Omni-Sense

Sense the dangers of everyday life before it's too late.

Team 1 – Christopher Cabrera, Michael McClendon, & Shawn Roemer

ETG 4950, Section 521F

Professor Yousef

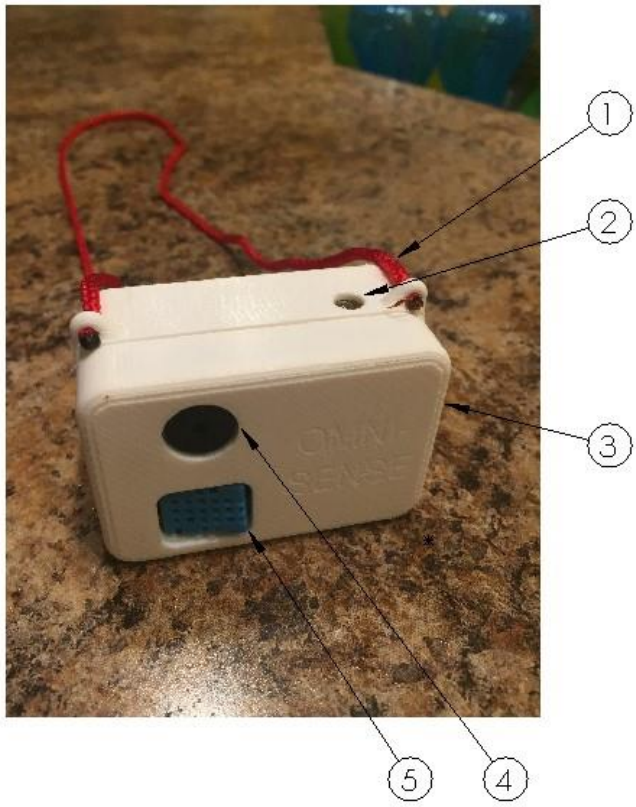
Fall 2018 Semester

Product Description

Omni-Sense is a fashionable and durable piece of jewelry that is engineered to save lives. Its sleek design is coupled with its functionality as a sensor for elements that can prove harmful to the body.

Omni-Sense will be used to detect potentially dangerous levels of either smoke, carbon monoxide, temperature and/or humidity, all while doubling as decorative jewelry. This device will be able to adapt to an individual's lifestyle, utilizing applications that range from detecting hazards for the elderly (in their environment) to professionals such as firefighters (in their persistently dangerous environment).

Omni-Sense will have future offerings of additional enclosure types, colors and lanyards that may be customized by the customer to fit their individual style.



1. Lanyard
2. LED
3. Housing
4. Buzzer
5. Sensor

Key Innovations

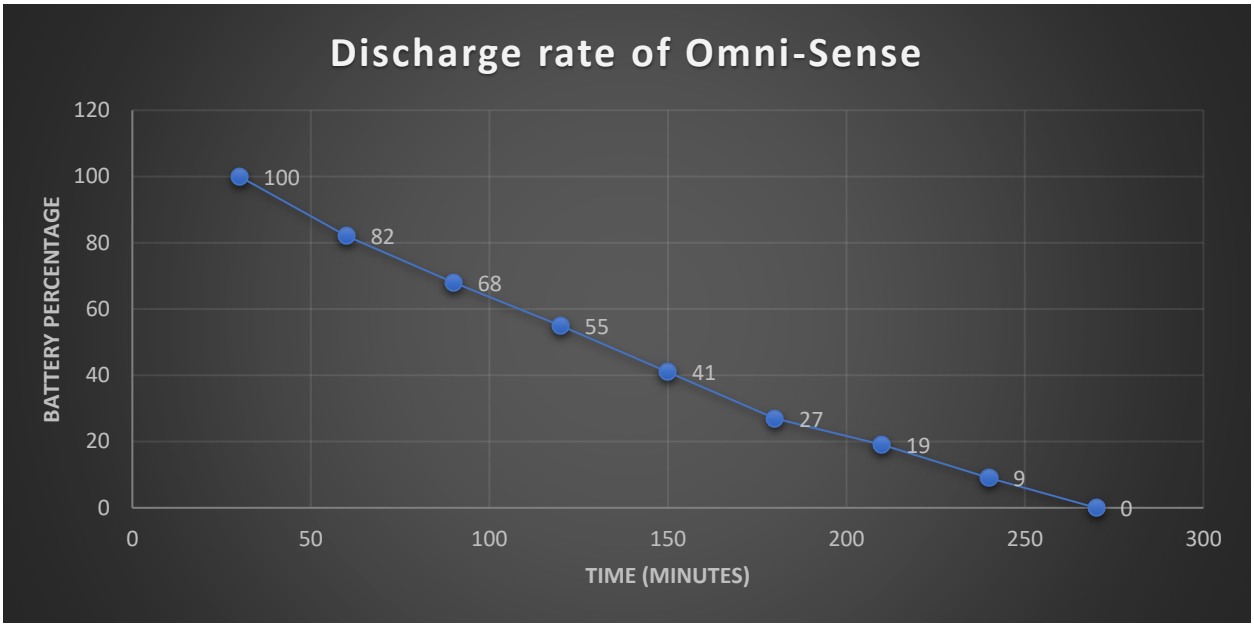
Omni-Sense offers some key innovations over existing/competitive products.

1. **Stylish Design**
    a. Different types of enclosures to fit the customer's style.
    b. Multiple enclosure color options, with the ability to special order custom colors.
    c. Multiple styles and lengths of lanyards.
2. **Durability**
    a. Strong yet light construction
    b. Shock-proof
    c. Splash resistant
3. **Adaptability**
    a. Able to be worn around the neck, or modifiable to be worn on the wrist, ankle or belt.
    b. Lanyard can be custom selected to fit the customer's wants/needs.
4. **Web Accessibility**
    a. Live 24/7 monitoring allowing caregivers or family to receive real-time reports of conditions.

Test Results

Omni-Sense was tested for battery discharge, functionality and visual pass/fail criteria.

1. **Battery Discharge Results:**



2. **Functionality Test Results:**

FUNCTIONALITY TESTING		
LED Light		
Pass	Fail	
✓		Did the light come on immediately after temp. threshold was met?
✓		Was the brightness of the light satisfactory?
✓		Was the correct indication light engaged?
✓		Did the light remain on until temp. returned to acceptable level?
Audible Buzzer		
Pass	Fail	
✓		Did the buzzer sound immediately after temp. threshold was met?
✓		Was the volume of the buzzer effective?
✓		Did the buzzer emit the correct audible response?
✓		Did the buzzer remain on until temp. returned to acceptable level?
Temperature Recognition		
Pass	Fail	
✓		Was Omni-Sense immediately responsive to undesirable temp.?
✓		Was there any evidence of static feedback (ie. audible or visible)?

3. Visual Testing Results:

VISUAL TESTING (VT)		
Casing Body		
Pass	Fail	
✓		Void of physical, structural damage.
✓		Finished surface smooth and burr-free.
✓		All internal components enclosed securely by casing body.
Lanyard		
Pass	Fail	
✓		Void of physical, structural damage.
✓		Both ends of lanyard secured in designated connection site.
✓		Lanyard length adequate, allowing comfortable positioning.
✓		Free of noticable discoloration

Overview of Market Size

The wide range of functionality makes Omni-Sense appealing to a very broad commercial market. The child necklaces are just one example of a piece for young children where the temperature of that environment is being constantly monitored, whereas the adult necklaces would align better with the older generation.

Several entrepreneurial savants suggest that a new startup company should show yearly projections going out 3 years. Also, a new company's roll out to geographic areas should happen over time. After introducing Omni-Sense to the United States in year 1, we will roll out to the following international markets over the following two years:

Year One Rollout

- ***United States – (population of 326,766,748) w/ 290 million internet users***

Year Two Rollout

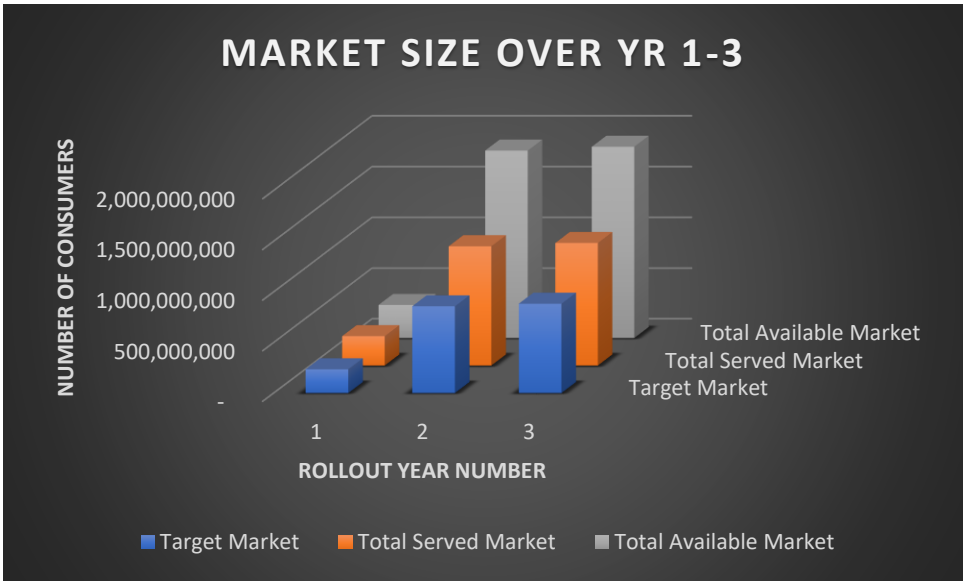
- ***China – (1,417,363,179) w/ 802 million internet users***
    - Despite a difficult regulatory and privacy rights environment, China is an attractive market for many. With 1.3 billion consumers, China is the largest world economy. Also, Chinese consumers appear eager to spend, however, it must be noted that this attractiveness also makes for a crowded marketplace.
- ***Canada – (37,090,725) w/ 32.12 million internet users***
    - Canada is a great place to get your global expansion plans off to a solid start because of its proximity to the U.S., its widespread mobile adoption, and its largely English-speaking population. For many startups, expanding into Canada is relatively painless.
- ***England – (66,573,504) w/ 54 million internet users***
    - England is a natural fit for U.S. marketers and an attractive market for business expansion. English consumers follow social media in much the same way as American consumers. This means that social media marketing that works in the U.S. has a high probability of success in English markets as well.

Year Three Rollout

- ***Australia – (24,904,997) w/ 22 million internet users***
    - Australia is an easy fit for startup expansion because language is not a large barrier and consumers in Australia have high levels of disposable income. With a thriving economy and a big preference for LinkedIn, Australia is very attractive to a content marketer.
- ***Ireland – (4,821,245) w/ 3.8 million internet users***
    - The Irish market may be small, but it is robust. Ireland takes a very pro-business stance and therefore attracts many larger U.S. companies. The Irish, like the English, are heavily invested in social media, with Facebook being the preferred platform.
- ***Hong Kong – (7,455,499) w/ 5.4 million internet users***
    - Hong Kong's economy hinges on international trade and commerce, making it an attractive choice for startups with an aggressive expansion strategy. However, startups must weigh the challenges versus the rewards to determine whether their products will be a good fit with consumers in Hong Kong.

The current populations listed are accurate as of Sunday, December 2, 2018, based on the latest United Nations estimates (www.worldometers.info). Internet usage info was obtained from www.internetlivestats.com.

	Year 1	Year 2	Year 3
Total Available Market	326,766,748	1,847,794,156	1,884,975,897
Total Served Market	290,000,000	1,178,120,000	1,210,220,000
Target Market	234,900,000	857,287,518	882,877,518



Even giant online real estate firm Zillow, which dominates the marketplace, has far more modest estimates for its own new venture in buying and flipping houses directly with consumers. The company's CEO recently said that if it could acquire 275,000 units a $3,500 profit each, it would be doing very well. That's about $1B a year from just one extra revenue stream, at just over 18% of the available market share.

Of course, most new startups can't expect to even command that much market share. Even if you could, most seasoned investors won't believe it until you prove it. Tx Zhuo of Karlin Ventures says, "If it's 1 to 5 percent of the pie, you have a realistic plan." Karlin Ventures is an early-stage venture fund based out of Los Angeles that has launched 42 companies in 4 different business sectors, totaling $145 million in capital.

With our plan, if we can sell a unit to 1 in every 7,000 Americans [at $99.99 ea.], we will gross $2.4 million in the first year from product sales alone. In addition, those 50,000 units need web accessibility [at $29.99 monthly], grossing another $17.9 million in the first year. Studies show that of the older adults who were living outside nursing homes or hospitals in 2010, nearly one third (11.3 million) lived alone, so if we could sell a unit to 1 in every 226 independent senior citizens, we would reach our mark. To put that into perspective, just calculating our senior citizen consumption (children product line excluded), we would only project less than 1% of the market share and still gross $20.3 million in our first year of existence.

Distribution Plan and Channels

Many successful medical device companies have highly effective marketing departments with huge budgets which enable them to spend their way to market awareness. Since monetary resources are not at our disposal, creativity and innovation are pivotal in reaching the masses; hence we will utilize both *outbound marketing* and *inbound marketing*. Outbound marketing is a traditional method of marketing seeking to obstruct potential customers. Outbound marketing includes activities such as trade shows, wellness demonstrations, and health fairs. It is costly, and the return on investment is much lower than inbound marketing because implementation is often costly. Unlike outbound marketing, with inbound marketing, you don't need to fight for your potential customers' attention. By creating content designed to address the problems and needs of your ideal customers, you attract qualified prospects and build trust and credibility for your business.

Outbound Marketing

1. Healthcare Providers
    a. Develop network of physicians
        i. Experts in their respected fields will help promote talk of the product and validate its usefulness, allowing their patients to trial our product with timely feedback through the provider(s).
            1. Have device available through Medicare/Medicaid
    b. Key Opinion Leaders (KOL)
        i. Also known as peer-to-peer selling, it is simply effective to have doctors speak about and on behalf of your products to other doctors.
        ii. Network will be strengthened as more physicians are recruited by their colleagues and integrated.
2. Wellness Demonstrations/Health Fairs
    a. Preventative medicine and public health intervention
3. Trade Shows
    a. Huge events where attendance is essential to put our product in front of customers.

Inbound Marketing

1. Website (marketing channel)
2. Search Engine Optimization (SEO)
    a. Getting found on Google, and the other search engines, is a basic tenet of internet marketing. An active and frequently updated business blog will be established, as this is the best way to ensure internet relevance.

Sales

With an extensive campaign to make Omni-Sense a household name in the medical device market, our product will be sold through healthcare providers, on Amazon, in big box stores, and through our own online store, enabling consumers to order directly from us without a distributor.

Bill of Materials

The following Bill of Material identifies all the materials needed for each unit to be built:

11	913T72	Lanyard	Nylon	1	McMaster-Carr www.mcmaster.com
10	92470A018	#0 Phillips Round Head Sheet Metal Screw, 3/16" Long	18-8 Stainless Steel	2	McMaster-Carr www.mcmaster.com
9	92470A103	#2 Phillips Round Head Sheet Metal Screw, 3/4" Long	18-8 Stainless Steel	4	McMaster-Carr www.mcmaster.com
8	92470A095	#2 Phillips Round Head Sheet Metal Screw, 1/4" Long	18-8 Stainless Steel	7	McMaster-Carr www.mcmaster.com
7	FBA_30	Electrical Wire	14 Gauge Copper	2 X 3"	Striveday™ https://striveday.aliexpress.com/store/1963631
6	008968	Battery Clip	Hard Plastic	2	Sun Founder www.sunfounder.com
5	EL-003	Battery	Varies	1	Elegoo Market www.elegoo.com
4	El-2560	Sensor Pack	Varies	1	Elegoo Market www.elegoo.com
3	LUA-12	Circuit Board	PCB	1	Makerfocus https://www.amazon.com/s?ie=UTF8&me=A1N6DLY3NQK2VM&page=1
2	L001	Lid	ABS Plastic	1	Ameritech Die & Mold South www.amdiemoldsouth.com
1	MH001	Main Housing	ABS Plastic	1	Ameritech Die & Mold South www.amdiemoldsouth.com
Item	Part Number	Description	Material	Qty	Supplier
Bill Of Materials					

Cost Per 1,000 Units

5	Mold Design & Manufacture - Lid	N/A	N/A	$80.00 for 1,000 parts[1]	1,000	$80.00
4	Mold Design & Manufacture – Main Housing	N/A	N/A	$60.00 for 1,000 parts[2]	1,000	$60.00
3	Direct Labor – Packaging & Shipping	$12	0.10	$1.20	1,000	$1,200.00
2	Direct Labor- Assembly Solder & Test	$12	1.00	$12.00	1,000	$12,000.00
1	Direct Material	N/A	N/A	$38.61	1,000	$38,610.00
Item	Description	Labor Rate ($/Hr)	Time(Hours)	Cost (Each)	Units (1,000)	Total $51,950.00
Cost Analysis						

1. Based on a manufactured mold that produces 100,000 parts at a cost of $8,000.

2. Based on a manufactured mold that produces 100,000 parts at a cost of $6,000.

Safety Standards, State Regulations and Federal Standards

Because of the purpose and functionality of Omni-Sense, it is considered a medical device respectfully. Medical devices can be categorized as Class I, II, or III. More specifically, Omni-Sense is a Class II Medical Device, described below:

1. **A Class II Medical Device**
    a. Complicated in design, moderate to high risk.
    b. Must have special labeling, meet mandatory performance standards and post-market surveillance.
        i. In general, most medical devices fall under the Class II categorization.

Omni-Sense must be in alliance with the requirements listed below:

1. **FDA 21 CFR 820.30 (Design Controls)**
2. **FDA 21 CFR 820.20c (Management Responsibility)**
3. **ISO 14971 (Risk Management to Medical Devices)**
4. **FDA 21 CFR 820.100 (Corrective Action and Preventative Action).**

Milestones Completed to Date

- Form core product design team – Complete
- Brainstorm product ideas – Complete
- Identify product design selection – Complete
- Research existing designs/patents to avoid patent infringement – Complete
- Kickoff meeting to define project scope/discuss project goals – Complete
- Develop project charter - Complete
- Identify project risks - Complete
- Identify team members' roles and responsibilities – Complete
- Develop conceptual design/artistic rendering – Complete
- Develop initial Work Breakdown Structure (WBS) – Complete
- Develop initial Project Network Diagram – Complete
- Identify procurement of purchased parts - Complete
- Perform initial cost estimation – Complete
- Place order for purchased parts – Complete
- 3D print/manufacture components for prototype – Complete
- Initial quality assembly/component fit check – Complete
- Initial PCB programming – Complete
- Battery discharge testing – Complete
- Functionality testing – Complete
- Non-destructive testing (visual inspection) – Complete
- Survey potential customers for product feedback – Complete
- Document comments/feedback from potential customers – Complete
- Determine and document areas for quality improvement – Complete
- Develop change management plan – Complete
- Design improvements based on initial testing – Complete
- Determine potential ethical and environmental issues – Complete
- Perform final testing – Complete
- Final quality check – Complete
- Identify suppliers for procuring resources for materials in bulk – Complete

- Complete cost analysis based on 1,000 units – Complete
- Create an overview of market size – Complete
- Identify safety standards that the product must conform to – Complete
- Develop marketing strategy for shows/expos – Complete
- Develop a user's manual – Complete
- Develop marketing brochure – Complete
- Fill out patent application – Complete
- Completed project documentation – Complete

Patent Template

Omni-Sense

United States Patent

Name on Patent: Christopher Cabrera, Shawn Roemer, Michael McClendon
Date: 11/28/2018

Abstract

Omni-Sense is a fashionable and durable piece of jewelry that is engineered to save lives. Its sleek design is coupled with its functionality as a sensor for elements that can prove harmful to the body.

Claims

Omni-Sense will be used to detect potentially dangerous levels of either smoke, carbon monoxide, temperature and/or humidity, all while doubling as decorative jewelry. This device will be able to adapt to an individual's lifestyle, utilizing applications that range from detecting hazards for the elderly (in their environment) to professionals such as firefighters (in their persistently dangerous environment).

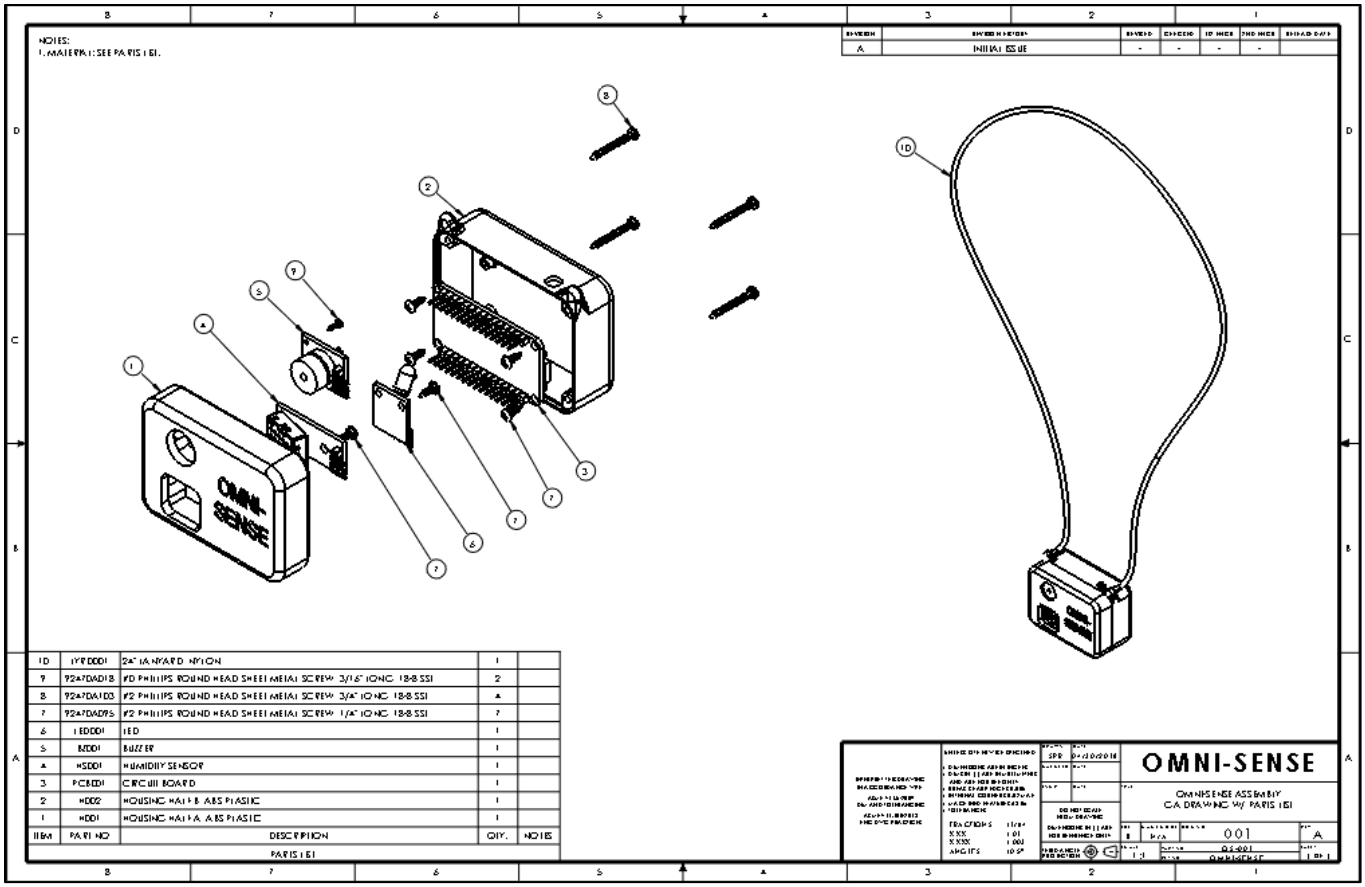
Description

Omni-Sense is a white rectangular cube that contains a blue temperature/humidity sensor in the front of the cube. It also contains a led bulb on top of the cube to commutate when dangerous levels of temperature or humidity. Likewise, in front of the cube is a small hole when a buzzer is located to give off a sound of alert when dangerous levels are also found.

Summary

Omni-Sense was created in the mindset of helping those who can't realize their environment around them. Omni-Sense provides a visual and auditory signal to alert those wearing it that their surrounding's temperature and humidity. It provides a green visual light that indicates the surroundings is at a normal level. When the temperature or humidity drops too low or gets too high, the led will light blue or red to indicate too cold, too hot, too much humidity.

Drawings:



ID	1YP0001	24" LANYARD, NYLON	1	
9	92A70AD018	#0 PHILLIPS ROUND HEAD SHEET METAL SCREW, 3/16" LONG, 18-8 SST	2	
8	92A70A1003	#2 PHILLIPS ROUND HEAD SHEET METAL SCREW, 3/4" LONG, 18-8 SST	4	
7	92A70AD095	#2 PHILLIPS ROUND HEAD SHEET METAL SCREW, 1/4" LONG, 18-8 SST	7	
6	LED001	LED	1	
5	BZD01	BUZZER	1	
4	HSD01	HUMIDITY SENSOR	1	
3	PCB001	CIRCUIT BOARD	1	
2	HD02	HOUSING, HALF B, ABS PLASTIC	1	
1	HD01	HOUSING, HALF A, ABS PLASTIC	1	
ITEM	PART NO	DESCRIPTION	QTY.	NOTES
		PARTS LIST		

Omni-Sense

User Manual

*Images shown in this user manual are for reference only.

Actual product may vary in color and design, but functionality will remain the same.

Notice: Always inspect Omni-Sense for visual defects and missing parts before using. If defective or missing parts are identified, return to the distributor.

Warning: Do not attempt to disassemble Omni-Sense, as it contains electronics that pose a shock hazard.

Warning: Do not submerge Omni-Sense, as it will cause the electronics to short-circuit.

Warning: Always use judgement when in potentially hazardous environments. Omni-Sense is designed to assist in identifying hazards, but cannot identify all potential hazards.

User Instructions:

Step 1. If worn around the neck, adjust the lanyard to a length that is both comfortable and practical **(Figure 1).**

If worn on the wrist or belt, adjust strap so that Omni-Sense is secure.

Figure 1

Step 2. Power on Omni-Sense via the power switch on right side.

Step 3. Verify that Omni-Sense is operational. A green light indicates that the conditions are safe based on specified parameters **(Figure 2)**.

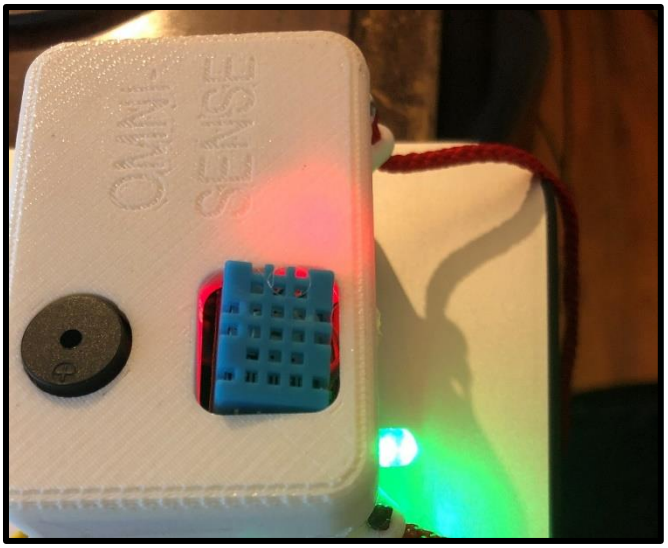


Figure 2

When temperature and/or humidity are above the specified parameters, Omni-Sense will warn the user with a red light indicator and audible buzzer **(Figure 3)**. The light will return to green and the buzzer will turn off when a safe level of temperature or humidity are returned **(Figure 2)**.

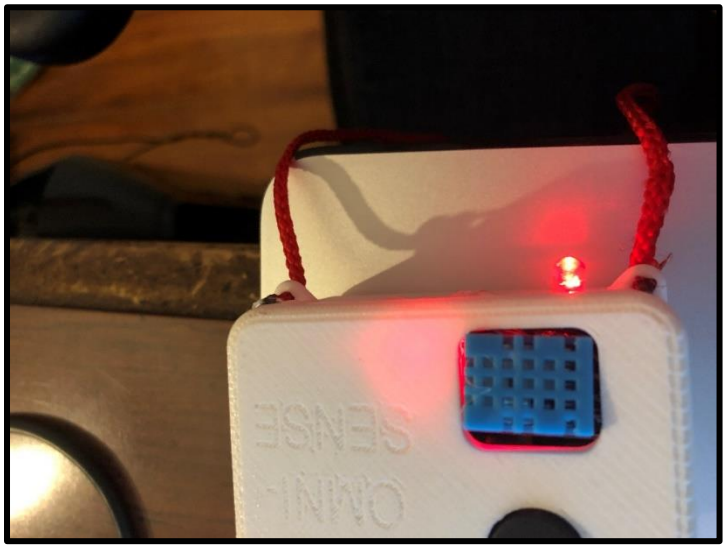


Figure 3

By default, 85°F and above, or a relative humidity above 80% will cause Omni-Sense to send a warning.

When temperature is below the specified parameters, Omni-Sense will warn the user with a blue light indicator and audible buzzer **(Figure 4)**. The light will return to green and the buzzer will turn off when a safe level of temperature is returned **(Figure 2)**.

Figure 4

By default, 50°F or below will cause Omni-Sense to send a warning.

Step 4. When finished using, power off Omni-Sense via the power switch on right side.