

INDICATOR	Met	Not Met	Comments
GENERAL			
Patient valuables and clothing is stored in a secure			
location during exam.			
Area is clean and free of dust and debris.			
Fire drills are up to date. Staff can verbalize the			
process for evacuating patients who are unable to			
evacuate themselves.			
Emergency Medical drills are conducted to test			
response.			
Resuscitation equipment is available for use. Staff			
are trained.			
MEDICAL RECORDS			
Prior to conducting a diagnostic imaging study, the			
hospital verifies the following:			
Correct patient			
Correct imaging site			
Correct patient positioning			
Correct imaging protocol			
Correct scanner parameters			
LICENSE			
Are all certifications and licenses posted and up to			
date?			
FACILITIES AND EQUIPMENT		ı	
Equipment is cleaned per policy and the			
Instructions for Use (IFU). Expectations are that			
staff have access to the equipment IFU and are			
following the cleaning and disinfection procedures			
listed there. Additionally, staff should be utilizing			
disinfectant wipes as per policy and with appropriate contact times as defined by the IFU.			
All equipment daily/weekly/monthly quality			
control checks are completed and documented.			
Probes are stored according to the manufacturer's			
IFU and in a means to prevent contamination. If			
cabinets are used, they are cleaned per the IFU.			
Probes are intact without frayed wiring or damage			
to housing.			
Vaginal probes are used with single-use sheaths.			
TROPHON			
Staff don the appropriate PPE.			
Spill kits are available.			
The IFUs are readily available to staff.			

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INDICATOR	Met	Not Met	Comments
Product (Hydrogen Peroxide) is not expired or past			
beyond use date as indicated by the IFU.			
Safety Data Sheets are readily available to staff.			
Initial debridement is conducted on the probe per			
the IFU.			
Contaminated probes requiring high-level			
disinfection are processed according to the			
Trophon IFU.			
Indicator discs are not expired.			
Documentation of processed probes is complete			
and without gaps or missing entries.			
Failed runs are resolved and documented per			
policy.			
Documentation of the probe number is made with			
the patient identification in the Trophon log to permit bi-directional tracing.			
Trophon machine is cleaned per IFU including the			
interior of the machine.			
Staff can articulate backup procedures in the event			
the Trophon machine is down.			
CHEMICAL HIGH-LEVEL DISINFECTION (GLUTERA	ALDEHYDE)		
Staff don the appropriate PPE.			
Spill kits are available.			
Test strips are not expired.			
The IFUs are readily available to staff.			
Product (Glutaraldehyde) is not expired or past			
beyond use date as indicated by the IFU.			
Safety Data Sheets are readily available to staff.			
Proper ventilation is in place per the IFU.			
Initial debridement is conducted on the probe per			
the IFU.			
Product is used at temperature as indicated by the			
IFU. Thermometer to measure temperature is			
calibrated.			
Probe soak times are per the IFU. Timer is			
calibrated per IFU.			
Probe rinse procedures are followed per the IFU.			
Probe drying is performed per the IFU.			
Logs include probe number and lot number of test			
strips and chemicals to ensure bi-directional			
tracing.			
CLINICAL POLICIES AND PROTOCOLS			

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INDICATOR	Met	Not Met	Comments
All policies are up to date and periodically reviewed			
according to the organization's timeframes.			
Written procedures or protocols are present for			
reporting critical testing results.			
Cleaning and disinfection procedures is performed			
per Spaulding's Classification:			
If a transducer is used in a sterile body cavity or			
sterile tissues, it is considered a critical device			
and requires sterilization.			
If a transducer is used on non-intact skin or museus membranes, such as a veginal, restal			
mucous membranes, such as a vaginal, rectal or oral, it is a semi-critical device and should			
undergo high-level disinfection.			
 If a transducer is only used on intact skin, it is 			
considered non-critical and, regardless of			
whether it is contaminated with blood, the			
minimum requirement is low-level or			
intermediate-level disinfection.			
If the transducer manufacturer reprocessing			
instructions indicate that an instrument should			
undergo high-level disinfection if used to assist			
with percutaneous procedures or if			
contaminated with blood, the organization			
must follow the manufacturer's IFU unless they			
have evidence to negate that instruction from			
the manufacturer.			
Contaminated probes are transported from point			
to use to processing areas in leakproof, puncture			
resistant containers labeled as biohazardous.			
QUALITY ASSURANCE AND PERFORMANCE IMP	ROVEMENT		
Data is collected on the timeliness of reporting			
critical results of tests and diagnostic procedures.			
Opportunities are addressed.			
STAFF COMPETENCIES AND QUALIFICATIONS			
Trophon/Chemical High Level Disinfection			
competencies are current.			
Employees or contractors, who inspect, test,			
calibrate, and maintain ultrasound services			
equipment are qualified to perform these actions.			