BME 590: Medical Instrumentation Design
Design Foundation Document

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We have adhered to the Duke Community Standard in completing this assignment.

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1 Design Context Review

1.1 Background

At Clinical Hospital San Rafaél Arcángel in Guanacaste, Costa Rica, the pathology lab of Dr. Emmanuel Gonzalez currently disposes of its tissue waste in a cemetery 5 km from the hospital. Upwards of 80 kg of human tissue waste is transported from the hospital to the cemetery every week, buried and treated with chemicals including xylon, alcohols, formalin, eosin, and hematoxylin. In addition to the inconvenience and expense of transportation, this cemetery is dangerously close to a local river, posing the risk of chemical or biohazardous contamination of the water supply. [1]

The pathology lab performs roughly 500 autopsies and 14,000 biopsies each year. While incineration is the standard method of tissue disposal, the nearest crematory is 300 km away from the hospital. The expense of tissue burial includes at least $800 per month for a service to remove the waste, $1,000 per year to use the space in the cemetery, and another $1,600 every year to excavate new holes, a cost of roughly $12,200 per year. Given the conditions, a cost-effective, safer disposal method is needed. [1]

Costa Rica is also well-known for its concern for environmental preservation and eco-tourism. As such, the hospital hopes to find a new solution which ensures minimal environmental impact. Chemical treatment is a common method of waste removal worldwide, but without proper disposal it carries the risk of contaminating water and soil. In many rural areas in developing countries, there is no easy access to a crematory. As discussed in the Market Analysis below, hospitals and clinics worldwide could benefit from other low-cost solutions for tissue disposal. Based on this analysis, a form of incineration or heat treatment is the best option. [1]

1.2 Current Technologies

The most straightforward approach is to develop a low-cost incinerator. The three most common types of incinerators are controlled air, excess air, and rotary kiln. Controlled air incinerators are the most common technology used in medical waste incinerators. They have two chambers separated by a narrow passage or chimney: the lower chamber where primary burning of the solid waste occurs, and the upper chamber where volatile waste continues to burn. In the first stage, air intake is limited to cause incomplete combustion. Excess air is then added in the secondary chamber, occasionally with more fuel, to complete combustion. These incinerators generally have low particulate matter emissions because the gas leaving the primary chamber has a relatively low velocity as a result of incomplete combustion. With low vapor velocities and steadier flow, particulate matter is less likely to be stirred from the mass of waste in the primary chamber. [2]

Excess air incinerators generally have two adjacent chambers separated by baffles, rather than an external chimney. Often, the secondary chamber is ignited first and brought to temperature. Once the set point is reached, the primary chamber where solid waste is held ignites. The primary waste burns completely, and the gases released are then burned again in the secondary chamber, both stages injecting fuel into the mixture. [2]

While controlled air and excess air incinerators leave waste stationary while burning, rotary kiln incinerators have a primary chamber which rotates on a small angle, moving the waste from the input to the exit as combustion occurs. Like other methods,

a secondary chamber is used to burn volatiles. In most rotary kilns, both chambers operate under excess air, resulting in higher gas velocities and higher levels of emissions. The motion of the burn platform agitates particulate matter more than excess air alone, and as such rotary kilns tend to have the highest levels of particulate matter. [2]

An alternative to incineration is pyrolysis, decomposition through high temperature not necessarily by incineration, often through inductive or resistive heating. This method is generally performed in an oxygen-poor environment to prevent combustion. Starving the environment of oxygen also prevents the formation of dioxins, toxic compounds which are often found as a result of combustion in the presence of excess oxygen. Inductive heating involves applying an alternating current to a coil, inducing a changing magnetic flux within the coil. A metal object placed in the center will experience induced eddy currents which dissipate as heat due to the resistance of the object in the field [3]. Resistive heating simply involves running a current through resistive elements. Both options may provide easier access to a fuel source than conventional incinerators/heat treatment options due to their dependence on electricity rather than combustion. Advantages of inductive heating include precise temperature control and smaller temperature changes in the coil itself, limiting the risk of circuit meltdowns.

Finally, plasma gasification may also be a solution. This process is occasionally used to convert municipal waste to reusable fuel sources. A high voltage is used to create an arc across two terminals, and an inert gas is passed between and ionized, resulting in temperatures greater than 14,000 °C. Waste exposed to these temperatures is decomposed into basic elements ultimately producing syngas, a mixture of hydrogen and carbon monoxide, and slag, residual waste of heavy metals and inorganic compounds. The syngas can be later purified and used for fuel elsewhere [4]. Although this is a highly efficient process with strong potential benefits, there are also risks associated with such high voltage and temperatures. Furthermore, access to large quantities of gases used in the plasma torch may be difficult to acquire in developing countries. Finally, the remaining slag has been found to contain significant quantities of acids and dioxins which can require further treatment [4].

1.3 Regulations

Regulations surrounding heat treatment, especially incineration, tend to focus on the emissions produced by the device rather than the degree of sterilization. It can be generally assumed that complete combustion will destroy most pathogens effectively. According to the United States Center for Disease Control, on-site incineration is a viable treatment option for microbiological, pathological and anatomic waste so long as "the incinerator is engineered to burn these wastes completely and stay within EPA emissions standards." Furthermore, the organization states, "from a microbiologic standpoint, waste need not be rendered sterile because the treated waste will not be deposited in a sterile site [5]." Thus the concern for the device meeting applicable regulations and standards rests more heavily on what the device emits during use than what is left of the waste after incineration. In the United States, the EPA sets these standards, and they are the most clear, complete, and available guidelines. These guidelines are used in this review, under the assumption that they would be more strict than those of most developing countries that this device will be targeted towards, but also with the understanding that individual countries policies would need to be followed should the product be released there.

Emissions in the U.S. are regulated by the EPA as mandated by the Clean Air Act. The most recent revision came in 2013 with an update to the Federal Implementation Plan for Hospital, Medical, and Infectious Waste Incinerators (HMIWI) in document 78 FR 28051. These rules set guidelines for emissions of the following nine substances for medical waste incinerators:

cadmium, carbon monoxide, hydrogen chloride, lead, mercury, nitrogen oxides, particulate matter, polychlorinated dibenzo-dioxins and polychlorinated dibenzofurans, and sulfur dioxide. Based on their size, devices under consideration would be classified as "Small Rural" or "Small," and affected by the least strict regulations. [6]

1.4 Competitive Products

To assess the current market, multiple companies which produce medical waste incinerators were contacted. Quotes and statistics from four manufacturers, Inciner8 International, GEI Works, Elastec, and FireLake Incinerators, are listed in Table 1 below. It was decided that the smallest units available will likely meet or exceed the customer needs.

Table 1: Summary of quotes received

Unit	Volume (m^3)	Waste Burn Rate ($\frac{kg}{hr}$)	Fuel Source	Price
GEI Works Helios 0.3	0.40	13.6-22.6	Diesel or Fuel Oil	$43,200
Inciner8 I8-10s	0.10	20	Diesel	$11,200
Elastec Mediburn	0.28	20	Diesel	$32,000-34,000
FireLake P16-SC4	0.27	unlisted	Liquid Petroleum, Natural Gas, or Fuel Oil	$35,950-39,950

All of these units use a two-chamber controlled air design, good for quick, efficient, low emission small-scale incineration. There is a large price range for devices currently on the market. Although the least expensive model quoted is likely in range of the budget of Hospital San Rafaél Arcángel, many locations in need of this technology may not be able to afford an $11,200 investment.

An alternative new design could involve pyrolysis using inductive heating. Although many companies and institutions use inductive heating for countless purposes from metal treatment and forging to kitchen stoves, there are limited commercially available waste management solutions which use this technology. Fuji Electric developed a prototype for municipal waste treatment in 2001, but it is not clear whether it reached production [3]. Similarly, although there are some plasma gasification plants in China and Japan [4], there are limited examples of small-scale medical waste solutions using this method.

There is a need for small-scale tissue waste management at low cost with low emissions. The goal of the *Ignis* team is to design a way to sterilize human tissue and chemical waste in hospitals and research settings without easy access to large-scale waste management facilities that quickly and safely neutralizes biohazards and reduces waste mass without significantly impacting water or air quality in the surrounding areas.

2 Market Analysis

Pathologists who produce waste from biopsies, autopsies, placentas, and contaminated liquids comprise a large portion of the market for a small medical waste management device. Researchers conducting human trials, such as those dealing with infectious diseases, also form a possible market segment. These groups of medical staff and researchers are especially in need when they are geographically separated from established medical waste disposal centers often found in larger cities and urban

areas [1]. In Costa Rica, there are 10 general hospitals, 7 regional hospitals, 13 peripheral hospitals, and 500 health clinics [7].

It is believed that most regional hospitals, peripheral hospitals, and the smaller health clinics are in locations without pre-existing medical waste incineration centers [1], and that approximately 15% of health clinics deal with pathology-related matters. Costa Rica's population of 4.857 million [8] was divided by the number of hospitals, 20, to get roughly 250,000 people per hospital. Similarly, the population was divided by the 75 clinics that could deal in pathology to get approximately 65,000 people per clinic. Using this ratio, the number of mid-size hospitals and health clinics across Latin America was estimated as shown in Table 2 in the Appendix. For Latin America, roughly 2,500 hospitals and 10,000 clinics would benefit from a small medical waste management system. According to Dr. Gonzalez, improper medical waste disposal is a large issue in Latin America as a whole, and as such the market was analyzed for that region. Likely, there is a large market outside of Latin America in other parts of the world.

In Latin America, there are 3,202 active clinical trials, with 2,097 being observational or interventional studies [9]. Assuming out of those 2,097 trials, roughly one half are interventional, or dealing with medical devices or procedures, then there are approximately 1,000 human clinical research operations that could be producing medical waste.

The current method of waste disposal for Hospital San Rafaél Arcángel is to transport the biological and liquid waste and bury it in cemetery plots. According to Dr. Gonzalez, the cost of this practice is over $12,000 per year, between the $800 monthly transportation expense, the $1,000 annual contract with the cemetery, and the $800 biannual excavation of a new hole. This solution leaves the medical waste largely untreated and buried in close proximity to a local water source. As much of the liquid waste is flammable, transporting it to a city with an established medical waste incinerator would be costly and dangerous. One current solution is a small medical waste incinerator, that can be installed on site at various hospitals and clinics.

There is currently a market for these incinerators, with four competing companies leading the way. As referenced in Table 1, these companies have competing volumes, waste burn rates, fuel sources, and prices. The prices range from $11,000 to $43,000, and while some hospitals and clinics could likely afford this expense, many may still be unable.

With mid-size hospitals such as Hospital San Rafaél Arcángel already paying over $10,000 per year for waste disposal, it should be reasonable to assume that hospitals of similar size will be willing to pay $10,000 as a one time expense for a medical waste management device. The smaller clinics likely do not have as much medical waste nor as much funding, and are therefore estimated to be able to pay roughly $1,000 for such a device. Clinical research teams are often underfunded, and can be assumed to only be able to pay $300 per unit.

The Total Addressable Market (TAM) for 2,500 mid-size hospitals paying $10,000 each is $25,000,000. For 10,000 small health clinics able to pay $1,000 each, the TAM is approximately $10,000,000. Finally, for 1,000 research labs conducting as many studies, and able to pay only $300 each, the TAM is $300,000. A combined TAM for Latin America on small medical waste incineration or management units is $35,300,000.

3 Customer Needs

Most devices are designed to make safety a priority, especially in medicine. With regard to medical waste management, this is important on two distinct fronts. First, it is essential that the device is safe to operate and poses minimal risk to the user. Second, it is also important that the resulting medical waste is safe to handle and easy to eliminate. In these two regards, the safe operation of the system and its ability to successfully treat and eliminate waste are the first priorities of the apparatus.

While safe operation of the device is easy to quantify, such as eliminating risk of explosions and decreasing the risk of burns or other injuries, sterilization guidelines are somewhat less clear [5]. Nevertheless, it will be important to ensure complete destruction of pathogenic waste to prevent the transmission of infectious agents.

Beyond the safety of the user, both Dr. Gonzalez and many administrative bodies worldwide are concerned with the emissions and pollutants produced by tissue disposal procedures [1]. The Costa Rican economy, like that of many Latin American countries, is highly dependent on tourism [10]. Although many countries strive to preserve their natural resources and environment, dependence on tourism provides an added incentive to keep the air and water clean. According to Dr. Gonzalez, this is one of the driving factors for his interest in the project, as he believes that the current method of tissue and fluid disposal is highly detrimental to the environment [1]. It is especially important because Dr. Gonzalez's lab is currently disposing of 60 - 100 L of untreated fluids like formalin into the sewer system [1]. As a result, eliminating waste and contaminants from the water supply is an extremely important component of this project, and to a lesser extent, so is the elimination or minimization of harmful gas emissions.

While these are the primary concerns of the users and governing bodies of medical waste disposal, there are two components that are crucial in all practices: time and money. Dr. Gonzalez's pathology lab generates roughly 80 kg of tissue waste and 80 L of hazardous fluids every week, and these must all be disposed of in a timely and cost effective manner [1]. The dangers of these wastes increase the more hospital staff and the surrounding environment are exposed to them. Dr. Gonzalez's current solution involves waste disposal every other day and costs over $10,000 per year; as such, the ideal solution would run quickly to dispose of waste as it is generated, and cost as little as possible. For an all-encompassing, prioritized list of customer needs, refer to Table 3.

4 Design Specifications

Working from Table 3, the device must be designed to meet requirements of user safety, complete sterilization, minimal environmental impact, and ease of use expected by our customer. First and foremost, to ensure user safety the device must meet or exceed the safety standards for inductive heating. Specifically this will be accomplished by isolating the operator from the extreme temperatures inside the device. Inclusion of a locking door, an emergency shutoff, and an emergency pressure release valve will help to ensure safety standards are met. Further, commonly touched areas including manual valves, control panels, and switches must not exceed 20 °C above ambient temperature.

In order to ensure sterilization of medical waste, the temperature must be properly monitored and controlled such that 0.6 kg of waste completes one heat cycle in 40 minutes. One heat cycle denotes that the induction coil heats up from 400 °C

to approximately 800 °C and then back down to 400 °C. To safely and accurately reach these temperatures, precise heating curves must be followed and the temperature must be measured at multiple locations within both chambers. In addition to sterilization, air quality is of great concern for incineration and heat treatment for waste management. The device must meet all EPA standards for emissions according to HMIWI guidelines [6], as well as the standards of the country in which it is being used. The Costa Rican government doesn't have official standards in this regard, so the French standard: NF X30-503: 2016 will be used at the recommendation of Luis Gene, a Master of Bio Ethics and knowledgeable resource on Costa Rica's waste management. The standard denotes sterilization as reducing the concentration of pathogens by 106.

As the device is intended for low-resource settings, cost is an important factor. Based on the Market Analysis, the device will be constructed at an approximate cost of $1,000. Replacement parts should be available at a low cost, and maintenance should be possible by local staff. Finally, to ensure ease of use, the user interface will be simple and limited. The materials required to run the device including fuel sources and consumables like filters should be easily accessible in the chosen market.

5 Design Specifications

The device must be designed to meet requirements of user safety, complete sterilization, minimal environmental impact, cost effectiveness, and ease of use. To ensure user safety, operators must be isolated from extreme temperatures inside the device. The unit must include a locking door, an emergency fuel shutoff, fuel isolation from the heating chamber by valves and distance in piping when assuming a liquid fuel supply source, and emergency pressure release valve. To prevent burns, commonly touched areas including manual valves, control panels, and switches must not exceed 20 °C above ambient temperature.

In order to sterilize medical waste, the temperature must be properly monitored and controlled. The current competitive incinerator design is two chambers, one upper and one lower, to heat up medical waste and then incinerate. These chambers are operated at 760-980 °C and 980-1095 °C, respectively [2]. To safely and accurately reach these temperatures, precise heating curves must be followed and the temperature must be measured at multiple locations within both chambers. In addition to sterilization, air quality is of great concern for incineration and heat treatment for waste management. The device must meet all EPA standards for emissions according to HMIWI guidelines [6], as well as the standards of the country in which it is being used.

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A Supporting Documentation

Table 2: Latin American countries with corresponding population, hospitals, and clinic values.

Latin American Country	Population	Approx. No. of Hospitals	Approx. No. of Clinics	Total Addressable Market
Brazil	204 mil	816	3138	$11M
Mexico	121 mil	484	1862	$6.7M
Colombia	48 mil	192	738	$2.7M
Argentina	43 mil	172	662	$2.4M
Peru	31 mil	124	477	$1.7M
Venezuela	30.6 mil	122	471	$1.7M
Chile	18 mil	72	277	$997K
Ecuador	16.3 mil	65	251	$901K
Guatemala	16.2 mil	65	249	$899K
Cuba	11.3 mil	45	174	$624K
Haita	11 mil	44	169	$609K
Bolivia	10.5 mil	42	162	$582K
Dominican Republic	9.98 mil	40	153	$553K
Honduras	8.95 mil	36	138	$498K
Paraguay	7 mil	28	108	$388K
Nicaragua	6.5 mil	26	100	$360K
El Salvador	6.46 mil	26	99	$359K
Costa Rica	4.857 mil	20	75	$275K
Panama	3.8 mil	15	58	$208K
Uruguay	3.3 mil	13	51	$181K
Total	611.7 mil	2,500	10,000	$35M

Table 3: Prioritized List of Customer Needs

Customer Need	Priority
Must Have Minimal Risk to User	1
Must Neutralize Biohazard	1
Must Not Contaminate Water Supplies	2
Must Have Clean Emissions	3
Time of Treatment Must Be Short	4