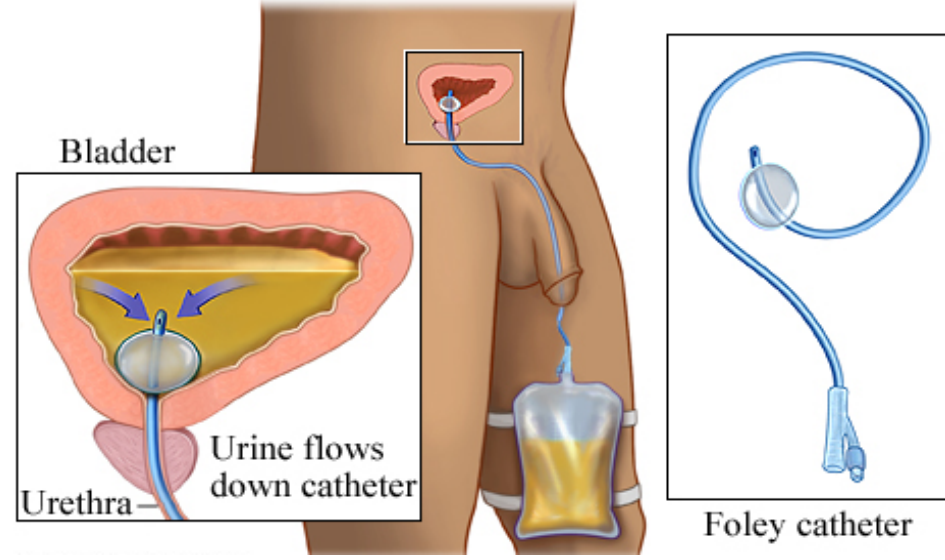




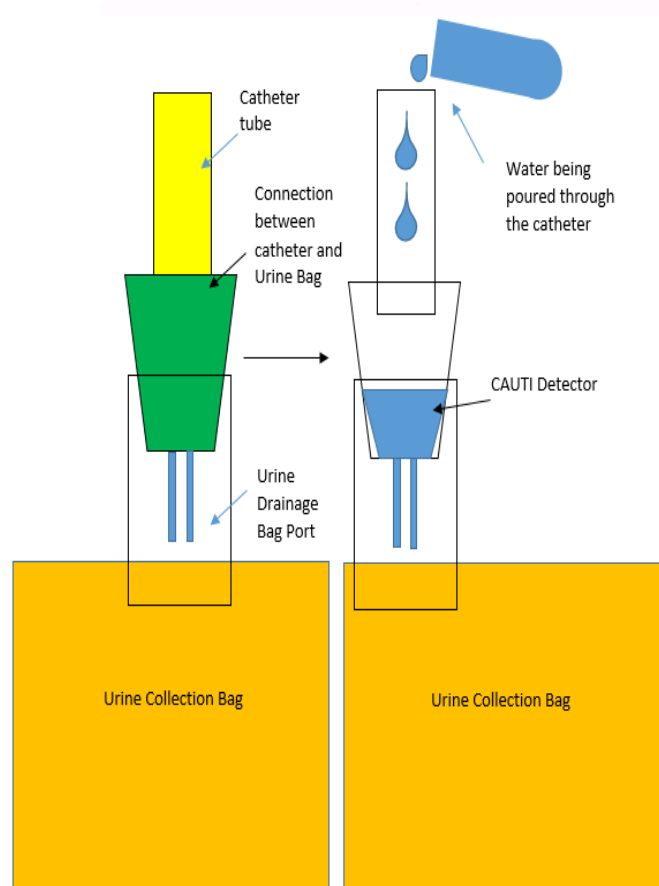
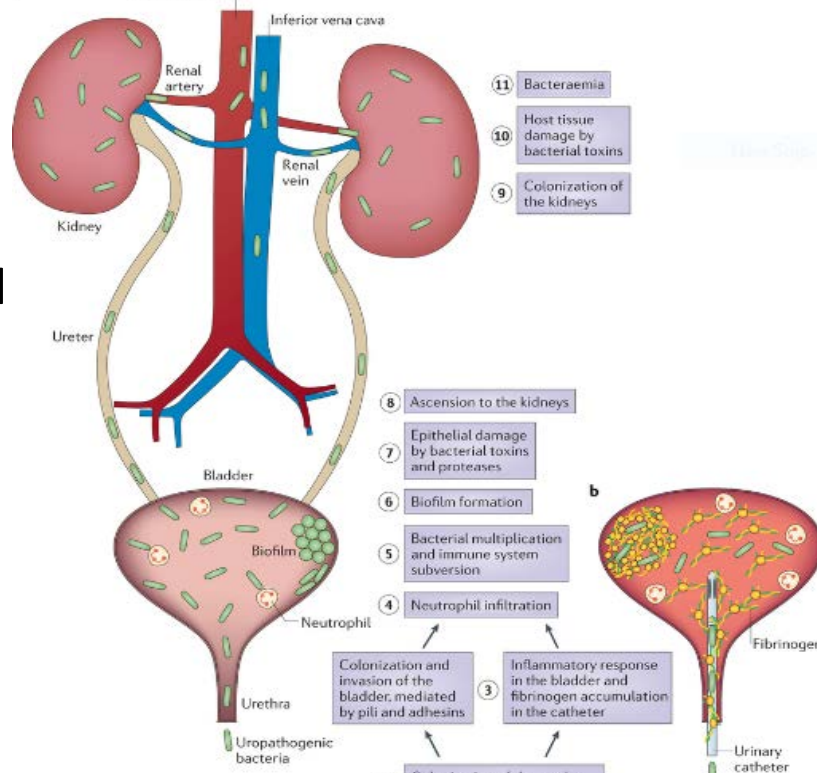
Abstract

Patients who lose the ability to urinate on their own become permanently dependent on catheters. A catheter is a device inserted through the urethra and into the bladder, which uses a pressure gradient to draw the urine out into a drainage bag.



The most commonly used catheters for hospitalized patients are Foley Catheters, which are typically used for long term purposes. Because the urethra is being left open at a wider state than usual, it is more susceptible for bacteria to enter the body. This means catheter dependent patients have a higher risk of contracting urinary tract infections (UTIs) than the average person.

A UTI is caused by an increased amount of microbes, such as fungi, viruses, and bacteria, in the urethra. The typical warning signs of a UTI are frequent urination and urination much more frequently than usual [1]. Because these patients are not urinating on their own, they would not be able to notice these symptoms, leaving the infection to spread upwards into the kidneys. Nurses and aides having difficulty detecting if there is an infection until the urine become cloudy or discolored, which is often in the later stages of the infection. Our product will give nurses and aides an easier way of knowing whether or not the patient has contracted the infection.

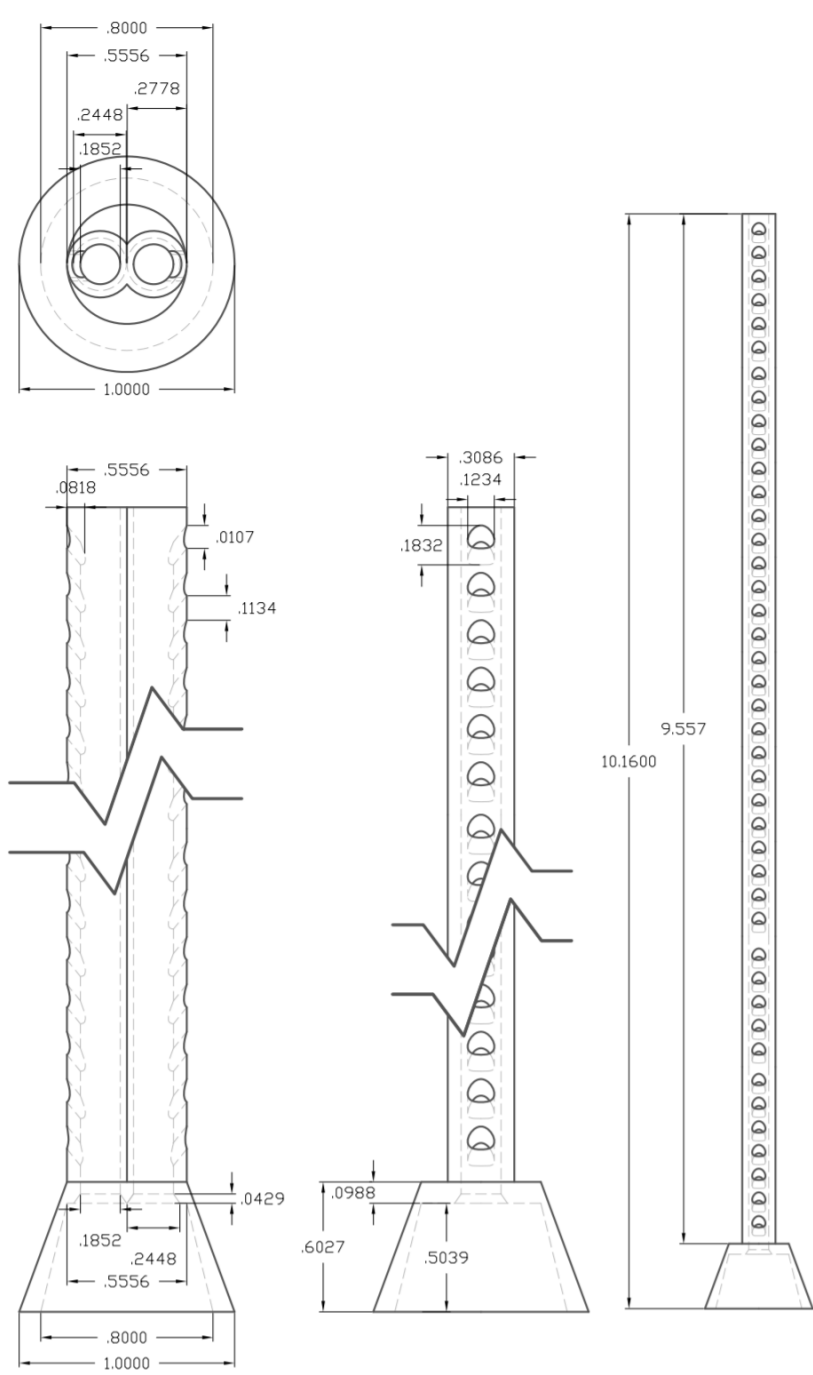


We designed a device to be placed inside the catheter, between the catheter tube and the urine drainage bag, that will change color upon contact with UTI markers, such as nitrites and leukocytes, in the urine. This device should last 8 hours, which is the amount of time before nurses change the drainage bag. This device would be available for physicians and hospitals to use for patients with urinary catheters. Our hope is that this device will provide a safe, easy, and cost efficient way of knowing whether or not a UTI is present. Overall, our device worked well and was able to detect leukocytes and nitrites in the urine and the CAUTI Detector would show a color change depending on which UTI marker was detected. However, we were not able to get the time release agent to allow for a continuous eight hour testing period.

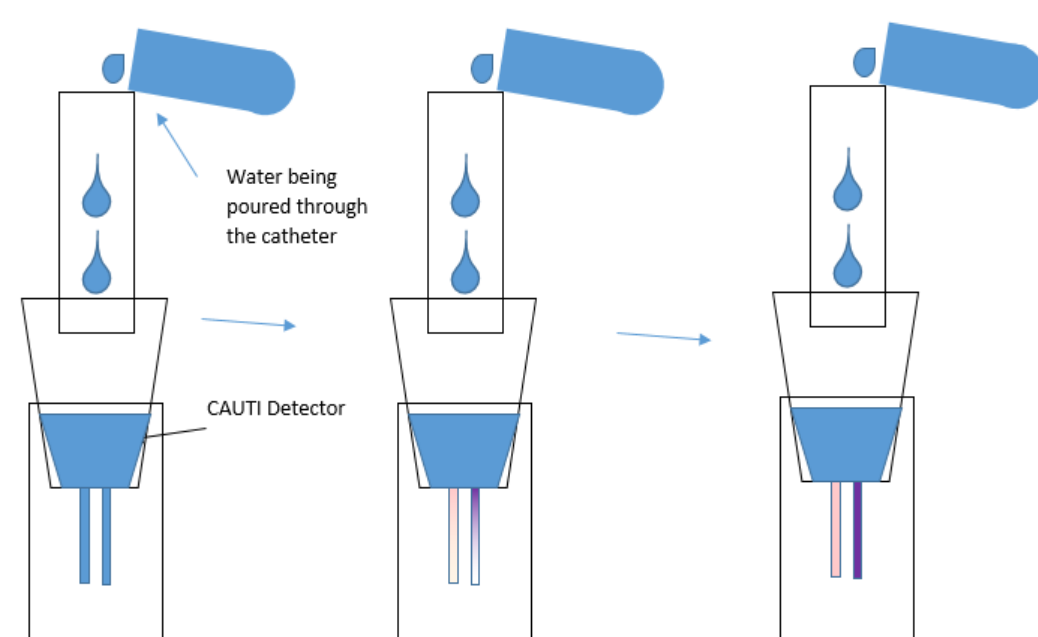
Customer Needs

- Easy to Use:** should be able to clip in and out of place easily
- Output is easy to interpret:** 95% of users should be able to interpret the correct outcome
- Safe to use:** does not contain harmful chemicals or reagents, is chemically stable, and follows FDA regulations
- Cost efficient:** should not cost more than a catheter ~\$5-\$8 or is covered under health insurance
- Time efficient:** results in under 2 minutes
- Test continuously:** should test efficiently up to 8 hours

Design Concept



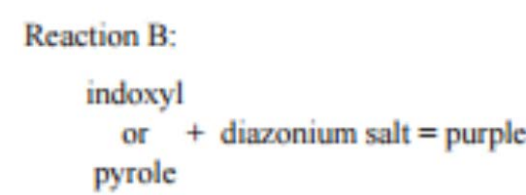
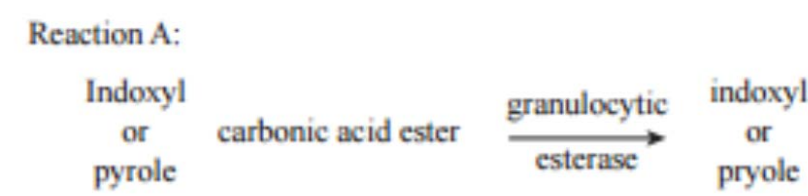
Our final design consists of a conical tube with two prongs attached to it. Each of these prongs will have a sponge covering which will have the reagents coated onto it, one for leukocyte testing and the other for nitrite testing. Essentially, this piece will resemble a funnel with two ends. The outermost diameter of this piece is 1.0 cm. This is because most catheter diameters are around 1.0-1.5 cm and this piece would fit between the drainage back and the connecting catheter tube. The length of the sensor will be 10.16 cm to allow enough room for the sponge to be seen through the catheter. We had to ensure that the sides of the prongs had small holes to ensure that the urine came in contact with the strips in order for the chemical reaction to take place. The image below represent the assembly and color change of the detector as UTI urine flows through.



The material used to create this piece is VeroClear RGD810. The material used for the testing strips is foam coated with the reagents needed to cause a color change when in contact with Leukocytes or Nitrites in the urine. In order to have the time release function and allow the CAUTI detector to last up to 8 hours, the entire device is coated with Surelease® Ethylcellulose Dispersion Type B NF.

UTI Test Strips

LEUKOCYTES 2 minutes	NEG	Trace	Small	Moderate	Large
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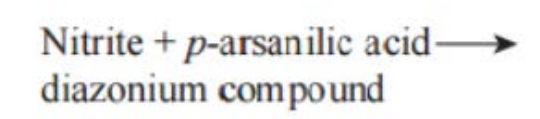


Steps to create Leukocytes Sponge:

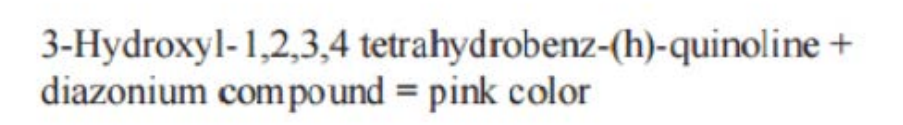
- Take 3g of Pyrrole Carbonic Acid Ester and add it to 10 ml of DI water under a fume hood to create a solution.
- Create 1.5 cm by 7 cm stripes from the foam.
- Dips the stripes into the solution above and add 0.5 g of tetrahydroxy-1,4-quinone hydrate on top of the wet solution and leave to dry for 10 minutes.
- Once dry they are ready to be used.

NITRITE 60 seconds	NEGATIVE	POSITIVE	POSITIVE
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Reaction A:



Reaction B:



Steps to create Nitrite Sponge:

- Take 2g of P-arsanilic Acid and add it to 10 ml of DI water under a fume hood to create a solution.
- Create 1.5 cm by 7 cm stripes from the foam.
- Dips the stripes into the solution above and leave to dry for 10 minutes.
- Once dry they are ready to be used.

Test Plan

- REF001: Test Case 010- Physical
- REF002: Test Case 020- Mechanical
- REF003: Test Case 030- Material
- REF004: Test Case 040- Functional
- REF005: Test Case 050 -Performance
- REF006: Test Case 060- Safety
- REF007: Test Case 070- Reliability

Test Case	Direct Requirement	Test	Pass/Fail
010	REQ010 REQ011 REQ012 REQ013	-Measure using caliper -Measure using caliper -Test for leakage in full system	Pass
020	REQ110 REQ120	-Place in hot water -Test compressive strength	Pass
030	REQ310 REQ320	-Put under a flow of false urine for 8 hours -Measure using caliper	Fail
040	REQ410 REQ420 REQ430	-Test time release by placing under warm water for 8 hours -Place in Various concentrations of leukocyte esterase -Place in Various concentrations of Nitrites	Pass
050	REQ510 REQ520	-Test flow of water through entire system (with catheter)	Pass
060	REQ610	-Test in comparison with current test strips	Pass

Acknowledgement

Dr. Michael Jaffe, John Hoinowski, Dr. Joel Schesser, Dr. William C. Hunter, Dr. Bryan Pfister, Richard Vincent, Sanjiv M. Chokshi, ESQ and Biomedical Engineering Department at NJIT

References

- [1] Catheter-associated Urinary Tract Infections (CAUTI). (2015, October 16). Retrieved October 20, 2016, from https://www.cdc.gov/HAI/ca_uti/uti.html
- [2] Hachem, R., Reitzel, R., Borne, A., Jiang, Y., Tinkey, P., Uthamanthil, R., ... Raad, I. (2009). Novel Antiseptic Urinary Catheters for Prevention of Urinary Tract Infections: Correlation of In Vivo and In Vitro Test Results. *Antimicrobial Agents and Chemotherapy*, 53(12), 5145-5149. <http://doi.org/10.1128/AAC.00718-09>
- [3] "UTI Testing." *Lab Tests Online: Empower Your Health. Understand Your Tests. A Public Resource on Clinical Laboratory Testing*. Lab Tests Online, n.d. Web. 03 Mar. 2017.