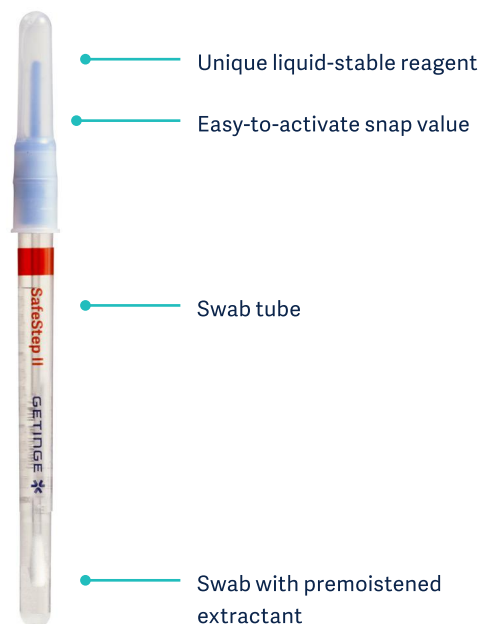


# Getinge Assured

## SafeStep Test II Swab

For use with all Getinge Assured SafeStep ATP Monitors

The Getinge Assured SafeStep Test II Swab provides a rapid, simple, and reliable way to detect ATP on the surface of surgical instruments, endoscopes, washer-disinfectors, examination rooms, operating rooms, restrooms, waiting rooms – anywhere that can harbor possible contaminants.



### Performance Characteristics

The Getinge Assured SafeStep ATP Monitor detects Adenosine Triphosphate (ATP), the universal energy molecule found in all animal, plant, bacterial, yeast, and mold cells. Product residues, particularly blood and bioburden, contain large amounts of ATP. After cleaning, all sources of ATP should be significantly reduced.

When ATP is picked up by the tip of the SafeStep II Test Swab and brought into contact with the unique, liquid stable Luciferase/luciferin reagent in the SafeStep II Test Swab tube, light is emitted in direct proportion to the amount of ATP present. The SafeStep II Test Swab is then placed in the Getinge Assured SafeStep ATP Monitor handheld unit where it measures the amount of Relative Light Units (RLU) generated and displays in just 15 seconds. The ATP Complete will detect 1/100,000th dilution of fresh blood, i.e. 0.2 mg protein per swab.

The handheld unit can then be synced to a PC and the data downloaded to an easy-to-use management software for tracking results. The software program can be used to run comparison charts and produce color trend analysis graphs and reports.

The Getinge Assured SafeStep ATP Monitor has been independently lab validated. Testing data available upon request.

## Key Features

- All-in-one sampling device
- Results in 15 seconds
- Unique liquid-stable reagent

## Precautions and Warnings

- Check expiration date on label to be sure product is suitable for use
- Do not use SafeStep Test II Swab test if it is accidentally already activated
- Hold the luminometer upright when taking readings
- Hold SafeStep Test II Swab test upright when activating
- Read SafeStep Test II Swab test within 30 seconds of activation
- Wear personal protective equipment while handling
- Avoid contact with skin, eyes and clothing

## Instructions for Use

Testing should be done after cleaning, prior to high-level disinfection or sterilization.

### Step 1: Swab

When collecting a sample, make sure to use aseptic techniques. Do not touch the swab or the inside of the sampling device with fingers.

1. On the Getinge Assured ATP Monitor press the power switch and let it calibrate for 15 seconds, a countdown on the screen will inform you when it has finished.
2. Holding the swab tube, twist and pull the top of the swab out of the swab tube. For Sponges, wet the tip and push through lumen. Cut the tip into the swab tube.

**FLAT SURFACES:** Thoroughly swab a standard 10 x 10 cm (4 x 4 inches) area of interest for a typical flat surface.

**MEDICAL DEVICES:** Ensure swabbing technique remains consistent for each swab.



## Storage

Keep in properly labeled containers. Keep out of the reach of children. 15 month shelf life (from date of mfg.) at refrigerated temperatures 36°F to 46°F (2°C to 8°C). 4 week shelf life at room temperatures 70°F (21°C). Test swabs should be left out at room temperature for 2 to 5 minutes before being used. Do not expose device to prolonged periods of direct heat, or sunlight.

## Other Uses for the Getinge Assured SafeStep ATP Monitor

The Getinge Assured SafeStep ATP Monitor, used in conjunction with Getinge Assured Test Sponges, is the only product that can provide an accurate numerical reading of the level of contaminants present inside the channel of medical devices after cleaning.

### Step 2: Snap and Shake

1. After swabbing desired test area, place swab back in swab tube. The sample can be left for up to four hours on the swab bud before activation; however, once activated the Test Swab Tube must be placed into the hand held device within 60 seconds to ensure a viable test.
2. To activate, hold the swab tube firmly and use the thumb and forefinger to break the valve by applying pressure against the bulb wall - about half-way up - until the blue nib inside snaps.
3. Squeeze the bulb several times to get the reagent to the bottom and gently shake for five to ten seconds to saturate the tip of the swab.



### Step 3: Verify

1. Place the Getinge Assured SafeStep ATP Monitor in an upright position, or on the included stand to ensure a proper reading.
2. Insert the test swab tube into Getinge Assured SafeStep ATP Monitor, close and press the OK button.
3. Allow the unit to countdown 15 seconds, thereby displaying the amount of RLU (Relative Light Units) that are present in the test sample.
4. For medical devices readings at or below 100 indicate that the swabbed area has a low level of contamination. For non-critical surfaces readings at or below 45 indicate that the swabbed area has a low level of contamination.
5. If the reading is greater than 100 (for scopes and surgical instruments) or greater than 45 (for non-critical surfaces), the swabbed/tested area should be considered to have moderate to high levels of contamination. Determine if additional cleaning and retesting is required.
6. If you are having repeated test failures on the same device please contact the device manufacturer for additional information.

#### Recommended Pass/Fail Criteria

Application	Pass (RLU)	Fail (RLU)
<b>Instrument Surfaces and Channels</b>	0 to 100	101 and over
<b>Sterile Processing - General</b> (all non-critical surfaces in procedure rooms, restrooms, waiting rooms, etc. for testing counters, bedrails, blood pressure cuffs, toilets, faucets, hand rails, beds, computers, I.V. poles, etc.)	0 to 45	46 and over



### Step 4: Download

1. At the end of each day/shift, the hand held device can be synced to a PC where the readings are downloaded to the SafeStep Software. If preferred, this step can be done bi-weekly or monthly.
2. The downloaded data can then be used to produce detailed reports that provide testing history which may then be used as a part of the facility's quality assurance program.
3. After the information has been uploaded into the computer, you may now power down the hand held device and unhook it from the PC. (The hand held device automatically stores readings and can be turned off when not in use).



### Ordering Information

Getinge Assured	Order Number
SafeStep ATP Monitor	61301606628
SafeStep Test Swabs (100/box)	61301606629
SafeStep 1mm Test Sponges (100/box)	61301606630
SafeStep 1.5mm Test Sponges (100/box)	61301606631
SafeStep 2mm Test Sponges (100/box)	61301606632
SafeStep 3mm Test Sponges (100/box)	61301606633
SafeStep 4mm Test Sponges (100/box)	61301606634
SafeStep 5mm Test Sponges (100/box)	61301606635
SafeStep Test Sponge Sample Pack (45/bag)	61301606693

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