.LCA software

SimaPro 9.4 was used to translate the life cycle inventory data provided into environmental impact. SimaPro is a commercially available life cycle assessment tool that integrates peer reviewed data and environmental impact methodologies to assist with modeling the environmental impact of a life cycle.

4.2.Ecoinvent

Ecoinvent data v3.7.1 was used to generate the LCA model and results in SimaPro 9.4. The “cut off” library was used for this study. Ecoinvent data is compiled from peer reviewed life cycle assessments and peer reviewed data sets. Most ecoinvent data is collected in Sweden and Europe and represents the industry average in these countries. Select data points, such as the average energy mix, have been collected for the United States and are included in the database. Ecoinvent data is one of the most complete datasets of all life cycle databases commercially available. It is assumed that operations in Europe and the United States are world class, with similar energy usage profiles and production wastes and emissions. It is assumed that ecoinvent data is representative of European and US operations. Geographically appropriate data was used where available in the ecoinvent database. Ecoinvent 3.7.1 data was compiled in April 2018 and is the most recent life cycle inventory data available at the time of the analysis.

Ecoinvent data is maintained by the Ecoinvent Research Centre. Created in 1997, the Ecoinvent Research Centre (originally called the Swiss Centre for Life Cycle Inventories) is a Competence Centre of the Swiss Federal Institute of Technology Zürich (ETH Zurich) and Lausanne (EPF Lausanne), the Paul Scherrer Institute (PSI), the Swiss Federal Laboratories for Materials Testing and Research (Empa), and the Swiss Federal Research Station Agroscope Reckenholz-Tänikon (ART).

The following is adapted from the Swiss Centre for Life Cycle Inventories, ecoinvent Centre, Code of Practice, Data v2.0 (2007), ecoinvent report No. 2.

The ecoinvent data comprise life cycle inventory data covering energy (including oil, natural gas, hard coal, lignite, nuclear energy, hydro power, photovoltaics, solar heat, wind power, electricity mixes, bioenergy), transport, building materials, wood (European and tropical wood), renewable fibres, metals (including precious metals), chemicals (including detergents and petrochemical solvents), electronics, mechanical engineering (metals treatment and compressed air), paper and pulp, plastics, waste treatment and agricultural products. The entire system consists of about 4,000 interlinked datasets. Each dataset describes a life cycle inventory on a unit process level. The functional unit of all these unit processes is either a product or a service (whereby the product may be as large as one complete power plant manufactured for producing electricity).

Categories and subcategories are also used to describe the elementary flows. Elementary flows are identified by the flow name (e.g. “Carbon dioxide, fossil”), the category and the subcategory and

the unit. Categories describe the different environmental compartments air, water, soil and resource uses. Subcategories further distinguish subcompartments within these compartments which may be relevant for the subsequent impact assessment step. The categories "air", "water" and "soil" describe the receiving compartment and are used for (direct) pollutant emissions whereas the category "resource" is used for all kinds of resource consumption. For instance, water consumption is recorded as an input in the category/subcategory "resource/in water". Land transformation and occupation is recorded as an input in the category/subcategory "resource/land".

4.3.DATASMART

Whileecoinvent 3.7.1 has some US datasets available, they are limited. DATASMART is a life cycle inventory package developed and maintained by Long Trail Sustainability to be a more accurate representation of US operations. Where possible, European specific data is replaced with US specific data, such as energy grids, transportation modes, and commodities, so the resulting database is a better representation of US operations. DATASMART 2021 was used for the analysis as it was the most recent version available.

DATASMART data can be identified by "US – EI" at the end of the process name and has been used for US energy grids and truck transport. More information is available here <https://longtrailsustainability.com/software/datasmart-life-cycle-inventory/>.

4.4.Global warming potential (aka carbon footprint)

Millipore Sigma and Sterilis Solutions are particularly interested in global warming potential and carbon footprint data as their customers are requesting this data. Global warming potential (GWP)³ is a method to allow comparisons of global warming impacts of different greenhouse gasses using a single, common unit. GWP measures how much energy the emissions of 1 ton of a greenhouse gas (GHG) will absorb over a given period of time relevant to the emissions of 1 ton of carbon dioxide. The larger the GWP, the more that a gas warms the earth compared to CO₂. For example, methane has a GWP of 28, as it is 28 times more potent than CO₂. The terms carbon footprint and global warming potential are often used interchangeably. It is calculated by applying the GWP of each GHG emission at each stage of the life cycle to determine the GWP of each gas and then summing those GWPs. Carbon footprint and GWP are expressed as "carbon dioxide equivalent", abbreviated CO₂e. All GHGs are calculated as if released or removed at the beginning of the assessment period without taking into account an effect of delayed emissions or removals. GHG emissions associated with upstream processes, generation, transmission, distribution, and downstream processes are included, specific to electricity use, water consumption, and the offset of virgin materials by recycled plastics. All waste treatment equipment (ie. Autoclave, Remediator, incinerator, recycling equipment), including materials, manufacturing, and end of life, are excluded from the study.

³ For more information on GWP, visit the EPA's Understanding Global Warming Potentials website at <https://www.epa.gov/ghgemissions/understanding-global-warming-potentials>

The greenhouse gases included in this study are carbon dioxide (CO₂), methane (CH₄), nitrous oxide (N₂O), and fluorinated gases (refrigerants). All gases are converted into CO₂ equivalents (CO₂e) using the characterization factors outlined in the IPCC Sixth Assessment Report (AR6)⁴. These factors represent GWP which is a measure the amount of energy that 1 ton of each gas will absorb over 100 years relative to the amount that CO₂ absorbs. The GWP of each gas used in this study is in Table 6. IPCC 2021 GWP 100yrs available in SimaPro 9.4 was used to calculate carbon impact.

Table 6. GWP of greenhouse gases in the study

Gas	GWP (kg CO ₂ e/kg)
CO ₂	1
CH ₄	28
NO ₂	273

4.5.Cumulative energy demand

Cumulative energy demand (CED) v1.11 was used to calculate total energy demand. Characterization factors are given for energy resources in five impact categories: non renewable fossil; non renewable nuclear; renewable biomass; renewable wind, solar, geothermal; and renewable water. Normalization is not a part of this method and total energy demand is the sum of the five individual categories. CED is a summation of industrial energy use and does not predict impacts of energy extraction, processing, or generation.

⁴ <https://www.ipcc.ch/assessment-report/ar6/>

5. Scenario life cycle inventories

This section gives an overview of the operations included in the study, details of the processes included and excluded from the scope of the study, and the data sources.

5.1. Waste treatment: Autoclave

Autoclaving is a popular hazardous medical waste treatment process where steam under pressure is used to kill harmful bacteria and viruses. The resulting waste is non-hazardous and can be disposed of as such. Autoclaves are used to reduce the hazard level of waste so that it can be landfilled with other waste, reducing costs for waste generators.

The scope of the autoclave process includes water and energy to run the autoclave and assumes that an equivalent amount of water is sent to wastewater treatment. The autoclave equipment itself is out of scope as it will process thousands of pounds during its lifetime. Autoclave inventory data is from literature⁵, scaled based on the mass of waste processed. Representative ecoinvent 3.7.1 datasets were chosen for each inventory data point. The inventory data is from a UK hospital’s steam sterilization autoclave from January to December 2018. The exact size of the autoclave is not provided, though it is implied that it is large. The autoclave uses pressurized steam via an industrial boiler, materials are sterilized at >146C for a minimum of 2 minutes, and the steam is extracted via a vacuum pump. It is assumed that autoclaves in other geographies will operate similarly; therefore the inventory data is applicable to all geographies included in the study. Foreground data remains the same regardless of geography and background geography specific ecoinvent 3.7.1 data were used to model the inventory for each geography included in the study.

Table 7. Autoclave waste treatment inventory

Material/process	Geography	Amount	unit
Inputs			
Tap water, at user/RER U	All	10.51	kg
Electricity, medium voltage, at grid		0.407	kWh
Electricity, medium voltage, production CH, at grid/CH U	EU - CH		
Electricity, medium voltage, production FR, at grid/FR U	EU - FR		
Electricity, medium voltage, production GB, at grid/GB U	EU - GB		
Electricity, medium voltage, production NORDEL, at grid/NORDEL U	EU - NORDEL		
Electricity, medium voltage, at grid, NERC, MRO/US US-EI U	US - MRO		
Electricity, medium voltage, at grid, NERC, NPCC/US US-EI U	US - NPCC		
Electricity, medium voltage, at grid, NERC, WECC/US US-EI U	US - WECC		
Electricity, oil ⁶		5.172	kWh
Electricity, oil, at power plant/UCTE U	EU – CH, NORDEL		

⁵ See Table 3 in Chantelle Rizan, Mahmood F. Bhutta, Malcom Reed, Rob Lillywhite, The carbon footprint of waste streams in a UK hospital, Journal of Cleaner Production, Volume 286, 2021, 125446, ISSN 0959-6526, <https://doi.org/10.1016/j.jclepro.2020.125446>

⁶ Ecoinvent 3.7.1 data for “electricity, oil” is the most representative process for “gas oil” burned during the autoclave process; the units are “kWh”. Therefore, the liters of gas oil (aka red diesel or medium diesel) per ton of waste provided by literature was scaled to 12 pounds of waste and then multiplied by 10kWh/1liter diesel.

Material/process	Geography	Amount	unit
Electricity, oil, at power plant/FR U	France		
Electricity, oil, at power plant/GB U	Great Britain		
Electricity, oil, at power plant/US** US-EI U	US – MRO, NPCC, WECC		
Waste treatment			
Wastewater, unpolluted {CH} market for wastewater, unpolluted Cut-off, U	All	10.51	kg

Waste treated offsite is transported 200km prior to treatment. This distance was chosen as literature indicates it is a realistic distance to an offsite autoclave⁷. Results show transport impact is minimal.

5.2. Waste treatment: Sterilis Solutions’ Remediator

The Remediator processes regulated medical waste by exposing it to high temperature steam. During the sterilization cycle, the steam is elevated to high pressures to kill pathogens, creating a sterile environment. The sterilized material is then ground in the device, reducing waste volume by up to 80%. Shredded waste may be collected in a drawstring bag or a reusable bin, allowing easy removal and transfer to disposal. The Remediator is sized such that it is typically located at the waste generation site and transport of waste to processing is not needed.

The Remediator scope includes distilled water and electricity needed to operate the equipment. The Remediator can process 14-15 cycles per day and has 97% reliability (3% cycles are rerun). Preventative maintenance includes annual calibration and replacing HEPA filters every six months. After five years of use, the Remediator is expected to need maintenance, including replacing pumps and valves. After ten years of use, the Remediator is refurbished and reused or recycled. Impacts due to the Remediator itself, including maintenance and the device, are excluded, as the Remediator is expected to process tens of thousands of pounds of waste during its lifetime and the impact per 12lbs processed waste is expected to be insignificant.

Data represents 2022 operations and the current Remediator model. The Remediator uses 300-350ml of distilled water per cycle, depending on the input from the waste stream. A conservative 350ml is used for the analysis. Throughout a cycle, distilled water gets converted to saturated steam, depressurizes, filtered through a condensing unit, and dripped into the shredded waste itself. Sixty percent of the water used for sterilization is evaporated during the Remediator process. Direct release of 210mL of water has insignificant carbon impact and is therefore excluded from the analysis. The remaining forty percent of the water is wasted; shredded material is wet when it comes out of the Remediator. The end of life treatment of this water is also excluded, as release via landfill or incineration is not expected to have significant carbon or energy impact.

Data for distilled water is not available. It is assumed that 0.12kWh is needed to produce 1 gallon of distilled water. This additional electricity, scaled to the volume of water needed, is included in the scope.

The Remediator uses an average of 0.8kWh electricity per cycle, including run energy and idle energy. The shredder uses the most energy. Electricity use per cycle is based on testing to show compliance with the “My Green Lab” initiative to obtain the ACT (Accountability, Consistency, and Transparency)

⁷ See Table 2 in *ibid*

Label. This testing was performed over a 24hr period in December 2021. The report was provided to the LCA practitioners for review. Sterilis Solutions collects energy use data from their current customers and confirmed that the My Green Lab energy use data is aligned with the energy consumption of their customers.

Autoclave uses 0.4kWh electricity and 5.2 kWh oil to process 12 pounds of waste. In contrast to the Remediator, the autoclave uses pressurized steam generated via an industrial boiler and water is extracted via a vacuum pump. These additional steps require oil to operate.

Table 8. Remediator inventory data

Material/process	Geography	Amount	unit	
Inputs				
Tap water, at user/RER U	All	350	mL	
Electricity, medium voltage, at grid		0.8	kWh	Remediator operation
Electricity, medium voltage, at grid		0.011	kWh	Distilled water production from tap water
Electricity, medium voltage, production CH, at grid/CH U	EU - CH			
Electricity, medium voltage, production FR, at grid/FR U	EU - FR			
Electricity, medium voltage, production GB, at grid/GB U	EU - GB			
Electricity, medium voltage, production NORDEL, at grid/NORDEL U	EU - NORDEL			
Electricity, medium voltage, at grid, NERC, MRO/US US-EI U	US - MRO			
Electricity, medium voltage, at grid, NERC, NPCC/US US-EI U	US - NPCC			
Electricity, medium voltage, at grid, NERC, WECC/US US-EI U	US - WECC			

5.3. Waste treatment & disposal: Regulated medical waste incineration

Traditionally regulated medical waste is transported offsite for incineration. The scope includes electricity and water supply and treatment for the incineration process. High temperature incineration is assumed and inventory data is from literature⁸, scaled based on the mass of waste processed. Ecoinvent 3.7.1 datasets were chosen for each inventory data point.

Literature was used to model direct air emissions resulting from the regulated medical waste incineration process. A 2022 study of the emissions from a medical waste incineration plant⁹ includes monthly data from March 2020 through June 2021 for kilograms of air emissions (dust, sulfur dioxide, carbon monoxide, nitrogen oxides, hydrogen chloride, hydrogen fluoride, total organic carbon, and carbon dioxide), and mass of waste disposed. The average normalized emissions (excluding March 2020 as an outlier) was used to model direct air emissions from the process. Dust is modeled as “suspended

⁸ See Table 4 in *ibid*

⁹ See Table 1 in Załuska, M., Werner-Juszczuk, A.J., Gładyszewska-Fiedoruk, K. (2022). Impact of COVID-19 Case Numbers on the Emission of Pollutants from a Medical Waste Incineration Plant. *Aerosol Air Qual. Res.* 22, 210399. <https://doi.org/10.4209/aaqr.210399>

solids, unspecified”. Geography specific ecoinvent 3.7.1 data were used to model the inventory for each geography included in the study.

Table 9. Regulated medical waste incineration inventory

Material/process	Geography	Amount	unit
Transport to RMWI			
Transport via truck		200	km
Transport, lorry 3.5-7.5t, EURO5/RER U	EU - all	200	km
Transport, lorry 3.5-7.5t, EURO5/US- US-EI U	US - all		
Inputs			
Tap water, at user/CH U	All	0.037	m3
Electricity, medium voltage, at grid		1.064	kWh
Electricity, medium voltage, production CH, at grid/CH U	EU - CH		
Electricity, medium voltage, production FR, at grid/FR U	EU - FR		
Electricity, medium voltage, production GB, at grid/GB U	EU - GB		
Electricity, medium voltage, production NORDEL, at grid/NORDEL U	EU - NORDEL		
Electricity, medium voltage, at grid, NERC, MRO/US US-EI U	US - MRO		
Electricity, medium voltage, at grid, NERC, NPCC/US US-EI U	US - NPCC		
Electricity, medium voltage, at grid, NERC, WECC/US US-EI U	US - WECC		
Wastewater, unpolluted {CH} market for wastewater, unpolluted Cut-off, U	All	0.037	m3
Direct air emissions			
Suspended solids, unspecified	All	0.035	kg
Sulfur dioxide	All	0.560	kg
Carbon monoxide	All	1.684	kg
Nitrogen oxides	All	2.643	kg
Hydrochloric acid	All	0.177	kg
Hydrogen fluoride	All	0.003	kg
Total organic carbon	All	0.226	kg
Carbon dioxide	All	1.780	kg

Waste treated offsite is transported 200km prior to treatment. This distance was chosen as literature indicates it is a realistic distance to an offsite autoclave¹⁰, data specific to transport distance to a RMW incinerator is not available, and it is assumed the distance to an incinerator is comparable to that of an autoclave. Results show transport impact is minimal.

5.4. Waste disposal: Landfill

Landfill impacts include the air and emissions resulting from landfilling the materials as well as the impact resulting from operating the landfill.

Transport to landfill is assumed to be a relatively short distance and is excluded from the analysis. Autoclave & RMWI transport distance of 200km (significantly farther than expected for landfill) contributes negligible impact, and it is expected that landfill transport would contribute a significantly smaller amount of impact.

¹⁰ See Table 2 in Chantelle Rizan, Mahmood F. Bhutta, Malcom Reed, Rob Lillywhite, The carbon footprint of waste streams in a UK hospital, Journal of Cleaner Production, Volume 286, 2021, 125446, ISSN 0959-6526, <https://doi.org/10.1016/j.jclepro.2020.125446>

Landfill waste data is not available for specific US or European regions. Therefore only two landfill waste scenarios are included; one for the US and one for Europe.

The waste materials were mapped to the appropriate ecoinvent 3.7.1 production level dataset, as these include inventory for production only. The materials are landfilled within the life cycle model. Both ABS and synthetic rubber are modeled as generic waste to landfill as material specific landfill impact is not available.

Table 10. Materials and ecoinvent 3.7.1 processes

Material	Ecoinvent 3.7.1 process	Note
High density polyethylene (HDPE)	Polyethylene, HDPE, granulate, at plant/RER U	
Polyisoprene	Synthetic rubber, at plant/RER U	Surrogate material, data not available for polyisoprene
Polypropylene (PP)	Polypropylene, granulate, at plant/RER U	
Low density polyethylene (LDPE)	Polyethylene, LDPE, granulate, at plant/RER U	
Polycarbonate (PC)	Polycarbonate, at plant/RER U	
Polystyrene (PS)	Polystyrene, general purpose, GPPS, at plant/RER U	
Polyvinyl chloride (PVC)	Polyvinylchloride, at regional storage/RER U	
Acrylonitrile butadiene styrene (ABS)	Acrylonitrile-butadiene-styrene copolymer, ABS, at plant/RER U	
Acrylic	Polymethyl methacrylate, sheet {RER} polymethyl methacrylate production, sheet Cut-off, U	PMMA is also known as acrylic
Silicone	Silicone product, at plant/RER U	
Miscellaneous	Kraft paper, bleached, at plant/RER U	Surrogate for “balance”; unidentified waste that ends up getting mixed in

5.5. Waste disposal: Recycling

The recycling disposal process includes the impact to sort all waste, shred and recycle polyethylene and polypropylene waste, landfill all remaining waste, and offset an equivalent mass of virgin polyethylene and polypropylene resin production. It is assumed that PP and PE can be sorted using existing technology. The ecoinvent sorting process represents single sort high tech, dual sort high and low tech, and multi sort low tech operations, typical of Europe and North America.

Table 11. Recycling inventory

Material/process	Geography	Amount	unit
Sort waste			
Mixed recyclables, sorted [incoming transport & sorting of mixed recyclables at municipal recycling facility (MRF)]		12	lbs
“Mixed recyclables, sorted at MRF NREL/RNA U” is modified for each geography by replacing “Electricity, at grid, US NREL” with geographic specific electricity grid datasets in Table 2	All		
Landfill all non-PE & PP waste at the MRF [all non-PE & PP materials in Table 1] In the SimaPro 9.4 model, these waste materials are sent to “Landfill/CH” disposal scenario	All	7.2	lbs
Recycle PE & PP waste			
Shredding/recycling process [PE & PP in Table 1]		4.8	lbs
“Polyethylene, high density, granulate, recycled {Europe without Switzerland}	EU – all		

Material/process	Geography	Amount	unit
polyethylene production, high density, granulate, recycled Cut-off, U” is modified by removing waste polyethylene from the process; then the dataset represents the shredding/recycling process only			
“Polyethylene, high density, granulate, recycled {US} polyethylene production, high density, granulate, recycled Cut-off, U” is modified by removing waste polyethylene from the process; then the dataset represents the shredding/recycling process only	US - all		
Polyethylene, HDPE, granulate, at plant/RER U [virgin production offset with recycled resin]	All	-1.8	lbs
Polyethylene, LDPE, granulate, at plant/RER U [virgin production offset with recycled resin]	All	-1.2	lbs
Polypropylene, granulate, at plant/RER U [virgin production offset with recycled resin]	All	-1.8	lbs

5.6. Waste disposal: Waste to energy

The waste to energy disposal process includes energy and emissions to incinerate all waste and offset an equivalent amount of grid energy produced by incinerating the waste materials.

Waste to energy emissions are modeled as the mix of materials incinerated, as it is assumed air emissions and other waste processing from municipal incinerators is similar to WTE incinerators.

The amount of grid energy created, and therefore offset, by the combustion of the waste was calculated using energy content and system efficiency data in EPA’s WARM Model¹¹ using Equation 1. For materials offset without energy content data available in WARM, literature sources are used. The amount of grid energy offset by the specific twelve pounds of material included in this study is 10.25 kWh and details are in .

Waste treated offsite is transported 200km prior to treatment. This distance was chosen as literature indicates it is a realistic distance to an offsite autoclave¹², data specific to transport distance to a waste to energy incinerator is not available, and it is assumed the distance to an incinerator is comparable to that of an autoclave. Results show transport impact is minimal.

Equation 1. Grid energy offset per material incinerated

$$energy\ content\ (kWh) = x * y * z * \frac{293\ kWh}{1\ million\ Btu} * \frac{1\ short\ ton}{2000\ lbs}$$

Where:

x = energy content (million Btu per short ton), see specific source(s) in below

y = mass burn combustion system efficiency (%)

z = pounds material processed per cycle

¹¹ EPA WARM v15 WARM v15 https://www.epa.gov/sites/default/files/2020-12/documents/warm_management_practices_v15_10-29-2020.pdf

¹² See Table 2 in Chantelle Rizan, Mahmood F. Bhutta, Malcom Reed, Rob Lillywhite, The carbon footprint of waste streams in a UK hospital, Journal of Cleaner Production, Volume 286, 2021, 125446, ISSN 0959-6526, <https://doi.org/10.1016/j.jclepro.2020.125446>

Table 12. Waste to energy kWh produced by incinerating 12lbs red bag waste

Material combusted	Energy content (million Btu/ short ton) x	Mass burn combustion system efficiency (%) y	Pounds per cycle z	Energy content (kWh)
HDPE ^a	39.97	17.8%	1.8	1.88
Polyisoprene ^b	38.37	17.8%	1.8	1.80
Polypropylene (PP) ^a	39.09	17.8%	1.8	1.84
Low-Density Polyethylene (LDPE) ^a	39.75	17.8%	1.2	1.24
Polycarbonate (PC) ^c	26.91	17.8%	1.2	0.84
Polystyrene ^a	36	17.8%	1.2	1.13
PVC ^a	15.75	17.8%	1.2	0.49
ABS ^c	34.26	17.8%	0.6	0.54
Acrylic ^c	23.10	17.8%	0.36	0.22
Silicon ^b	16.14	17.8%	0.36	0.15
Balance of waste is miscellaneous ^d	10	17.8%	0.48	0.13

^a x, y, z from Exhibit 5-2. EPA WARM v15, https://www.epa.gov/sites/default/files/2020-12/documents/warm_management_practices_v15_10-29-2020.pdf

^b energy content (x) from <https://core.ac.uk/download/pdf/340564.pdf> Formulation and Burning Behaviour of Fire Retardant Polyisoprene Rubbers, August 2011, David John Kind; see Table 5, average of Calc & Lit values; mass burn combustion system efficiency (y) not available for this resin & “Mixed Plastics” EPA WARM data used as a surrogate

^c energy content (x) from <https://www.fire.tc.faa.gov/pdf/tn97-8.pdf> Heats of Combustion of High Temperature Polymers, Sept 1998, DOT/FAA/AR-TN97/8; see Table 1; mass burn combustion system efficiency (y) not available for this resin & “Mixed Plastics” EPA WARM data used as a surrogate

^d energy content (x) and mass burn combustion system efficiency (y) data for “Mixed MSW” is used as a surrogate from Exhibit 5-2. EPA WARM v15, https://www.epa.gov/sites/default/files/2020-12/documents/warm_management_practices_v15_10-29-2020.pdf

Table 13. WTE process inventory

Process	Geography	amount	unit
Truck transport to WTE facility		200	km
Transport, lorry 3.5-7.5t, EURO5/RER U	EU - all		
Transport, lorry 3.5-7.5t, EURO5/US- US-EI U	US - all		
Incineration of the study waste mix		12	lbs
In the SimaPro 9.4 model, the materials are sent to “Municipal solid waste (waste scenario) {CH} treatment of municipal solid waste, incineration” disposal scenario	EU - all		
In the SimaPro 9.4 model, the materials are sent to “Incineration/US US-EI U” disposal scenario	US - all		
Grid energy [offset with WTE; specific processes in Table 2]		-10.25	kWh
The grid energy in Table 2 is modeled for each geography	All		

6. Results

Life cycle global warming potential (GWP, aka carbon footprint) and cumulative energy demand results are presented for the waste treatment and disposal methods included in the study.

Results represent the average treatment and disposal results across the seven geographies in the study. Results represent 12 pounds of red bag medical waste and is limited to waste treatment and disposal processes only. Avoided burden is used to model impacts, therefore waste to energy scenarios include the emissions from burning waste in an incinerator as well as offsetting 10.25kWh grid energy and the recycling scenario includes the impacts of sorting waste, recycling the PE and PP portions of the waste, offsetting equal masses of virgin PE and PP, and landfilling remaining waste.

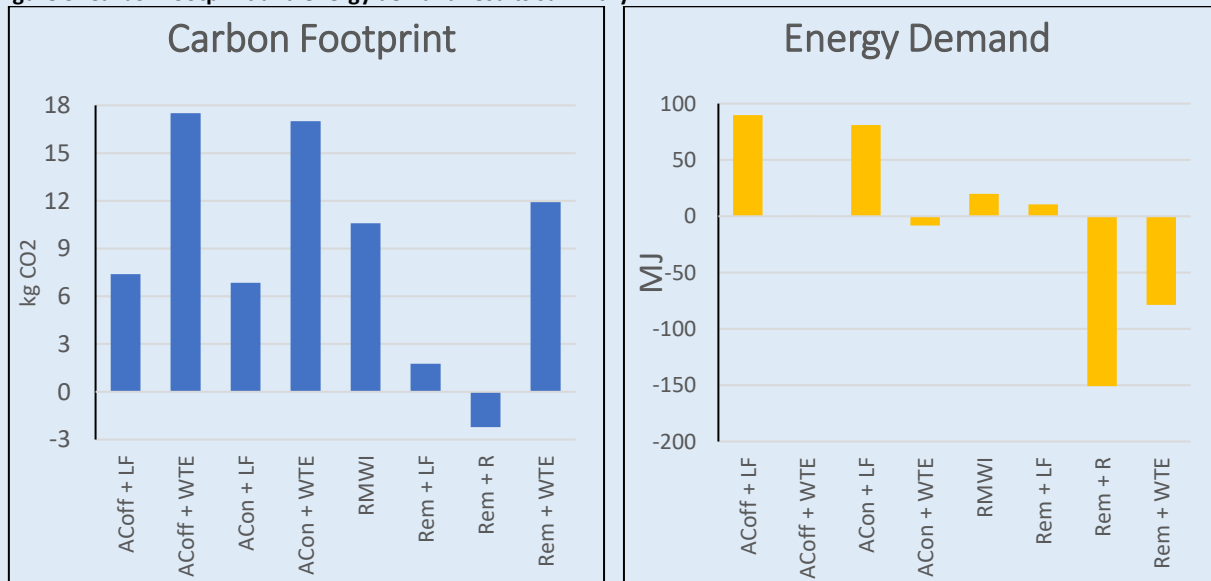
Waste treatment via the Remediator has the lowest impact as the Remediator operation carbon footprint is 95% less than autoclave and 97% less than RMWI due to the Remediator using significantly less energy to process the waste.

Disposing of waste via recycling has the lowest impact, due to carbon and energy savings from virgin material offset.

RMWI has high carbon impact due to direct greenhouse gas emissions from burning plastic waste.

WTE has tradeoffs. WTE is the highest carbon footprint disposal method as emissions produced from burning plastic are more than the emissions saved by offsetting grid energy production. Waste to energy has significant energy savings, as the amount of grid energy offset is ten times the energy needed for incineration.

Figure 3. Carbon footprint and energy demand results summary



Grid mix accounts for the difference in impact between geographies. Autoclave + landfill, RMWI, and Remediator + landfill and recycling scenarios have low variability and WTE scenarios have the highest variability among geographies.

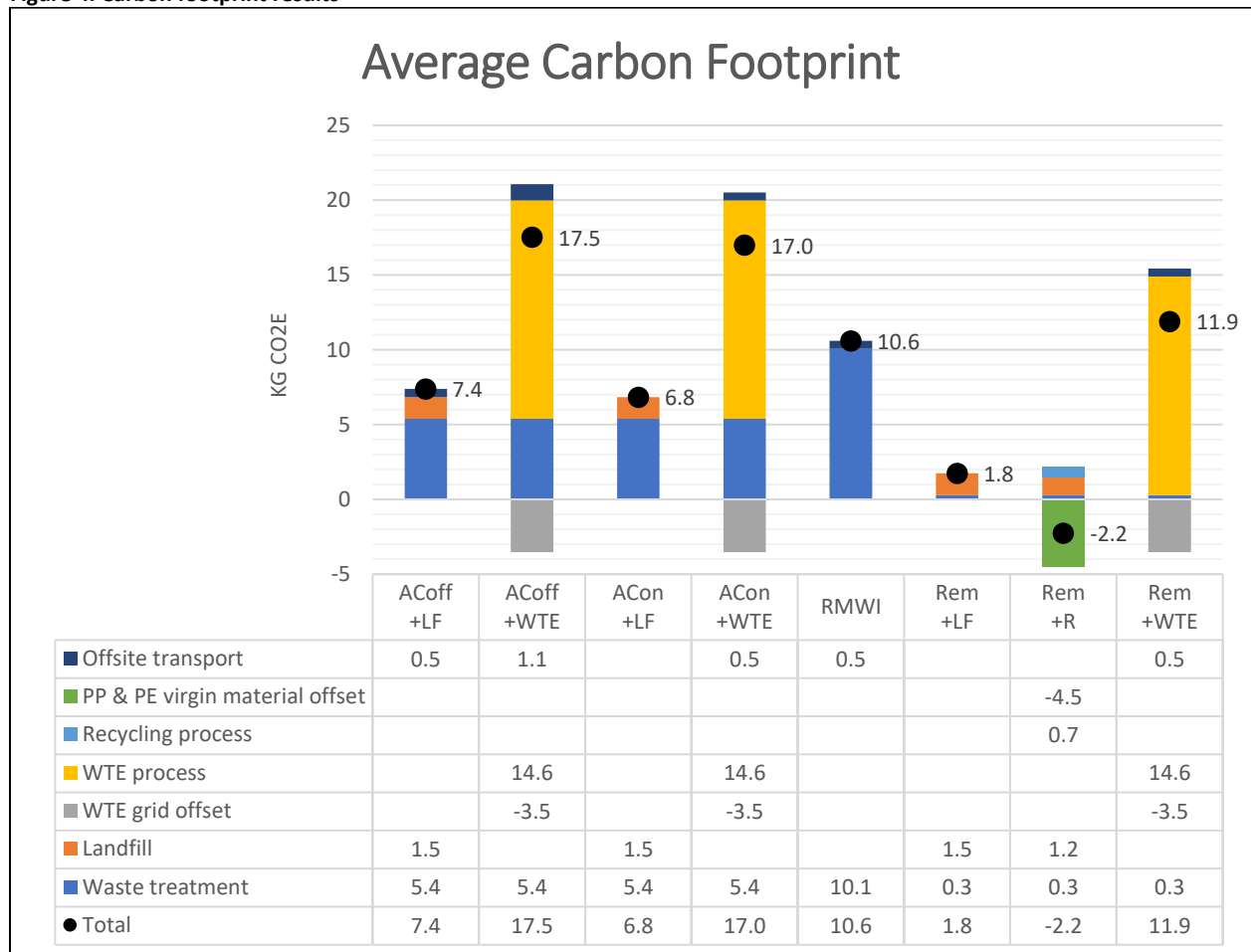
6.1. Average carbon footprint

Remediator + recycling has the lowest carbon footprint, due to the amount of virgin material offset by the recycling of PE and PP in the waste material.

Waste treatment processes + waste to energy have the highest footprints. Emissions from burning the plastic waste are more than the emissions saved by offsetting grid energy production.

The carbon footprint to operate the Remediator is 95% less than an autoclave and 97% less than RMWI, due to the Remediator using less energy than the other treatment processes.

Figure 4. Carbon footprint results



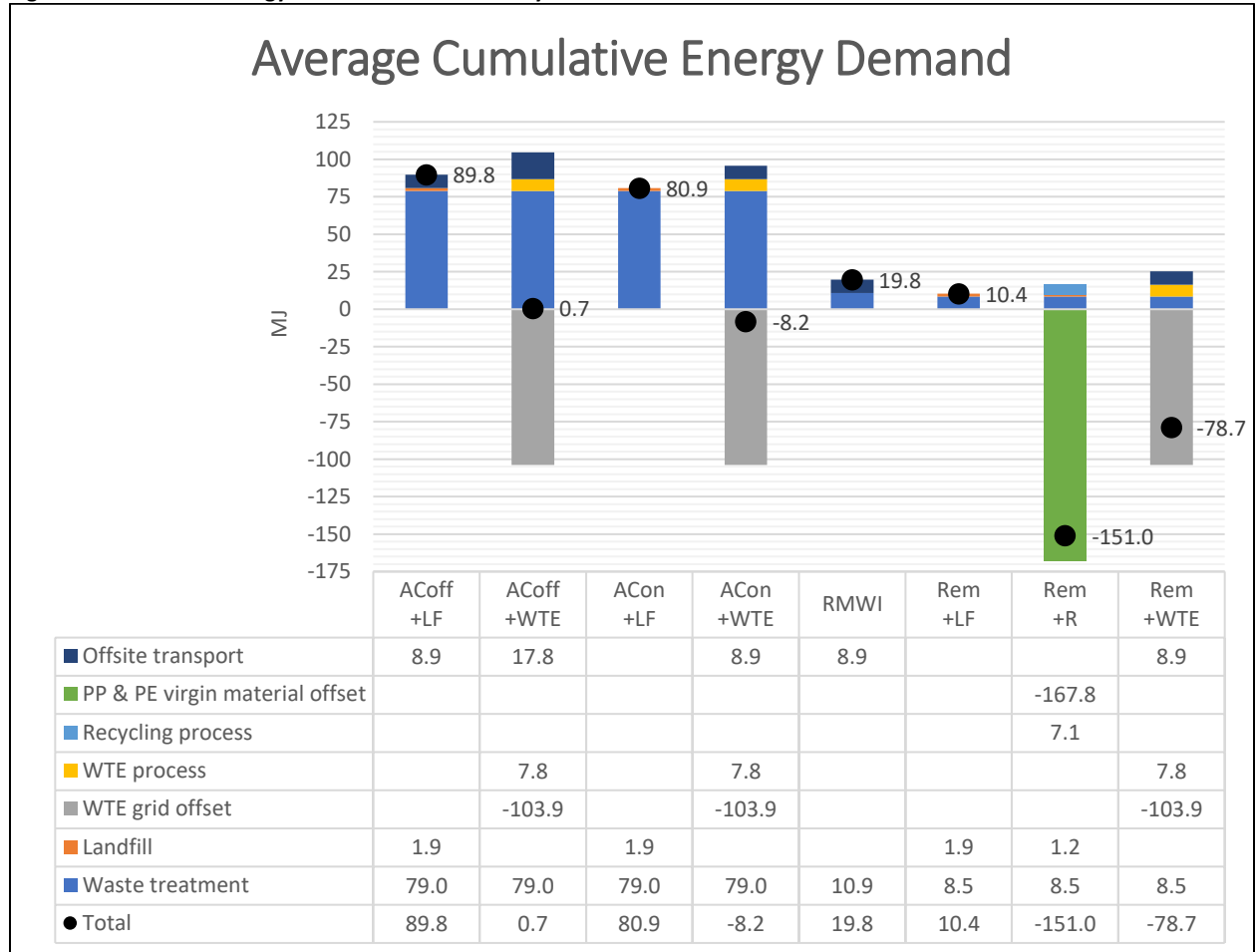
6.2. Energy Demand

Remediator + recycling has the lowest energy demand, due to the amount of energy saved from recycling PE & PP rather than producing virgin material.

Waste to energy grid offset is ten times more than the energy needed for incineration.

Remediator energy demand is significantly less than an autoclave and RMWI. The Remediator uses 0.8 kWh, autoclave uses 0.4kWh and 0.5L diesel, and RMWI uses 1.1kWh to process the waste.

Figure 5. Cumulative energy demand results summary



6.3. Geographic-specific results

Landfill carbon footprint and energy demand does not vary among geographies. Region specific data is not available for transport; therefore all European geographies have the same offsite transport carbon footprint and energy demand and all US regions have the same carbon footprint and energy demand. US regions have about an 8% higher carbon footprint and 2% higher CED than Europe.

The main driver of the difference in carbon footprint and energy demand between geographies is due to the grid mix. Generally, geographies with a higher portion of hard coal have a grid mix with a higher carbon footprint and those with a higher mix of renewables and nuclear energy have a lower carbon footprint. Similarly, geographies with a higher portion of nuclear and fossil fuel energy have a higher CED and those with a high portion of renewables have a low CED.

Table 14. Energy grid makeup and comparative impact per kWh

Geographic Region	Hard coal in grid mix	Natural gas in grid mix	Nuclear in grid mix	Renewables in grid mix	Comparative carbon footprint per kWh	Comparative CED per kWh
Switzerland (CH)	0%	0%	40%	57%	LOW	LOW
France (FR)	4%	4%	78%	12%	LOW	HIGH
Great Britain (GB)	33%	42%	20%	3%	HIGH	MID
NORDEL	9%	6%	26%	57%	MID	LOW
US Midwest (MRO)	36%	22%	8%	24%	HIGH	MID
US Northeast (NPCC)	0%	42%	32%	25%	MID	HIGH
US West (WECC)	20%	32%	8%	39%	MID	MID

Appendix A: Carbon footprint results by geography and *Appendix B: CED results by geography* contain all scenario results for all geographies included in the study. Results show the difference in energy grid makeup affects waste treatment and disposal scenarios differently. One geography does not have a lower footprint across all scenarios.

- WTE scenarios have the highest variability among results, due to the variability in carbon and energy demand of grid mixes across the geographies. WTE in high carbon footprint geographies (Great Britain & US Midwest) have a lower carbon footprint. This is because the amount of grid emissions offset by the WTE process has a higher reduction effect in high carbon footprint grid areas than in areas with a low carbon footprint grid. Therefore, WTE has the highest carbon savings in areas with a high portion of coal and natural gas in the grid mix. In contrast, low impact grids (Switzerland & France) have the lowest carbon savings, as the energy is offsetting a grid with already low impact.
- Autoclave + landfill scenarios have some variability among results, again due to the variability in carbon and energy demand of the grid mixes. Landfill impact is the same, regardless of geography, so the difference is due to the energy needed to run the autoclave.
- RMWI has low variability among geographies. RMWI uses a relatively small amount of energy to process waste, therefore variability is minor.
- Remediator + recycling has low variability among geographies. The impact to landfill non-PE and PP waste and offset virgin PE & PP production is the same regardless of geography and contributes over 70% of impact. Therefore, the difference between geographies is due to the energy needed to operate the Remediator, sort waste and grind PE and PP.

- Remediator + landfill has low variability among geographies as operating the Remediator requires relatively small amount of energy to process waste and landfill impact is the same, regardless of geography.

Table 15. Standard deviation of scenario results

Scenario	Carbon footprint standard deviation ¹	CED standard deviation
Autoclave offsite + landfill	0.9	11.6
Autoclave offsite + WTE	1.5	18.0
Autoclave onsite + landfill	0.9	11.6
Autoclave onsite + WTE	1.5	18.0
RMWI	0.3	1.7
Remediator + landfill	0.2	1.0
Remediator + recycling	0.2	3.4
Remediator + WTE	2.1	15.6

¹ Color coding: green are the 33% lowest values, orange are the 33% middle values, and red are the 33% highest values

6.4. Gravity analysis

Gravity analysis identifies the life cycle stages, processes, and materials that contribute the most energy demand and global warming potential.

For waste treatment via autoclave, Electricity from oil contributes 97% of GWP and 95% of CED and grid energy contributes the remaining 3% GWP and 5% CED.

Grid energy contributes 99% GWP and CED for waste treatment via the Remediator and RMWI.

Disposing of waste via landfill impact is highly dependent on the mix of waste materials. In the baseline, synthetic rubber and ABS make up 23% of the waste by mass and contribute 52% of the landfill impact. Synthetic rubber and ABS to landfill are modeled as average municipal waste to landfill as material specific data is not available. Paper is 4% of waste by mass and contributes 17% of the GWP and CED.

For the recycling scenario, the impact savings when offsetting virgin PE and PP production is significantly more than the impact of the recycling process and landfilling the remaining waste materials. Altering the ratio of waste materials such that more or less PE and PP is in the waste mix has the potential to significantly change the impact of the recycling scenario.

Table 16. US-NPCC waste treatment via recycling contributing processes

Process	GWP, kg CO2e	CED, MJ
Sorting waste	0.6	3.3
Shredding/processing waste	0.2	2.4
HDPE virgin offset	-1.6	-63.1
LDPE virgin offset	-1.2	-43.3
PP virgin offset	-1.7	-61.3
Landfill remaining waste	1.2	1.2
Total	-2.6	-160.8

In the waste to energy scenario, the GWP savings from grid energy offset (4.3kg CO2e for US-NPCC) is significantly less than the GWP of incinerating the waste (15kg CO2e for US-NPCC). The GWP contribution of the specific wastes in the mix is aligned with the makeup by mass and no materials in the waste mix contribute significantly more or less GWP. In contrast, the CED savings from grid energy offset (-121MJ for US-NPCC) significantly offsets the energy needed to incinerate the materials (9MJ for

US-NPCC), resulting in a negative CED. PVC is 10% of the waste mix by mass and contributes 75% of the incineration CED.

6.5.Sensitivity analysis

The goals of the sensitivity analyses are to understand how assumptions in data and methodology and uncertainty in the data may affect the LCA results. Sensitivity analysis results are important as they help understand the relative importance of assumptions made and quality of the data.

6.5.1 Autoclave energy use

A second study provides a range of energy required to process medical waste via autoclave¹³. The low end, mid point, and high end of the range were used to extrapolate the amount of energy required to process 12 pounds of waste and the percent of baseline was calculated for each. The geographic average autoclave treatment impact was then scaled based on the percent of the baseline to estimate the impact of operating an autoclave with these energy needs.

Study data and results are in Table 17. Results show that the energy ranges have significant impact on the Autoclave impact. The low energy use scenario reduces Autoclave impact by 80%, midpoint energy use reduces Autoclave impact by 20% and the high energy use scenario increases Autoclave impact by 35%.

Table 17. Autoclave energy sensitivity values compared to the baseline¹⁴

	Energy to treat waste	Affect on GWP (kg CO2e, % of baseline)	Affect on CED (MJ, % of baseline)
Autoclave, baseline, geographic avg.	0.41 kWh grid energy 5.17 kWh oil	5.4, baseline	79, baseline
Autoclave, sensitivity, low end of range	1.1 kWh grid energy	1.0, 20%	15, 20%
Autoclave, sensitivity, range mid point	4.35 kWh grid energy	4.2, 78%	62, 78%
Autoclave, sensitivity, high end of range	7.62 kWh grid energy	7.3, 137%	108, 137%

6.5.2 Uncertainty analysis

Monte Carlo analysis was used using SimaPro 9.4. Ecoinvent 3.7.1 life cycle inventory data contains uncertainty. In the uncertainty analysis, SimaPro 9.4 software randomly selects data points within the uncertainty range for each piece of inventory data to model the possible range of results with a 95% confidence level. One thousand different scenarios were run in SimaPro 9.4 using IPCC 2021 GWP 100yr and CED.

Uncertainty analysis was performed for the NPCC geography only (Northeast US) as baseline results show that the NPCC geography GWP and CED results are the closest to the average across all

¹³ Zikhathile T, Atagana H, Bwapwa J, Sawtell D. A Review of the Impact That Healthcare Risk Waste Treatment Technologies Have on the Environment. Int J Environ Res Public Health. 2022 Sep 22;19(19):11967. doi: 10.3390/ijerph191911967. PMID: 36231269; PMCID: PMC9565833.

¹⁴ Low end of range, midpoint, and high from ibid

geographies. While the actual values for other geographies will vary from those of NPCC, it is expected that the trends will be similar. The detailed results of the uncertainty analyses are in *Appendix C: Uncertainty analysis details*.

Uncertainty analysis is important when determining how to interpret the results of this study. GWP results show that RMWI, landfill, and recycling, regardless of waste treatment method, have the lowest uncertainty and therefore lowest range of results. In contrast, waste to energy has a significantly higher range and uncertainty compared to all other treatment and disposal scenarios. CED has a similar pattern – RMWI, landfill and recycling have the lowest uncertainty and waste to energy has the highest uncertainty.

When looking at specific processes within the life cycles, RMWI, Remediator operation, the recycling process, and the virgin PE and PP offset have the lowest GWP uncertainty and waste to energy has the highest uncertainty. The waste to energy process includes emissions from incinerating the waste as well as the energy grid offset with WTE production. Waste to energy has a high uncertainty due to a relatively high level of uncertainty associated with grid energy GWP and CED and the amount of energy offset at 10.25kWh. While Autoclave and RMWI also use energy from the same grid, the amount of energy they use is significantly smaller at 0.4 and 1 kWh, respectively, therefore the uncertainty range is also minimized.

Figure 6. GWP uncertainty results, US-NPCC

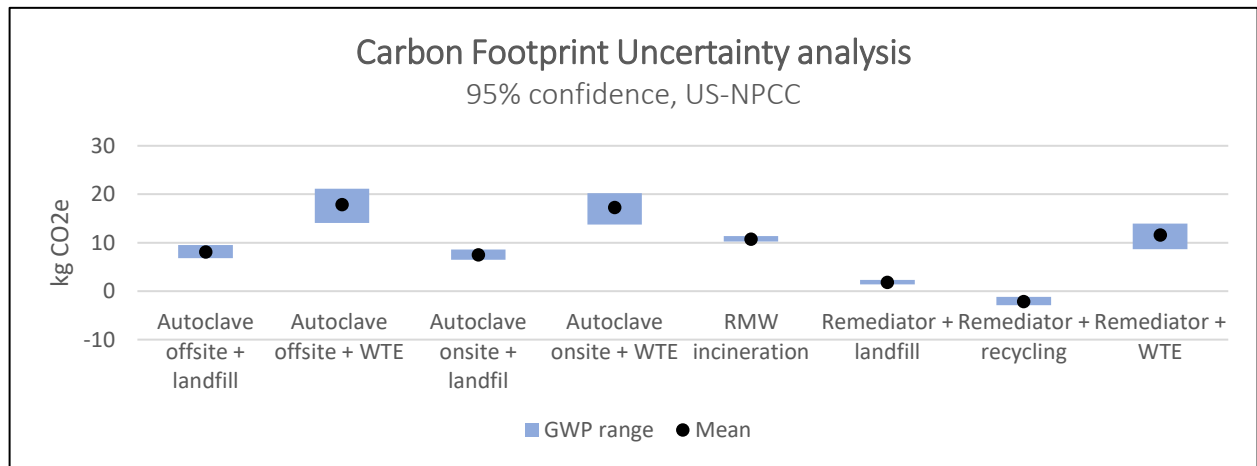
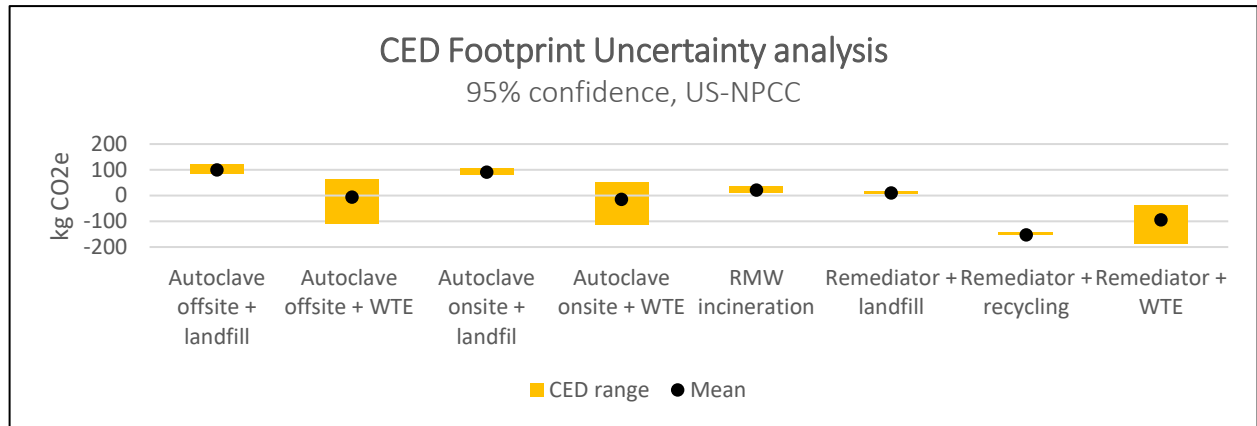


Figure 7. CED uncertainty results, US-NPCC



6.5.3 Assumptions and surrogate data

Not all data for this analysis was available therefore some assumptions and surrogate materials and processes were required. These assumptions were documented throughout section 4 *Life Cycle Inventory*. The impact of those assumptions and surrogate materials on the results was analyzed.

Table 18. Study assumptions and impact on results

Treatment/disposal method	Assumption	Reasoning	Impact on Results
All methods	“Synthetic rubber” material used to represent polyisoprene in the waste mix	Material, landfill, and incineration data is not available for polyisoprene. Polyisoprene is one type of synthetic rubber.	Polyisoprene makes up 15% of waste mass and contributes 43% of landfill GWP and 23% landfill CED. Synthetic rubber is a high impact material and the best surrogate for polyisoprene; it is not expected that polyisoprene data would significantly change these results.
Autoclave offsite, RWMI, and WTE	200km transport distance to offsite autoclave, RMWI, and WTE	Discussions with MilliporeSigma and Sterilis Solutions determined 200km to be a reasonable and realistic distance to travel to an offsite autoclave and incinerators.	200km transport contributes 3-10% GWP across all treatment + disposal scenarios and all geographies included in the study. For CED, 200km transport contributes 10% to autoclave offsite, 50% to RMWI, and negates the carbon savings from waste to energy in some geographies. This shows the importance of transport distance, especially for RWMI and WTE options and supports including transport distance as a variable in the Environmental Calculator Tool.
WTE	Direct emissions equivalent to emissions from municipal incineration of the same materials	It is not expected that the makeup and amount of emissions from a waste to energy incinerator will differ from those of a municipal waste incinerator.	Sensitivity analysis was not performed for this assumption as it is the best data available.
WTE	Mass burn consumption system efficiency	Mass burn consumption system efficiency data was not available for all	Sensitivity analysis was not performed for this assumption as it is the best data available.

Treatment/disposal method	Assumption	Reasoning	Impact on Results
	is assumed 17.8% for all materials	materials in the waste mix. It is assumed that the same efficiency would apply to all waste, regardless of waste type.	

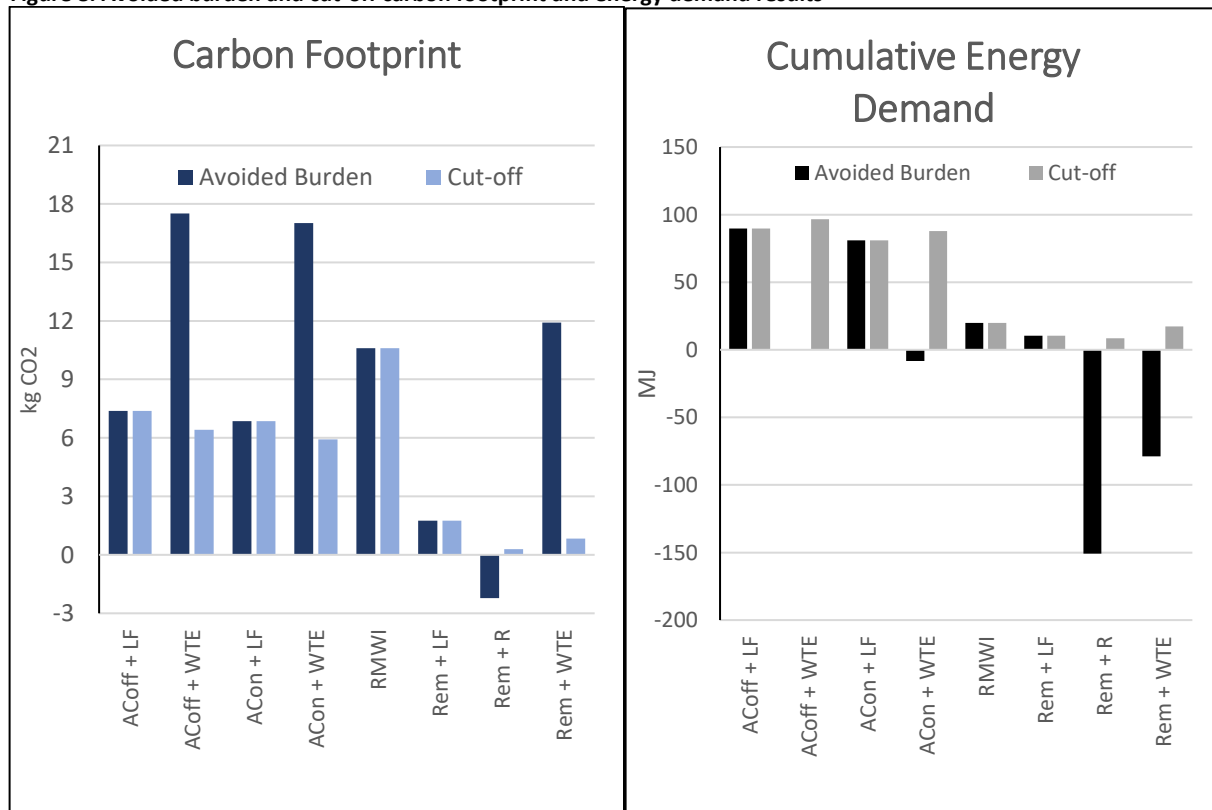
6.5.4 Cut-off allocation results

The goal of this section is to compare and contrast how allocation of recycling materials and waste to energy can affect environmental impact. In the cut-off method, the impact and benefit of recycling materials and incinerating them for energy is allocated to the future user of the materials and energy. The generator of the materials to be recycled and incinerated for energy receives zero impact for the end of life of the materials.

Landfill and RMWI results are equivalent when using avoided burden and the cut-off method, as neither processes result in the offset of other materials.

Cut-off method results show that recycling and waste to energy are always preferable to landfill. Recycling and waste to energy are burden free, as the trade-offs seen with avoided burden aren't visible.

Figure 8. Avoided burden and cut-off carbon footprint and energy demand results



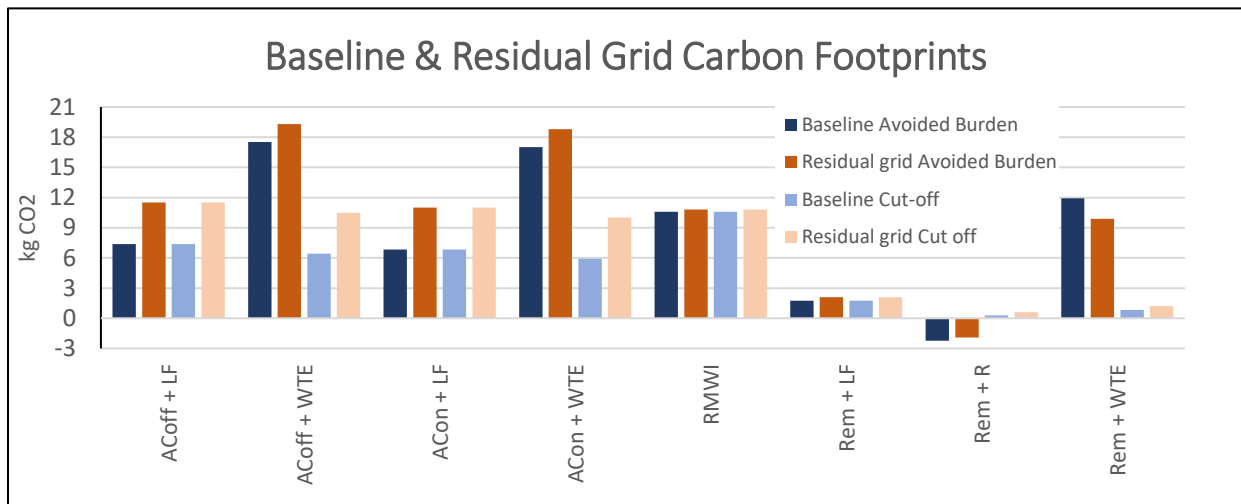
6.5.4 Residual energy grid results

The baseline analysis uses energy grids reflecting the electricity consumption of the regions included in the study. Renewable energy sources that may be sold or exported as renewable electricity are not excluded from the baseline grids. Because all geographies included in the study include some portion of renewable energy, a sensitivity analysis using residual grid mixes was performed.

For European countries, the country specific residual grid mix kilograms of carbon per kWh from AIB¹⁵ are used. Switzerland has a full disclosure system in place; therefore, the residual mix is zero and the residual mix impact for Switzerland remains unchanged. For US geographies, the portion of renewable sources (except nuclear and hydroelectric) are removed from the grid mix supplied by ecoinvent 3.7.1 and the kgCO₂e/kWh was calculated for the residual grid. In all cases, the residual grid mix was applied to the four processes with direct energy use: autoclave operation, Remediator operation, RMW incineration, and WTE grid offset. Carbon emissions were calculated for the seven waste treatment + disposal scenarios, using both cut off and avoided burden allocation, at all seven geographies. The geography specific results were averaged and are found in Figure 9

Baseline and residual grid carbon footprints show that the specific values for the residual mix increased and the trend remains the same for all scenarios except Remediator + WTE avoided burden. The kg CO₂e/kWh residual grid mix is higher than that of the baseline grid mix, as all geographies except Switzerland contain some portion of renewable energy in their baseline mix. Once the renewable energy is removed, the impact per kWh increases. The Remediator + WTE scenario offsets 10.25 kWh of grid energy. Because the residual grid mix has higher emissions per kWh than the baseline grid, the residual grid mix Remediator + WTE avoided burden results are expected to be lower than the baseline results. This is inline with the baseline conclusion that geographies with low renewables and high coal and fossil fuel energy sources benefit the most from WTE.

Figure 9. Baseline and residual grid mix average carbon footprint results



¹⁵ Association of Issuing Bodies, 2023, “residual mixes” in <https://www.aib-net.org/sites/default/files/assets/facts/residual-mix/2023/RM%20calculation%20results.xlsx>

When looking at specific geographies, NORDEL’s residual mix scenario results have the highest increase compared to the baseline results. This is due to the significant difference in the production mix and residual mix emission factors¹⁶.

Comparing the impact of treating waste via the Remediator or autoclave, the residual grid mix results support those of the baseline grids. Using the baseline energy grids, the carbon footprint of waste treatment via the Remediator is 95% less than that of autoclave (baseline 0.3kgCO₂e via Remediator and 5.4kg CO₂e via autoclave); the difference is reduced slightly with the residual grids and treatment via the Remediator is 93% less than autoclave (residual mix 0.6kg CO₂e via Remediator and 9.5kg CO₂e via autoclave).

6.6. Product carbon footprint of Remediator operation

The average product carbon footprint to operate the Remediator to process 12 pounds of waste is 0.3 kg CO₂e; this is equivalent to 0.05 kg CO₂ per kg waste processed. The carbon footprint is independent of the waste mix. The UK and US midwest have notably higher carbon footprints due to the higher amount of coal and natural gas in the grid mixes compared to the other geographies.

Figure 10. Product carbon footprint of Remediator operation

Geography	kg CO ₂ e/12 pounds waste processed	kg CO ₂ e/kg waste processed
Switzerland	0.11	0.02
France	0.08	0.01
NORDEL, Nordic countries	0.14	0.03
United Kingdom	0.49	0.09
US Midwest	0.51	0.09
US Northeast	0.28	0.05
US West	0.42	0.08
Europe average	0.20	0.04
US average	0.41	0.07
All geographies average	0.29	0.05

6.7. ISO 14067 emission reporting categories for operating the Remediator

ISO 14067 7.2 requirements for Carbon Footprint of Products study report requires the emissions in *Figure 11. ISO 14067 emission reporting categories* to be reported. There are no GHG emissions and removals from direct land use change as there is no land use change during farming, processing, and storage and distribution or aircraft transport as no materials are transported via air.

Figure 11. ISO 14067 emission reporting categories

GHG emission category	GHG emissions per 12 pounds waste processed, kg CO ₂ e	Description	Application to this study
GHG emissions and removals linked to main life cycle stage	See <i>Results</i> section	Absolute and relative GHG emissions for each stage are	The CO ₂ e for each material and process in

¹⁶ Denmark, Finland, Norway, Sweden average production mix 0.10 kgCO₂e/kWh and average residual mix 0.45 kgCO₂e/kWh from <https://www.aib-net.org/sites/default/files/assets/facts/residual-mix/2023/RM%20calculation%20results.xlsx>.

GHG emission category	GHG emissions per 12 pounds waste processed, kg CO2e	Description	Application to this study
in which they occur, including relative and absolute contribution of each		reported	the life cycle is reported in the <i>Results</i> section
Net fossil GHG emissions and removals	0.3	Carbon that is contained in fossilized material	Total emissions
Biogenic GHG emissions and removals	0	Carbon derived from biomass, material of biological origin, excluding material embedded in geological formations and material transformed to fossilized material	No biogenic carbon in the operation of the Remediator
GHG emissions and removals resulting from direct land use change	0	Change in the human use of land within the relevant boundary; land use change happens when there is a change in the land-use category as defined by IPCC (ie. from forest to cropland)	No direct land use change from Remediator operation
GHG emissions and removals resulting from aircraft transportation	0	GHG emissions from aircraft transportation	No materials are transported via aircraft

7. Discussion

The goal of the study was to calculate the carbon footprint and cumulative energy demand of waste treatment and disposal options for 12 pounds hazardous medical waste with a specific waste makeup. Results form the basis of the MilliporeSigma & Sterilis Solutions' Environmental Impact Calculator Tool, where the footprint of hazardous medical waste management and disposal can be calculated for the geographies included in this analysis.

Study completeness and consistency are excellent. Primary data is used for all waste treatment methods and waste disposal methods are based on the most accurate, up to date data available via ecoinvent 3.7.1 and the US EPA. The study methodology was applied consistently among geographies included in the study as well as the waste treatment and disposal scenarios. The high level of completeness and consistency further support the baseline and sensitivity results of the study.

Waste treatment via Autoclave and RMWI has a higher impact than the Remediator due to the amount of energy needed to process the waste. The Remediator uses 95% less energy to treat waste. RMWI has a high carbon impact due to the direct greenhouse gas emissions from the incineration process. Sensitivity analysis results show that the amount of energy needed for the autoclaving process can significantly affect its carbon footprint, reducing it by up to 80% or increasing it by up to 37%, though it remains below that of operating the Remediator.

Disposing of waste via recycling has lower carbon and energy impacts than WTE and landfill as the recycling process impacts are offset by the savings when offsetting virgin material production. Recycling impacts are significantly dependent on the waste mix, as only PE and PP are recycled. Waste mixes with high portions of PP and/or PE will have more impact savings. In contrast, waste mixes with little or no PP and/or PE may result in a net carbon footprint and energy demand as materials are not recycled. This study assumes that the collected PE and PP can be easily separated from the other materials and integrated into the recycling stream/process. Successfully recycling the material is a hurdle that Millipore Sigma and Sterilis Solutions are working towards, as it is not nearly as common place as landfill or WTE.

WTE is the highest carbon footprint disposal method and has significant energy savings. Emissions produced from burning plastic waste are more than the emissions saved by offsetting grid energy; this is especially true for geographies with a grid mix with a high portion of renewables. In contrast, the amount of grid energy offset is ten times the energy needed for incineration, resulting in significant energy savings. WTE has a high range of GWP and CED uncertainty compared to other scenarios due to the high level of uncertainty associated with grid energy GWP and CED and the amount of energy offset with WTE.

While uncertainty is higher with WTE, the uncertainty range of Remediator + WTE CED encompasses the range of Remediator + Recycling; therefore, it cannot be determined from an energy demand perspective, whether Remediator + recycling or WTE is lower. Similarly, the low end of the Autoclave + WTE CED range overlaps the high end of the Remediator + WTE CED values. Therefore, it cannot be determined which of the scenarios has a lower energy demand. Furthermore, the Remediator + landfill CED uncertainty results overlap Autoclave + WTE.

Transport distance can contribute significant GWP and CED, depending on the scenario and geography.

200km transport contributes 3-10% GWP across all treatment + disposal scenarios and all geographies included in the study. For CED, 200km transport contributes 10% to autoclave offsite, 50% to RMWI, and negates the carbon savings from waste to energy in some geographies. This shows the importance of transport distance, especially for RMWI and WTE options and supports including transport distance as a variable in the Environmental Calculator Tool.

When looking at the range of results among the geographies, autoclave operation and WTE process have the largest range, due to the amount of energy needed to operate the autoclave and offset during the WTE process. The energy grid makeups of the geographies included in the study in Table 2 vary significantly, with Switzerland and France having a high portion of renewable and nuclear energy. The impact of RMWI incineration, operating the Remediator, and the recycling process has less variability amongst the geographies, due to the low amount of energy needed for these processes.

The baseline study used avoided burden allocation as Millipore Sigma and Sterilis Solutions are interested in understanding the difference between waste that is recycled and waste to energy. In the cutoff method, both recycling and WTE have zero impact. It is assumed the market is underutilized and the availability of recycled material offsets the production of virgin material and the energy created by waste to energy offsets grid energy. Regardless of allocation method, recycling has lower GWP and CED than landfill and WTE has lower CED than landfill. WTE has a lower GWP than landfill when using the cutoff method and a higher GWP than landfill when using the avoided burden method. Carbon emissions from burning plastic are greater than the emissions saved by offsetting grid energy production. Comparing the cutoff and avoided burden method results shows the importance of allocation for systems with recycling and waste to energy and that avoided burden may be more comprehensive when considering the impacts of a system.

This study is only representative of red bag medical waste with the specific mix of materials stated; treated via autoclave, regulated medical waste incineration, or the Remediator; and landfilled, recycled, or waste to energy for the geographies included in the study. It is not intended to represent all waste treated and disposed via these or any other methods. The study excluded the manufacture and end of life of waste treatment and disposal equipment, including an autoclave, incinerator, and the Remediator. It is expected that including the equipment will increase the GWP and CED impact of all treatment and disposal options incrementally and insubstantially, given the large mass of waste that can be treated and disposed via the equipment during its useful life. While the Remediator is expected to process tens of thousands of pounds of waste during its useful life, this may be less than the volume of waste processed by an autoclave or incinerator. It is important to note that the size of the Remediator and subsequent mass of material is significantly less than a large autoclave and incinerator. It is not expected that including the equipment will alter the conclusions of the assessment.

8. Conclusions

Processing waste via the Remediator is the lowest carbon footprint and energy demand treatment method. The carbon footprint and energy demand of the Autoclave waste treatment process can vary significantly based on the amount of energy used to process waste. Sensitivity analyses show that the Autoclave carbon footprint is at least three times more and energy demand is at least 1.75 times that of the Remediator¹⁷.

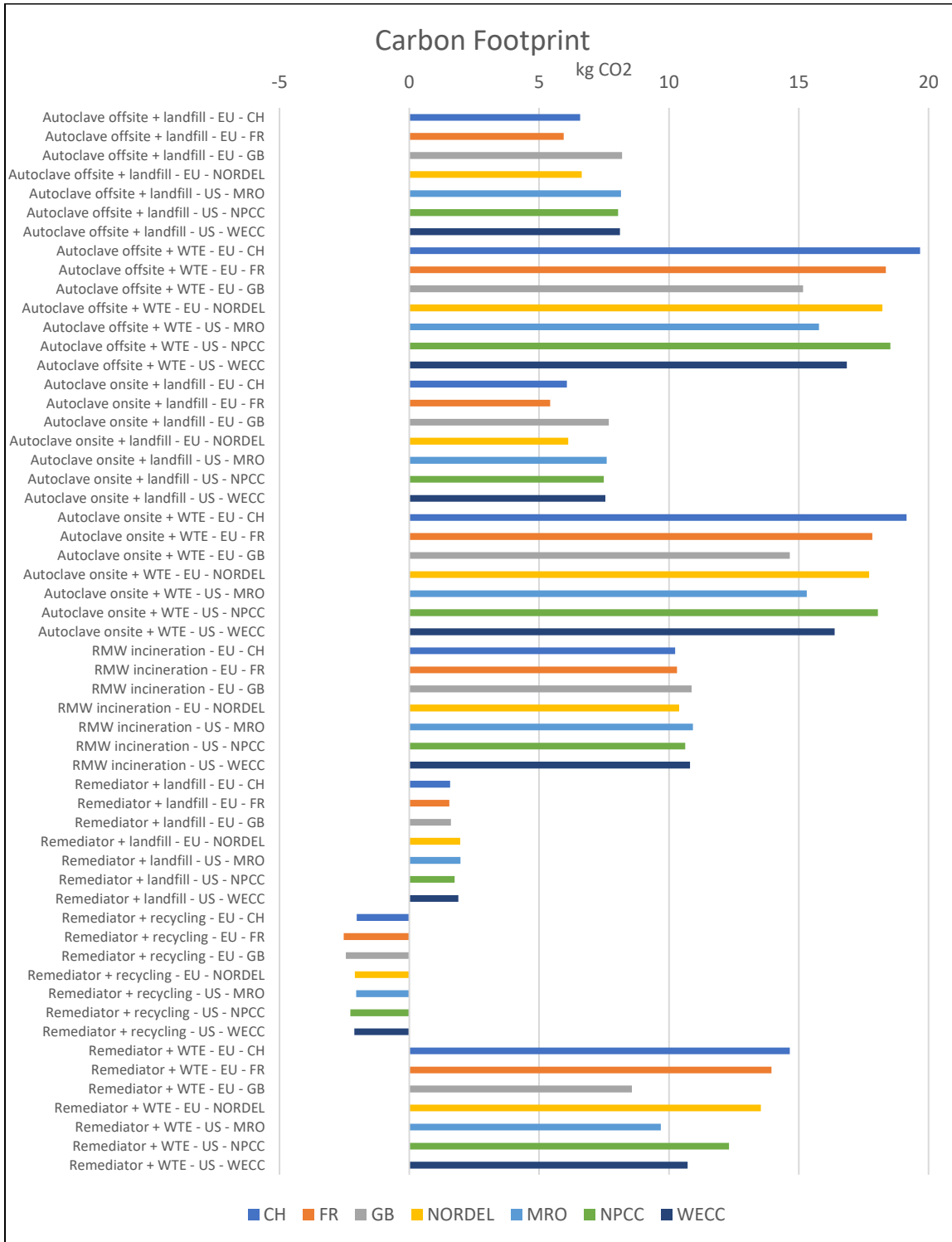
Geographies with a low portion of renewable energy and high portion of hard coal will benefit most from WTE. Uncertainty analysis shows that WTE carbon footprint and CED have a lot of variability in the results based on the grid mix. Grid mixes with a high portion of fossil fuels will benefit more from WTE than areas with renewables as the emissions from burning plastic are significantly less than those of burning coal, and more than those from renewable energy sources.

Recycling may be preferable in locations where the grid mix has a high portion of renewable energy. Geographies with high portions of renewables may benefit more from recycling waste than WTE, as burning waste may produce more carbon emissions and require more energy than the existing grid.

Remediator + landfill has lower carbon emissions than Autoclave + WTE and may not have lower CED than Autoclave + WTE. Uncertainty results show Remediator + landfill has less carbon emissions than Autoclave + WTE and the CED values overlap.

¹⁷ Autoclave sensitivity analysis shows 1.0-7.3kgCO₂e and 15-108 MJ per 12lbs waste processed and Remediator footprint is 0.3kg CO₂e and 8.5MJ per 12lbs waste processed

Appendix A: Carbon footprint results by geography

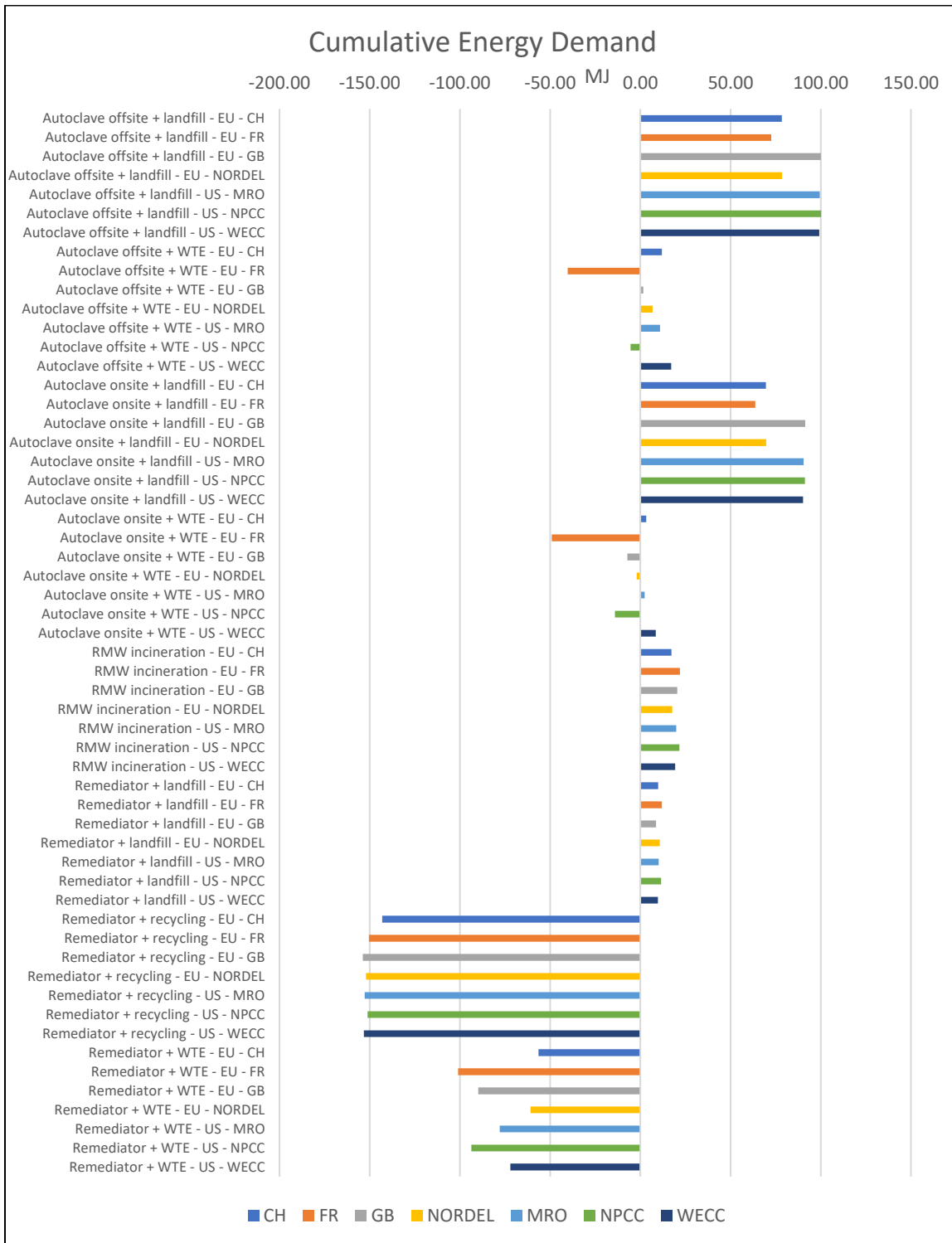


SCENARIO	Autoclave operation, kgCO2e	Offsite transport, kgCO2e	Landfill, kgCO2e	CUT-OFF total, kgCO2e	WTE process, kgCO2e	AVOIDED BURDEN total, kgCO2e
Autoclave offsite + landfill - EU - CH	4.60	0.52	1.46	6.58		6.58
Autoclave offsite + landfill - EU - FR	3.97	0.52	1.46	5.95		5.95
Autoclave offsite + landfill - EU - GB	6.22	0.52	1.46	8.20		8.20
Autoclave offsite + landfill - EU - NORDEL	4.66	0.52	1.46	6.64		6.64
Autoclave offsite + landfill - US - MRO	6.13	0.56	1.46	8.16		8.16
Autoclave offsite + landfill - US - NPCC	6.02	0.56	1.46	8.05		8.05
Autoclave offsite + landfill - US - WECC	6.09	0.56	1.46	8.12		8.12
Autoclave offsite + WTE - EU - CH	4.60	1.03		5.63	14.04	19.67
Autoclave offsite + WTE - EU - FR	3.97	1.03		5.00	13.35	18.35
Autoclave offsite + WTE - EU - GB	6.22	1.03		7.25	7.92	15.17
Autoclave offsite + WTE - EU - NORDEL	4.66	1.03		5.70	12.53	18.23
Autoclave offsite + WTE - US - MRO	6.13	1.03		7.17	8.61	15.78
Autoclave offsite + WTE - US - NPCC	6.02	1.03		7.06	11.47	18.52
Autoclave offsite + WTE - US - WECC	6.09	1.03		7.12	9.73	16.86
Autoclave onsite + landfill - EU - CH	4.60		1.46	6.06		6.06
Autoclave onsite + landfill - EU - FR	3.97		1.46	5.43		5.43
Autoclave onsite + landfill - EU - GB	6.22		1.46	7.68		7.68
Autoclave onsite + landfill - EU - NORDEL	4.66		1.46	6.13		6.13
Autoclave onsite + landfill - US - MRO	6.13		1.46	7.60		7.60
Autoclave onsite + landfill - US - NPCC	6.02		1.46	7.49		7.49
Autoclave onsite + landfill - US - WECC	6.09		1.46	7.55		7.55
Autoclave onsite + WTE - EU - CH	4.60	0.52		5.12	14.04	19.15
Autoclave onsite + WTE - EU - FR	3.97	0.52		4.48	13.35	17.84
Autoclave onsite + WTE - EU - GB	6.22	0.52		6.73	7.92	14.65
Autoclave onsite + WTE - EU - NORDEL	4.66	0.52		5.18	12.53	17.71
Autoclave onsite + WTE - US - MRO	6.13	0.56		6.70	8.61	15.31
Autoclave onsite + WTE - US - NPCC	6.02	0.56		6.58	11.47	18.05
Autoclave onsite + WTE - US - WECC	6.09	0.56		6.65	9.73	16.38

SCENARIO	Offsite transport, kgCO2e	RWM incineration, kgCO2e	CUT-OFF total, kgCO2e	AVOIDED BURDEN total, kgCO2e
RMW incineration - EU - CH	0.52	9.72	10.24	10.24
RMW incineration - EU - FR	0.52	9.79	10.31	10.31
RMW incineration - EU - GB	0.52	10.36	10.88	10.88
RMW incineration - EU - NORDEL	0.52	9.88	10.40	10.40
RMW incineration - US - MRO	0.56	10.37	10.93	10.93
RMW incineration - US - NPCC	0.56	10.07	10.63	10.63
RMW incineration - US - WECC	0.56	10.25	10.81	10.81

SCENARIO	Remediator operation, kgCO2e	Offsite transport, kgCO2e	Landfill, kgCO2e	CUT-OFF total, kgCO2e	WTE process, kgCO2e	Recycling process, kgCO2e	PE & PP material savings, kgCO2e	Recycling process leftovers to LF, kgCO2e	AVOIDED BURDEN total, kgCO2e
Remediator + landfill - EU - CH	0.11		1.46	1.57					1.57
Remediator + landfill - EU - FR	0.08		1.46	1.54					1.54
Remediator + landfill - EU - GB	0.14		1.46	1.60					1.60
Remediator + landfill - EU - NORDEL	0.49		1.46	1.96					1.96
Remediator + landfill - US - MRO	0.51		1.46	1.97					1.97
Remediator + landfill - US - NPCC	0.28		1.46	1.75					1.75
Remediator + landfill - US - WECC	0.42		1.46	1.89					1.89
Remediator + recycling - EU - CH	0.11			0.11		1.14	4.47	1.20	-2.02
Remediator + recycling - EU - FR	0.08			0.08		0.67	4.47	1.20	-2.53
Remediator + recycling - EU - GB	0.14			0.14		0.69	4.47	1.20	-2.44
Remediator + recycling - EU - NORDEL	0.49			0.49		0.68	4.47	1.20	-2.10
Remediator + recycling - US - MRO	0.51			0.51		0.72	4.47	1.20	-2.04
Remediator + recycling - US - NPCC	0.28			0.28		0.72	4.47	1.20	-2.27
Remediator + recycling - US - WECC	0.42			0.42		0.73	4.47	1.20	-2.12
Remediator + WTE - EU - CH	0.11	0.52		0.62	14.04				14.66
Remediator + WTE - EU - FR	0.08	0.52		0.59	13.35				13.95
Remediator + WTE - EU - GB	0.14	0.52		0.66	7.92				8.57
Remediator + WTE - EU - NORDEL	0.49	0.52		1.01	12.53				13.54
Remediator + WTE - US - MRO	0.51	0.56		1.07	8.61				9.69
Remediator + WTE - US - NPCC	0.28	0.56		0.85	11.47				12.32
Remediator + WTE - US - WECC	0.42	0.56		0.98	9.73				10.72

Appendix B: CED results by geography



SCENARIO	Autoclave operation, MJ	Offsite transport, MJ	Landfill, MJ	CUT-OFF total, MJ	WTE process, MJ	AVOIDED BURDEN total, MJ
Autoclave offsite + landfill - EU - CH	67.7	8.8	1.9	78.4		78.4
Autoclave offsite + landfill - EU - FR	61.8	8.8	1.9	72.6		72.6
Autoclave offsite + landfill - EU - GB	89.4	8.8	1.9	100.1		100.1
Autoclave offsite + landfill - EU - NORDEL	67.9	8.8	1.9	78.6		78.6
Autoclave offsite + landfill - US - MRO	88.6	9.0	1.9	99.5		99.5
Autoclave offsite + landfill - US - NPCC	89.3	9.0	1.9	100.2		100.2
Autoclave offsite + landfill - US - WECC	88.3	9.0	1.9	99.2		99.2
Autoclave offsite + WTE - EU - CH	67.7	17.6		85.2	-73.2	12.0
Autoclave offsite + WTE - EU - FR	61.8	17.6		79.4	-119.7	-40.3
Autoclave offsite + WTE - EU - GB	89.4	17.6		107.0	-105.4	1.6
Autoclave offsite + WTE - EU - NORDEL	67.9	17.6		85.4	-78.6	6.8
Autoclave offsite + WTE - US - MRO	88.6	17.6		106.1	-95.1	11.0
Autoclave offsite + WTE - US - NPCC	89.3	17.6		106.8	-112.2	-5.4
Autoclave offsite + WTE - US - WECC	88.3	17.6		105.9	-88.7	17.1
Autoclave onsite + landfill - EU - CH	67.7		1.9	69.6		69.6
Autoclave onsite + landfill - EU - FR	61.8		1.9	63.8		63.8
Autoclave onsite + landfill - EU - GB	89.4		1.9	91.3		91.3
Autoclave onsite + landfill - EU - NORDEL	67.9		1.9	69.8		69.8
Autoclave onsite + landfill - US - MRO	88.6		1.9	90.5		90.5
Autoclave onsite + landfill - US - NPCC	89.3		1.9	91.2		91.2
Autoclave onsite + landfill - US - WECC	88.3		1.9	90.3		90.3
Autoclave onsite + WTE - EU - CH	67.7	8.8	1.9	76.4	-73.2	3.2
Autoclave onsite + WTE - EU - FR	61.8	8.8		70.6	-119.7	-49.1
Autoclave onsite + WTE - EU - GB	89.4	8.8		98.2	-105.4	-7.2
Autoclave onsite + WTE - EU - NORDEL	67.9	8.8		76.6	-78.6	-1.9
Autoclave onsite + WTE - US - MRO	88.6	9.0		97.5	-95.1	2.4
Autoclave onsite + WTE - US - NPCC	89.3	9.0		98.2	-112.2	-14.0
Autoclave onsite + WTE - US - WECC	88.3	9.0		97.3	-88.7	8.5

SCENARIO	Offsite transport, MJ	RWM incineration, MJ	CUT-OFF total, MJ	AVOIDED BURDEN total, MJ
RMW incineration - EU - CH	8.8	8.4	17.2	17.2
RMW incineration - EU - FR	8.8	13.2	22.0	22.0
RMW incineration - EU - GB	8.8	11.7	20.5	20.5
RMW incineration - EU - NORDEL	8.8	9.0	17.7	17.7
RMW incineration - US - MRO	9.0	11.0	19.9	19.9
RMW incineration - US - NPCC	9.0	12.7	21.7	21.7
RMW incineration - US - WECC	9.0	10.3	19.3	19.3

SCENARIO	Remediator operation, MJ	Offsite transport, MJ	Landfill, MJ	CUT-OFF total, MJ	WTE process, MJ	Recycling process, MJ	PE & PP material savings, MJ	Recycling process leftovers to LF, MJ	AVOIDED BURDEN total, MJ
Remediator + landfill - EU - CH	8.0		1.9	10.0					10.0
Remediator + landfill - EU - FR	10.0		1.9	11.9					11.9
Remediator + landfill - EU - GB	6.7		1.9	8.7					8.7
Remediator + landfill - EU - NORDEL	8.9		1.9	10.8					10.8
Remediator + landfill - US - MRO	8.3		1.9	10.2					10.2
Remediator + landfill - US - NPCC	9.6		1.9	11.6					11.6
Remediator + landfill - US - WECC	7.8		1.9	9.7					9.7
Remediator + recycling - EU - CH	8.0			8.0		15.4	167.7	1.2	-143.1
Remediator + recycling - EU - FR	10.0			10.0		6.1	167.7	1.2	-150.5
Remediator + recycling - EU - GB	6.7			6.7		5.9	167.7	1.2	-153.9
Remediator + recycling - EU - NORDEL	8.9			8.9		5.6	167.7	1.2	-152.0
Remediator + recycling - US - MRO	8.3			8.3		5.5	167.7	1.2	-152.7
Remediator + recycling - US - NPCC	9.6			9.6		5.7	167.7	1.2	-151.2
Remediator + recycling - US - WECC	7.8			7.8		5.6	167.7	1.2	-153.2
Remediator + WTE - EU - CH	8.0	8.8		16.8	-73.2				-56.4
Remediator + WTE - EU - FR	10.0	8.8		18.7	-119.7				-101.0
Remediator + WTE - EU - GB	6.7	8.8		15.5	-105.4				-89.8
Remediator + WTE - EU - NORDEL	8.9	8.8		17.7	-78.6				-60.9
Remediator + WTE - US - MRO	8.3	9.0		17.2	-95.1				-77.9
Remediator + WTE - US - NPCC	9.6	9.0		18.6	-112.2				-93.7
Remediator + WTE - US - WECC	7.8	9.0		16.7	-88.7				-72.0

Appendix C: Uncertainty analysis details

Uncertainty analysis was performed for the NPCC geography only (Northeast US) as baseline results show that the NPCC geography GWP and CED results are the closest to the average across all geographies. It is assumed that other geographies will have a similar range of results. While the actual values for other geographies will vary from those of NPCC, it is expected that the trends will be similar.

Uncertainty analysis was performed using SimaPro 9.4 Monte Carlo analysis with 1,000 runs at 95% confidence for both CED and GWP.

Table C1. Waste treatment + disposal scenario uncertainty analysis results; GWP in kg CO2e, CED in MJ

SCENARIO	GWP LOW (2.5%)	GWP HIGH (97.5%)	GWP MEAN	GWP RANGE	CED LOW (2.5%)	CED HIGH (97.5%)	CED MEAN	CED RANGE
Autoclave offsite + landfill - US - NPCC	6.8	9.6	8.0	2.7	85	120	100	35
Autoclave offsite + WTE - US - NPCC	14.1	21.2	17.8	7.1	-110	66	-5	176
Autoclave onsite + landfill - US - NPCC	6.5	8.6	7.5	2.1	80	105	91	25
Autoclave onsite + WTE - US - NPCC	13.8	20.2	17.3	6.5	-115	51	-14	166
RMW incineration - US - NPCC	10.2	11.4	10.7	1.2	12	37	22	26
Remediator + landfill - US - NPCC	1.4	2.3	1.8	1.0	7	17	11	10
Remediator + recycling - US - NPCC	-2.9	-1.2	-2.2	1.6	-155	-145	-152	9
Remediator + WTE - US - NPCC	8.6	14.0	11.6	5.3	-188	-37	-94	151

Table C2. Waste treatment + disposal module uncertainty analysis results; GWP in kg CO2e, CED in MJ

MODULE	GWP LOW (2.5%)	GWP HIGH (97.5%)	GWP MEAN	GWP RANGE	CED LOW (2.5%)	CED HIGH (97.5%)	CED MEAN	CED RANGE
Autoclaved waste onsite, 12lbs - US - NPCC	5.3	6.8	6.0	1.5	78	103	89	26
RMW incineration, 12lbs - US - NPCC	9.9	10.4	10.1	0.5	7	22	13	15
Remediator device operation - US - NPCC	0.2	0.6	0.3	0.4	5	16	10	11
Remediator waste composition	17.2	18.2	17.6	1.0	447	476	461	29
Transport 200km, 12lbs waste - US	0.3	1.0	0.6	0.6	5	15	9	10
Remediator waste to energy - US - NPCC	8.1	12.4	10.7	4.3	-198	-68	-113	130
Remediator waste to landfill - US	1.2	1.8	1.4	0.6	2	1	2	-1
Remediator recycling, 12lbs - US - NPCC	0.5	1.1	0.7	0.6	5	7	6	2
Recycled PE & PP material savings	4.5	4.5	4.5	0.0	168	168	168	0
Recycling process leftover material to landfill	1.0	1.6	1.2	0.6	3	-1	1	-4

Appendix D: Critical Review Statement



Final Critical Review Statement

Date	October 21, 2024
Title of the study	Life Cycle Assessment of Sterilis Remediator and Hazardous Medical Waste Treatment and Disposal Methods
The commissioner of the LCA study	Millipore Sigma/Sterilis Solutions
The practitioners of the LCA study	Kate Winnebeck, Pure Strategies
The exact version of the report to which the critical review statement belongs	October 2024
The reviewers	Nathan Ayer, EarthShift Global (Chair) Terrie Boguski, Harmony Environmental, LLC Cassandra Thiel, Clinically Sustainable Consulting
Description of the review process, including information on:	
— whether the review was performed based on ISO 14044:2006, 6.2 or 6.3;	The review was based on ISO 14067, including Annex B for comparative PCF studies, with reference to supporting standards ISO 14044:2006 and ISO/TS 14071:2014.
— whether the review was performed in parallel or at the end of the study;	The review was performed at the end of the study.
— whether the review included or excluded an assessment of the LCI model;	The reviewers reviewed the unit process data but did not review the PCF models.
— whether the review included an analysis of individual data sets;	The reviewers did not analyze individual data sets.
Description of how comments were provided, discussed, and implemented;	Comments were provided via Excel and discussed through email. This included two rounds of comments.
Panel Decision	The study meets the ISO 14067 standard for Carbon Footprint of a Product (PCF).
Applicability of Study Results	This study provides carbon footprint results for the Remediator process for converting biohazardous waste into non-hazardous waste for recycling, as developed by Millipore Sigma and Sterilis Solutions. The results are compared with several conventional disposal methods for handling red bag medical waste. The study methods were reviewed relative to the ISO 14067 standards for the Carbon Footprint of a Product (PCF). The study also includes an assessment of cumulative energy demand but does not consider other potential life cycle impacts associated with these waste management options. The study results are only applicable to the specific waste management processes included in this analysis and may not be representative of the environmental performance of other medical waste management technologies.

Critical Review Summary

A Critical Review of **Life Cycle Assessment of Sterilis Remediator and Hazardous Medical Waste Treatment and Disposal Methods** has been carried out by Nathan Ayer, EarthShift Global, Terrie Boguski, Harmony Environmental, LLC, and Cassandra Thiel, Clinically Sustainable Consulting. The review has been carried out according to ISO 14067:2018 for a comparative PCF prepared for third party review. This review statement in no way endorses the products, technologies or approaches mentioned in the study. The reviewers assessed this PCF study and supporting documents to determine if the following conditions were met:

- The methods used to carry out the PCF are consistent with the International Standards (ISO 14067, ISO/TS 14071, ISO 14044);
- The methods used to carry out the PCF are scientifically and technically valid;
- The data used are appropriate and reasonable in relation to the goal of the study;
- The interpretations reflect the limitations identified and the goal of the study; and
- The study report is transparent and consistent.

To conduct this critical review, after a review of adherence to ISO 14067, the reviewers carefully assessed the assumptions and data used to develop the models to ensure the data were transparent and consistent and the data and assumptions were reasonable. The methods were reviewed for validity and consistency and the results were reviewed to ensure they were not over or understated. The study went through two rounds of revisions based on reviewer comments. After the final round there were no objections, and this final review statement was prepared.

Final Review Statement

All the issues raised by the reviewers have been properly addressed in the PCF report, and the reviewers assess that overall, the PCF report is in conformance with and fulfills the requirements in ISO 14067 for a comparative PCF report.

Are the methods used to carry out the PCF consistent with the international standards (ISO 14067; ISO/TS 14071, ISO 14044)?

The reviewers find that the study is consistent with the relevant ISO standards. The methodology is clearly described, and all modeling assumptions are documented and explained.

Are the methods used to carry out the PCR scientifically and technically valid?

The reviewers find that the methods used to carry out the PCF are scientifically and technically valid.

Are the data used appropriate and reasonable in relation to the goal of the study?

The reviewers find that the use of data is appropriate and reasonable in relation to the goal of the study.

Do the interpretations reflect the limitations identified and the goal and scope of the study?

The reviewers find that the interpretations reflect the limitations identified and the goal of the study.

Is the study report transparent and consistent?

The reviewers find that the study report is transparent and consistent.

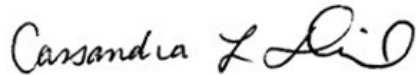
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Nathan Ayer, PhD LCACP (Chair)



Terrie Boguski



Cassandra Thiel, PhD

Appendix E: Critical Review Comments and Responses

Details of the critical review comments in alignment with ISO 14067 and ISO 14071 from the reviewers and response by the LCA practitioner have been provided to MilliporeSigma and Sterilis Solutions and is considered confidential.