DEPARTMENT OF HEALTH AND HUMAN SERVICES **CENTERS FOR MEDICARE & MEDICAID SERVICES** OMB NO. 0938-0391 (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY COMPLETED **IDENTIFICATION NUMBER:** AND PLAN OF CORRECTIONS A. BUILDING 14C0001185 08/02/2022 **B. WING** NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE WESTERN DIVERSEY SURGICAL CENTER 2744 N WESTERN AVE , CHICAGO, Illinois, 60647 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE COMPLÉTION TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE DATE APPROPRIATE DEFICIENCY) Q0000 INITIAL COMMENTS Q0000 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: Q0240 INFECTION CONTROL Q0240 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

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

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.

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days bllowing the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program

ABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

ORM CMS-2567 (02/99) Previous Versions Obsolete

Event ID: 4F240-H1

Facility ID: 7000037

If continuation sheet Page 1 of 6

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS (X1) PROVIDER/SUPPLIER/SIDENTIFICATION NUMBER: 14C0001185		LIA	(X2) MULTIPL A. BUILDING B. WING	E CONSTRUCTION	(X3) DATE SURV 08/02/2022	EY COMPLET		
NAME OF PROVIDER OR SUPPLIER WESTERN DIVERSEY SURGICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2744 N WESTERN AVE , CHICAGO, Illinois, 60647					
SUMMARY STATEMENT (EACH DEFICIENCY MUST BITTED REGULATORY OR LSC IDENTITY	E PRECEDED BY FULL	ID PREFIX TAG		OVIDER'S PLAN OF H CORRECTIVE ACT CROSS-REFERENC APPROPRIATE DE	TION SHOULD BE SED TO THE	(X5) COMPLETIC DATE		
O240 Continued from page 1 instruction for use to perform hig disinfection, on the ultrasound monduct vaginal ultrasounds. Seat Q-0245.	nachine used to	Q0240			x			
0242 INFECTION CONTROL PROGR	RAM	Q0242				11		
CFR(s): 416.51(b)						N.		
The ASC must maintain an ongo to prevent, control, and investiga and communicable diseases. In infection control and prevent pro documentation that the ASC has selected, and implemented natio infection control guidelines.	ate infections addition, the gram must include s considered,	1				31 - 1 31 - 1		
This STANDARD is NOT MET as	s evidenced by:		11					
Based on document review and determined that the Facility's fail that the infection control program post-procedural infection surveill detection through ongoing data analysis.	ed to ensure n included lance and		I o					
Findings include:		1						
1. On 08/01/2022 the Facility's parinfection Control Plan* dated 03 reviewed and included, "The in plan will be monitored and evaluated Performance Committee1. Infection will be collected, analyzed and transformation obtained will be given Manager or designee, and used care, as well as improve practice.	I/01/2008 was Infection control Interest of the section control data Interest of the office Into the Office It of t					19725 17		
the implementation of its infection control plan" The Facility's was provide the infection control surv	n/exposure s requested to reillance of data					15 E 50		
tracking and trending for a sample patients. The Facility was unable documents regarding infection or surveillance. 2. On 08/02/2022 at	to provide	j				in di		
Nurse Manager (E #2) an intervie #2 stated that there is an infection but there is no data being collect	ew was conducted. E on control plan, ded if any		Hanne			ac		
patients developed infections after E #2 stated that the Nurse Praction makes the phone calls and is not practitioner obtains information of data collection of post-procedure	itioner (E #3) t sure if the nurse on patient for	-0-1	4 1 V/O					
On 08/02/2022 at 9:20 AM, the N (E #3) was interviewed. E #3 stat	lurse Practitioner	₽						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 14C0001185		IA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY COMPLE A. BUILDING 08/02/2022 B. WING			Y COMPLETED		
	OF PROVIDER OR SUPPLIER	NTER	-1		EET ADDRESS, CITY, STATE, ZIP COD IN WESTERN AVE, CHICAGO, Illinois,		
(X4) ID PREFIX TAG		E PRECEDED BY FULL	ID PREF TAC	FIX	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CROSS-REFERENCED T APPROPRIATE DEFICIE	I SHOULD BE TO THE	(X5) COMPLETION DATE
	Continued from page 2 five percentage possibility of paticinfection after a surgical procedure that there no data collected from post procedural infections. E #3 s do any type of surveillance after t procedure. 4.On 08/02/2022 at 1 Medical Director (MD #1) was intested that he was not aware that not conducting surveillance of poinfections. MD #1 stated that ther infection after any surgical procedure that they plan to hire a conoversee the infection control pracfacility.	ient developing ire. E #3 stated i the patients of stated "We do not the 10:00 AM, the terviewed, MD #1 st the Facility was ost procedural re is risk for edure, MD #1 insultant to	Q024	12			
Q0244	INFECTION CONTROL PROGRA	AM - QAPI	Q024	44			
	CFR(s): 416.51(b)(2)		ĺ				[
	[The program is -]						
	An integral part of the ASC's qua and performance improvement p	program					
	This STANDARD is NOT MET as	•					
	Based on document review and in determined that the Facility failed ongoing collection of data of post infections was included as an inte their quality assessment and per improvement program to ensure of post procedure infections.	d to ensure at procedure tegral part of rformance					3
	Findings include: 1. On 08/01/20/2 Committee Meeting Minutes for 0 was reviewed. The meetings were and sign-in sheet included the ke facility attending the committee meeting minutes includiscussion such as: credentialing policies and procedures, tissue reinfection control report on hand hinfection control prioritized risk for control -COVID pandemic, envirocensus report and employee rela Consulting Committee Meeting minclude data of the ongoing survepost-procedure infections. 2. On 0 11:30 AM, the Nurse Manager (Einterviewed. E #2 stated that their infection control plan, but there is	01/2021 - 07/2022 re held quarterly, ey members of the meetings. The uded topics of g, approval of review report, the hygiene, or Infection onment of care, ated agenda. The minutes did not eillance of 08/02/2022 at E #2) was er is an s no data being					
	collected if any patients develope after the procedure. E #2 stated to MS-2567 (02/99) Previous Version	that there is no					2

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS (X1) PROVIDER/SUPPLIE IDENTIFICATION NUMBER 14C0001185			(X2) MULTIPLE CONSTRUCTION (X3) DATE SURV A. BUILDING 08/02/2022 B. WING		VEY COMPLETE	
	OF PROVIDER OR SUPPLIER TERN DIVERSEY SURGICAL CE	NTER	A 2014	REET ADDRESS, CITY, STATE, ZIP CO 44 N WESTERN AVE , CHICAGO, III ind	MAN HILANDA T	
(X4) ID PREFIX TAG	SUMMARY STATEMENT (EACH DEFICIENCY MUST BE REGULATORY OR LSC IDENT	PRECEDED BY FULL	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTION CROSS-REFERENCE APPROPRIATE DEFI	ON SHOULD BE D TO THE	(X5) COMPLETION DATE
20244	Continued from page 3 data that is presented regarding developing infections after the pi consulting committee meetings. 10:00 AM, the findings were disc Medical Director (MD #1). MD # not aware of any data regarding developing any type of infections at the consulting committee mee that they plan to hire a consultar infection control practices at the	ocedure at the 3. On 8/02/2022 at sussed with the stated that he is patient's being presented tings. MD #1 stated	Q0244			
20245	INFECTION CONTROL PROGR CFR(s): 416.61(b)(3)	AM	Q0245	1 - 50 h	per ne per est	
	The program is -		-1			
	Responsible for providing a plan preventing, identifying, and mand and communicable diseases and implementing corrective and prethat result in improvement.	aging infections for immediately				
71	This STANDARD is NOT MET as	evidenced by:	il.	A STATE OF THE STA		1121
5.	Based on document review and it determined that the Facility falled an infection control plan/program implemented by falling to ensure manufacturer's instruction for use high-level disinfection, on the ultrused to conduct vaginal ultrasour potentially placed all patients that vaginal ultrasound at risk for infecommunicable diseases.	to ensure that was fully to follow the to perform asound machine nds. This t required a	Ī			sher 1
	Findings include:					
	1. On 08/01/2022 at approximate Facility's policy titled, "Cleaning, Sterilization, and Disinfection Gu 02/20/2018 was reviewed and incontrol to the processing technician will instruments manufacturer's IFU (use) to determine the requiremente validated cleaning and processing practices will concurrent IFUSurgical instruments should be cleaned and decontain the manufacturer's validated, writused for disinfection will be based	idelines" dated studed, "A.3: The review the instructions for it for replicating ssing methodsThe ed periodically inply with the most ts and equipment inated according to ten IFUmethods				

...semi-critical ...risk of infection to the patient ...semi-critical: items that come in contact with

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;

L Swanson

Administrator

IDPH RESPONSE FORMAT

Prefix Tag F	Paragrapi	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	07/27/22
			the purchase of Trophone EPR for High Level Disinfection of ultrasound probes.	08/03/22
			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	08/13/22 08/16/22
			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.	08/16/22

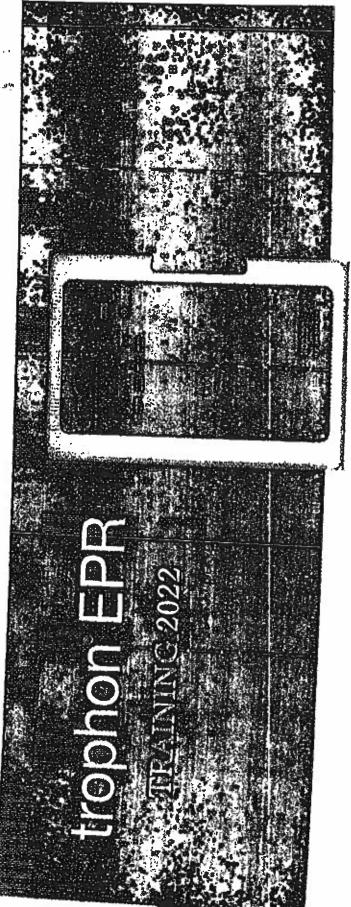
Q-0242	Infection Control Plan		
		The Infection Control Plan was revisited by the infection control committee and a plan to prioritize risk for infection control was done. The prioritized risk was post-operative infection follow-up of patients. For the purpose of Infection Control follow-up of patients: 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	07/27/22
		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	08/13/22
		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.	08/16/22
Q-0242		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.	08/16/22
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 cail. Data will be collected by the nurse practioner on a monthly basis, analyzed, trended and reported to the infection contro committee.	8/16/2022

Q-0245

The Infection Control Plan was revisited by the Infection Control Committee and 8/17/2022 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. Please see attached supprting document 8/17/2022 that the 2 probes with corresponding SN are subjected successfully to Trophon HLD.

In-service was conducted with the staff on 8/17/2022 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

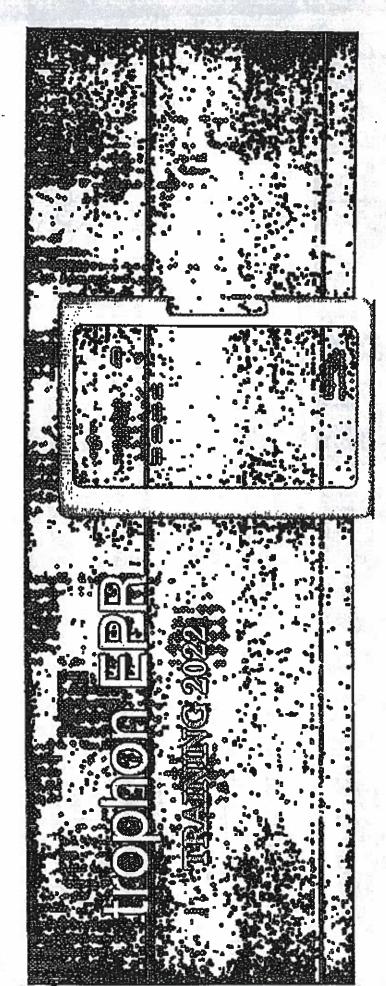


Leslie Aguirrre

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

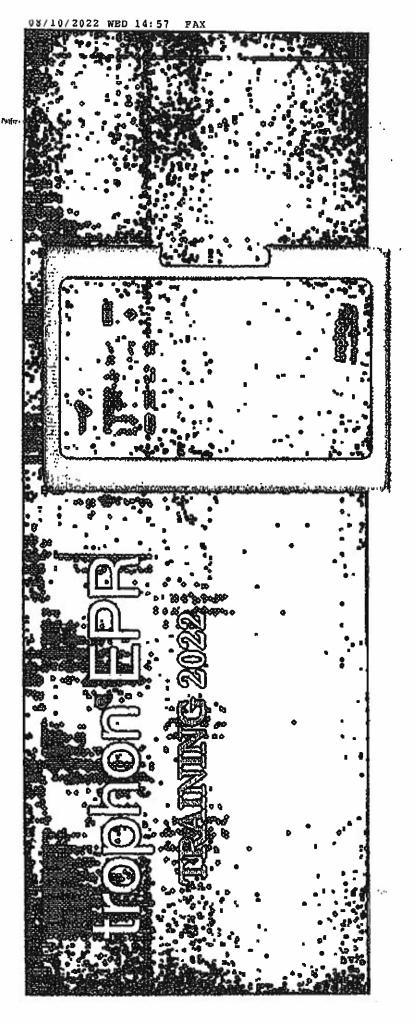
nanosonics Implication Promotive Library



Alexa Tulea

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

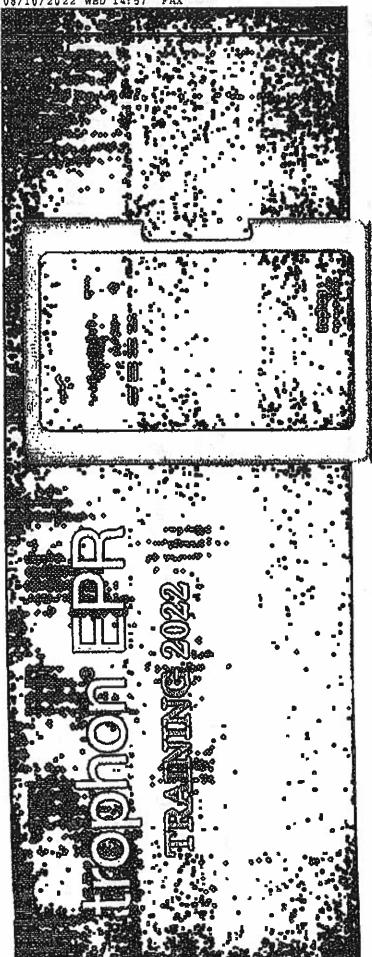




iauw Devi Gunawan

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



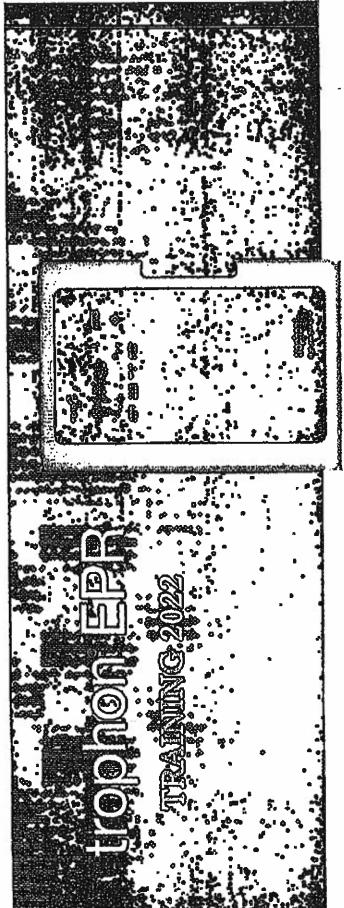


Marie Frukacz

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

This certificate expires 12 months after the date of issue.

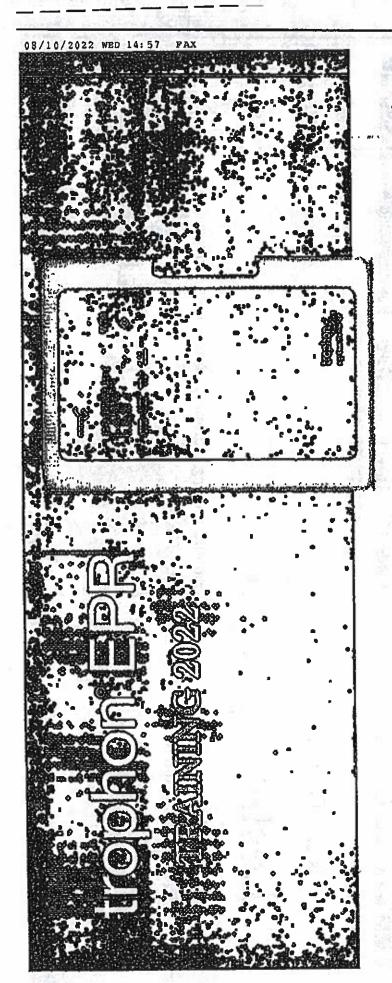




Leslie Aguirrre

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





NATALIYA KUKURUZA

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



Cleaning, Disinfection, and Sterilization of Patient-Care Items

Appendix 6: TROPHON® COMPETENCY SHEET

NAME	Marie Frukacz DATE 8/18/22	
1.	Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR manual.	user
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. 	ı
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.	ng
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	

Cleaning, Disinfection, a		and the second				
	eck CI color agair OTH the CI and L(r use. If either the	CD screen must	indicate a suc	cessful cycle	e for the probe	
METNOT N	MET					
10. Remove and w	ripe the probe usin	g a clean, dry s	ingle use cloth	ı .		
METNOT	MET					
11. Close the chan	nber door. The pr	obe is now read	y for use.			
METNOT I	MET					
12. Record the HL	D cycle on the log	or printed sticke	er.			
METNOT N	MET					
n II a						
Notes: • At the completion	on of a cycle, remo	ove probe imme	diately to ensu	ıre faster wa	rm up times. If	-
 Purging the Tro 	may be longer. save power, Trop phon of disinfecta facturer's instruction	nt is required if t	the device is to	be moved	or if Sonex-HL@	
NANOSONICS, INC	A-Gila					
Trainer:	Mari	Fredaco				
Date:	e	Frefaco			42 10	
5 7 743					<i>J</i> [*] =	

Cleaning, Disinfection, and Sterilization of Patient-Care Items

Appendix 6: TROPHON® COMPETENCY SHEET

NAME	ALEXA TUKO	DATE	8/11/2
1.	Put gloves on. Note: wear gloves at all times manual.	when required as	described in the Trophon EPR user
MET_	NOT MET		
2.	Pre-clean the probe before the high-level disir manufacturer's instructions for use (IFUs).	nfection (HLD) cy	cle, following the probe
MET_	NOT MET		
3.	Ensure the probe is clean and free of all visible a. Use Sani Cloths to clean		_
	b. Wipe the transducer cord and all surface friction and work from cleanest to dirties c. Dry the transducer with a soft, dry cloth d. Visually inspect the transducer to ensur	st areas. 1.	·
MET_	NOT MET		
4.	Load the clean, dry probe into the Trophon dis a. The probe is secured high in the chamb b. Probe does not contact the chamber w	ber with tip of pro	
MET_	NOT MET		
5.	Place a new red Trophon chemical indicator (up.		tor holder with the red side facing
	a. Note: a new Cl is to be used for every	cycle.	
MET_	NOT MET		
6.	Close the chamber door and confirm whether a. If yes, press Start. b. If no, follow the LCD screen prompts.	the probe is both	clean and dry.
MET	NOT MET		
_	At the end of the 7 minute HLD cycle, TropholoREMOVE AND WIPE PROBE."	n's LCD screen s	tates: "CYCLE COMPLETE
MET_	NOT MET		•
8.	Open the chamber door.		
MET_	NOT MET		

IC 0008

Cleaning, Disinfection, and Sterilization of Patient-Care Items 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. **NOT MET** MET 10. Remove and wipe the probe using a clean, dry single use cloth. NOT MET_ 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. NOT MET 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.

Trainer:

Trainee:

Date:

8-15-22

Eleaning, Disinfection, and Sterilization of Patient-Care Items

IC 0008

Appendix 6: TROPHON® COMPETENCY SHEET

NAME	SWANSON	, Lutre		ATE	8/16/12	
1.	Put gloves on. Note: manual.	wear gloves at	all times when re	quired as de	scribed in the Trophor	n EPR user
MET_	NOT MET					
2.	Pre-clean the probe I			(HLD) cycle,	following the probe	
MET_	NOT MET_					
3.	Ensure the probe is a. Use Sani Clot	hs to clean				
	friction and wo	ork from cleane: ucer with a soft	st to dirtiest areas i, dry cloth.	•	d dry prior to HLD.	ñ. Use
MET_	NOT MET_					
4.	Load the clean, dry p a. The probe is s b. Probe does no	ecured high in	the chamber with	tip of probe	nsuring: above embossed line.	
MET_	NOT MET_	 				•
5.	up.			the indicator	holder with the red sid	de facing
MET	a. Note: a new C		for every cycle.			
MET_	NOT MET_					
6.	a. If yes, press S b. If no, follow th	itart.	·	de is both cle	an and dry.	
MET_	NOT MET_					
7.	At the end of the 7 m		e, Trophon's LCD	screen state	es: "CYCLE COMPLE	TE
MET_	NOT MET_					
8.	Open the chamber do	ог.				
MET_	NOT MET_					

Page 18 of 29

Cleanir	ng, Disinfection, and Sterilization of Patient-Care I	tems	
9.	Remove CI, check CI color against the color a. Note: BOTH the CI and LCD screen meady for use. If either the CI or Troph	nust indicate a successful c	ycle for the probe to be
MET_ 11 MET_	NOT MET 2. Record the HLD cycle on the log or printed st	eady for use.	
IVIE I	V NOT WET		unc so sed to se
Notes:	At the completion of a cycle, remove probe in remains in chamber, the Trophon will shut do warm up times may be longer. Sleep mode: to save power, Trophon will enter Purging the Trophon of disinfectant is required expired. Manufacturer's instructions for purging the Trophon of the complete expired.	wn heaters to ensure probe or sleep mode after 2 hours d if the device is to be mov	e is protected. Therefore, of inactivity. ed or if Sonex-HL® has
Traine	DSONICS, INC er: Abhre M ee: J. Swanson Date: 8-16-27	— III	II =

Cleaning, Disinfection, and Sterilization of Patient-Care Items

Appendix 6: TROPHON® COMPETENCY SHEET

NAME	Loslic	Aguirre	DATE	8-15-W	
1.	Put gloves on. Note manual.	: wear gloves at a	ıll times when required as	described in the Trophon EPF	₹ user
MET_	NOT MET_				
2.	Pre-clean the probe manufacturer's instru		evel disinfection (HLD) cy Js).	cle, following the probe	
MET_	NOT MET_			,	
3.	 Use Sani Clot 	hs to clean	all visible debris, bioburd		
	friction and we c. Dry the transc	ork from cleanest lucer with a soft, o	to dirtiest areas.	cer until it is visually clean. Us and dry prior to HLD.	ře –
MET_	NOT MET				
4.	a. The probe is s	secured high in the	phon disinfection chambe e chamber with tip of pro mber wall at any point.	er ensuring: De above embossed line.	
MET_	NOT MET_				
5.	up.			tor holder with the red side faci	ing
	a. Note: a new C	I is to be used for	every cycle.		
MET_	NOT MET				
6.	Close the chamber d	oor and confirm water.	hether the probe is both	clean and dry.	
	b. If no, follow the		mpts.		
MET_	NOT MET_				
7.	At the end of the 7 m	inute HLD cycle, 1 PROBE."	Гrophon's LCD screen st	ates: "CYCLE COMPLETE	
MET_	NOT MET_			•	
8.	Open the chamber do	or.			
MET_	NOT MET_				
IC 0008				B	_

Page 18 of 29

Cleaning, Disinfection, and Sterilization of Patient-Care Items 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. NOT MET MET 10. Remove and wipe the probe using a clean, dry single use cloth. 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. NOT MET_____ 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 Sahah Rus

Trainee: Loslic Agurre

Date: ____

© Cleaning, Disinfection, and Sterilization of Patient-Care Items

Appendix 6: TROPHON® COMPETENCY SHEET

NAME	De Grun	awan	DATE	8-16-22	
_: 1.	Put gloves on. Note manual.	: wear gloves at all ti	mes when required as d	escribed in the Trophon EPR use	r
MET_	NOT MET_				
2.	Pre-clean the probe manufacturer's instru		disinfection (HLD) cycle	e, following the probe	
MET_	NOT MET_				
3.	a. Use Sani Clor	hs to clean	visible debris, bioburden		
	friction and wo	ork from cleanest to ducer with a soft, dry	dirtiest areas.	n until it is visually clean. Use	
MET_	NOT MET				
4.	a. The probe is	_	on disinfection chamber on the chamber with tip of probe the chall at any point.	•	
MET_	NOT MET_				
5.	up.			r holder with the red side facing	
AAPT		I is to be used for ev	very cycle.		
MET_	NOT MET_				
6.	a. If yes, press S		ether the probe is both cloots.	ean and dry.	
MET_	NOT MET_				
7.	At the end of the 7 m	inute HLD cycle, Tro PROBE."	ophon's LCD screen state	es: "CYCLE COMPLETE	
MET_	NOT MET_				
8.	Open the chamber do	or.			
MET_	NOT MET_				

IC 0008

Cleaning, Disinfection, and Sterilization of Patient-Care Items 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. NOT MET **MET** 10. Remoye and wipe the probe using a clean, dry single use cloth. NOT MET 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: Date:

Cleaning, Disinfection, and Sterilization of Patient-Care Items

Appendix 6: TROPHON® COMPETENCY SHEET

NAME	_ NEDRANO	Donsy	DATE	8/11/2
1.	Put gloves on. Note manual.	wear gloves at a	all times when required as o	lescribed in the Trophon EPR user
MET_	NOT MET_			
2,	Pre-clean the probe manufacturer's instru	before the high-lections for use (IF	evel disinfection (HLD) cycle Us).	e, following the probe
MET_	NOT MET_			
3.	 Use Sani Clot 	ns to clean	all visible debris, bioburden	
	friction and wo	rk from cleanest	all surfaces of the transduce to dirtiest areas.	or until it is visually clean. Use
	c. Dry the transd	ucer with a soft, o	dry cloth.	
	d Visually inspec	ot the transducer	to ensure it is both clean ar	nd dry prior to HLD.
MET_	NOT MET			ı
4.	 The probe is s 	ecured high in th	phon disinfection chamber of chamber with tip of probe mber wall at any point.	ensuring: above embossed line.
MET_	NOT MET			
5.	Place a new red Trop up.	hon chemical inc	licator (CI) into the indicator	r holder with the red side facing
	a. Note: a new C	is to be used for	every cycle.	
MET_	NOT MET			
6.	Close the chamber do	oor and confirm w	hether the probe is both cle	ean and dry.
	a. If yes, press Sib./If no, follow the		moto	
MET		cob screen pro	inpts.	
MET_	NOT MET			
7.	At the end of the 7 mi	nute HLD cycle, ⁻ PROBE."	Trophon's LCD screen state	es: "CYCLE COMPLETE
MET_	NOT MET			
8.	Open the chamber doc	or.		
MET_	NOT MET			
C 0008				

Cleaning, Disinfection, and Sterilization of Patient Care Items

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.

NOT MET

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

NOT MET

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

NOT MET____

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

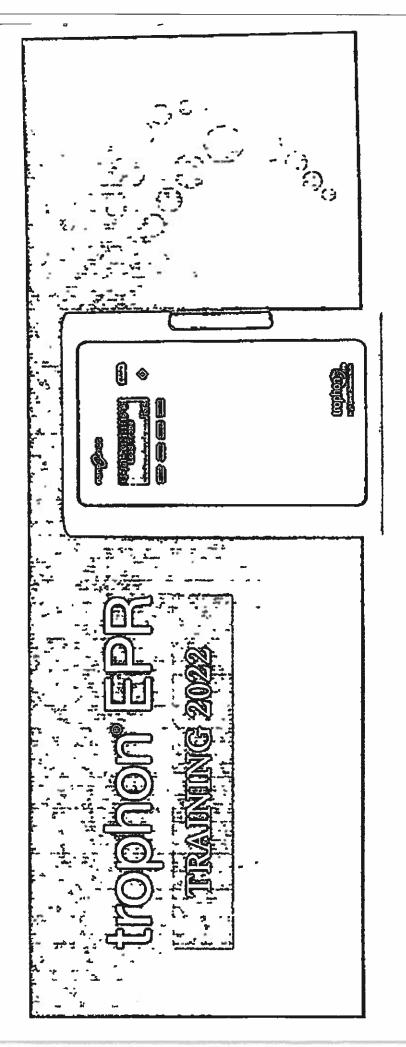
MET NOT MET

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.

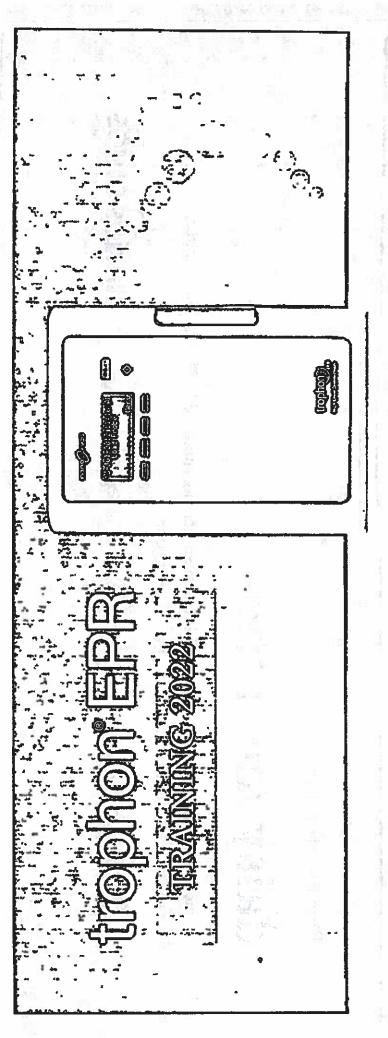


daisy medrano

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

This certificate expires 12 months after the date of issue.

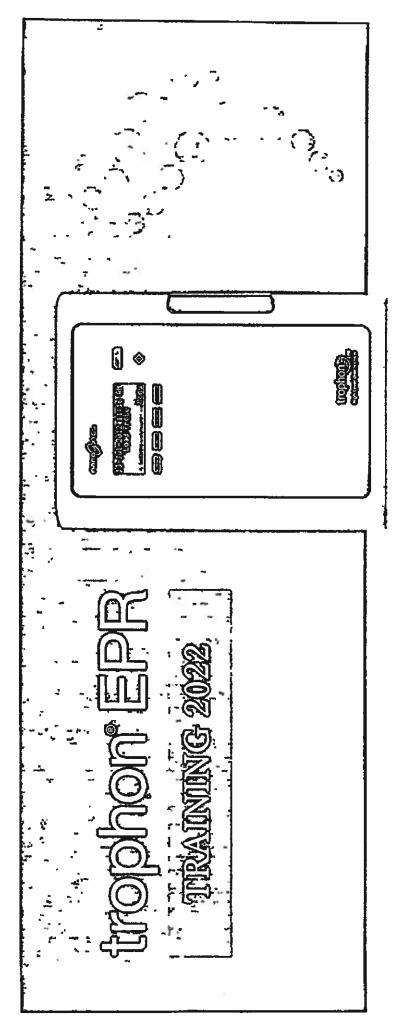




Andriy Martyniv

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





suhi Garcia

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



		 	-



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:

Employee Signature:

Date

nanosonics

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Nanosonics academy, com



trophon® EPR Competency

Name Gilbert Garcia

Date 8/15/2Z

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

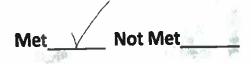
Complete and pass the online trophon EPR quiz.

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.



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0.0	4C-0	9L-RS		TONOLOGIA
1	4C-RS	AB2-6	DA I	
	4C-8C	AB2-7	6	in the property of the contract of the contrac
	4D10L	AB2-7-D	ERB	
Γ	4016L	AB2-7-PS	G3S \	(-)
RS	4D3C-L	A[14-8	1121	A SHAME WALL
-SC	406C-L	ACR-6	112L-RS	
S-0	408C	BERC	739	
-As	4DE7C	BERCS	1739-RS	
FPA	43	C1-6-D	ICS-0	20
5C	44-0	C1-5-RS	ICS-4-D	*]
vay lens	540.	C1-6-D	ICS-9H	
cs	5C	C2-6-RC	IC5-9W-R	
ey lone	6C8	C5-9-D	L3-12-0	
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*	58-R5	C364		The state of the s
	68	C386		
	-	CAL		## TAP

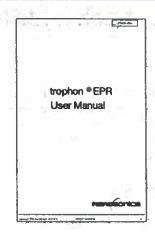


1.4

Put gloves on.

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

Met____ Not Met____

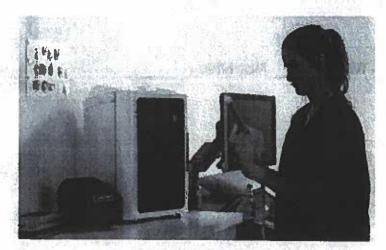




1.5

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

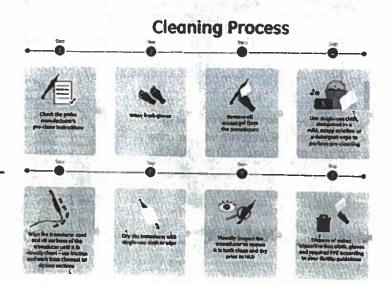
Met____ Not Met____



1.6

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

Met____ Not Met____





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____











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_V

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

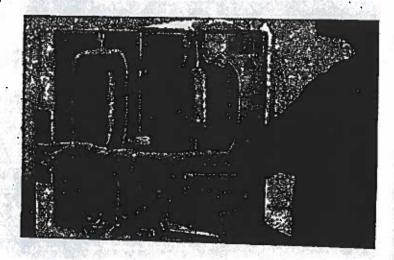
1.13

Open the chamber door.

Met

Not Met







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 fall, repeat the cycle.

Met \ Not Met





1.15

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

Met____ Not Met____

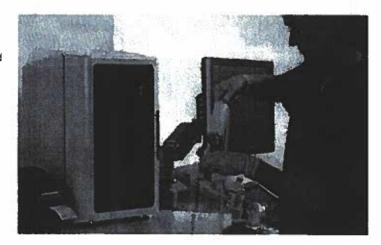




1.16

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

Met_____ Not Met_____

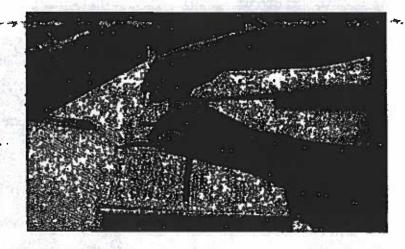


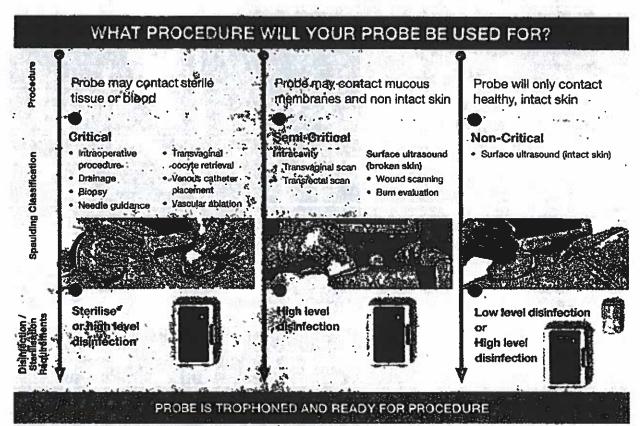


Maria to 7

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

Met_____ Not Met____





- 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)

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



trophon® EPR Competency

Arnold Sabater Ry Date 8/15/22

1. TROPHON EPR OPERATION

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



Complete and pass the online trophon EPR quiz.



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.

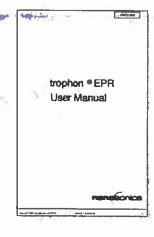
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	100	QL-RS		monov'en me
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Δ T	4C-8C	AB2-7	GA.	
	4D10L	AB2-7-D	EPB7	
1	4016L	AB2-7-RS	G3S	(-)
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-sc	406C-L	AC2-5	1121RS	
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sc	44-0	C1-5-RS	IC5-9-D	* -
pray tens	546L	C1-6-D	ICS-9H	T
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ty tens	5CS	C2-9-D	L3-12-D	
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	56-RS	C364		Service his tors of the service product of the service of
	45	C366		to the educations of a desire of the desire is as proportional or as a position
	-	Can		1010



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.

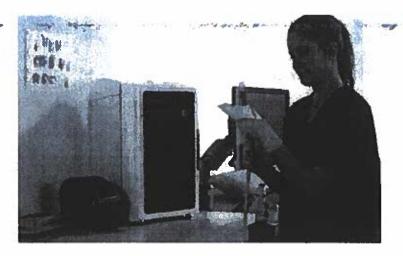
Met____ Not Met____





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

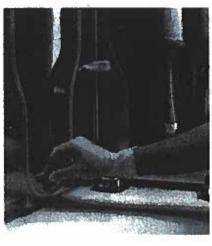
Place a Chemical Indicator into the locator at the base of the chamber door, red side up.

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

Met____ Not Met____











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



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/

Not Met Met

Open the chamber door.







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____

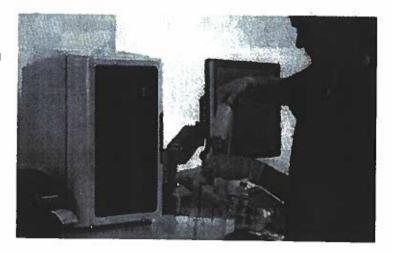




1.16

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

Met____ Not Met





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

Not Met



WHAT PROCEDURE WILL YOUR PROBE BE USED FOR?

Probe may contact sterile tissue or blood



Critical

- Jintraoperative procedure
- Drainage
- Biopsy
- Needle guidance
- - Transvaginal çocyte 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 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

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



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, ROMS
Trainer Signature:
Title: Clin Apps Sparalist
Employee Signature:
Date: $8/15/77$



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Nanosonics, Inc. (Distributor) 7205 E 87th Street Indianapolis, IN 48256 USA T 1-844-TROPHON 1-844-876-7466 E info@trophon.com www.nanosonics.us

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Manosonics Europe GmbH (EU Representative)
Poppenbütteler Bogen 68 22399 Hamburg Germany
T +49 40 48868885 E info@nanosonics.eu www.nanosonics.eu

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Appendix 5: TROPHON® Log

High-Level Disinfection Log For Trophon EPR Serial # __/86.40 -009

START A NEW PAGE WHEN LOADING A NEW POWER CARTRIDGE OR NEW BOX OF CHEMICAL INDICATORS

CARTRIDGE REPLACEMENT: WHEN LOADING WAS A SOME CARTRIDGE, START A NEW PLOT. DOCUMENT GATE LOADED, LOT # & EXP. DATE.

CHEMICAL INDICATOR BOX: WHEN OPENING WHEN BOY OF CHEMICAL INDICATORS, START WASHED RAGE. DECUMENT LOT # AND EXP. DATE.

CYCLE RESULTS: PLACE LABEL IN SQUARES BELOW.

LABELING YOUR READY-TC-USE PROBE INITIAL IN THE SMALL BOY BELOW ("INIT") A 1. LABEL IS PLACED ON THE CLEAN US PAGGE COVER.

	CARTRIDGE REPLACEMENT			CHEMICAL INDICATOR REPLACEMENT		
	Date Loaded & Lot #	Expiration 2023 ~ /		1 PO 8 / 6	Expiration Date 2023 • 03 • 02	
17/	trophon)) 08/2022 07:58 SN:18640	17/08/	tropl 2022 08:48			
Disir India	offection: PASS Cycle #: Scator: PASS FAIL	490 Disinfect	ion: PASS : PASSIZ FAI	Cycle #: 5491 L□		
Prob	rator:	Probe:	·	Green		
Note	700	Notes:	Test	Rein		
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	κη.					
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					:	
				22		
	2 ⁷⁷ Label Placed on C					
	Ultrasound Frobe Co	over		Placed on Clean und Probe Cover	Z rd Label Placed on Clean Ultrasound Probe Cover	

American Health Care Centers

List of Staff Competent to Use Trophon EPR

Name	Initial	1 2 2 2
Arnold Sabater RN (super trainer)	- Cope	
Andrei MArtyniv, SA (super trainer)	Allaston	7
Gilbert Garcia, ORT (super trainer)	66	and the same of th
Daisy Medrano, ORT	D.M.	_
Julie Swanson, Faculty Administration	Joan	
Devi Gunawan, APN	DG	90
Leslie Aguirre, US ledn	LA-	4 11
Alexa Tulea CR Staff	AT	
Marie Frukacz Manager	MF	- 4
Natasha Kukuruza Ulstech _		pending competency
Pacci	44 00 530	
Green = SN : BT	162 6609	