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Item #	User Needs Intended Uses	Design Inputs (Technical Requirement)	Acceptance Criteria I/Goal Limit	Design Outputs	Design Verification (Outputs = Inputs)	Design Validation (User Needs Met)
1.0	Customer Requirements (e.g. Functional)					
1.1	I fast results	results display in 30 seconds or less		CAD model and Arduino code	when device is tested the results display within 30 seconds of the cap being secured on the device	test users respond that the time it took to display the results was satisfactory
1.2	easy to use	Average user can input and get results in 30 seconds; input volume less than 5 in*3; amount of instructions required for first use should be no more than 8 steps		CAD model, 3D printed prototype	when testing the device users are able to input food, secure the cap, and get results within time limit.	test users operating the device without instructions are able to do so and report on a survey that using the device was not difficult
1.3	3 reliably detects gluten in prepared food	able to detect gluten at various levels in ppm (which is the unit for gluten measured), rate of false negatives is <5% , rate of false positives is <5%		CAD model, anitbody ELISA test protocol	Design leads to direct contact of antibodies and food sample once secured. when lab tested with known gluten-level samples the device displays expected results	testing of foods brought in by test users shows results that match their expectations. users report feeling confident using the device on unknown foods
1.4	easy to understand results Product Performance Requirements (e.g.	user at seventh grade reading level can interpret results in 45 seconds, results can be read from up to 1 feet away in 380 -700 nm of brightness		CAD model, Arduino LCD setup	Display is tested in different brightness settings and with users of varying reading levels (7th grade or higher). All users in all settings can accurately explain the results and whether they would eat the food	test users report on survey that they understand the results every time they used it
2.0	Mechanical)					
2.1	l light-weight	weighs less than 3 pounds		CAD model, building materials	device weighs less than stated limit when tested with various food samples, and both with and without the spoon and anitbody capsule	users report feeling comfortable carrying the device
2.3	liong battery life, alert when low on battery	able to remain usable for 20 hourswhen it is below 20% percentage a notification will be displayed to charge the device		CAD model	The device battery life is characterized using a voltmeter or multimeter. Additionally the battery level displayed is record to analyze if the display changes as the battery power becomes lower. users respond to low battery alert by plugging in device or stopping use without receiving instructions.	users report being satisfied with the length of the battery life and state that it does not interfere with their use of the device
2.4	Easy to operate the different components	Have a light that turns on in 3 sec when components are placed properly in the device. Have an alert that goes off in 3 second if sample size is insufficient, some component of the antibody test isn't working, removable components were not cleaned properly, or spoon is defective.		CAD model	Protocol is implemented to check that the light turns on when the removable components are placed properly. Another protocol is performed to check that the applicable alerts are displayed for when there is insuffient sample, antibody test issues, cleaning issues, or defective spoon being used.	test users are able to operate it and put the components together without reporting significant difficulty, without instructions, and without seeing the device used by someone else
3.0	Biocompatability Requirements					
3.1	will not contaminate food that is being tested	there is not an more than 5 g change of mass in food composition		building materials, CAD model	Device drawings that show that the antibodies are contained in the device and are not placed in contact with the larger meal. Accerterated life and vibrations tests are conducted on the spoon to ensure the disposable spoon is sterile when it comes into contact with the meal.	users report feeling safe eating the rest of the meal after it has been tested
3.2	easy to clean	user can clean the entire thing in 4 minutes		CAD model, building materials	Removable components are subjected to humidity and temperature tests that simulates the same conditions of a dishwasher. Cyclic loading of these removable components is also conducted to assess the lifetime this component can be removed and placed back into device. Tolerances for material roughness is characterized.	users without instructions are able to clean the device and feel comfortable using it again on new food

3.3	Safe for users - no adverse physical, chemical, electrical harm (i.e. radiation)	Radiation on contact less than 50 µSv. Chemical on contact such as BPA less than 2mg. Material durability is 10 years and over 6000 psi. Electrical wiring are up to code, so that current is less than 8 amperes and will not harm users.	b	uilding materials, CAD model	Protocols to analyze radiation and chemical contact are performed. The different materials composing the device undergo static loading tests to characterize durability and stiffness. The current generated from the electrical wiring is tested using a voltmeter. The speed of alerts being displayed that warn users of some type of user harm occuring is characterized.	users report feeling safe operating, handling, and transporting the device
4.0	Regulatory Requirements					
4.1	Clinically tested for gluten detection	used in 5 studies to prove that is compatible/reliable	E	ELISA protocol, CAD model	Clinical studies are conducted to assess the compatability and reliability of the device detecting gluten.	users trust that the devices has been sufficiently tested and verified
4.2	food-safe	Less than x amount of chemical and physical byproduct from solution	h	uilding materials	The toxicity of device materials is characterized. Vibrations, static loading, cyclic loading, and humidity and temperature tests are performed to analyze the chemical and physical byproduct from the device under various conditions.	users are confident that their food is safe after being in
	Interfaces with Other Systems	systemet a for solution				
5.0	interfaces with other systems					
5.1	standard charger	charges in 6 hrs	c	SAD model	device charging port matches dimensions and electrical components of commonly available standard charger. device with no battery power is plugged in and full battery alert shown within the stated time limit	users report that they already have or could easily obtain a charger that matches the device
6.0	Other					
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6.1	low/no waste	device can be used without obviously degrading for 100 uses // generates less than X grams of waste per use	b	uilding materials, CAD model	Conduct vibration testing to test the sterile packaging of the disposable spoon and to make sure the spoon performs do not wear down. Conduct cyclic laoding and temperature and humidity tests to verify that the device can be reused for X uses.	users estimate that the device will last a long time and many tests and recharges, they do not feel that it creates unnecessary waste
6.2	can be carried in a purse/backpack	volume less than 70 in^3, dimensions less than 3.25 by 3.25 by 6.5; weight less than 15lbs	c	CAD model	Conduct cyclic loading and temperature and humidity tests to verify that the outer portion of the device resembles a thermos by the same volume, height, width, and length (70, 6.5, 3.25, 3.25) even after X uses.	test users report on survey that they are comfortable transporting the device in public, and that it does not create additional burden in the form of another bag
6.3	quiet/low profile (not disruptive in public space)	noise level less than 40 decibals	c	CAD model	Conduct accelerated life test to determine the X uses the device can used so that the noise level is less than 40 decibels	users do not report embarrassment or physical discomfort when operating the device in a public place or with friends
6.4	tests the entire meal for contamination	concludes if gluten is present in up to 10% of food, minimum amount of food is 5 grams	С	SAD model	test meal is created such that certain components are known to be contaminated, but not others, and another such that one location is contaminated but not the rest. device displays positive results for these meals when user tested	users report feeling confident that the results displayed accurately reflect the entire meal, and feel safe eating their meal on getting a negative result
6.5	can test both solid and liquid food, both hot and cold	able to detect gluten in liquid of 1-250000 cps viscosity range, 3.5mm^-3 density range // able to function on food within 50-80 degrees F	с	SAD model	meals are created (both with and without contamination) of liquid foods like soup or smoothies and solid foods like sandwiches, pasta, and cake. meal temperature is also varied between stated limits. device results matches predicted results when tested by users. users are able to clean the device and use it for a new sample	users report feeling confident that they will be able to use the device, get results, and clean the device on any foods that they usually encounter