

Item #	User Needs Intended Uses	Design Inputs (Technical Requirement)	Acceptance Criteria		Design Outputs	Design Verification (Outputs = Inputs)	Design Validation (User Needs Met)
			M/Goal	Limit			
<b>1.0 Customer Requirements (e.g. Functional)</b>							
1.1	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	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, antibody 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	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
<b>2.0 Product Performance Requirements (e.g. Mechanical)</b>							
2.1	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 antibody capsule	users report feeling comfortable carrying the device
2.3	long battery life, alert when low on battery	able to remain usable for 20 hours--when 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 of the device	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 insufficient 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
<b>3.0 Biocompatibility Requirements</b>							
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. Accelerated 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



