

 <h1>Starling</h1>	Document Number:	WI-016
	Version:	See GG
	<b>WORK INSTRUCTION:</b> <b>FINAL HOUSING ASSEMBLY</b>	

## 1 PURPOSE

- 1.1 The purpose of this work instruction is to define the procedure for assembling the UrinDx device in-house.

## 2 SCOPE

- 2.1 This procedure applies to Starling Medical assembly processes performed in-house.
- 2.2 This procedure is to be performed following WI-014 and WI-015..

## 3 OTHER APPLICABLE DOCUMENTS

- 3.1 WI-014 *UrinDx Initial Housing Assembly*
- 3.2 WI-015 *UrinDx PCB Assembly*

## 4 RESPONSIBILITIES

- 4.1 **QUALITY ASSURANCE (QA)** is responsible for approving this work instruction document and ensuring all quality checkpoints are adhered to.
- 4.2 **MANUFACTURING** shall be responsible for gathering the appropriate materials and equipment, wearing appropriate PPE, performing the assembly procedure, and performing all quality inspection activities described therein.
- 4.3 **MANUFACTURING** shall also be responsible for completing form WI-014-A *Initial Housing Assembly Form*.
- 4.4 **MANUFACTURING** shall also be responsible for completing form WI-016-A *UrinDx Final Assembly Form*.

## 5 DEFINITIONS

- 5.1 N/A

## 6 EQUIPMENT

- 6.1 Personal Protective Equipment (PPE) should be worn at all times during the assembly process.
  - 6.1.1 Nitrile Gloves
  - 6.1.2 Lab coat
  - 6.1.3 Eye Protection



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- 6.2 Kanglibang Medical Adhesive, KN-300B
- 6.3 Small, Phillips-head screwdriver
- 6.4 Small, 2.5mm hex key
- 6.5 Adhesive dispenser with necessary accessories:
  - 6.5.1 Yaeccc adhesive dispenser (EID-012)
  - 6.5.2 14 gauge disposable luer needle
- 6.6 Starling Medical Testing App

## 7 MATERIALS

Part Number	Description	Quantity
DW-01101	Molded, UrinDx, Housing, Top	1
DW-01102	Molded, UrinDx, Housing, Bottom	1
DW-01014	Hardware, UrinDx, Battery, AA, 3.6V	2
DW-01022	Hardware, UrinDx, Spacer, Unthreaded, Nylon, 5mm L, M3	2
DW-01128	Label, UrinDx, Device Information	1
DW-01009	Hardware, UrinDx, Screw, 18-8SS, Socket Head, Hex Drive, M3x6mm	10
DW-01030	Hardware, UrinDx, Screw, 18-8SS, Pan Head, Thread-forming, M3x5mm	2
DW-01031	Hardware, UrinDx, Screw, 18-8SS, Pan Head, Thread-forming, M3x12mm	2
DW-01020	Hardware, UrinDx, Battery Pull Tab	1
DW-01428	Label, UrinDx, Device Information	1
DW-01047	Hardware, UrinDx, Adhesive, Liquid, KN-300B	AR

Table 1 - List of materials for assembly



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### 8 PROCEDURE

- 8.1 Obtain the equipment and materials listed in Sections 6 and 7. *Be sure PPE equipment is being worn before starting the assembly process.*

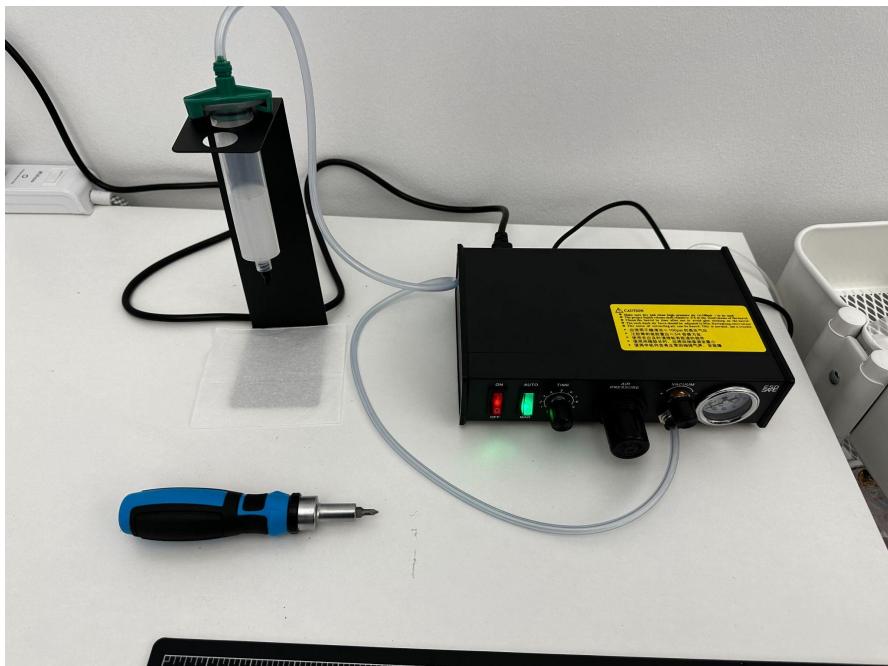


Figure 1 - Assembly tools

- 8.2 Install the 17 gauge needle to the disposable syringe for dispensing adhesive during assembly. *Note: The needle can be either straight or angled.*



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Figure 2 - 17 gauge needle assembled onto syringe.

- 8.3 Place the 2x M3 screws, 12mm long into the holes on the back of the board.



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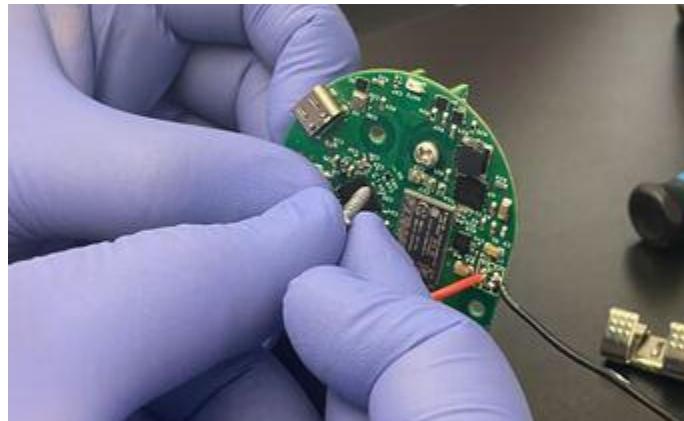


Figure 3 - Positioning 12mm screws on board

- 8.4 Place the 2 spacers onto the screws on the top side of the PCB.

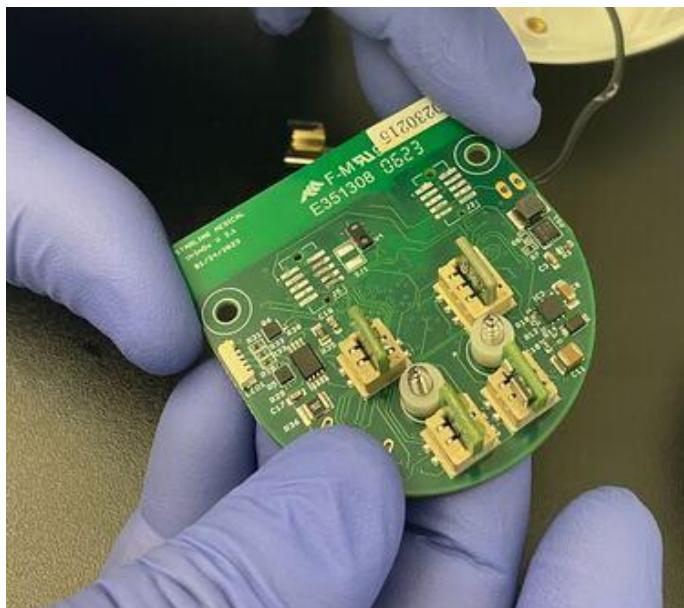


Figure 4 - Placing unthreaded spacers onto screws

- 8.5 Place the board, sensors-side down, into the housing. Ensure that the screws on the PCB are lined up with the holes, as shown.



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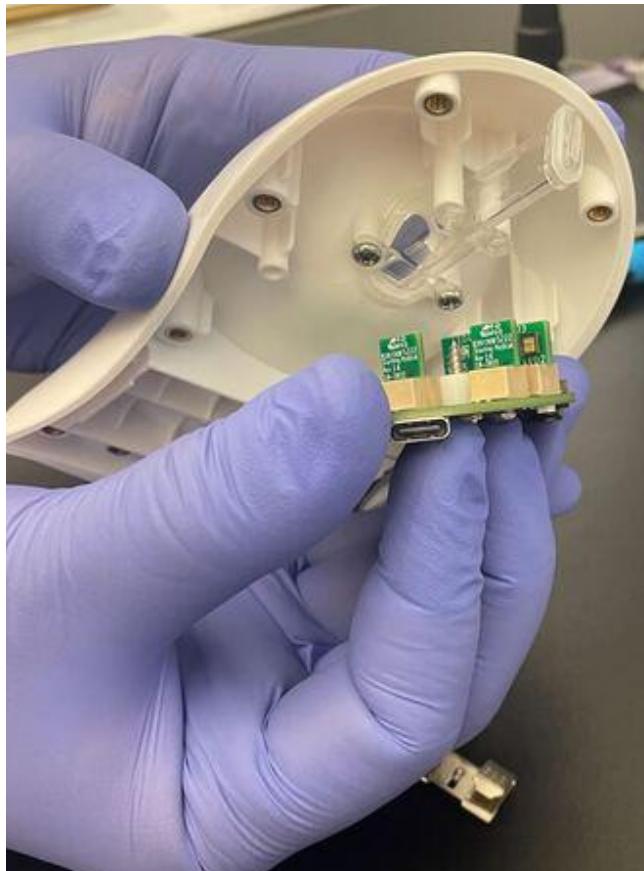


Figure 5 - Positioning the PCB onto the top housing



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Figure 6 - PCB with sensors positioned on top housing for screwing down

- 8.6 Screw the PCB into the UrinDx Housing with the 2x M3 screws, 12mm long.

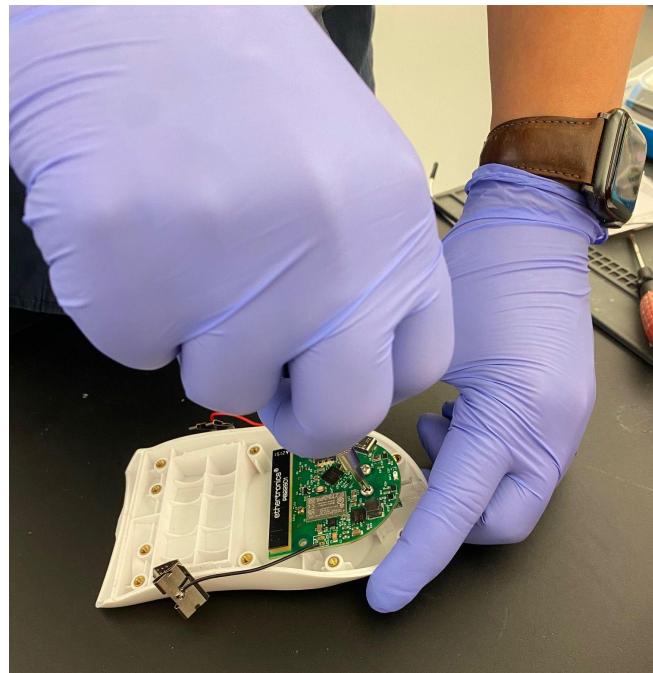


Figure 7 - Securing PCB onto housing with 12mm self-tapping screws



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- 8.7 Attach the battery clips to the housing as shown.

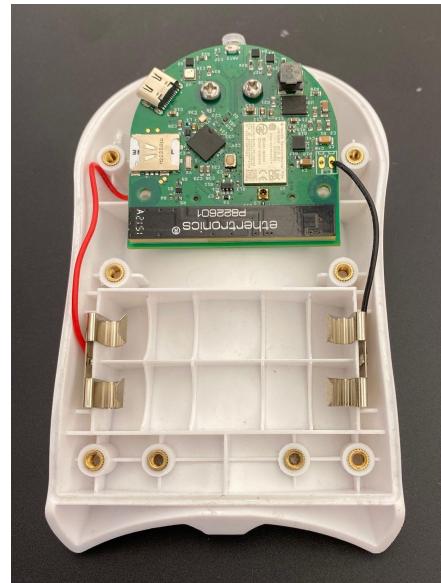
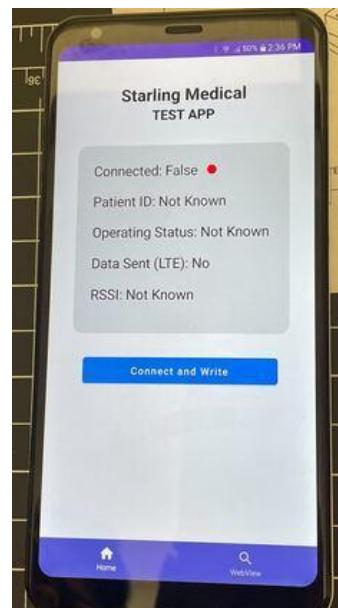


Figure 8 - Attaching battery clips onto housing

- 8.8 Open the Starling Medical Testing App. *Note: For this test, you need to attach the batteries. Once step 8.11 has been completed, you will remove the batteries to attach the pull tab.*



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Figure 9 - Factory test app

- 8.9 Cover the ambient light sensor as described in WI-015 Step 8.18 to trigger the device.
- 8.10 Click “Connect and Write” in the app.
- 8.11 Ensure all sensors and LED values are within range. Any values outside of acceptable range will be displayed in red.

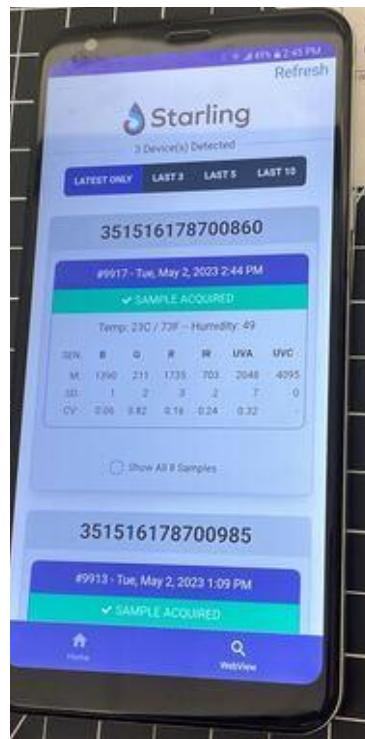


Figure 10 - Factory test app LED and sensor value display



**Before proceeding to Step 8.12, ensure all sensor and LED values are within the specified range.**



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- 8.12 Obtain the 2 lithium batteries and the battery pull tab.

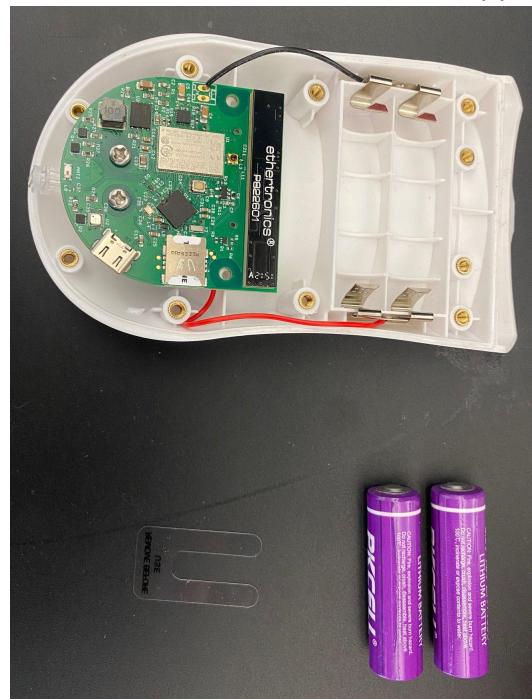


Figure 11 - Battery pull tab and batteries

- 8.13 Place the battery pull tab into the battery slots before loading the batteries, as shown.

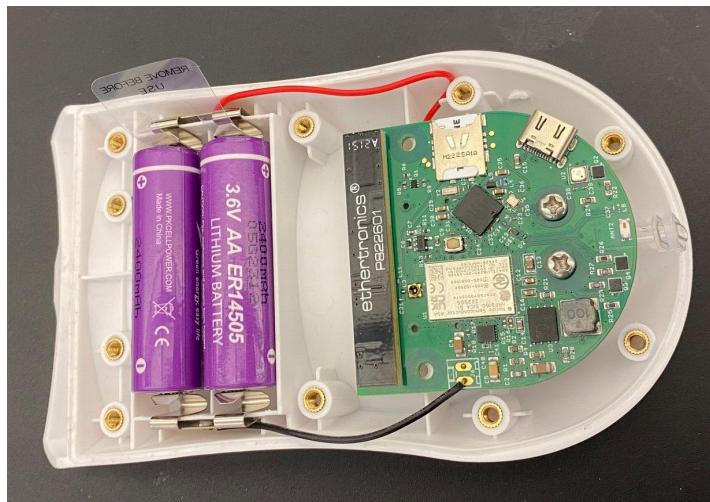


Figure 12 - Battery pull tab and batteries assembled



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- 8.14 Before closing the housing, dispense silicone adhesive on top of the perimeter O-ring. ***It is important that silicone adhesive is NOT dispensed where the pull tab will rest.***

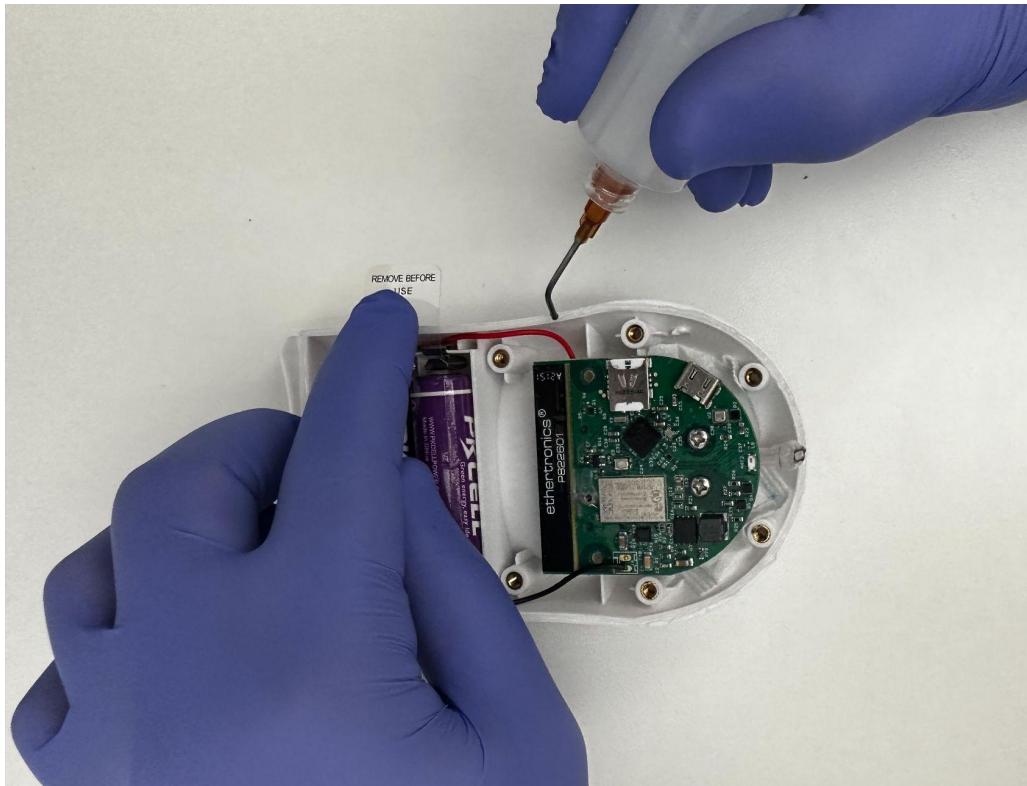


Figure 13 - Dispensing adhesive over perimeter O-ring

- 8.15 Dispense silicone adhesive on top of the O-ring on the cuvette outlet.



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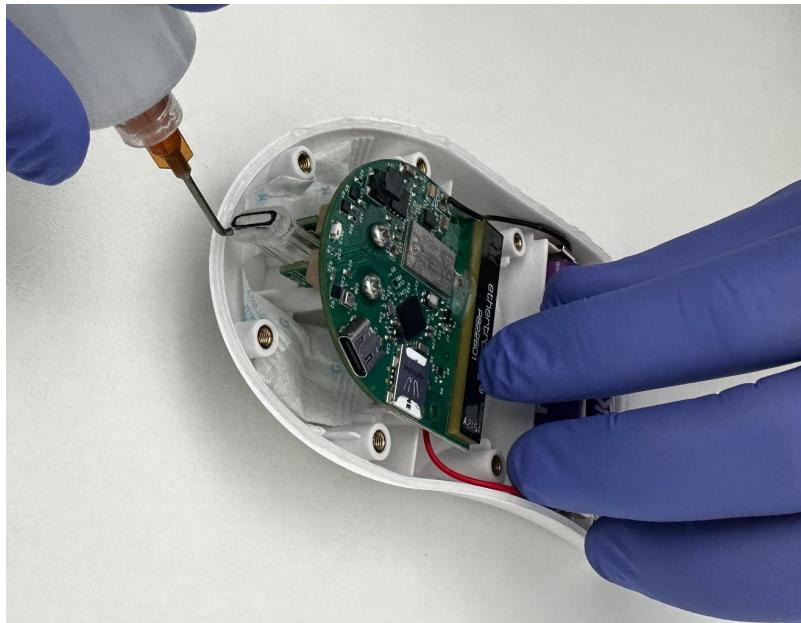


Figure 14 - Dispensing adhesive over cuvette outlet o-ring

- 8.16 Before the silicone adhesive cures, place on the other half of the housing, ensuring that the battery pull tab sticks out.



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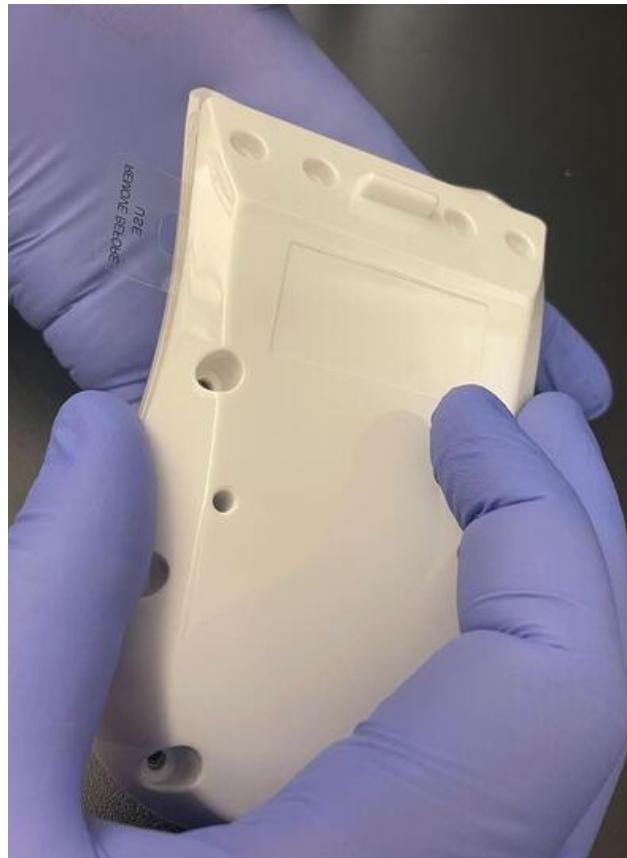


Figure 15 - Bottom housing attachment

- 8.17 Use the screwdriver and the 10, M3x0.5mm 6mm screws to secure the housing.



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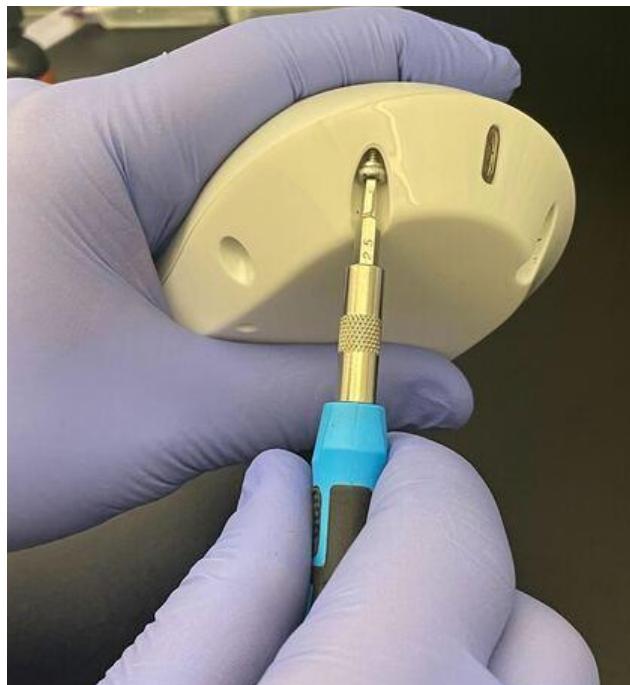
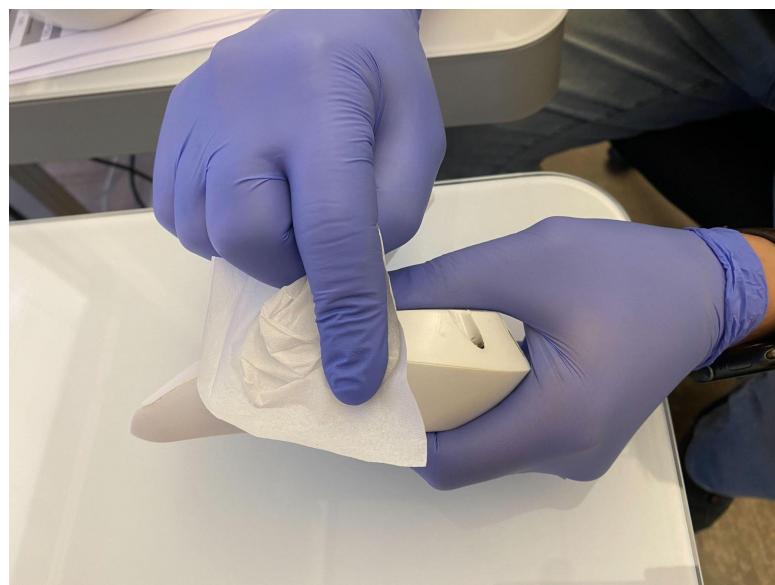


Figure 16 - Bottom housing being secured with screws

- 8.18 Wipe away excess adhesive that may have squeezed out when tightening the housing screws.





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Figure 17 - Excess glue being wiped away



## QUALITY INSPECTION POINT

**Before proceeding to Step 8.19, ensure all excess adhesive has been removed and there are no gaps, bubbles throughout the housing perimeter. Allow adhesive to cure before proceeding to next step**

- 8.19 Again, using the syringe, apply silicone adhesive over the housing screws. Make sure the entire screw is covered with the silicone adhesive to ensure sealing.

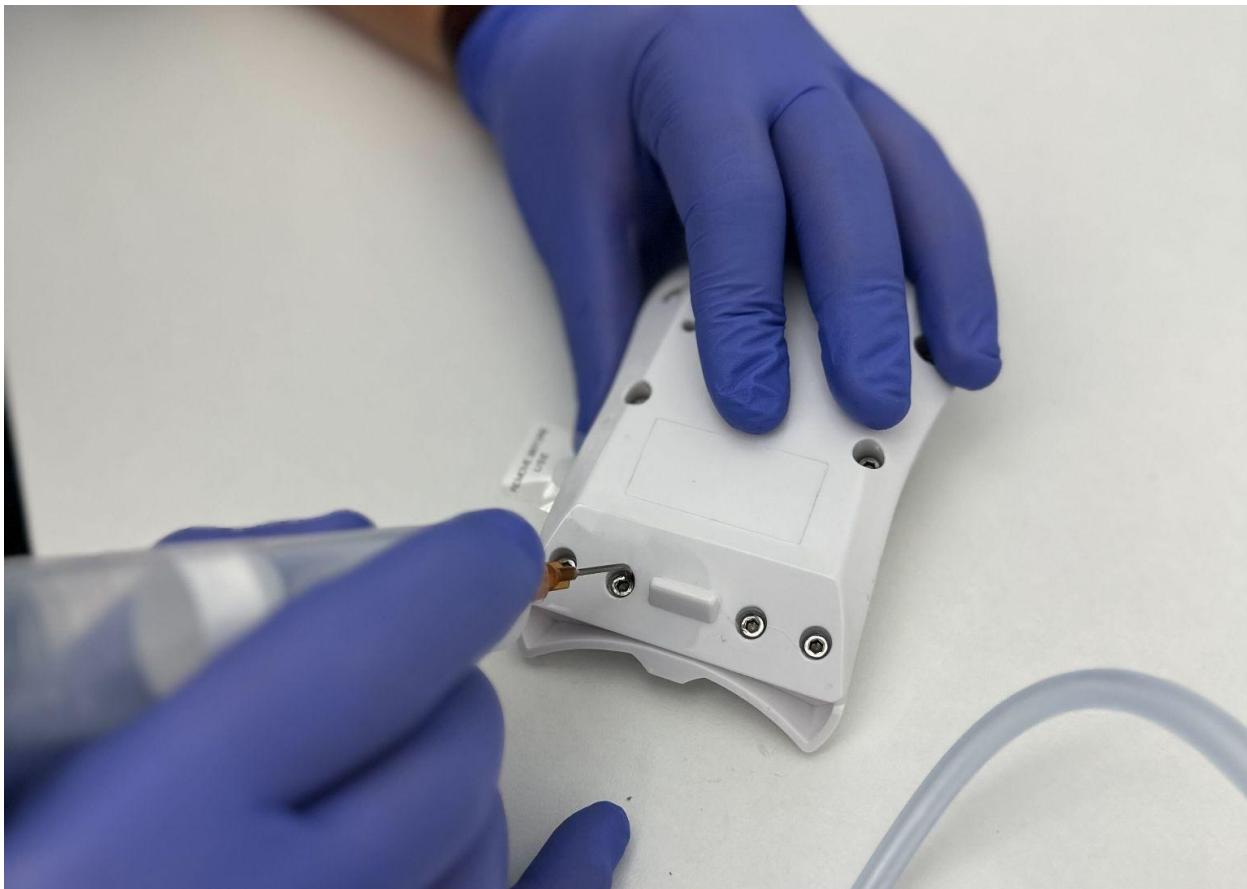


Figure 18 - Application of adhesive around housing screws



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- 8.20 Inspect the cuvette outlet for any holes in the adhesive. If any weak points are present, fill them in with silicone adhesive and wipe away the excess.



## QUALITY INSPECTION POINT

**Before proceeding to Step 8.21, ensure that there are no gaps or bubbles between the housing and cuvette outlet. If any gaps or weak spots are detected, repeat Step 8.21**

- 8.21 Once housing has been sealed, proceed to attaching the label. Make sure all of the important information in the label is correct (Lot number, manufacture date, serial number and UDI).

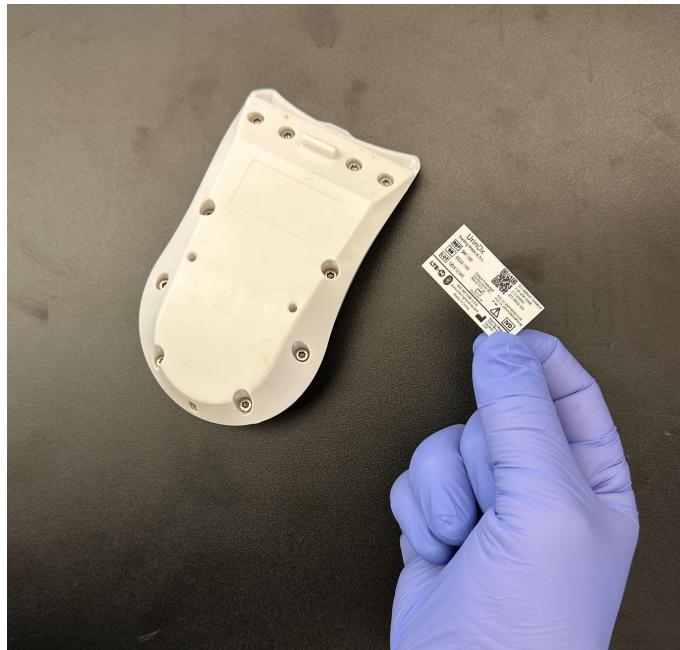


Figure 19 - Label

- 8.22 Carefully apply the label inside the cutout of the bottom housing.



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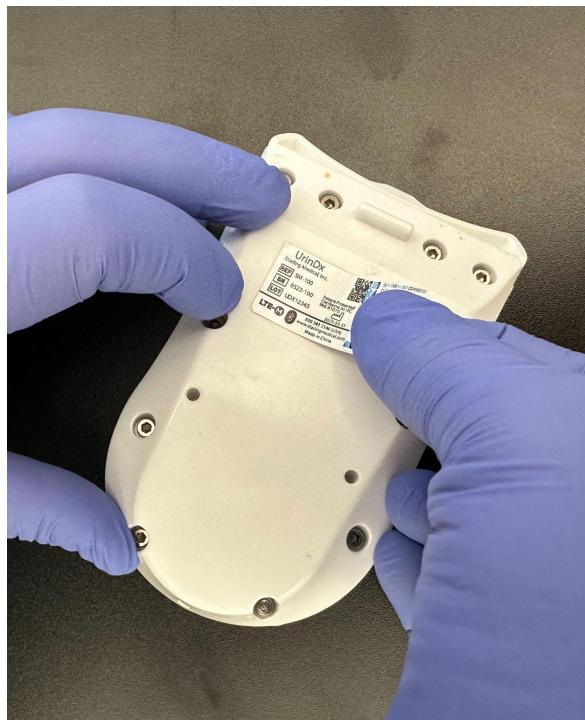


Figure 20 - Applying label to bottom housing.



### QUALITY INSPECTION POINT

Ensure that the label is placed in the right orientation



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Figure 21 - Final placement of the label

## 9 FORMS

9.1 WI-016-A UrinDx Final Assembly Form.

## 10 RECORDS

10.1 All records associated with [WI-016](#) will be kept in accordance with SOP-001 *Document Control*.

## 11 VERSION HISTORY

Version	Description of Change
0	New Document
1	Included placement of the device label and fixed wiring colors.
2	Included the use of a pneumatic adhesive dispenser in the assembly process.