



Product Requirements Document - Non Medical

Introduction

1	Purpose	The purpose of the Product Requirements Document (PRD) or product specification is to clearly and unambiguously articulate the product's purpose, features, functionality, and behavior for the development team.
2	Scope	PH Monitoring System.
3	References	Standards that apply to the device.
4	Product Description	Some sample text about what the product is.
5	Intended Use	Some sample text about how the product will be used.

Explanation

Requirements Column Head	Requirements Column Head
ID	Each requirement has a reference number. It can be helpful to use a letter-number combo (e.g. H=hardware). Critical Subsystems can have their own letter (e.g. D=Display)
Component(s)	Component is a high-level category of the requirements such as System, Accessory, etc which is useful if the product has multiple pieces or models
Sub component	Subcomponent is related to work-effort domain (e.g. is the requirement implemented in hardware, software, both?)
Source	Can be used to show connection to a reference document, stakeholder specification or another requirement in this list
Importance	Shall = must have; Should = desired
Requirement	Details about the implementation target for each requirement. Should be pass/fail where possible. Test against PRD
Notes/Comments/Questions	Findings or logic that might influence implementation noted by architect, concept team or engineering; How does this comment modify the requirement? Is this agreed?
Updated Comments	Results of investigation into comment

Requirements

ID	Component(s)	Sub component	Source	Importance	Requirement	Notes / Comments / Questions	Updated Comments
Hardware							
H1	System	Hardware		Shall	Using off the shelf sensor, Voler shall implement a PH sensor to give system ability to measure PH levels in solution tank.		
H2	System	Hardware		Shall	Using off the shelf sensor, Voler shall implement a tilt sensor to give system ability to detect tilt > 45°. Sensor accuracy shall be +/- 45° .		
H3	System	Hardware		Shall	Using off the shelf sensor, Voler shall implement a temperature sensor to give system ability to measure ambient temperature. Sensor accuracy shall be +/- 1°C with 0.5° C resolution.	if COGS > \$1.20, then relax requirement to 2 deg	Found sensor @ \$0.92
H4	System	Hardware		Shall	Using off the shelf sensor, Voler shall implement a temperature sensor to give system ability to measure nutrient fluid temperature. Sensor accuracy shall be +/- 1°C with 0.5° C resolution.	if COGS > \$1.20, then relax requirement to 2 deg	Found sensor @ \$0.92
H5	System	Hardware		Shall	Using off the shelf sensor, Voler shall implement a total dissolved solids (TDS) sensor to give system ability to measure dissolved solids in solution tank.		
H6	System	Hardware		Shall	Voler shall implement capacitive level sensors to give system ability to measure fluid amounts in fresh water and solution tanks. Sensor accuracy shall be +/- 5% of full scale with resolution 10% of full scale.		
H7	System	Hardware		Shall	Voler shall implement weight sensors to give system ability to measure low levels of fluid in solution bottles. One sensor for each nutrient A, nutrient B, PH+, and PH- solution bottle. Sensor accuracy shall be +/- 5% of full scale with resolution 10% of full scale.		
H8	System	Hardware		Shall	An LED board shall be implemented to house red / white LED array. System shall contain total of 12 LED pods in similar arrangement to prototype. 4 LED pods in top of unit and 3 LED pods in each of the 3 tiers.		

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Hardware							
H16	System	Hardware	OP Spec 3.7	Shall	System shall be able to operate in ambient temperature between 0°C to 85°C.	Need humidity level	
H17	System	Hardware	Marketing	Should	System should include list of target countries to be offered for sale.		
H18	System	Hardware	ID - Vers.2	Shall	System shall include a backlit logo using RGB LED(s) to display different colors according to the system status. Backlight shall display the following color scheme: White for system running, yellow for system paused, red for system issue, blue for system wireless pairing activity.		
H19	System	Hardware		Shall	System shall include ability in hardware to modulate LED intensity from 0-100%, with 0% being LEDs off and 100% being maximum allowed LED light.		
H20	System	Hardware		Shall	System shall include a backlit power button where button backlight is green when power is on.		
H21	System	Hardware		Shall	System shall have the ability to vary the drive voltage for the main circulation (distribution pump).		

ID	Component(s)	Sub component	Source	Importance	Requirement	Notes / Comments / Questions	Updated Comments
Software							
S1	System	Software	H1	Shall	Main board shall be able to measure PH sensor and derive PH value from reading. PH value shall be provided over WiFi. PH value to be used as feedback for fluid mix algorithm.		
S2	System	Software	H2	Shall	Main board shall be able to measure tilt sensor reliably, provide tilt condition feedback, and disable fluid pumps if mechanical tilt > 45°.		
S3	System	Software	H3	Shall	Main board shall be able to measure ambient temperature and provide temperature value over WiFi.		
S4	System	Software	H4	Shall	Main board shall be able to measure nutrient fluid temperature and provide temperature value to user GUI on test application and/or user app.		
S5	System	Software	H5	Shall	Main board shall be able to measure TDS sensor and derive TDS value from reading. TDS value shall be provided over WiFi. TDS value to be used as feedback for fluid mix algorithm.		
S6	System	Software	H6	Shall	Main board shall be able to measure capacitive fluid level sensors on fresh water and nutrient tanks and derive fluid level from readings. Level values shall be provided to user via WiFi.		
S7	System	Software	H6	Shall	System shall provide low fluid level alarms for fresh water and nutrient tanks. Low level threshold shall be user defined independently for each tank via WiFi.		
S8	System	Software	H7	Shall	Main board shall be able to measure hall-effect sensors on each of the 4 chemical bottles and convert to remaining fluid value. Values shall be provided to user via WiFi.		

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Software							
S9	System	Software	H7	Shall	System shall provide low fluid level alarms for each of the 4 chemical bottles. Low fluid threshold shall be user defined and common to all 4 bottles. Low fluid threshold shall be stored in non-volatile memory on main board.		
S23	System	Software	H1-H7	Shall	System shall include global sensor sampling rate at which all sensors are sampled in seconds. Rate shall be user-defined via GUI and have range 1-60 seconds in 1 second interval. Time accuracy shall be +/- 0.1 sec and value shall be stored in non-volatile memory on main board.		
S24	System	Software	H9	Shall	System shall include equilibrium delay value in seconds. Value shall be a time delay from addition of any one of the 4 chemicals to the time sensor readings are taken. Value range shall be 1-60 seconds with 0.1 second accuracy.		
S25	System	Software		Shall	System should include a software clock used for control timing. Clock will require re-sync after a system power cycle but can be done automatically by user app.		
S26	System	Software		Should	System should include PC-based test application used to develop/debug design. Application gateway to system can be either WiFi module or BLE module.		
S33	System	Hardware and Software		Shall	A cellular modem shall be added to enable monitoring of usage and to send a signal to enable or disable use of the machine.		
S34	System	Hardware and Software		Shall	A display shall be added to show machine status. There will be no touchscreen support.		
S36	System	Hardware and Software		Shall	The operating life shall be designed to target 5 years of use, 6 hours per day, 5 days per week.		

ID	Component(s)	Sub component	Source	Importance	Requirement	Notes / Comments / Questions	Updated Comments
Software							
S37	System	Hardware and Software		Shall	An AC power outlet shall be provided to power the LED lighting for the magnifying glass.		
S38	System	Hardware and Software		Shall	A cabling diagram of the internal electronics shall be completed.		
S39	System	Hardware and Software		Shall	There will be two momentary switches to control the unit. The on/off momentary switch will switch the display on and off. The treatment momentary switch will enable/disable the blower and heater. A single press of each momentary switch will toggle between on/off (display on/off switch) and enable/disable (treatment switch). Turning off the display via the on/off switch shall also turn off the blower/heater if it was on.		

ID	Component(s)	Sub component	Source	Importance	Requirement	Notes / Comments / Questions	Updated Comments
Cellular Connection/Data							
C1	Cellular	Software	S33	Shall	Usage data shall be recorded on the unit that includes elapsed time used and serial number of the tip for each session.		
C2	Cellular	Software	S33	Shall	Usage data shall be maintained on the unit for a minimum of 35 days in a non-volatile fashion. If the data has not been uploaded in 35 days, it is subject to deletion from the unit.		
C3	Cellular	Software	S33	Shall	The unit shall communicate to a server on the Internet through the cellular modem.		
C4	Cellular	Software	S33	Shall	The unit shall attempt to connect to the server at least once per day and upload usage data, which includes the tip serial number and time used.		
C5	Cellular	Server and Software	S33	Should	The unit shall have the capability of being remotely enabled/disabled from the server.		
C6	Cellular	Software	S33	Shall	The unit shall operate normally if there is no cellular connection. If a unit has been previously remotely disabled, it will remain remotely disabled.		
C10	Cellular	Hardware	S33	Shall	The network carrier for the cellular modem shall be T-Mobile.		
C11	Cellular	Hardware	S33	Shall	The SIM card on the cellular modem shall be removable. Each unit will need a unique SIM card.		
C12	Cellular	Hardware and Software	S33	Shall	The cellular modem shall provide Internet connectivity to the single board computer (SBC).		
C13	Cellular	Hardware	S33	Shall	Voler shall set up an example server on the Internet that will display the data from a single unit.		

ID	Component(s)	Sub component	Source	Importance	Requirement	Notes / Comments / Questions	Updated Comments
Display							
D1	Display	Hardware and Software	S34	Shall	The display shall be driven from the single board computer (SBC).		
D2	Display	Hardware	S34	Shall	The display shall be a TFT wide format 4.3" diagonally measured color display with LED backlighting.		
D3	Display	Software	S34	Shall	There shall be five display screens to be designed.		
D6	Display	Software	S34	Shall	The second screen shall be present when the unit is turned on and is warming up to temperature. The screen is equivalent to the blue LED on the original clinical unit. See figure 3.		
D7	Display	Software	S34	Should	The third screen shall be present when the unit is ready to use. This is equivalent to the green LED on the original clinical unit. See figure 4.		



About Voler System

We provide full-service R&D consulting from concept and design to production of medical devices for human use. Since 1979, clients have turned to us for reliable new products and test systems involving sensors and measurement electronics. Our multidisciplinary team knows the regulatory process and procedures and delivers high-quality products on-time and on-budget.

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