STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14C0001185	A. BUILDING B. WING	08/02/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WESTERN DIVERSEY SURGICAL CENTER	2744 N WESTERN AVE , CHICAGO, Illinois, 60647

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q0000	INITIAL COMMENTS An investigation was conducted on 8/2/2022 for Complaint #IL 2295984/71328/222930. The Facility was not in compliance with the Condition for Coverage, 42 CFR 416.51, Infection Control for Ambulatory Surgical Centers as evidenced by:	Q0000		
Q0240	INFECTION CONTROL CFR(s): 416.51 The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is NOT MET as evidenced by: Based on observation, document review and interview it was determined that the Facility failed to ensure adherence to effective infection control practices related to the high-level disinfection of the equipment used for vaginal ultrasounds and the ongoing implementation of the infection control surveillance of post-surgical infections. This potentially affects all patients that present to the Facility that require surgical services. As a result, the Condition for Coverage, 416.51 Infection Control was not in compliance. Findings include: The Facility failed to ensure that the infection control program included post-procedural infection surveillance and detection through ongoing data collection and analysis. See deficiency cited at Q-0242.The Facility failed to ensure ongoing collection of data of post procedure infections was included as an integral part of their quality assessment and performance improvement program to ensure ongoing surveillance of post procedure infections. See deficiency cited at Q-0244. The Facility failed to ensure that an infection control plan/program was fully implemented by failing to ensure to follow the manufacturer's	Q0240		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 14C0001185	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETE 08/02/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WESTERN DIVERSEY SURGICAL CENTER	2744 N WESTERN AVE , CHICAGO, Illinois, 60647

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETIO DATE
Q0240	Continued from page 1 instruction for use to perform high-level disinfection, on the ultrasound machine used to conduct vaginal ultrasounds. See deficiency cited at Q-0245.	Q0240		
Q0242	INFECTION CONTROL PROGRAM CFR(s): 416.51(b) The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is NOT MET as evidenced by: Based on document review and interview, it was determined that the Facility's failed to ensure that the infection control program included post-procedural infection surveillance and detection through ongoing data collection and analysis. Findings include: 1. On 08/01/2022 the Facility's policy titled, "Infection Control Plan" dated 03/01/2008 was reviewed and included, "...The infection control plan will be monitored and evaluated by the Performance Committee ...1. Infection control data will be collected, analyzed and trended. Information obtained will be given to the Office Manager or designee, and used to improve patient care, as well as improve practice's performance in the implementation of its infection/exposure control plan ..." The Facility's was requested to provide the infection control surveillance of data tracking and trending for a sample of selected patients. The Facility was unable to provide documents regarding infection control surveillance. 2. On 08/02/2022 at 11:30 AM, the Nurse Manager (E #2) an interview was conducted. E #2 stated that there is an infection control plan, but there is no data being collected if any patients developed infections after the procedure. E #2 stated that the Nurse Practitioner (E #3) makes the phone calls and is not sure if the nurse practitioner obtains information on patient for data collection of post-procedure infections. 3. On 08/02/2022 at 9:20 AM, the Nurse Practitioner (E #3) was interviewed. E #3 stated that there is	Q0242		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 14C0001185	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 08/02/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WESTERN DIVERSEY SURGICAL CENTER	2744 N WESTERN AVE , CHICAGO, Illinois, 60647

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q0242	Continued from page 2 five percentage possibility of patient developing infection after a surgical procedure. E #3 stated that there no data collected from the patients of post procedural infections. E #3 stated "We do not do any type of surveillance after the procedure." 4.On 08/02/2022 at 10:00 AM, the Medical Director (MD #1) was interviewed. MD #1 stated that he was not aware that the Facility was not conducting surveillance of post procedural infections. MD #1 stated that there is risk for infection after any surgical procedure. MD #1 stated that they plan to hire a consultant to oversee the infection control practices at the facility.	Q0242		
Q0244	INFECTION CONTROL PROGRAM - QAPI CFR(s): 416.51(b)(2) [The program is -] An integral part of the ASC's quality assessment and performance improvement program This STANDARD is NOT MET as evidenced by: Based on document review and interview, it was determined that the Facility failed to ensure ongoing collection of data of post procedure infections was included as an integral part of their quality assessment and performance improvement program to ensure ongoing surveillance of post procedure infections. Findings include: 1. On 08/01/2022, the Consulting Committee Meeting Minutes for 01/2021 – 07/2022 was reviewed. The meetings were held quarterly, and sign-in sheet included the key members of the facility attending the committee meetings. The committee meeting minutes included topics of discussion such as: credentialing, approval of policies and procedures, tissue review report, the infection control report on hand hygiene, infection control prioritized risk for infection control -COVID pandemic, environment of care, census report and employee related agenda. The Consulting Committee Meeting minutes did not include data of the ongoing surveillance of post-procedure infections. 2. On 08/02/2022 at 11:30 AM, the Nurse Manager (E #2) was interviewed. E #2 stated that there is an infection control plan, but there is no data being collected if any patients developed infections after the procedure. E #2 stated that there is no	Q0244		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 14C0001185	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETE 08/02/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WESTERN DIVERSEY SURGICAL CENTER	2744 N WESTERN AVE , CHICAGO, Illinois, 60647

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETIO DATE
Q0244	Continued from page 3 data that is presented regarding patients developing infections after the procedure at the consulting committee meetings. 3. On 8/02/2022 at 10:00 AM, the findings were discussed with the Medical Director (MD #1). MD #1 stated that he is not aware of any data regarding patient's developing any type of infections being presented at the consulting committee meetings. MD #1 stated that they plan to hire a consultant to oversee the infection control practices at the	Q0244		
Q0245	INFECTION CONTROL PROGRAM CFR(s): 416.51(b)(3) The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement. This STANDARD is NOT MET as evidenced by: Based on document review and interview it was determined that the Facility failed to ensure that an infection control plan/program was fully implemented by failing to ensure to follow the manufacturer's instruction for use to perform high-level disinfection, on the ultrasound machine used to conduct vaginal ultrasounds. This potentially placed all patients that required a vaginal ultrasound at risk for infection and communicable diseases. Findings include: 1. On 08/01/2022 at approximately 10:00 AM, the Facility's policy titled, "Cleaning, Sterilization, and Disinfection Guidelines" dated 02/20/2018 was reviewed and included, "...A.3: The sterile processing technician will review the instruments manufacturer's IFU [instructions for use] to determine the requirement for replicating the validated cleaning and processing methods ...The manufacturer's IFU will be reviewed periodically and processing practices will comply with the most current IFU ...Surgical instruments and equipment should be cleaned and decontaminated according to the manufacturer's validated, written IFU ...methods used for disinfection will be based on ...semi-critical ...risk of infection to the patient ...semi-critical: items that come in contact with	Q0245		

American Health Care Centers

DBA: Western-Diversey Surgical Center

2744 N. Western Ave., Chicago, IL 60647

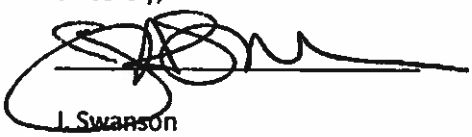
Dept of Health & Human Services
CMS – Chicago, Survey and Operation Group
233 North Michigan Ave., Suite 600
Chicago, IL 60601-5519

Attn: Wilda Melendez/Annette Hodge

August 17, 2022

We at Western-Diversey Surgical Center are planning to resume procedures on August 24, 2022 (Wednesday).

Sincerely;



J. Swanson

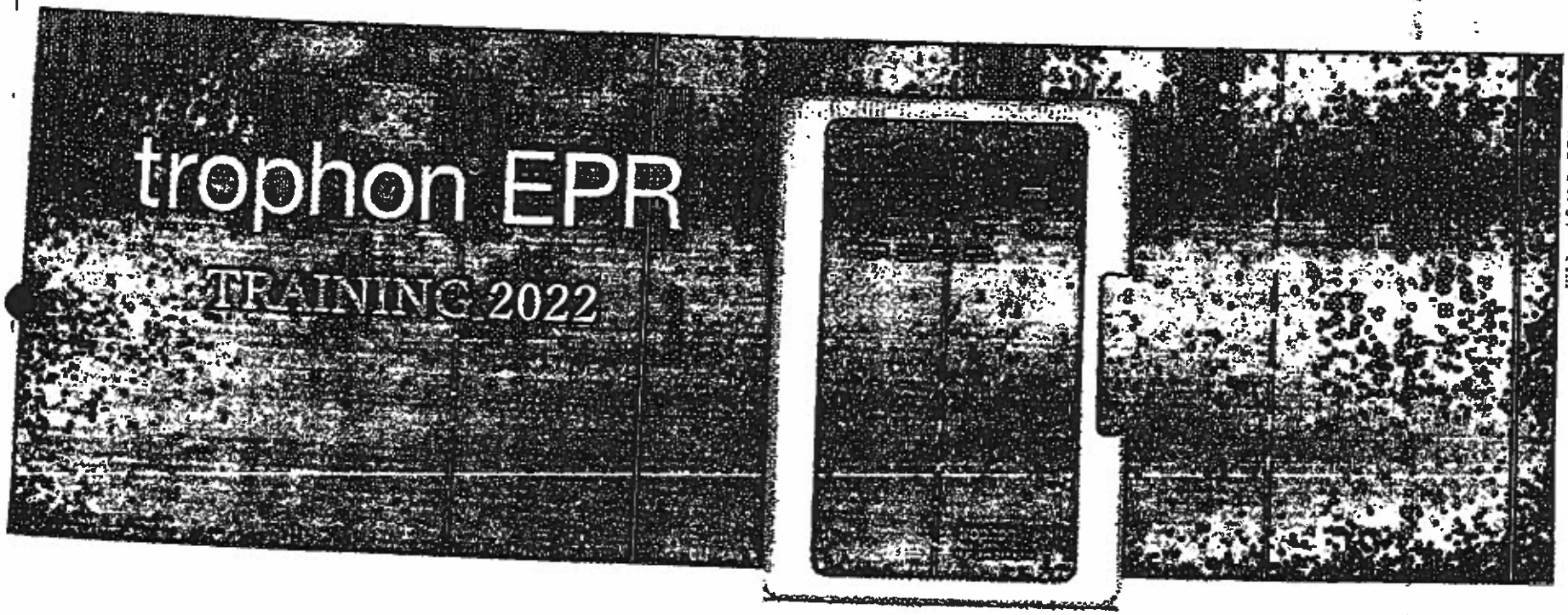
Administrator

IDPH RESPONSE FORMAT

Prefix Tag	Paragraph	Title	Plan of Corrective Action	Date
Q0240	4	Surveillance of post-procedure infections	Because of the sensitivity of the procedures being performed, the consulting committee has decided on writing a letter in a pre-formatted form to survey all patients that had procedures performed to follow-up for post-operative infections. This data will be collected by the infection control coordinator, analyzed and trended weekly for the next 4 weeks and quarterly thereafter and will be reported to the infection control meeting which is part of the quarterly consulting meeting. The collection of data will be started on Sep. 2022. Please see attached format of follow-up form.	08/16/22
Q-0244		HLD	All procedures at the facility was temporarily postponed until deficiency has been resolved. The consulting committee has approved the purchase of Trophone EPR for High Level Disinfection of ultrasound probes. Staff took online course with certificate in preparation for the Trophon training. Staff training on the use of Trophon EPR was conducted by Nanosonics field trainer for the use of Trophon EPR 3 of the staff was also trained to be "Super Trainer" for the annual competency of the staff. The staff will be monitored for comptency on a monthly basis for the next 6 months and annully therefater.	07/27/22 08/03/22 08/13/22 08/16/22 08/16/22

Q-0242	Infection Control Plan	The Infection Control Plan was revisited by the infection control committee and a plan to prioritize risk for infection control was done. The prioritized risk was post-operative infection follow-up of patients. For the purpose of Infection Control follow-up of patients: a letter was created to be sent to the provider to conduct surveillance of post-operative infection of the patient when they follow-up with their provider, the data will be collected monthly, analyzed, trended and will be reported to the Infection Control Committee which meets quarterly with the consulting committee.	08/16/22
Q-0245	Infection Control Program "Cleaning and Sterilization of Instruments"	All procedures at the facility was temporarily postponed until deficiency has been resolved. The consulting committee has approved the purchase of Trophone EPR for High Level Disinfection of ultrasound probes. Staff took online course with certificate in preparation for the Trophon training. Staff training on the use of Trophon EPR was conducted by Nanosonics field trainer for the use of Trophon EPR 3 of the staff was also trained to be "Super Trainer" for the annual competency of the staff. Policy and Procedure for High Level Disinfection of Ultrasound Probes was created and approved by the consulting committee for implementation Addendum: The log book for the Trophon' EPR HLD will be monitored daily for the next 3 months, and monthly thereafter by the Infection Control Coordinator.	07/27/22 08/03/22 08/13/22 08/16/22 08/16/22 08/16/22
Q-0242 Q-0244	Follow-up for Infection	A post op infection follow-up for elective abortion will be conducted and data will be collected for patients that follow-up or were able to call. Data will be collected by the nurse practioner on a monthly basis, analyzed, trended and reported to the infection control committee.	8/16/2022

Q-0245	The Infection Control Plan was revisited by the Infection Control Committee and prioritized risks was identified, for which a planned data collection was presented The surveillance indicators planned were: Hand Hygiene, Personal Protective Equipment (PPE), Injection Safety and Medication Handling, Equipment Reprocessing, Environmental Cleaning and Handling og BG minitoring eqiupt. The above indicators data collection will be conducted daily during procedure days, collected monthly, analyzed and trended and will be reported to the quarterly infection control committee meeting. These activities will be conducted for the next 3 months on daily basis, weekly thereafter and monthly therefter. Please see attached sample form.	8/17/2022
	Please see attached supprting document that the 2 probes with corresponding SN are subjected successfully to Trophon HLD.	8/17/2022
	In-service was conducted with the staff on cleaning and disinfection of surgical equip. with Spaulding Classification, in conjunction Trophon EPR was instituted for use after extensive training and certification of staff the manufacturers instructions will be followed on the Trophone EPR for HLD. Oversite will be conducted by the Infection control coordinator on a daily basis for the next 3 months and monthly thereafter	8/17/2022



This certifies that

Leslie Aguirrre

has successfully completed the trophon EPR product training approved by Nanosonics Limited.
This certificate expires 12 months after the date of issue.

Date of issue: 10 Aug 2022

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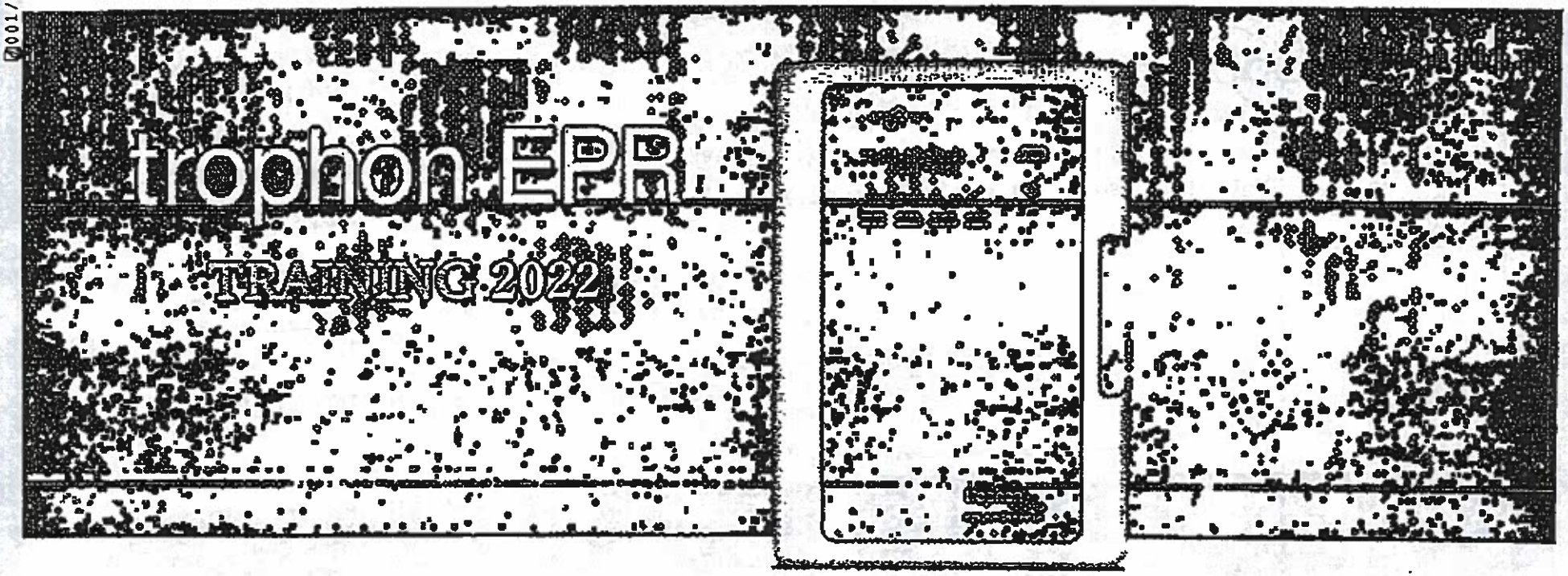
Infection Prevention. For Life.



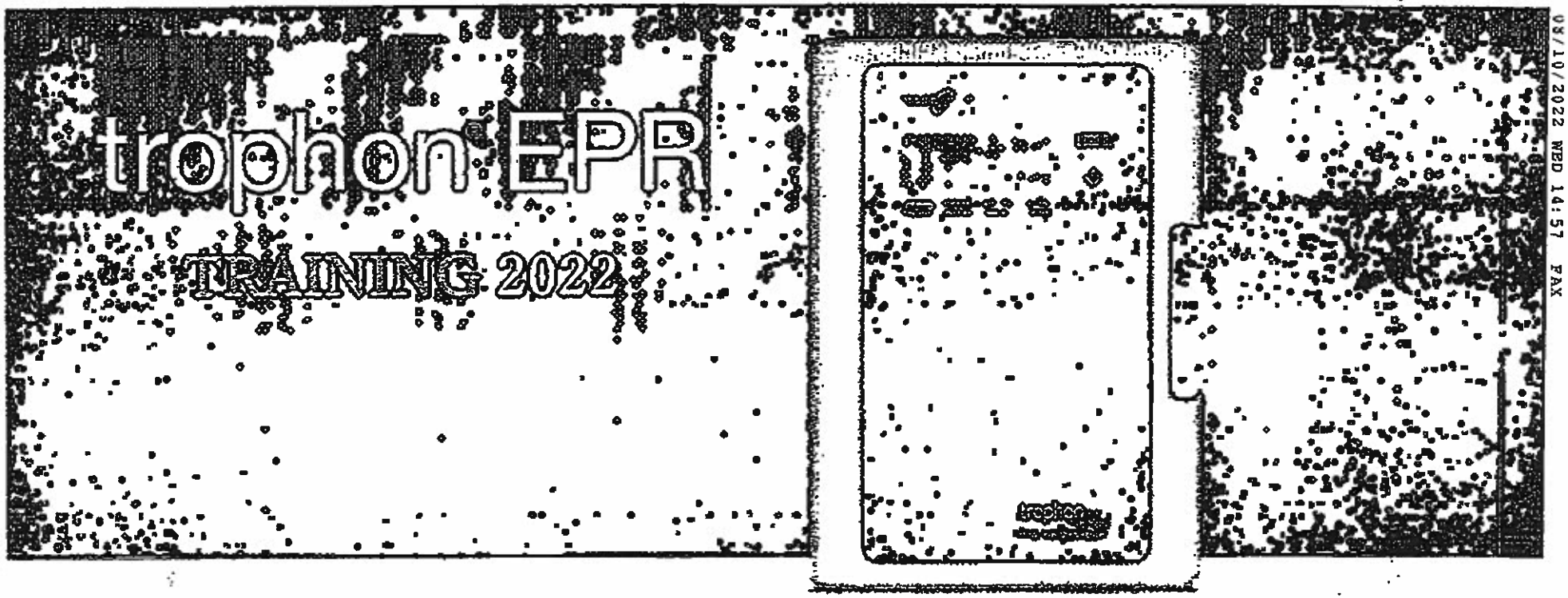
This certifies that

Alexa Tulea

has successfully completed the trophon EPR product training approved by Nanosonics Limited.
This certificate expires 12 months after the date of issue.

Date of issue: 10 Aug 2022

nanosonics
Infection Prevention For Life.



This certifies that

Liauw Devi Gunawan

has successfully completed the trophon EPR product training approved by Nanosonics Limited.

This certificate expires 12 months after the date of issue.

Date of issue: 10 Aug 2022

nanosonics
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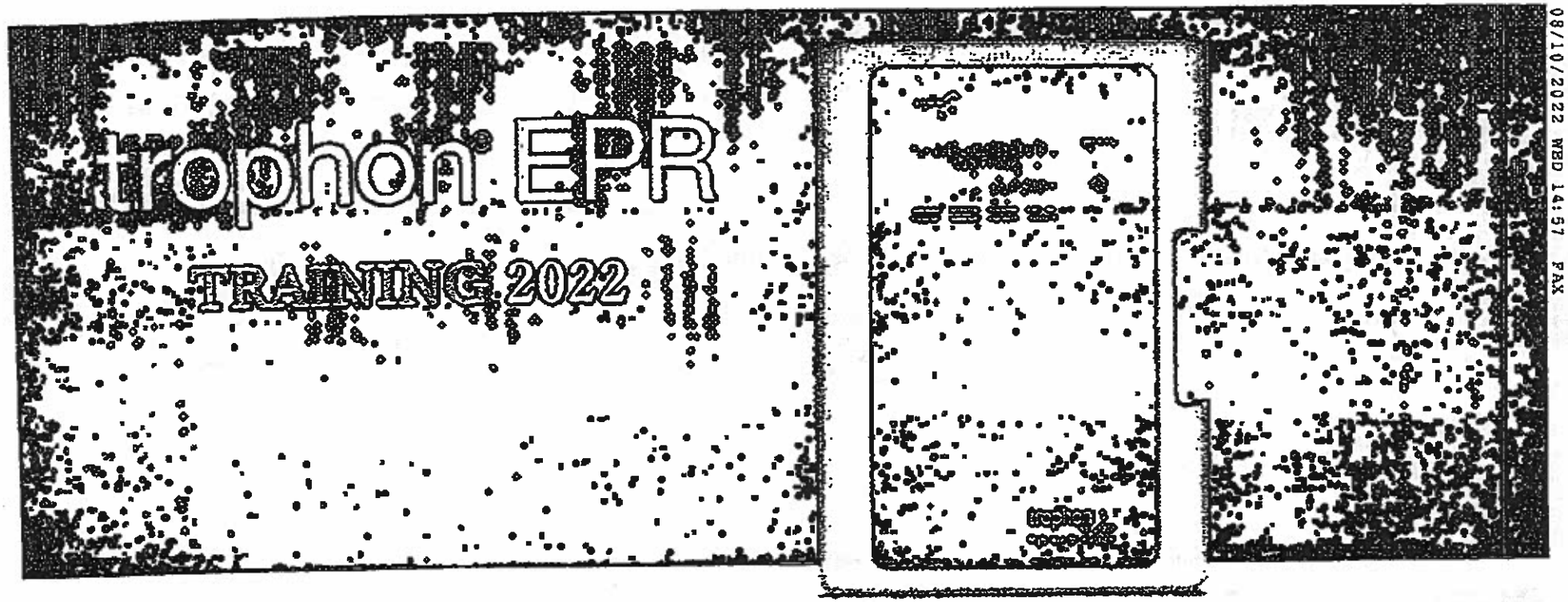

This certifies that

Marie Frukacz

has successfully completed the trophon EPR product training approved by Nanosonics Limited.

This certificate expires 12 months after the date of issue.

Date of issue: 10 Aug 2022

nanosonics
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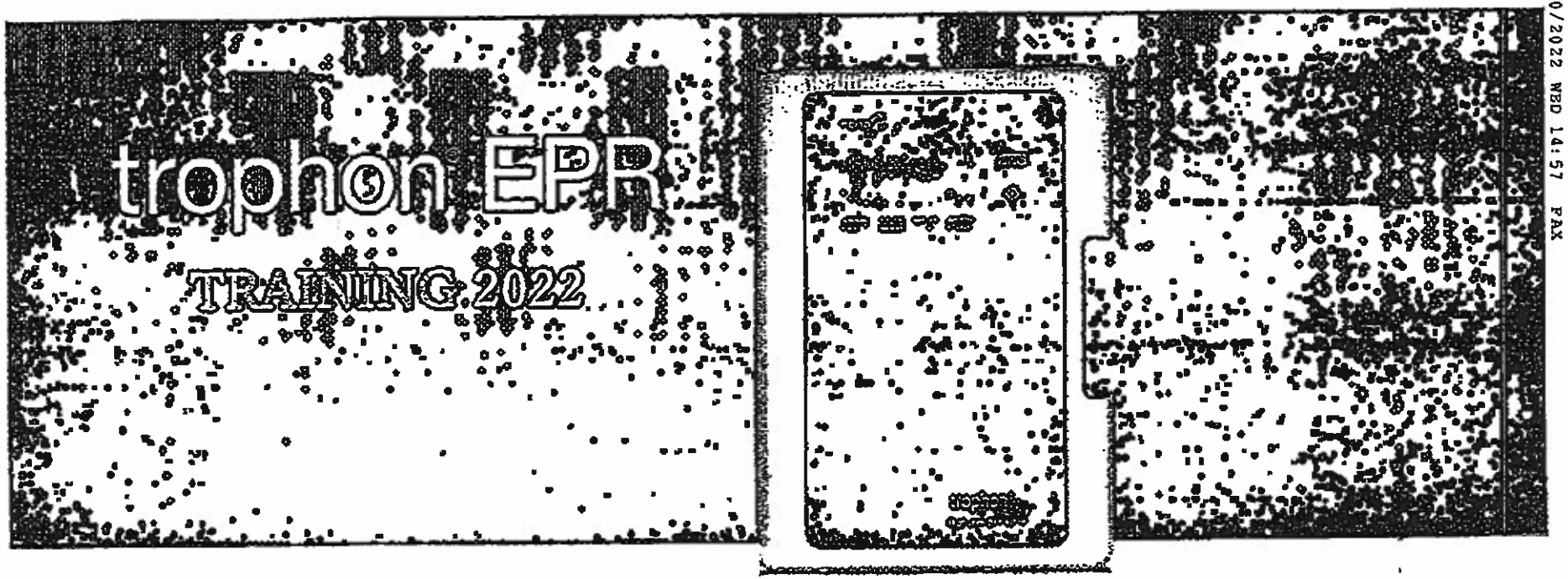


This certifies that

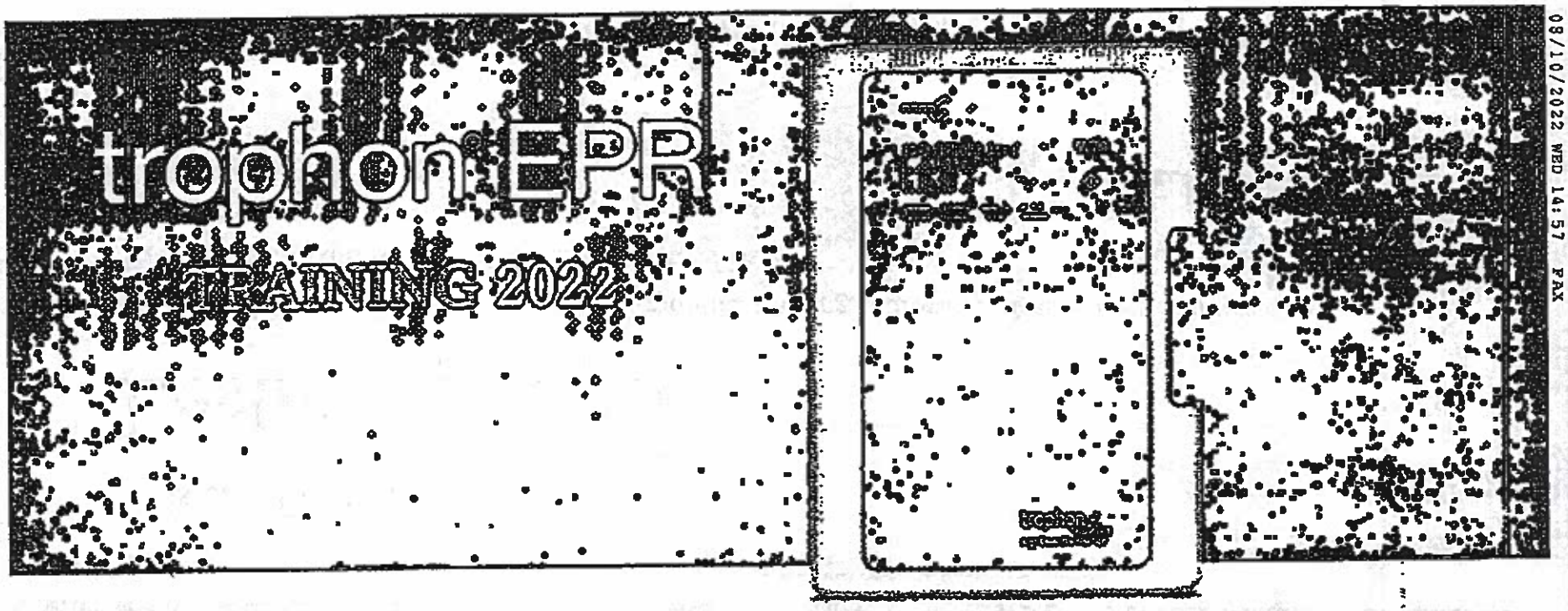
Leslie Aguirrre

has successfully completed the trophon EPR product training approved by Nanosonics Limited.

This certificate expires 12 months after the date of issue.

Date of issue: 10 Aug 2022

nanosonics
Infection Prevention. For Life.



This certifies that

NATALIYA KUKURUZA

has successfully completed the trophon EPR product training approved by Nanosonics Limited.
This certificate expires 12 months after the date of issue.

Date of issue: 10 Aug 2022

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Infection Prevention. For Life.

Appendix 6: TROPHON® COMPETENCY SHEET

NAME Marie Frukacz DATE 8/17/22

1. Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR user manual.

MET ✓ NOT MET

2. Pre-clean the probe before the high-level disinfection (HLD) cycle, following the probe manufacturer's instructions for use (IFUs).

MET ✓ NOT MET

3. Ensure the probe is clean and free of all visible debris, bioburden, gel, or other soil.
   a. Use Sani Cloths to clean
   b. Wipe the transducer cord and all surfaces of the transducer until it is visually clean. Use friction and work from cleanest to dirtiest areas.
   c. Dry the transducer with a soft, dry cloth.
   d. Visually inspect the transducer to ensure it is both clean and dry prior to HLD.

MET ✓ NOT MET

4. Load the clean, dry probe into the Trophon disinfection chamber ensuring:
   a. The probe is secured high in the chamber with tip of probe above embossed line.
   b. Probe does not contact the chamber wall at any point.

MET ✓ NOT MET

5. Place a new red Trophon chemical indicator (CI) into the indicator holder with the red side facing up.
   a. Note: a new CI is to be used for every cycle.

MET ✓ NOT MET

6. Close the chamber door and confirm whether the probe is both clean and dry.
   a. If yes, press Start.
   b. If no, follow the LCD screen prompts.

MET ✓ NOT MET

7. At the end of the 7 minute HLD cycle, Trophon's LCD screen states: "CYCLE COMPLETE REMOVE AND WIPE PROBE."

MET ✓ NOT MET

8. Open the chamber door.

MET ✓ NOT MET

9. Remove CI, check CI color against the color chart on the CI carton and discard.
   a. Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

MET ✓ NOT MET_____

10. Remove and wipe the probe using a clean, dry single use cloth.

MET ✓ NOT MET_____

11. Close the chamber door. The probe is now ready for use.

MET ✓ NOT MET_____

12. Record the HLD cycle on the log or printed sticker.

MET ✓ NOT MET_____

Notes:

- At the completion of a cycle, remove probe immediately to ensure faster warm up times. If probe remains in chamber, the Trophon will shut down heaters to ensure probe is protected. Therefore, warm up times may be longer.
- Sleep mode: to save power, Trophon will enter sleep mode after 2 hours of inactivity.
- Purging the Trophon of disinfectant is required if the device is to be moved or if Sonex-HL® has expired. Manufacturer's instructions for purging the Trophon must be meticulously followed.

NANOSONICS, INC

Trainer: _____

Trainee: Maria Fraga

Date: 8-N-22

Appendix 6: TROPHON® COMPETENCY SHEET

NAME ALEXA TUKO DATE 8/17/22

1. Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR user manual.

MET ✓ NOT MET

2. Pre-clean the probe before the high-level disinfection (HLD) cycle, following the probe manufacturer's instructions for use (IFUs).

MET ✓ NOT MET

3. Ensure the probe is clean and free of all visible debris, bioburden, gel, or other soil.
   a. Use Sani Cloths to clean
   b. Wipe the transducer cord and all surfaces of the transducer until it is visually clean. Use friction and work from cleanest to dirtiest areas.
   c. Dry the transducer with a soft, dry cloth.
   d. Visually inspect the transducer to ensure it is both clean and dry prior to HLD.

MET ✓ NOT MET

4. Load the clean, dry probe into the Trophon disinfection chamber ensuring:
   a. The probe is secured high in the chamber with tip of probe above embossed line.
   b. Probe does not contact the chamber wall at any point.

MET ✓ NOT MET

5. Place a new red Trophon chemical indicator (CI) into the indicator holder with the red side facing up.
   a. Note: a new CI is to be used for every cycle.

MET ✓ NOT MET

6. Close the chamber door and confirm whether the probe is both clean and dry.
   a. If yes, press Start.
   b. If no, follow the LCD screen prompts.

MET ✓ NOT MET

7. At the end of the 7 minute HLD cycle, Trophon's LCD screen states: "CYCLE COMPLETE REMOVE AND WIPE PROBE."

MET ✓ NOT MET

8. Open the chamber door.

MET ✓ NOT MET

9. Remove CI, check CI color against the color chart on the CI carton and discard.
   a. Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

MET ✓ NOT MET_____

10. Remove and wipe the probe using a clean, dry single use cloth.

MET ✓ NOT MET_____

11. Close the chamber door. The probe is now ready for use.

MET ✓ NOT MET_____

12. Record the HLD cycle on the log or printed sticker.

MET ✓ NOT MET_____

Notes:

- At the completion of a cycle, remove probe immediately to ensure faster warm up times. If probe remains in chamber, the Trophon will shut down heaters to ensure probe is protected. Therefore, warm up times may be longer.
- Sleep mode: to save power, Trophon will enter sleep mode after 2 hours of inactivity.
- Purging the Trophon of disinfectant is required if the device is to be moved or if Sonex-HL® has expired. Manufacturer's instructions for purging the Trophon must be meticulously followed.

NANOSONICS, INC

Trainer: _____

Trainee: 8-N-22 Alexa Tulea

Date: 8-N-22

Appendix 6: TROPHON® COMPETENCY SHEET

NAME SWANSON, Julie DATE 8/16/22

1. Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR user manual.

MET ✓ NOT MET

2. Pre-clean the probe before the high-level disinfection (HLD) cycle, following the probe manufacturer's instructions for use (IFUs).

MET ✓ NOT MET

3. Ensure the probe is clean and free of all visible debris, bioburden, gel, or other soil.
   a. Use Sani Cloths to clean
   b. Wipe the transducer cord and all surfaces of the transducer until it is visually clean. Use friction and work from cleanest to dirtiest areas.
   c. Dry the transducer with a soft, dry cloth.
   d. Visually inspect the transducer to ensure it is both clean and dry prior to HLD.

MET ✓ NOT MET

4. Load the clean, dry probe into the Trophon disinfection chamber ensuring:
   a. The probe is secured high in the chamber with tip of probe above embossed line.
   b. Probe does not contact the chamber wall at any point.

MET ✓ NOT MET

5. Place a new red Trophon chemical indicator (CI) into the indicator holder with the red side facing up.
   a. Note: a new CI is to be used for every cycle.

MET ✓ NOT MET

6. Close the chamber door and confirm whether the probe is both clean and dry.
   a. If yes, press Start.
   b. If no, follow the LCD screen prompts.

MET ✓ NOT MET

7. At the end of the 7 minute HLD cycle, Trophon's LCD screen states: "CYCLE COMPLETE REMOVE AND WIPE PROBE."

MET ✓ NOT MET

8. Open the chamber door.

MET ✓ NOT MET

9. Remove CI, check CI color against the color chart on the CI carton and discard.
   a. Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

MET ✓ NOT MET_____

10. Remove and wipe the probe using a clean, dry single use cloth.

MET ✓ NOT MET_____

11. Close the chamber door. The probe is now ready for use.

MET ✓ NOT MET_____

12. Record the HLD cycle on the log or printed sticker.

MET ✓ NOT MET_____

Notes:

- At the completion of a cycle, remove probe immediately to ensure faster warm up times. If probe remains in chamber, the Trophon will shut down heaters to ensure probe is protected. Therefore, warm up times may be longer.
- Sleep mode: to save power, Trophon will enter sleep mode after 2 hours of inactivity.
- Purging the Trophon of disinfectant is required if the device is to be moved or if Sonex-HL® has expired. Manufacturer's instructions for purging the Trophon must be meticulously followed.

NANOSONICS, INC

Trainer: A Fichter RN

Trainee: J. Swanson

Date: 8-16-22

Appendix 6: TROPHON® COMPETENCY SHEET

NAME Leslie Aguirre DATE 8-15-17

1. Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR user manual.

MET ✓ NOT MET

2. Pre-clean the probe before the high-level disinfection (HLD) cycle, following the probe manufacturer's instructions for use (IFUs).

MET ✓ NOT MET

3. Ensure the probe is clean and free of all visible debris, bioburden, gel, or other soil.
   a. Use Sani Cloths to clean
   b. Wipe the transducer cord and all surfaces of the transducer until it is visually clean. Use friction and work from cleanest to dirtiest areas.
   c. Dry the transducer with a soft, dry cloth.
   d. Visually inspect the transducer to ensure it is both clean and dry prior to HLD.

MET ✓ NOT MET

4. Load the clean, dry probe into the Trophon disinfection chamber ensuring:
   a. The probe is secured high in the chamber with tip of probe above embossed line.
   b. Probe does not contact the chamber wall at any point.

MET ✓ NOT MET

5. Place a new red Trophon chemical indicator (CI) into the indicator holder with the red side facing up.
   a. Note: a new CI is to be used for every cycle.

MET ✓ NOT MET

6. Close the chamber door and confirm whether the probe is both clean and dry.
   a. If yes, press Start.
   b. If no, follow the LCD screen prompts.

MET ✓ NOT MET

7. At the end of the 7 minute HLD cycle, Trophon's LCD screen states: "CYCLE COMPLETE REMOVE AND WIPE PROBE."

MET ✓ NOT MET

8. Open the chamber door.

MET ✓ NOT MET

9. Remove CI, check CI color against the color chart on the CI carton and discard.
    a. Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

MET ✓ NOT MET_____

10. Remove and wipe the probe using a clean, dry single use cloth.

MET ✓ NOT MET_____

11. Close the chamber door. The probe is now ready for use.

MET ✓ NOT MET_____

12. Record the HLD cycle on the log or printed sticker.

MET ✓ NOT MET_____

Notes:

- At the completion of a cycle, remove probe immediately to ensure faster warm up times. If probe remains in chamber, the Trophon will shut down heaters to ensure probe is protected. Therefore, warm up times may be longer.
- Sleep mode: to save power, Trophon will enter sleep mode after 2 hours of inactivity.
- Purging the Trophon of disinfectant is required if the device is to be moved or if Sonex-HL® has expired. Manufacturer's instructions for purging the Trophon must be meticulously followed.

NANOSONICS, INC

Trainer: A. Schuh ✓

Trainee: Leslie Aguirre

Date: 8-11-22 ✓

Appendix 6: TROPHON® COMPETENCY SHEET

NAME D. Gunawan DATE 8-16-22

1. Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR user manual.

MET ✓ NOT MET

2. Pre-clean the probe before the high-level disinfection (HLD) cycle, following the probe manufacturer's instructions for use (IFUs).

MET ✓ NOT MET

3. Ensure the probe is clean and free of all visible debris, bioburden, gel, or other soil.
   a. Use Sani Cloths to clean
   b. Wipe the transducer cord and all surfaces of the transducer until it is visually clean. Use friction and work from cleanest to dirtiest areas.
   c. Dry the transducer with a soft, dry cloth.
   d. Visually inspect the transducer to ensure it is both clean and dry prior to HLD.

MET ✓ NOT MET

4. Load the clean, dry probe into the Trophon disinfection chamber ensuring:
   a. The probe is secured high in the chamber with tip of probe above embossed line.
   b. Probe does not contact the chamber wall at any point.

MET ✓ NOT MET

5. Place a new red Trophon chemical indicator (CI) into the indicator holder with the red side facing up.
   a. Note: a new CI is to be used for every cycle.

MET ✓ NOT MET

6. Close the chamber door and confirm whether the probe is both clean and dry.
   a. If yes, press Start.
   b. If no, follow the LCD screen prompts.

MET ✓ NOT MET

7. At the end of the 7 minute HLD cycle, Trophon's LCD screen states: "CYCLE COMPLETE REMOVE AND WIPE PROBE."

MET ✓ NOT MET

8. Open the chamber door.

MET ✓ NOT MET

9. Remove CI, check CI color against the color chart on the CI carton and discard.
    a. Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

MET ✓ NOT MET_____

10. Remove and wipe the probe using a clean, dry single use cloth.

MET ✓ NOT MET_____

11. Close the chamber door. The probe is now ready for use.

MET ✓ NOT MET_____

12. Record the HLD cycle on the log or printed sticker.

MET ✓ NOT MET_____

Notes:

- At the completion of a cycle, remove probe immediately to ensure faster warm up times. If probe remains in chamber, the Trophon will shut down heaters to ensure probe is protected. Therefore, warm up times may be longer.
- Sleep mode: to save power, Trophon will enter sleep mode after 2 hours of inactivity.
- Purging the Trophon of disinfectant is required if the device is to be moved or if Sonex-HL® has expired. Manufacturer's instructions for purging the Trophon must be meticulously followed.

NANOSONICS, INC

Trainer: _____

Trainee: D. Gunawan, RN

Date: 8-14-17

Appendix 6: TROPHON® COMPETENCY SHEET

NAME LEDRANO, Daisy DATE 8/K/22

1. Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR user manual.

MET ✓ NOT MET

2. Pre-clean the probe before the high-level disinfection (HLD) cycle, following the probe manufacturer's instructions for use (IFUs).

MET ✓ NOT MET

3. Ensure the probe is clean and free of all visible debris, bioburden, gel, or other soil.
   a. Use Sani Cloths to clean
   b. Wipe the transducer cord and all surfaces of the transducer until it is visually clean. Use friction and work from cleanest to dirtiest areas.
   c. Dry the transducer with a soft, dry cloth.
   d. ✓ Visually inspect the transducer to ensure it is both clean and dry prior to HLD.

MET ✓ NOT MET

4. Load the clean, dry probe into the Trophon disinfection chamber ensuring:
   a. The probe is secured high in the chamber with tip of probe above embossed line.
   b. ✓ Probe does not contact the chamber wall at any point.

MET ✓ NOT MET

5. Place a new red Trophon chemical indicator (CI) into the indicator holder with the red side facing up.
   a. Note: a new CI is to be used for every cycle.

MET ✓ NOT MET

6. Close the chamber door and confirm whether the probe is both clean and dry.
   a. If yes, press Start.
   b. ✓ If no, follow the LCD screen prompts.

MET ✓ NOT MET

7. At the end of the 7 minute HLD cycle, Trophon's LCD screen states: "CYCLE COMPLETE REMOVE AND WIPE PROBE."

MET ✓ NOT MET

8. Open the chamber door.

MET ✓ NOT MET

9. Remove CI, check CI color against the color chart on the CI carton and discard.
   a. Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

MET ✓ NOT MET_____

10. Remove and wipe the probe using a clean, dry single use cloth.

MET ✓ NOT MET_____

11. Close the chamber door. The probe is now ready for use.

MET ✓ NOT MET_____

12. Record the HLD cycle on the log or printed sticker.

MET ✓ NOT MET_____

Notes:

- At the completion of a cycle, remove probe immediately to ensure faster warm up times. If probe remains in chamber, the Trophon will shut down heaters to ensure probe is protected. Therefore, warm up times may be longer.
- Sleep mode: to save power, Trophon will enter sleep mode after 2 hours of inactivity.
- Purging the Trophon of disinfectant is required if the device is to be moved or if Sonex-HL® has expired. Manufacturer's instructions for purging the Trophon must be meticulously followed.

NANOSONICS, INC

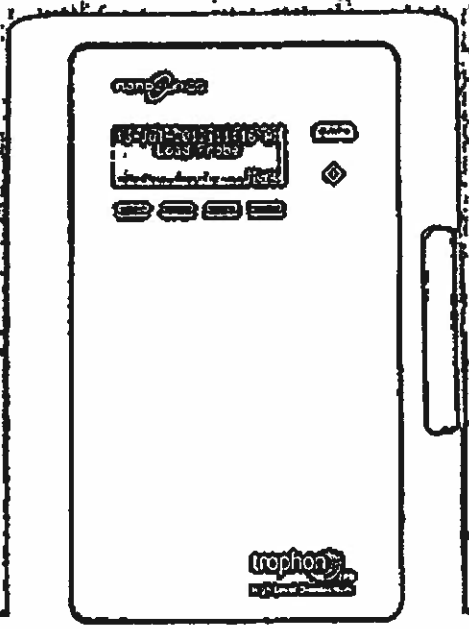
Trainer: A Schuster RN

Trainee: D. Medrano, ORS

Date: 8/15/17

trophon® EPR

TRAINING 2022



This certifies that

daisy medrano

has successfully completed the trophon EPR product training approved by Nanosonics Limited.

This certificate expires 12 months after the date of issue.

Date of issue: 12 Aug 2022

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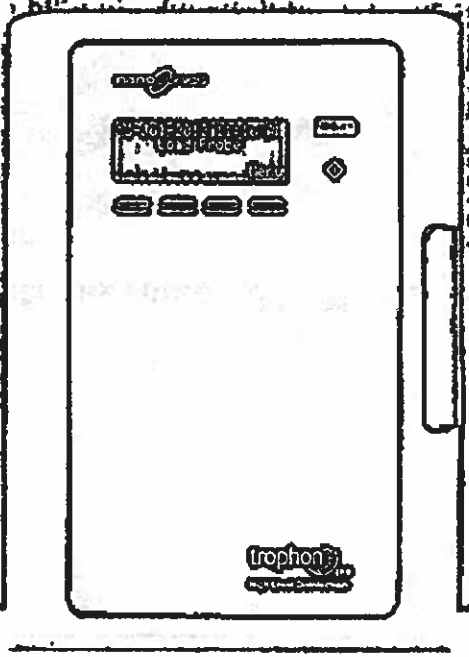
trophon® EPR

TRAINING 2022



This certifies that

Andriy Martyniv

has successfully completed the trophon EPR product training approved by Nanosonics Limited.
This certificate expires 12 months after the date of issue.

Date of issue: 12 Aug 2022

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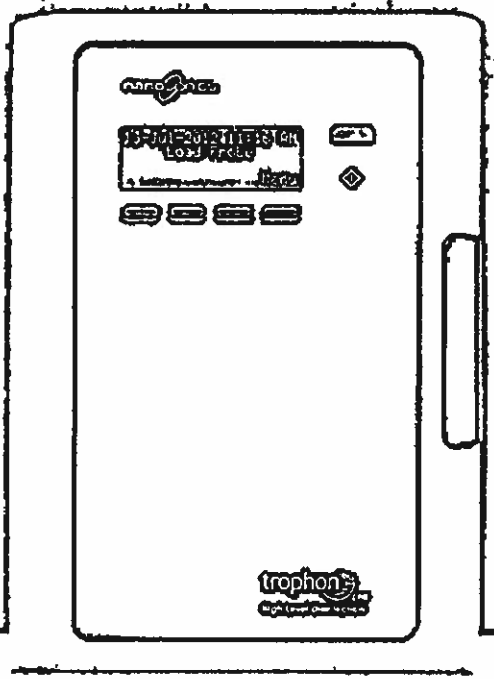
trophon® EPR

TRAINING 2022



This certifies that

suhi Garcia

has successfully completed the trophon EPR product training approved by Nanosonics Limited.
This certificate expires 12 months after the date of issue.

Date of issue: 13 Aug 2022

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Notes:

At the completion of a cycle, remove probe immediately to ensure faster warm-up times.

If probe remains in chamber, the trophon EPR will shut down heaters to ensure probe is protected. Therefore, warm-up times may be longer.

Sleep mode – to save power, trophon EPR will enter sleep mode after two hours of inactivity.

Purging the trophon EPR of disinfectant is required if the device is to be moved or if NanoNebulant®/Sonex-HL® has expired. This involves removal of all disinfectant from the system. Purging may be implemented manually via trophon LCD screen (if relocating or transporting trophon) or it may be prompted automatically (if NanoNebulant®/Sonex-HL® cartridge has expired).

Empty the waste drawer when prompted by the trophon EPR LCD screen.

Note: Wear gloves when handling the waste drawer.

Trainer (Print Name): Megan Stacy, RPMS

Trainer Signature: [signature]

Title: Clin Apps Specialist

Employee Signature: [signature]

Date: 8-15-22

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trophon® EPR Competency

Name Gilbert Garcia **Date** 8/15/22

1. TROPHON EPR OPERATION

1.1

Watch the trophon EPR training video (if not previously completed). This will take approximately 5 minutes.

Met ✓ **Not Met** _____

1.2

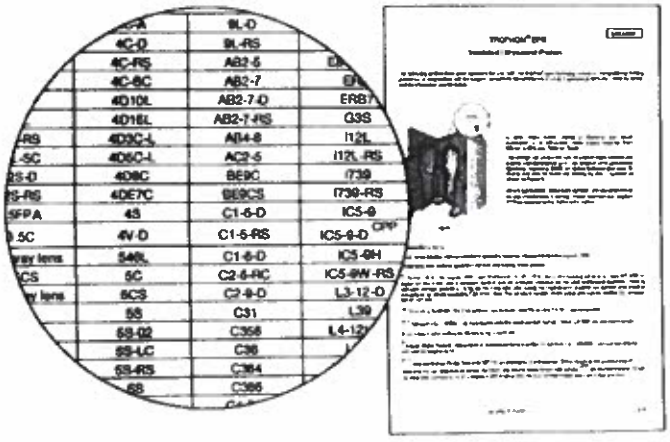
Complete and pass the online trophon EPR quiz.

Met ✓ **Not Met** _____

1.3

Check the trophon EPR Validated Probes List at your local Nanosonics/trophon website, under the trophon menu/trophon Probe compatibility. A hard copy of the list can be downloaded.

Met ✓ **Not Met** _____



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1.4

Put gloves on.

Note: Wear gloves at all times when required as described in the *trophon® EPR User Manual.*

Met ✓ **Not Met** _____

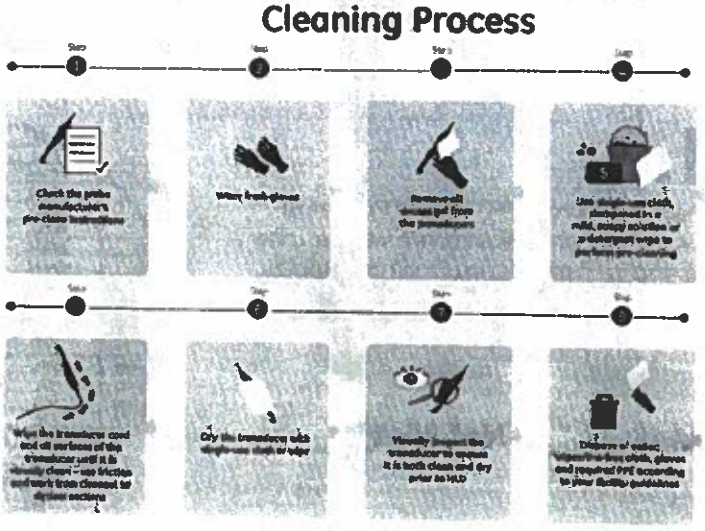
1.5

Pre-clean the probe before the high level disinfection (HLD) cycle, following the probe manufacturer's instructions.

Met ✓ **Not Met** _____

1.6

Ensure the probe is clean and free of all visible debris, bioburden, gel or other soil.



Met ✓ **Not Met** _____

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1.7

Dry the probe – ensure there is no visible moisture or drops of liquid on the probe.

Met ✓ **Not Met**_____

1.8

Load the clean, dry probe into the trophon EPR disinfection chamber, ensuring:

- Probe is secured high in the chamber with tip of probe above embossed line
- Probe does not contact the chamber wall at any point

If you have a curved probe, check the *trophon EPR Validated Probes List* at your local Nanosonics/trophon website or download the list from the Nanosonics training site, to see if you need the CPP accessory.

Met ✓ **Not Met**_____

1.9

Place a Chemical Indicator into the locator at the base of the chamber door, red side up.

Note: A new Chemical Indicator to be used for every cycle

Met ✓ **Not Met**_____

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1.10

Close the chamber door and confirm whether the probe is both clean and dry

- If yes, select "Yes" then press Start
- If no, follow the LCD screen prompts

Met ✓ **Not Met**_____

1.11

At the end of the seven minute HLD cycle, trophon EPR's LCD screen states: CYCLE COMPLETE REMOVE AND WIPE PROBE.

Met ✓ **Not Met**_____

1.12

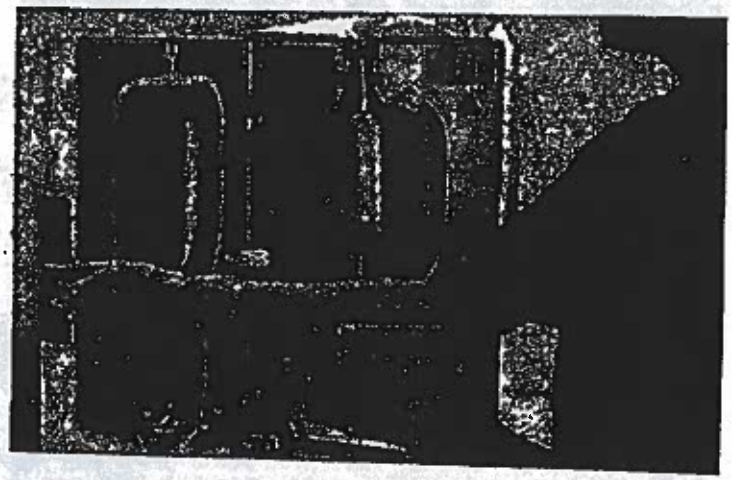
Wear new gloves.

Met ✓ **Not Met**_____

1.13

Open the chamber door.

Met ✓ **Not Met**_____



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1.14

Remove CI, check CI colour against the colour chart on the CI box and discard.

Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

Met ✓ **Not Met**_____

1.15

Remove and wipe the probe using a dry, single use cloth.

Met ✓ **Not Met**_____

1.16

Insert the probe into a trophon Clean Ultrasound Probe Cover and wrap the securing tie around the cable stain relief.

Met ✓ **Not Met**_____

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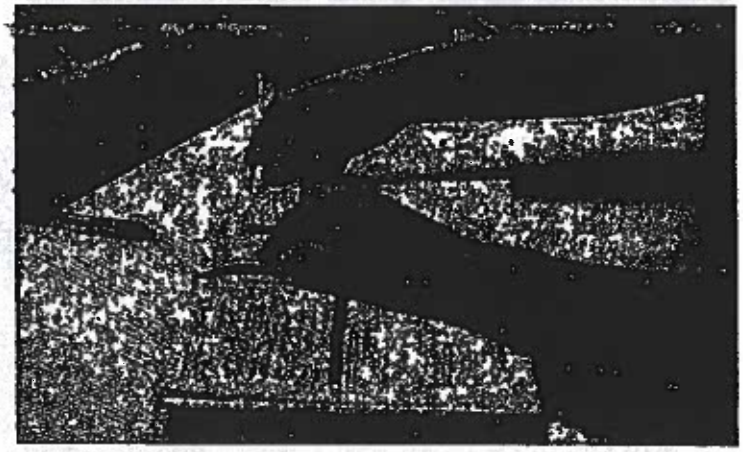
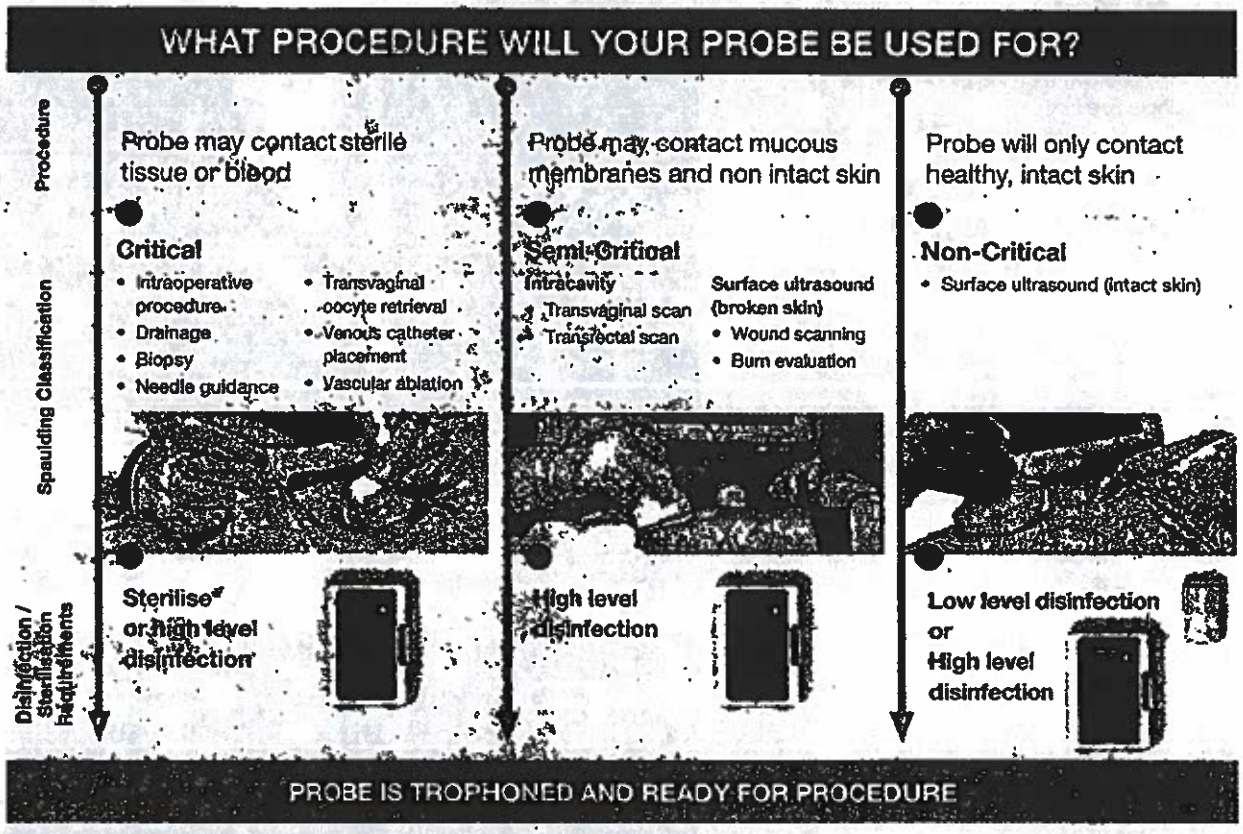
1.17

Record the high level disinfection cycle on the log or printed sticker. Store the probe correctly for later use

Met ✓ **Not Met** _____





* Critical probes should be sterilised, or can also be high level disinfected and used with a sterile sheath.[1]

[1] Rutala WA, Weber DJ, HICPAC. Guideline for Disinfection and Sterilization in Healthcare Facilities. USA: Centers for Disease Control; CDC 2008 (https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfectionguidelines.pdf)

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trophon® EPR Competency

Name Arnold Sabater RN **Date** 8/15/22

1. TROPHON EPR OPERATION

1.1

Watch the trophon EPR training video (if not previously completed). This will take approximately 5 minutes.

Met ✓ **Not Met** ____

1.2

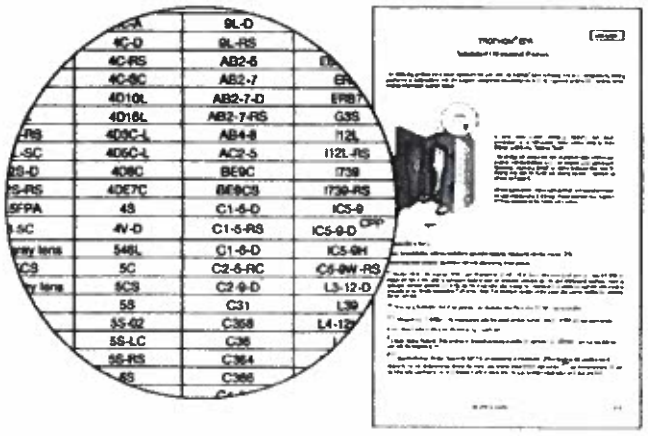
Complete and pass the online trophon EPR quiz.

Met ✓ **Not Met** ____

1.3

Check the trophon EPR Validated Probes List at your local Nanosonics/trophon website, under the trophon menu/trophon Probe compatibility. A hard copy of the list can be downloaded.

Met ✓ **Not Met** ____



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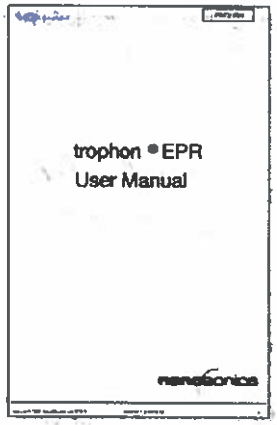
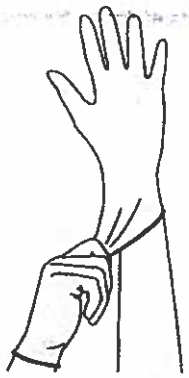
1.4

Put gloves on

Note: Wear gloves at all times when required as described in the *trophon® EPR User Manual.*

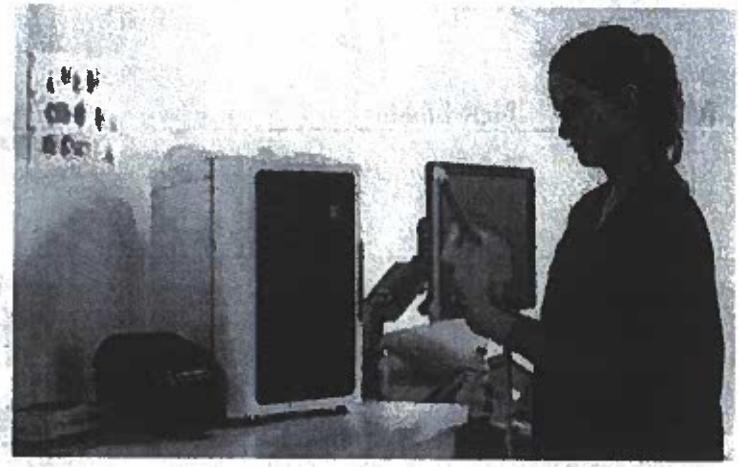




Met ✓ **Not Met** _____

1.5

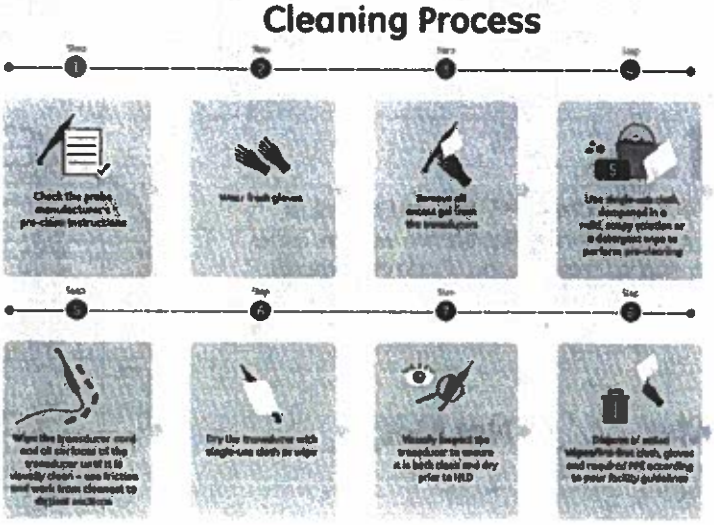
Pre-clean the probe before the high level disinfection (HLD) cycle, following the probe manufacturer's instructions.



Met ✓ **Not Met** _____

1.6

Ensure the probe is clean and free of all visible debris, bioburden, gel or other soil.



Met ✓ **Not Met** _____

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1.7

Dry the probe – ensure there is no visible moisture or drops of liquid on the probe.

Met ✓ **Not Met**_____

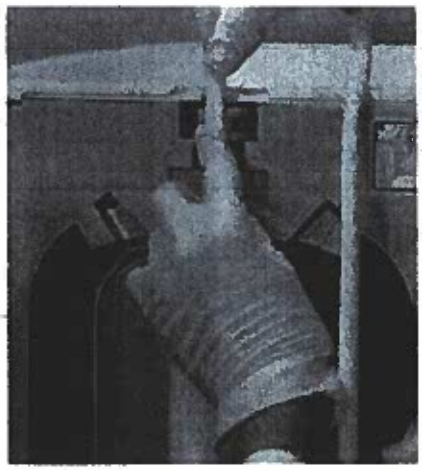
1.8

Load the clean, dry probe into the trophon EPR disinfection chamber, ensuring:

- Probe is secured high in the chamber with tip of probe above embossed line
- Probe does not contact the chamber wall at any point

If you have a curved probe, check the *trophon EPR Validated Probes List* at your local Nanosonics/trophon website or download the list from the Nanosonics training site, to see if you need the CPP accessory.

Met ✓ **Not Met**_____



1.9

Place a Chemical Indicator into the locator at the base of the chamber door, red side up.

Note: A new Chemical Indicator to be used for every cycle

Met ✓ **Not Met**_____

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1.10

Close the chamber door and confirm whether the probe is both clean and dry

- If yes, select "Yes" then press Start
- If no, follow the LCD screen prompts

Met ✓ **Not Met**_____

1.11

At the end of the seven minute HLD cycle, trophon EPR's LCD screen states: CYCLE COMPLETE REMOVE AND WIPE PROBE.

Met ✓ **Not Met**_____

1.12

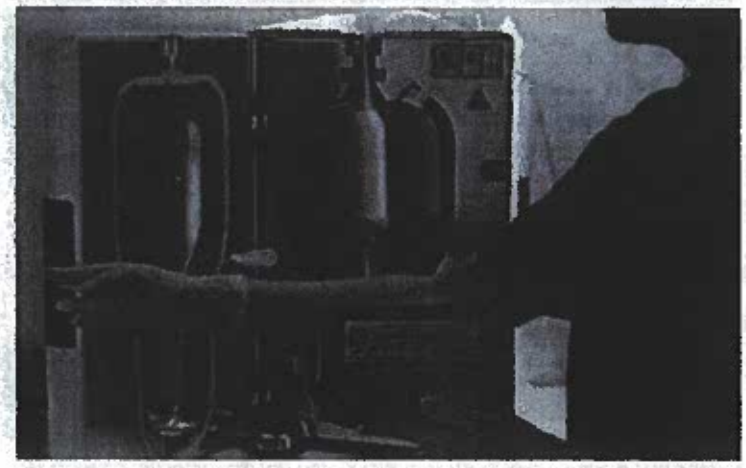
Wear new gloves.

Met ✓ **Not Met**_____

1.13

Open the chamber door.

Met ✓ **Not Met**_____



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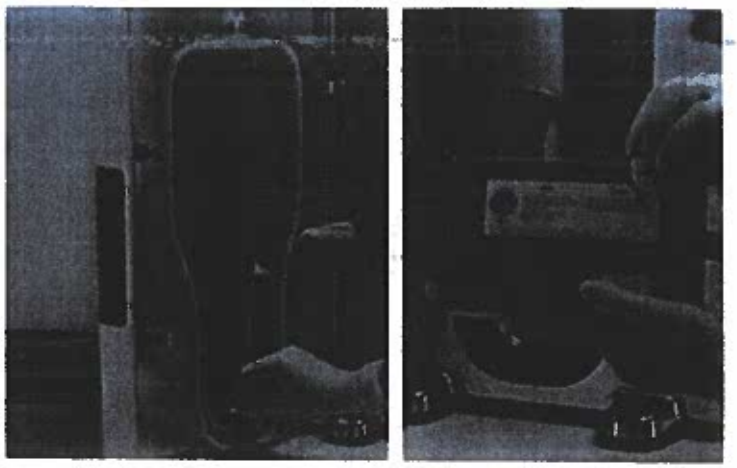
1.14

Remove CI, check CI colour against the colour chart on the CI box and discard.

Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

Met ✓ **Not Met**_____



1.15

Remove and wipe the probe using a dry, single use cloth.

Met ✓ **Not Met**_____

1.16

Insert the probe into a trophon Clean Ultrasound Probe Cover and wrap the securing tie around the cable stain relief.

Met ✓ **Not Met**_____

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7

e high level disinfection cycle on the
ted sticker. Store the probe correctly
e.

✓ **Not Met**_____

WHAT PROCEDURE WILL YOUR PROBE BE USED FOR?

Probe may contact sterile tissue or blood

Critical

- Intraoperative procedure
- Drainage
- Biopsy
- Needle guidance
- Transvaginal oocyte retrieval
- Venous catheter placement
- Vascular ablation

Probe may contact mucous membranes and non intact skin

Semi-Critical

Intracavity
- Transvaginal scan
- Transrectal scan

Surface ultrasound (broken skin)
- Wound scanning
- Burn evaluation

Probe will only contact healthy, intact skin

Non-Critical

- Surface ultrasound (intact skin)

Sterilise[1] or high level disinfection

High level disinfection

Low level disinfection or High level disinfection

PROBE IS TROPHONED AND READY FOR PROCEDURE

robes should be sterilised, or can also be high level disinfected and used with a sterile sheath.[1]

A, Weber DJ, HICPAC. Guideline for Disinfection and Sterilization in Healthcare Facilities. USA: Centers for Disease Control;
3 (https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfectionguidelines.pdf)

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Notes:

At the completion of a cycle, remove probe immediately to ensure faster warm-up times.

If probe remains in chamber, the trophon EPR will shut down heaters to ensure probe is protected. Therefore, warm-up times may be longer.

Sleep mode – to save power, trophon EPR will enter sleep mode after two hours of inactivity.

Purging the trophon EPR of disinfectant is required if the device is to be moved or if NanoNebulant®/Sonex-HL® has expired. This involves removal of all disinfectant from the system. Purging may be implemented manually via trophon LCD screen (if relocating or transporting trophon) or it may be prompted automatically (if NanoNebulant®/Sonex-HL® cartridge has expired).

Empty the waste drawer when prompted by the trophon EPR LCD screen.

Note: Wear gloves when handling the waste drawer.

Trainer (Print Name): Megan Stacy, RDMS

Trainer Signature: [signature]

Title: Clin Apps Specialist

Employee Signature: [signature]

Date: 8/15/22

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Appendix 5: TROPHON® Log

High-Level Disinfection Log
For Trophon EPR Serial # 18640-009

START A NEW PAGE WHEN LOADING A NEW SONEX CARTRIDGE OR NEW BOX OF CHEMICAL INDICATORS
CARTRIDGE REPLACEMENT: WHEN LOADING A NEW SONEX CARTRIDGE, START A NEW PAGE. DOCUMENT DATE LOADED, LOT # & EXP. DATE.
CHEMICAL INDICATOR BOX: WHEN OPENING A NEW BOX OF CHEMICAL INDICATORS, START A NEW PAGE. DOCUMENT LOT # AND EXP. DATE.
CYCLE RESULTS: PLACE LABEL IN SQUARES BELOW
LABELING YOUR READY-TO-USE PROBE INITIAL IN THE SMALL BOX BELOW ("INIT"), AFTER LABEL IS PLACED ON THE CLEAN US PROBE COVER

CARTRIDGE REPLACEMENT		CHEMICAL INDICATOR REPLACEMENT	
Date Loaded & Lot #	Expiration Date	Lot Batch #	Expiration Date
8/15/22 C11001	2023-10-06	21P0810	2023-03-02

trophon
17/08/2022 07:58 SN:18640-009
Disinfection: PASS Cycle #: 5490
Indicator: PASS FAIL
Operator:
Probe: Red
Notes: Test

trophon
17/08/2022 08:48 SN:18640-009
Disinfection: PASS Cycle #: 5491
Indicator: PASS FAIL
Operator:
Probe: Green
Notes: Test Run

	2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover
	2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover
	2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover
	2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover		2nd Label Placed on Clean Ultrasound Probe Cover

American Health Care Centers

List of Staff Competent to Use Trophon EPR

Name	Initial
Arnold Sabater RN (super trainer)	
Andrei MArtyniv, SA (super trainer)	
Gilbert Garcia, ORT (super trainer)	GG
Daisy Medrano, ORT	D.Me.
Julie Swanson, Faculty Administrator	
Devi Gunawan, APN	DG
Leslie Aguirre, U/S tech	LA
Alexa Tulea, OR staff	AT
Marie Frukacz, Manager	MF
Natasha Kukuraza U/S tech	Pending competency

[redacted] Red = SN: 64400530

[redacted] Green = SN: B7626609