

Home Sleep Apnea Testing (HSAT)

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SUMMARY

Obstructive Sleep Apnea (OSA) is estimated to affect 54 million adults in the United States between the ages of 30-69 (1). Due to the high prevalence of the disorder, there are significant costs and other access barriers associated with evaluating all patients suspected of having OSA with the gold standard test, full in-lab Polysomnography (PSG). Although Home Sleep Apnea Testing (HSAT) has limitations, when used as an alternative method to diagnose OSA in adults it may be less costly and more efficient in some populations. This technical guideline provides guidance for the appropriate use of HSAT by sleep professionals.

HSAT can be used as an alternative to full, attended PSG for the diagnosis of OSA in uncomplicated adult patients meeting clinical eligibility criteria. Unattended HSAT studies can be used for evaluating hospital or other facility inpatients, or patients in the home. Often, the determination for HSAT to be used in place of an attended PSG is initiated by the insurance carrier, but approved by a board certified sleep specialist. HSAT can also be used to monitor non-PAP treatments for sleep apnea, such as oral appliance therapy (OAT). There are a large and increasing number of HSAT devices for use in alternative settings. A technically adequate HSAT device incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or peripheral arterial tonometry (PAT) with oximetry and actigraphy (2). The technical requirements for these channel types should meet the standards outlined in the current *AASM Manual for the Scoring of Sleep and Associated Events* (3). A single HSAT recording should be conducted over at least one night (2,4,5). If a HSAT result is negative, inconclusive or technically inadequate, polysomnography should be performed to rule out the diagnosis of OSA (2).

Properly credentialed sleep technologists, working under the direction of the medical director of the sleep center or practice, must apply HSAT sensors or educate patients in sensor application, as well as manually review, and score or edit the automated scoring of the raw data. Sleep technologists are trained in patient interaction, age-related competencies, facilitating patient education and the diagnostic and therapeutic modalities used in sleep technology. As such, they are well suited for the dispensing of HSAT devices. The instruction provided by the sleep technologist on how to successfully use the device, the symptoms and consequences of OSA, and the benefits of treatment can set the stage for long-term treatment adherence. The technical skill and experience of the sleep technologist also ensures a low HSAT failure rate and adherence to infection control protocols.

KEY DEFINITIONS

Actigraphy: A device typically worn on the wrist or ankle for sleep assessment which uses an accelerometer to record and integrate the occurrence and degree of limb movement activity over time. Mathematical algorithms are then applied to these data to estimate wakefulness and sleep.

Home Sleep Apnea Test (HSAT): An alternative medical test for the diagnosis of OSA in uncomplicated adults presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.

Peripheral Arterial Tonometry (PAT): A non-invasive method to assess vascular function which uses a

finger-mounted pneumo-optical sensor. Episodes of upper airway obstruction cause episodic vasoconstriction of digital vascular beds due to activation of the sympathetic nervous system, which results in attenuation of the PAT signal.

Polysomnography (PSG): The standard medical test for the diagnosis of OSA in adult patients when concern arises for OSA.

Portable Monitor (PM): A device that can be used for evaluating suspected sleep disordered breathing in a variety of settings alternative to the in-lab PSG. These small portable devices record physiological data that is uploaded or transmitted back to the sleep center for scoring and interpretation. The specific use of each device is limited by the data channels available and used.

PM device classification: PM devices were originally classified based on the number of recording channels, type of recordings and the circumstances in which the device was used, closely mirroring the current CPT codes. The most recent classification utilizes sleep, cardiovascular, oximetry, position, effort and respiratory (SCOPER) parameters to categorize PM devices (5).

Type II PM: full unattended polysomnography (≥ 7 channels)

Type III PM: limited channel devices (usually 4–7 channels)

Type IV PM: 1 or 2 channels usually including oximetry as one of the parameters

Respiratory disturbance index (RDI): In the context of type III and IV portable monitoring devices, RDI refers to an index of events over recording time rather than sleep time.

Universal Precautions: Avoidance of potentially infectious materials from patient bodily fluids by use of personal protective equipment (PPE) and infection control techniques.

1.0 SCOPE

This guideline is intended to provide guidance for the technologist performing and scoring HSAT in accordance with AASM Guidelines (5, 6). The scope of this guideline is restricted to adult patients with a high pretest probability of moderate to severe OSA, determined by a board-certified sleep specialist to be eligible for HSAT.

1.1 Indications for HSAT

HSAT is a confirmatory test for patients with high pretest probability of moderate-to-severe OSA. Specifically, HSAT with a technically adequate device can be used for the diagnosis of OSA in **uncomplicated** adult patients presenting **only** with signs and symptoms that indicate an increased risk of moderate to severe OSA. HSAT can be used as an alternative to full, attended polysomnography (PSG) for the diagnosis of OSA in adult patients meeting clinical eligibility criteria (5). Patients presenting to physicians with complaints of snoring with or without associated excessive daytime sleepiness and **no other comorbidities** are the likeliest candidates for HSAT. Patients should have uncomplicated medical histories.

An uncomplicated patient is defined by the absence of:

1. Conditions that place the patient at increased risk of non-obstructive sleep-disordered breathing (e.g., central sleep apnea, hypoventilation and sleep related hypoxemia). Examples of these conditions include significant cardiopulmonary disease, potential respiratory muscle weakness due to neuromuscular conditions, history of stroke and chronic opiate medication use.

2. Concern for significant non-respiratory sleep disorder(s) that require evaluation (e.g., disorders of central hypersomnolence, parasomnias, sleep related movement disorders) or interfere with accuracy of HSAT (e.g., severe insomnia).
3. Environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT.

1.2 Contraindications for HSAT

Home sleep apnea testing is contraindicated in (2):

- Patients with significant cardiopulmonary disease and other significant sleep disorders.
- Patients taking opioids.
- Patients with uncontrolled psychiatric disorders.
- Patients with any form of neuromuscular disease.
- Patients with significant safety-related issues related to driving or work.
- Patients with a noted lack of an appropriate living situation.
- Pregnant patients.
- Patients suffering with alcoholism or alcohol abuse.
- Patients suspected of having Central Sleep Apnea or Cheyne-Stokes Breathing.
- Patients with uncontrolled hypertension, or patients taking more than one hypertension medication.
- Patients with Congestive Heart Failure.
- Patients under the age of 17 (this may vary by state).
- Patients with COPD and an FEV1 or less than 65%.
- Patients with any form of cognitive dysfunction that cannot be assisted by another caregiver or family member.
- Blind patients who cannot be assisted by another caregiver.
- Patients who have suffered a history of stroke within the past 180 days.
- Patients suspected of suffering with any significant sleep disorder other than OSA (e.g., CSA, parasomnia, narcolepsy, severe insomnia).
- Patients within 180 days of discharge as an inpatient for recent Myocardial Infarction.
- Patients receiving medication for an enlarged prostate.
- Patients complaining of insomnia.
- Patients with a BMI >35 and an associated complaint of excessive daytime sleepiness or hypertension.
- Patients with suspected obesity hypoventilation.
- Patients with known or documented severe hypoxemia.

2.0 INSTRUMENTATION

The PM device used for HSAT by a sleep center should be chosen carefully by the technical staff and medical director for its intended purpose. There are a wide variety of PM devices and manufacturers. Type III HSAT devices can be further classified into:

- a) Nasal pressure, chest and abdominal respiratory inductance plethysmography
- b) Peripheral arterial tonometry (PAT) with oximetry and actigraphy.

It is imperative to read and follow manufacturer guidelines and instructions for use. HSAT equipment considerations should include the requirements suggested by the AASM guidelines. Consider devices which provide options to monitor:

Sleep study, unattended, simultaneous recording;

1. heart rate,
2. oxygen saturation,
3. respiratory analysis (e.g., by airflow or peripheral arterial tone)
4. sleep time.

OR

1. heart rate,
2. oxygen saturation, and
3. respiratory analysis (e.g., by airflow or peripheral arterial tone)

OR

1. heart rate,
2. oxygen saturation,
3. respiratory airflow, and
4. respiratory effort (e.g., thoracoabdominal movement)

Additional factors to consider include: the cost of the device, the cost of consumables (cannulas, disposable sensors), ease of use by the patient, recording parameters, data transmittance, ability to customize the raw data view, ability to customize reports, database features, and the availability of technical support.

2.1 Initializing the PM Device

Most PM devices require re-charging or replacing the batteries, and previous study results must be cleared before a new recording can be acquired. Once the device is connected to a computer and the manufacturer's software, previous patient information can be cleared and new patient information can be entered and the device initialized to collect new data. Devices can be set to start at a preset time, or can be manually started by the patient at bedtime. It is important to know the maximum recording time capability, which might range from one to seven or more nights of recording time. When chain of custody features are required to verify the identity of the patient's data that is recorded, a security cable, non-removable sensor, or other feature may need to be applied on site.

2.2 Physiological and Recording Parameters

For type II HSAT devices that record sleep parameters EEG electrodes should be placed according to the International 10-20 system of Electrode Placement (7). The recommended EEG derivation is F4-M1, C4-M1, and O2-M1 recorded at a minimum sampling rate of 200 Hz with impedances of 5 K Ω or less. The recommended sampling rate is 500 Hz; filter settings for this parameter are LFF 0.3 Hz and HFF 35 Hz. EOG electrodes should be placed at E1 and E2 according to the *AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications standards* (4). The recommended EOG derivation is E1-M2, E2-M2 recorded at a minimum sampling rate of 200 Hz with impedances of 5 K Ω or less. The recommended sampling rate is 500 Hz; filter settings for this parameter are LFF 0.3 Hz and HFF 35 Hz. Chin EMG electrodes should be placed above and below the mandible on the mental and

submental muscles of the chin as specified in the *AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications* standards. The derivation for recording chin EMG consists of a submental electrode referred to the electrode placed above the mandible on the mental muscle. The minimum sampling rate is 200 Hz. The recommended sampling rate is 500 Hz. Filter settings for this parameter are LFF 10 Hz and HFF 100 Hz.

Type III HSAT devices that do not record sleep parameters most commonly utilize a nasal air pressure transducer to record airflow. Use of an oronasal thermal sensor is recommended but optional. Using a thermal sensor does make the detection of apneas more accurate, since mouth breathing can appear as apneic respiration when measured by nasal-only sensors. The recommended respiratory effort sensor is calibrated or uncalibrated respiratory inductance plethysmography (RIP). The minimum acceptable sampling rate for the collection of respiratory data is 25 Hz. The preferred sampling rate is 100 Hz, which improves the ability to assess artifact and visualize cardiogenic oscillations. Filter settings for the respiratory data parameters are LFF 0.1 Hz, HFF 15 Hz.

The recommended blood oxygen sensor is a pulse oximeter with an averaging time of ≤ 3 seconds. Finger probes can be reusable or disposable, but in both cases secure attachment is important. A slipped or disconnected oximeter probe is one of the more common reasons for HSAT failure. The minimum recommended sampling rate is 10 Hz. The preferred sampling rate is 25 Hz, which improves the ability to recognize artifacts.

The minimum acceptable sampling rate for recording body position using a body position sensor is 1 Hz. A pulse rate is generally obtained from the pulse oximeter. The minimum acceptable sampling rate is 10 Hz. The preferred sampling rate is 25 Hz, which improves the ability to recognize artifacts. When it is used in conjunction with the oximetry signal, the pulse rate signal may assist with oximeter artifact detection. If ECG is recorded, modified Lead II is the recommended placement for recording the electrocardiogram (ECG). The minimum acceptable sampling rate is 200 Hz. The recommended sampling rate of 500 Hz improves waveform definition. Filter settings for ECG are LFF 0.3 (which minimizes waveform distortion), HFF 70 Hz. Snoring can be derived from the nasal air pressure transducer signal, or can be recorded as a separate channel with a piezo sensor or microphone device with or without decibel meter output. The minimum acceptable sampling rate for the collection of snoring sound or vibration data is 200 Hz. The preferred sampling rate is 500 Hz, which improves waveform definition. Filter settings are LFF 10 Hz, HFF 100 Hz.

For additional information regarding the HSAT sensor requirements, refer to the *AASM Manual for the Scoring of Sleep and Associated Events*.

Recording devices are categorized as:

Type I: Full attended polysomnography (≥ 7 channels) **is only possible in a laboratory setting**

Type II: Full unattended polysomnography (≥ 7 channels)

Type III: limited channel devices (usually 4–7 channels)

Type IV: 1 or 2 channels usually including oximetry as one of the parameters

HSAT testing, thus, typically utilizes **only type III devices**. These devices come with considerable limitations. Limitations include:

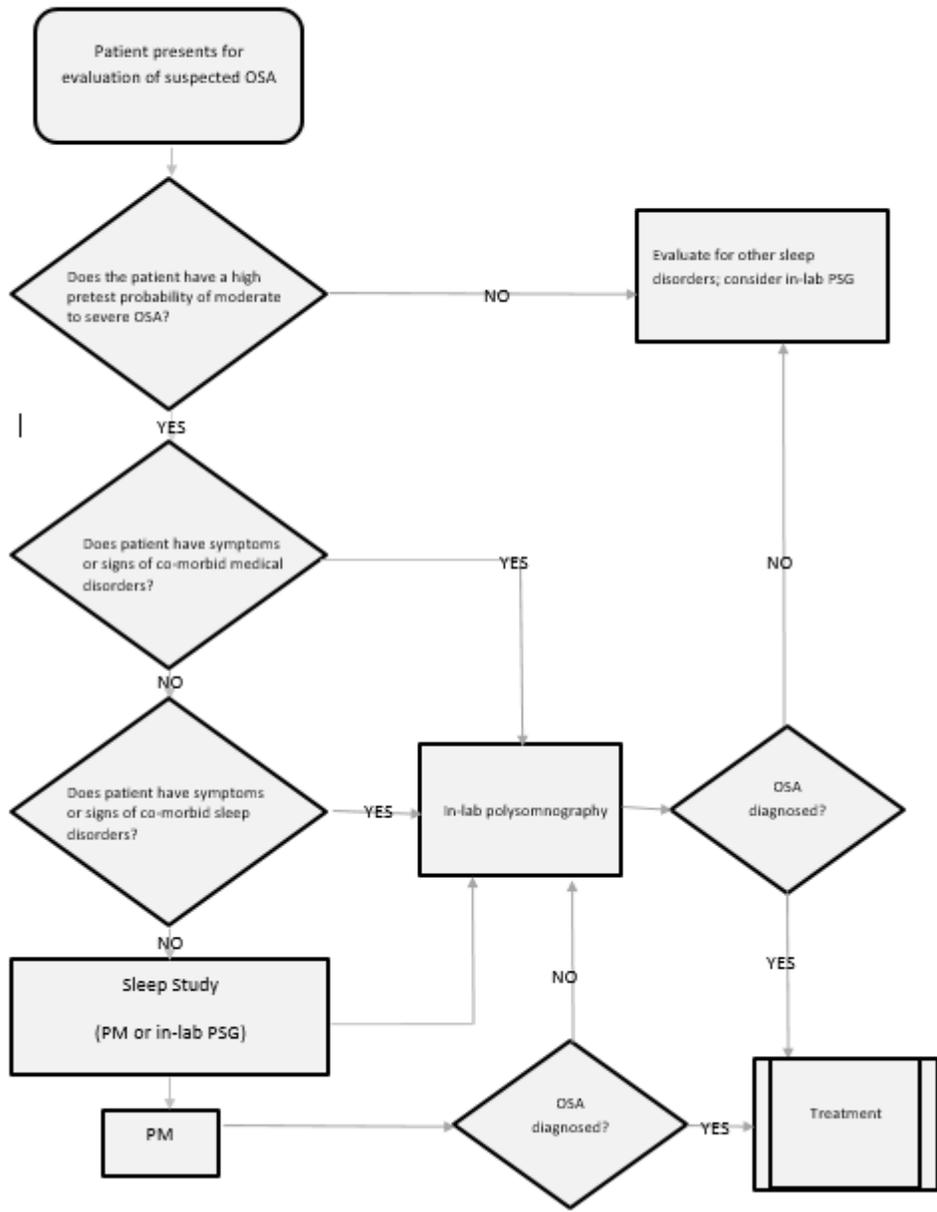
1. HSAT typically does not monitor sleep stages.
2. HSAT cannot rule out OSA.
3. HSAT cannot clearly identify discrete respiratory events (OA, CSA, OH, RERAs) that can be identified in an attended PSG.

A recent study (8) found that HSAT showed limited prospective cohort data that suggested that the unattended Type III devices could identify OSA and CSA in patients with chronic stable CHF in order to predict cardiovascular outcomes. While single night studies with these devices may work well with individuals with moderate to severe OSA, the patients with milder OSA may require further investigations either in a sleep center setting or a multiple night (at least two) HSAT. The study sheds light on the utility of conducting more than one night of HSAT in order to get a better understanding of the patient's sleep as variations such as body positions the patient may have slept in, exposure to alcohol, medications, or stress may have profound effects on the results.

A technically adequate diagnostic HSAT recording must include a minimum of four hours of technically adequate oximetry and flow data, obtained during a recording attempt that encompasses the habitual sleep period of the individual being monitored.

Flow chart depicting recommended pathway of patients considered for PM (6).

Portable Monitoring Decision Tree



3.0 METHODOLOGY FOR PATIENT EDUCATION AND INSTRUCTION

The HSAT device can be provided to the patient during an office visit (preferable) or by mail. Methods for patient education and instruction can include providing one-to-one instruction, group instruction, virtual instruction, or instruction by mail and phone if the patient is unable to get to the sleep center. Face-to-face patient interaction is preferable since it allows for physical exploration of the device and components, and the opportunity for the patient to ask questions. Instruction should minimally include information about the proper placement and application of sensors, device information, and how to initiate testing.

This is also a great opportunity to engage patients in their sleep health. Providing information on proper sleep hygiene, the symptoms, pathophysiology, and health consequences of OSA, and the benefits of treatment can help set the stage for a successful test as well as acceptance and adherence to treatment. A demonstration by the technologist educator can be followed by having the patient demonstrate the application of the device and sensors themselves. This allows for questions to come up and for the educator to correct anything that is incorrectly applied.

Many manufacturers provide a link to an online video instruction. Written instructions with pictorial diagrams of each component and step in the process should also be provided to the patient to take home as a reference. When devices are mailed, all information normally supplied by the technologist educator should be made available in printed and/or audio/video format. It is important for the patient to be given a 24-hour access phone number for technical support if any questions or problems arise. Patients must be instructed to call 911 for any medical emergencies while at home.

Patients undergoing HSAT should be instructed to try to follow their regular routine as much as possible and avoid napping or consuming caffeine after lunch on the day of testing. For patients on regular medications, the physician should indicate if any changes to the regimen are needed on the day of the test. Finally, the patient should be reminded to use a sleep log and/or indicate on the device when they get into bed and attempt sleep.

4.0 DOCUMENTATION

As with full attended polysomnography, the sleep technologist is responsible for ensuring that all required documentation, including history, physical exam, previous test results, medication list, referral and insurance information, and physician's orders, is available and reviewed prior to dispensing the HSAT device for testing. Patient identification and insurance verification should be completed at intake, as well as documentation that privacy notices were made available to the patient. The sleep center may require the patient to sign a return agreement that would include the date and location that the device is expected to be returned as well as the fees for late return or replacement. A form that includes pre-sleep and post-sleep questions should be provided to the patient with the device, with instructions for completing and returning it for the interpreting physician's review.

A comprehensive database should be kept to track HSAT procedures, diagnosis codes, turnaround time, and failure rates. Optimally, this data should be tied to patient outcomes. Technical failures due to equipment malfunction must be documented and the study repeated. Patient records should comply with HIPAA and patient confidentiality regulations and be stored and archived in a secure and organized manner according to policy.

5.0 DEVICE RETURN AND DATA DOWNLOAD

Timely return of the device is desired to enable it to be available for subsequent use, and to expedite test interpretation, diagnosis, and treatment. If possible, data should be checked against quality standards and a device should be re-dispensed at the same visit when a failure is detected. This is important since facilities must be able to provide data regarding the reliability of tests and the adequacy of the data on a quarterly basis.

The HSAT device must be downloaded for manual review by the scoring technologist. This can be accomplished via cloud or desktop-based software. The raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician. The raw data may also be made available remotely on a secured website or server, depending on facility protocols.

6.0 HSAT SCORING AND REPORTING

HSAT Scoring should only be performed by qualified sleep technologists. The expertise of a sleep technologist who has conducted and scored full polysomnographic studies and is competent in identifying significant events, artifacts, and normal sleep phenomenon is necessary to evaluate when the patient might be awake, moving, or mouth breathing, so that these episodes are not mistaken for sleep disordered breathing.

The scoring technologist:

- Evaluates if the minimum data collection requirement has been met, as determined by the sleep center;
- Manually edits and verifies results of automated analysis of raw data, if provided;
- Identifies artifact, inadequate signals and study failures;
- Scores events in accordance with the most current version of the AASM scoring manual; utilizing rules for respiratory flow and/or effort appropriate for the type of device and its recording parameters;
- Accurately marks respiratory events by type, oxygen desaturations, and fail periods (periods with complete or partial data loss);
- Prepares a scored report, which should indicate that the study was manually edited, and communicates any limitations to the recorded data, including failures;
- Documents and communicates study issues to the interpreting sleep specialist; and
- Makes the scored raw data and reports available to the interpreting sleep specialist.

7.0 QUALIFICATIONS OF SLEEP TECHNOLOGISTS

Sleep technologists performing HSAT must demonstrate knowledge of the application and limitations of the device. The sleep technologist educates and instructs patients and caregivers in the application of the HSAT device in the home environment, or may apply the device directly. The scoring technologist must be able to accurately mark events, identify artifact, and prepare a scoring summary. Scoring personnel must adhere to state licensure requirements. If no state licensure requirements are mandated, scoring personnel should hold one of the following credentials or be medical staff or PhD board-certified in sleep medicine.

- RPSGT
- RST
- CRT-SDS
- CPSGT

- RRT-SDS

Non-credentialed personnel (i.e. new graduate, or on the job trainee) may only score under the supervision of credentialed personnel.

7.1 Training of Sleep Technologists

All technical personnel must be trained by the Medical Director of the sleep center, a board-certified sleep specialist, a registered sleep technologist (RPSGT, RST), or a respiratory therapist with the SDS credential (CRT-SDS or RRT-SDS).

8.0 SLEEP CENTER ORGANIZATION AND RECORD KEEPING

Sleep technologists performing HSAT studies should follow the sleep center departmental policy and procedure manual guidelines. Patient medical records, in either print or electronic format, should be organized and available for use in the sleep center. HIPAA guidelines must be followed to meet documentation and confidentiality requirements. Records and recordings must be secure, retrievable and stored in accordance with state guidelines for the length of time designated by the statutes (generally a seven-year minimum for adults, and 7 years after the 18th birthday of a minor).

8.1 Quality Assurance

Scoring accuracy should be assessed against the reference sleep specialist a minimum of once per quarter according to current accreditation standards for AASM accredited centers. Failure rate, re-test rate, CPAP compliance at 12 weeks and scoring and interpretation turnaround time should be tracked and maintained at benchmarks set by the sleep center.

9.0 EQUIPMENT SAFETY

Equipment and sensor use and maintenance must meet manufacturer standards. All equipment used for HSAT must be visually inspected monthly and maintained at regularly scheduled maintenance intervals per manufacturer recommendations, and those actions must be logged. Electronic equipment used in conducting HSAT must be tested for safety by a credentialed biomedical engineer or electrician at least annually with appropriate documentation recorded. Between each patient, after the data has been downloaded, the device must be checked to verify that no prior patient information is on the device before it is issued to the next patient. If data is corrupted, the device must be checked and tested before it is returned to service.

10.0 INFECTION CONTROL

Sleep technologists must use standard precautions (9) to prevent the spread of infectious disease. Frequent hand washing is essential for protection of both patient and technologist, and should be performed before and after all patient contact and after glove removal. The technologist must wear gloves when handling contaminated equipment. When disposable equipment is utilized, the equipment should be used for one single patient and not reused. Infection control policies and procedures should be followed consistently within the facility.

10.1 Equipment Decontamination

All equipment and sensors that come into contact with the patient are handled as contaminated per sleep center policy and procedure. Clean and dirty equipment must be kept in separate areas designated as clean or dirty. All dirty equipment must be cleaned and disinfected after each use according to manufacturer guidelines. Single use items must be discarded after each use. Adhesive residue must be removed from sensors and the device container should also be cleaned and disinfected.

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