



TAGBS0203

User Manual

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1. Summary

This manual describes the characteristics and applications of the MYSphERA TAGBS0203 FCC ID: 2ACLYTAGBS0203.

2. Copyright & trademarks

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3. FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The MySphera TAGBS0203 has been designed and complies with the safety requirements for portable (<20cm) RF exposure in accordance with FCC rule part §2.1093 and KDB 447498 D01."

4. Declaration of Conformity

MYSphERA hereby declares that this TAGBS0203 is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. A copy of the Declaration of Conformity can be found at mysphera.com/declaration-of-conformity

5. Characteristics and applications

MYSphERA Tag (TAGBS0203) is a fundamental part among MYSphERA location system. This device transmits an identification frame which includes an Organizationally Unique Identifier (OUI) every few seconds (3 seconds by default). This period can be modified upon request for longer battery life when 3 seconds location precision is not required.

Any other device in MYSphERA family is capable of receiving and processing identification frames, and either identify a certain Tag when approached inside a pre-determined range, or send information about its position to MYSphERA Location Platform server which will calculate its location inside a monitored area.

Thanks to the ultra-low-power technology used in the design of MYSFERA Tracking Sensor, its CR2354 coin battery life reaches values higher than 4 years, with a location period of 10 seconds.

MYSFERA Tag is prepared to fit the most common hospitalary plastic identification bands for patients. It also can be stuck to any asset assuring fixation during the whole life of the tag.

It meets the IP-67 normative, guaranteeing 1 meter immersion up to 30 minutes without internal leakages. It allows the user to wear the device while washing hands or taking a shower without further consequences. This is also important during the cleaning procedure, where water or common disinfectants can be used to keep the Tag as clean as possible.

Two versions of the Tag are available: with or without button. The button may be used for emitting several alerts to the system. Both versions have 3 LED indicators (green, yellow, red) to give notifications to the user.

MYSFERA Tag can be also used to locate assets (furniture, other devices...). This is done by attaching the Tag to the asset by using a fixing bracket that allows replacing the sensor when the battery is low. The Tag is able to detect automatically if it is set or removed from the bracket.

FEATURES

- Personal and asset location.
- Battery life:
 - Up to 1 year at high responsiveness location.
 - Up to 4 years at low responsiveness location.
- User interface including a press button with configurable function and LEDs to indicate user-defined states such as: battery low, in use, identify...



Figure 1 MYSFERA Tags

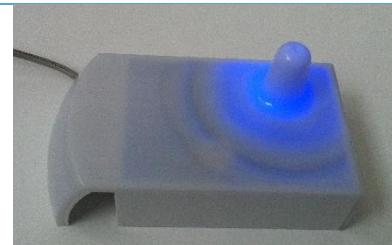
6. Tag assignment

A specific Tag can be added to the system, in order to locate its position, by assigning it to a patient or asset. This procedure can be done using several applications: the MYSFERA software (MYHOSPITAL), the hospital's own HIS and a specific software for assets logistics (by an integration with MYHOSPITAL).

To add a new Tag from the assignment feature of the specific software, select the person or asset to locate and then read the tag using a MYSFERA Reader.

Blue indicator:

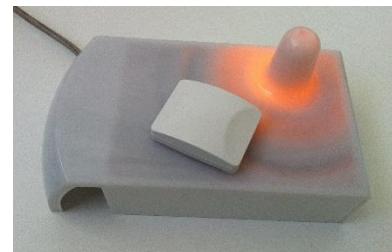
Reader ready to read Tags (unlocked).



Orange indicator:

Tag read correctly. Reader locked.

To unlock the Reader remove the Tag until the indicator becomes blue.



Red indicator:

Tag with low battery. Reader locked.

To unlock the Reader remove the Tag until the indicator becomes blue.



Figure 2 MYSFERA Reader states.

Once the assignment is completed, the system starts tracking the Tag, storing every position of the person or asset.

For assets or professional (physician, nurses...) tags, they are assigned only once until the end of the battery life, when the Tag shall be replaced.

For patient tags, they are assigned to the person until the moment it leaves the hospital, when the device shall be freed in the application and cleaned to be ready for a new user.

Depending on the desired security level, the Tag may only be freed by reading it with the Reader in the application.

7. Tag use for assets

MYSFERA Tags are designed to be attached to assets by using a fixing bracket. Although due to the different forms of every asset and the diversity of the surfaces and materials, as well as the different security measures required in every scenario, the procedure to attach the device may vary from one asset to another.

In the pictures below, there are some examples of installations in different assets:





Figure 3 Tag installation examples

8. Tag use for patients

MYSFERA Tags are designed to be wrist worn as a bracelet using a paper or plastic band. The band can be introduced through the slots in the lower part of the case as shown in the picture below.



Figure 4 Patients Tag

9. Tag use for professionals

MYSFERA tags can be also be worn in a neck lace using a setup as showed in the pictures below.

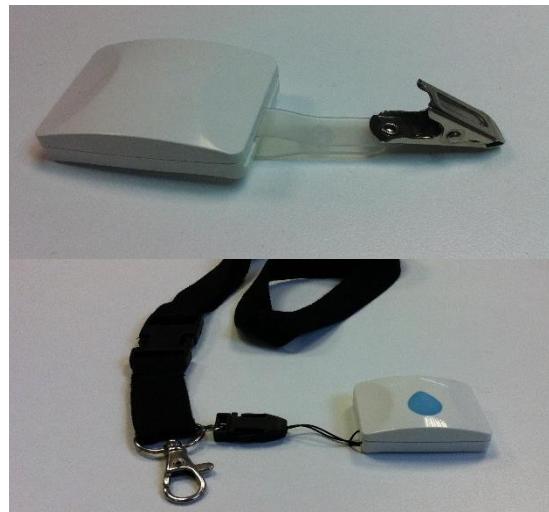
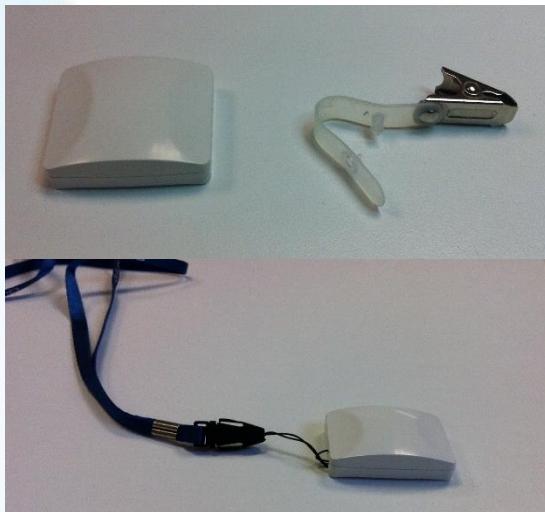


Figure 3 Setup examples for professionals

10. Cleaning and disinfecting

These general cleaning instructions are indicated for active tags of the TSB-SPHERAhospital solution. It is important that you clean the tags according to the following procedures.

Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient-care items is not necessary, health-care policies must identify, primarily on the basis of the items' intended use, whether cleaning, disinfection, or sterilization is indicated.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process.

Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Decontamination removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

The methods followed for TSB-SPHERAhospital tags are similar to the one used to disinfect oral and rectal thermometers, hospital pagers, scissors, stethoscopes,...

The tag fulfills IP-67 normative, allowing be disinfected by liquids and fluids. IP67 signifies protection against the effects of immersion from 15 cm to 1 m for 30 min without water ingress. The tag can be worn permanently by the patient during hospitalization, even getting shower or any washing activities.

10.1. Chemical solutions

Disinfection is a process by which vegetative growing forms of pathogenic organisms are killed.

Four types of chemical solutions are recommended to be used during disinfection, depending of the kind of action: quick or medium/slow action

Disinfectants	Disinfectants	Disinfectants
Didecyldimethylammoniumchloride based product e.g. Instrunet spray®, Meliseptol rapid	Quick action Ready-to-use, fast-acting alcoholic spray disinfectant For medical equipment such as hospital beds, mattress covers, treatment chairs, and other small sized alcohol-resistant surfaces	

Alcohol (70%) Isopropyl, ethyl alcohol, methylated spirit.	Quick action Smooth metal surfaces, table tops and other surfaces on which bleach cannot be used.	Flammable, toxic, to be used in well- ventilated area, avoid inhalation. To be kept away from heat sources, electrical equipment, flames, hot surfaces. Should be allowed to dry completely, particularly when using diathermy as it can cause diathermy burns.
Glutaraldehyde(2%)	Medium/slow action For disinfection of endoscopes, respiratory therapy equipment and for materials that are destroyed by heat. Can work as a sterilant if contact time is 6-8 hrs and if used under strictly controlled condition.	Eye and nasal irritant, may cause asthma and skin allergies, hence should be used in well ventilated area, keep covered with well fitting lids. Eye protection, plastic apron and gloves should be worn while handling
Bis-(3-Aminopropyl)-dodecylamine (9,9%)-Propinato Didecilmetilpolioxietilammonium 12% e.g. Darodor Sinaldehyd 2000	Disinfectant cold - high - dumping Cold chemical disinfectant immersion high. Without aldehydes. Bactericidal. Fungicide. Virucidal. Application for Hospital Hygiene, Pharmaceutical, Medical and Health Consultation Livestock	It is a corrosive liquid and can cause injury to the skin and mucosa. Some cases of allergic contact dermatitis have also been reported among health care workers.

Reference: Blood Safety and Laboratory Technology. Guidelines on Prevention and Control of Hospital Associated Infections. World Health Organization (WHO)

Before equipment is to be disinfected or sterilized, it should be thoroughly cleaned to remove any visible dirt or secretions. This involves washing with water and detergent (soap). Protective clothing (an apron, gloves and a facemask) should be worn.

Each tag shall be wiped with chemical disinfectant solutions described on the table above. In case of glutaraldehyde-based disinfectant dilution, the tag shall be wiped by immersion several minutes.

Glutaraldehyde is a high-level disinfectant most frequently used as a disinfectant for heat-sensitive equipment such as dialysis instruments, surgical instruments, suction bottles, bronchoscopes, endoscopes, and ear, nose, and throat instruments. Glutaraldehyde is also used as a tissue fixative in histology and pathology laboratories and as a hardening agent in the development of x-rays. Glutaraldehyde products are marketed under a variety of brand names and are available in a variety of concentrations (solutions range in concentration from 2 – 3.4%), with and without surfactants.

Disinfect tags with an EPA (US Environmental Protection Agency) - registered hospital disinfectant using the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute.

10.2. The process

Disinfect any tag after using it on a patient who is on contact precautions before using this equipment on another patient.

1. Remove the band or fixing bracket of the Tag.



2. Clean the tag (both sides) to remove any visible dirt or secretions. This involves washing with water and detergent (soap). It is recommended to use a brush to enhance cleaning.



3. Wipe the tag with chemical disinfectant products as described in the table above following the instructions of the product label.

Figure 6 Cleaning process

11. Storage and disposal

11.1. Storage

When the Tags are not being used, they should be stored in a clean, dry area. Otherwise it may become a source of contamination.

Store the tags under the following ambient conditions:

- Temperature: -10°C to 50°C (14°F to 122°F)
- Relative Humidity: 20% to 80% (no condensation)

11.2. Disposal

DO NOT OPEN ANY TAG

At the end of the battery life, the Tag shall be returned to the manufacturer for battery replacement. Contact MYSFERA before disposing of the Tags. This product should not be treated as household waste.

By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste-handling of this product.