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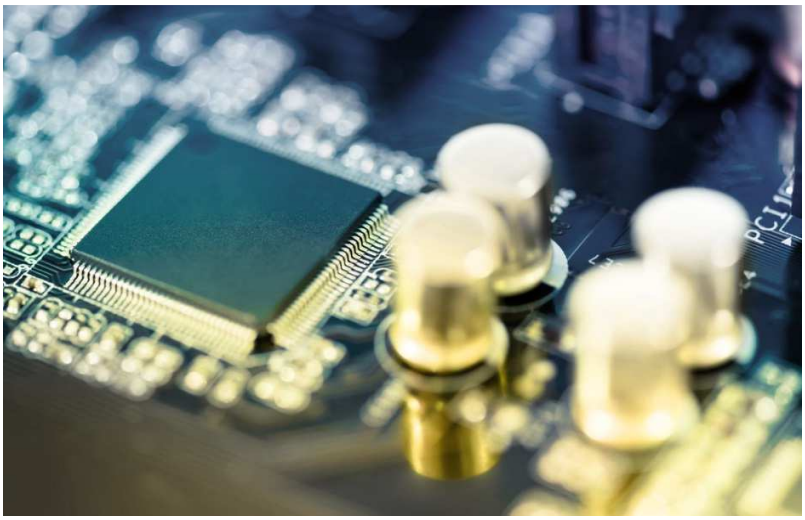

LIFE CYCLE ASSESSMENT

GEM® Sensor Card

Instrumentation Laboratory
A Werfen Company
Our Passion. Your Results.

Instrumentation Laboratory delivers innovating market-leading solutions for Hemostatis and Critical Care *in vitro* diagnostic testing.

The GEM® Sensor Card is used for the GEM® family of blood gas analyzer equipment. The disposable cartridge functions as the heart of the GEM analyzer where the testing process takes place. The sensor card is the primary unit of the cartridge and is the location of all electrochemical sensors which the GEM systems use for measuring and reporting concentrations of critical care analytes in blood.

PREPARED FOR:
Instrumentation Laboratory Co.
180 Hartwell Road
Bedford, MA
01730

DATE: April 18, 2017
VALID: 5 Years

NON-CONFIDENTIAL VERSION

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INTRODUCTION

The purpose of the environmental Life Cycle Assessment (LCA) is to support Instrumentation Laboratory's exemption application in line with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, referred to as RoHS II. The LCA produces quantified environmental impact information on the GEM® Sensor Card and two potential alternative material composition options, as described below.

PRODUCT INFORMATION

Manufacturer Information

Instrumentation Laboratory is a leading manufacturer of equipment used for analysis of critical care analytes in blood used in hospitals and laboratories in all world markets. Instrumentation Laboratory operates under ISO 14001 and is committed to meeting European and country specific environmental requirements.

Instrumentation Laboratory manufactures the GEM Premier diagnostic medical analyzers for the EU Market. These instruments are used to measure the blood of patients and provide clinicians with accurate measurements of specific analytes, vital to medical diagnosis and patient treatment. The reported analytes include, among others, pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate and hematocrit.

Product Description

The sensor card in the disposable cartridge is made of polyvinyl chloride (PVC). Use of PVC as the sensor card material dates back to the 1980s when the GEMStat and GEM 6 analyzers were first launched, and the same molded card has been carried forward to the currently manufactured analyzers (GEM Premier 3000, GEM Premier 3500, GEM Premier 4000 and GEM Premier 5000). The sensor card is located in the disposable cartridge which is used in these instruments. Electrochemical sensors for the following critical care analytes are located on the sensor card: partial pressure of oxygen and carbon dioxide (pO_2 and pCO_2), pH, Na^+, K^+, Ca^{++}, Cl, glucose, lactate and hematocrit.

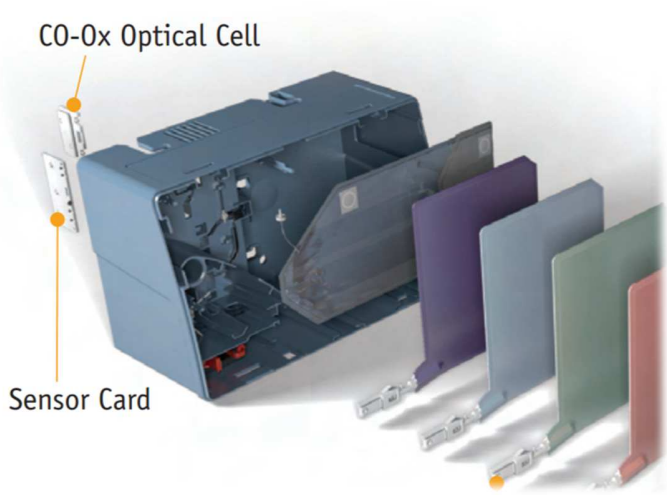

Figure 1: GEM Sensor Card Illustration

Material Content

The GEM® Sensor Card contains lead stabilizer in order to function in the cartridges of the GEM® family of critical care analyzers. The presence of lead requires an exemption from the European Directive RoHS II. Thus, this Life Cycle Assessment evaluates the environmental impact of the current PVC card with lead stabilizer, compared with two potential alternatives with reduced lead content.

The proprietary and confidential GEM® 3000/3500 Sensor Card configurations have been provided to the LCA practitioners and included in the LCA. However, they are not shown here for confidentiality reasons. The current card weighs 3.2 grams, the majority of which is PVC, with a small amount of tribasic lead sulfate stabilizer. The potential alternative cards also weigh 3.2 grams and also consist mainly of PVC. Alternative #1 has an organic (lead-free) heat stabilizer instead of tribasic lead sulfate stabilizer. Alternative card #2 has an organic heat stabilizer and barium sulfate instead of tribasic lead sulfate stabilizer. The LCA compares the environmental impacts associated with these three configurations.

GEM® Sensor Card weight varies between the series of analyzers. The weight of each GEM® Sensor Card series is as follows:

- GEM® 3000/3500 Sensor Card: 3.2g
- GEM® 4000 Sensor Card: 5.1g
- GEM® 5000 Sensor Card: 3.8g

The GEM® 3000/3500 Sensor has been analyzed in this LCA. Should values for the GEM® 5000 Sensor Card environmental impacts be required, they can be scaled according to changes in overall weight per card. The weight of the GEM 5000 card is 119% of the weight of the GEM 3000 card, so the environmental impacts shown in this report can be scaled by 119% to achieve GEM 5000 results. The GEM 4000 card has a slightly different composition, which means that scaling will produce an approximate result. Multiplying the GEM 3000 results by 159% will produce approximate GEM 4000 results.

METHODOLOGY

LCA Framework

The LCA and report were prepared in accordance with *ISO 14044: 2006 Environmental Management – Life Cycle Assessment – Requirements and Guidelines*. The Life Cycle Impact Assessment and impact category results are presented following the ReCiPe 2008 method, developed and widely accepted in the European Union (EU). The ReCiPe method evaluates 18 mid-point impact categories, as demonstrated in Table 2 below. To facilitate the LCA and perform the impact assessment, Intertek utilized SimaPro 8.3 LCA software, with data from the Ecoinvent 3.3 database and the National Renewable Energy Laboratory (NREL) U.S. Life Cycle Inventory Database. The data in these built-in resources were applied for commonly used materials, products and processes when internationally accepted generic information is required.

Functional Unit

The declared functional unit for this LCA is **1 GEM® 3000/3500 Sensor Card**.

Boundary

The system boundary for this LCA is defined as 'cradle-to-grave', representing raw material extraction and pre-processing, production, distribution, use and end of life stages. Transportation between stages is also accounted for within the system boundary. Figure 2 overleaf shows the LCA stages and system boundary.

Allocation

Allocation for this LCA followed the requirements and guidance of ISO 14044:2006, which gives preference to mass based allocation.

Cut-Off Criteria

As per the guidance of ISO 14044:2006, there is a minimum cut-off for inputs and outputs by mass, energy and environmental impact. Any material component that is below 1% by mass is excluded from the analysis. It is anticipated that the energy and environmental impacts of the components present below 1% will not be significant for the purpose of the LCA comparison between the current and alternative card configurations.

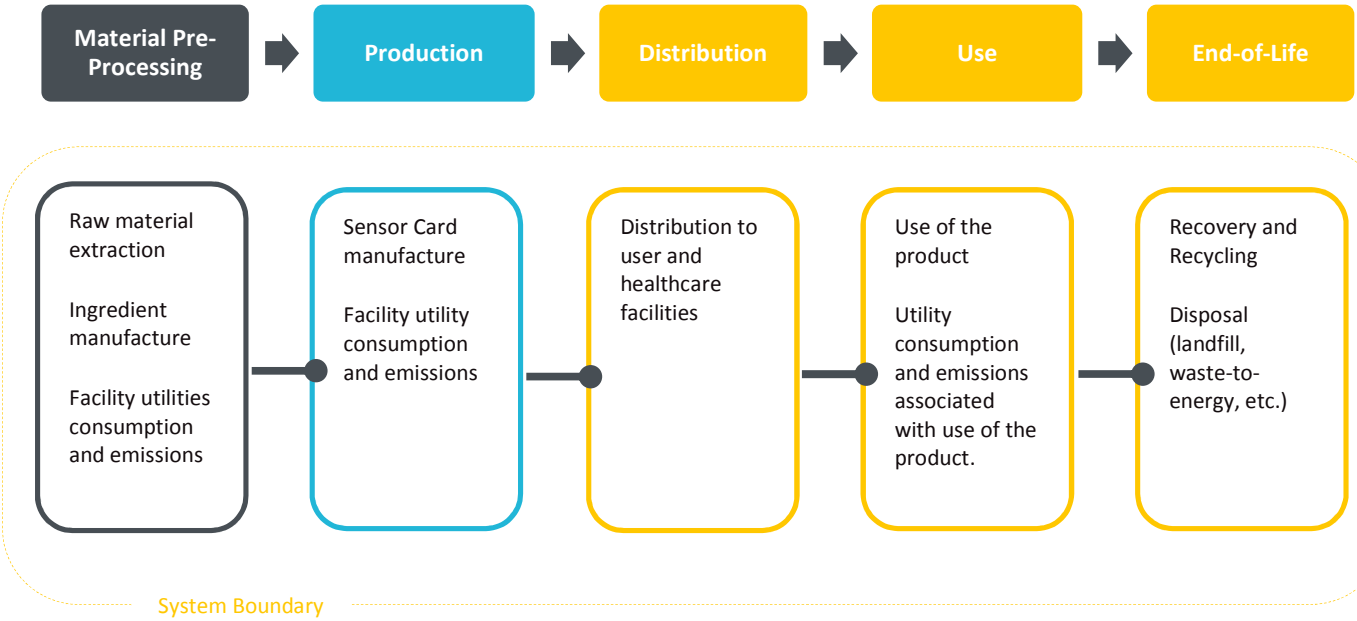

Figure 2: GEM® Sensor Card LCA System Boundary

Assumptions

The following assumption are applicable to this LCA:

- The card is assumed to be manufactured in the US and used in Europe.
- The current card and the two alternatives are all assumed to provide the same functionality and lifespan.
- Both alternative GEM® Sensor Card configurations contain an Organic Based Stabilizer (OBS) for thermal stability. This is to replace the heat stabilizing properties of lead in the current card. The particular OBS sourced by Instrumentation Laboratory as a potential option for the GEM® Sensor Card is proprietary to the chemical supplier, and exact information could not be obtained on the precise compounds used in the OBS. An approximate formulation was used in the LCA, based on discussion with the vendor.

ENVIRONMENTAL PERFORMANCE

Carbon Footprint

Carbon Footprint, a common term for Global Warming Potential (GWP) or Climate Change, is a recognized measure of Greenhouse Gas (GHG) impact, in units of CO_2 equivalent. The overall life cycle carbon footprint of 1 GEM® 3000/3500 Sensor Card is summarized below for the three options:

Current: 10.5 gCO_2 eq.

Alternative #1: 13.9 gCO_2 eq.

Alternative #2: 13.5 gCO_2 eq.

The chart below illustrates that carbon footprint comparison between the current GEM® 3000/3500 Sensor Card material configuration and the two alternatives.

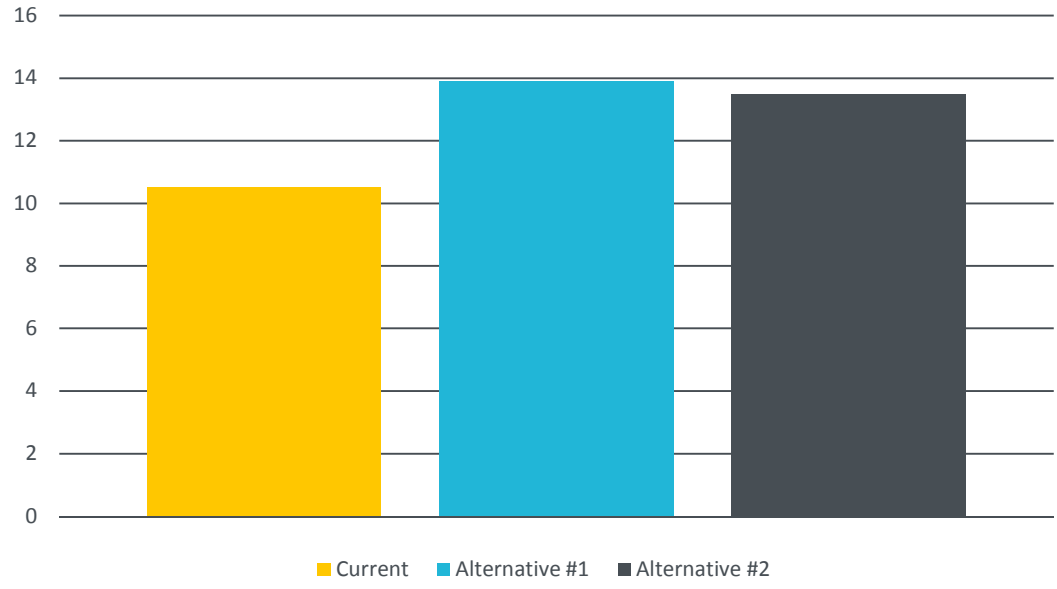

Figure 3: Carbon Footprint, Three GEM® Sensor Card Configurations

Life Cycle Environmental Impacts

Environmental impacts were assessed over the whole life cycle using the standard European ReCiPe impact assessment method. The results for 1 GEM® 3000/3500 Sensor Card in all three configurations are shown in the table below.

Table 1:Environmental Impact, Three GEM® Sensor Card Configurations

IMPACT CATEGORY	UNIT	CURRENT CARD	ALTERNATIVE #1	ALTERNATIVE #2
Climate Change	**kg CO_2 eq.**	0.0105	0.0139	0.0135
Ozone Depletion	**kg CFC[1]-11 eq.**	1.03E-09	1.33E-09	1.38E-09
Terrestrial Acidification	**kg SO_2 eq.**	6.00E-05	7.08E-05	6.89E-05
Freshwater Eutrophication	**kg P eq.**	2.34E-07	2.69E-07	2.63E-07
Marine Eutrophication	**kg N eq.**	9.53E-07	3.03E-05	2.90E-05
Human Toxicity	**kg 1,4-DB[2] eq.**	0.0023	0.0017	0.0016
Photochemical Oxidant Formation	**kg NMVOC[3] eq.**	2.67E-05	3.69E-05	3.63E-05
Particulate Matter Formation	**kg PM10 eq.**	1.83E-05	2.30E-05	2.25E-05
Terrestrial Ecotoxicity	**kg 1,4-DB eq.**	5.09E-07	8.52E-07	8.51E-07
Freshwater Ecotoxicity	**kg 1,4-DB eq.**	1.84E-05	2.35E-05	2.33E-05
Marine Ecotoxicity	**kg 1,4-DB eq.**	1.65E-05	2.07E-05	2.02E-05
Ionizing Radiation	**kg U^{235} eq.**	1.34E-04	2.27E-04	2.62E-04
Agricultural Land Occupation	**m^2 yr.**	9.25E-05	2.02E-05	1.97-05
Urban Land Occupation	**m^2 yr.**	5.09E-05	6.87E-05	6.95E-05
Natural Land Transformation	**m^2**	4.81E-07	9.32E-07	11.4E-07
Water Depletion	**m^3**	5.24E-05	10.1E-05	10.9E-05
Metal Depletion	**kg Fe eq.**	3.67E-04	2.79E-04	2.73E-04
Fossil Depletion	**kg oil eq.**	3.88E-03	5.53E-03	5.50E-03

[1] Chlorofluorocarbon
[2] 1,4 Dichlorobenzene
[3] Non Methane Volatile Organic Carbon compound

Life Cycle Energy Consumption

The Cumulative Energy Demand (CED) for 1 GEM® 3000/3500 Sensor Card in all three configurations is shown in the table below.

Table 2: Cumulative Energy Demand, Three GEM® Sensor Card Configurations

IMPACT CATEGORY	UNIT	CURRENT	ALTERNATIVE #1	ALTERNATIVE #2
Non-Renewable, Fossil	**MJ**	0.172	0.246	0.244
Non-Renewable, Nuclear	**MJ**	0.0034	0.0068	0.0067
Non-Renewable, Biomass	**MJ**	3.98E-07	6.13E-07	6.73E-07
Renewable, Biomass	**MJ**	6.50E-04	14.5E-04	14.2E-04
Renewable Wind, Solar, Geo	**MJ**	2.04E-04	3.61E-04	3.57E-04
Renewable, Water	**MJ**	1.09E-03	1.95E-03	1.93E-03

INTERPRETATION

Environmental Performance

The current card and the two potential alternatives offer environmental performance that is of the same order of magnitude. The current card is somewhat superior to the two potential alternatives. The Current GEM® Sensor Card has a carbon footprint of 10.5 gCO2eq, compared with 13.9 and 13.5 for the two alternatives (lower carbon footprint is better). The carbon footprint of the current card is 22% lower than the next lowest card. Considering 23 environmental impact measures (ReCiPe and CED), the current card has the lowest environmental impacts in 20 categories, and the highest in the remaining 3 categories. The results of the CED analysis demonstrate that the Current GEM® Sensor Card consumes less energy in its production, distribution, use and disposal than both Alternative #1 and Alternative #2. Thus, overall, the results of the LCA indicate that the Current GEM® Sensor Card has lower environmental impact (superior environmental performance) than Alternative #1 and Alternative #2.

Human Health Performance

LCA methodology focuses on environmental (ecological) impacts rather than toxicology, but the ReCiPe method does provide one general human health parameter termed Human Toxicity. This category is considered approximate by the scientific panel that developed the measure. On this measure, the Current GEM® Sensor Card scored 2.3 grams 1,4-DBeq, while the potential alternative cards scored 1.7 grams and 1.6 grams (lower is better). All three card configurations showed Human Toxicity results within the same order of magnitude, with the Current GEM® Sensor Card being 43% higher impacts than the alternative cards. Since the results of all three card configurations show Human Toxicity impacts within the same order of magnitude and the ReCiPe method developers consider results in this category to be approximate, difference in results are not considered significant between the Current GEM® Sensor Card, Alternative #1 and Alternative #2.

The U.S. Environmental Protection Agency (EPA) has developed an alternative LCA impact methodology, Tool for Reduction and Assessment of Chemical and Other Environmental Impacts (TRACI). The TRACI method is more commonly used in the U.S. than in Europe, so this study focused on the European ReCiPe method as reported above. However, for comparison purposes, a TRACI 2.1 impact assessment was also carried out for the three GEM® Sensor Card configurations. TRACI reports Human Toxicity in Comparative Toxic Units (CTU) for both carcinogenic and non-carcinogenic sub-categories. These sub-categories are often reported as a combined CTU value. The results of the TRACI impact assessment for Human Toxicity showed the Current GEM® Sensor Card was found to have the highest impact in the carcinogenic sub-category and the lowest impact in the non-carcinogenic sub-category. Furthermore, the combined Human Toxicity values were not significantly different, supporting the ReCiPe results discussed above.

In addition, there is another human health aspect that is worth noting even though it is outside the scope of this LCA: if the alternative cards are found to reduce performance of the blood gas analyzer, the alternative cards could negatively impact human health.

Conclusion

The overall results of the LCA show that the Current GEM® Sensor Card had lower environmental impacts in most of the ReCiPe environmental impact categories. The carbon footprint of the current card is lower than that of both Alternative #1 and Alternative #2 cards. Additionally, the Current GEM® Sensor Card consumes less energy over its life cycle compared to the two alternatives. Based on the results of the LCA, in terms of environmental impacts the Current GEM® Sensor Card performs better than the currently available alternatives.

Disclaimer

This LCA was prepared in accordance with ISO 14044:2006 for an exemption application for RoHS II. The environmental impact results were reported using standard methods and impact categories, but there may be relevant environmental impacts beyond those disclosed by LCA results. The results in the LCA are estimations of potential impacts. The accuracy of results in different LCAs may vary as a result of methodological choices, background data assumptions and quality of data collected. Not all LCAs are comparative assertions and are either not comparable or have limited comparability to other materials, products or processes when they cover different life cycle stages, are based on different product category rules or are missing relevant environmental impacts. Such comparisons can be inaccurate and could lead to the erroneous selection of materials or products which are higher impact, at least in some impact categories. Any comparison of LCA results shall be subject *to ISO 14025: 2006 Environmental Labels and Declarations – Type III Environmental Declarations – Principals and Procedures*.

Data Quality

Time Related Coverage

Most of the data used in this LCA are secondary data taken from existing LCI databases and updated as of 2017.

Geographical Coverage

The geographical boundary of this LCA is focused on manufacture in the United States, and distribution, use and disposal in the European Union. While the product is used and distributed to other jurisdictions, these are outside of the scope of this LCA and report. However, results are expected to be similar for any geographical region.

Precision

Secondary data was obtained from publicly available and internationally recognized Life Cycle Inventory databases, including Ecoinvent 3.3 and the NREL US Life Cycle Inventory database. They are expected to reflect the studied systems closely, but may not be accurate for all potential production systems.

Completeness and consistency

LCA practitioners have evaluated secondary data for completeness and ensured that all assumptions and cut-off criteria were clearly stated where required. This LCA is considered to have a satisfactory degree of completeness. Secondary data were used to evaluate the majority of the stages of the LCA shown in Figure 2. For all stages, assumptions and methodology were applied consistently. Any modifications and assumptions were documented in the Assumptions section of the report. Global consolidated values for each component were selected for the Life Cycle Impact Assessment in the Ecoinvent 3.3 database for consistency across product components.

Reproducibility
Should the same primary and secondary data be available and selected, this LCA is considered to be reproducible.

Critical Review
This LCA is not intended for use in comparative assertions or disclosed to the public, thus a critical review was not applied to this LCA as per ISO 14044:2006 guidance.

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