

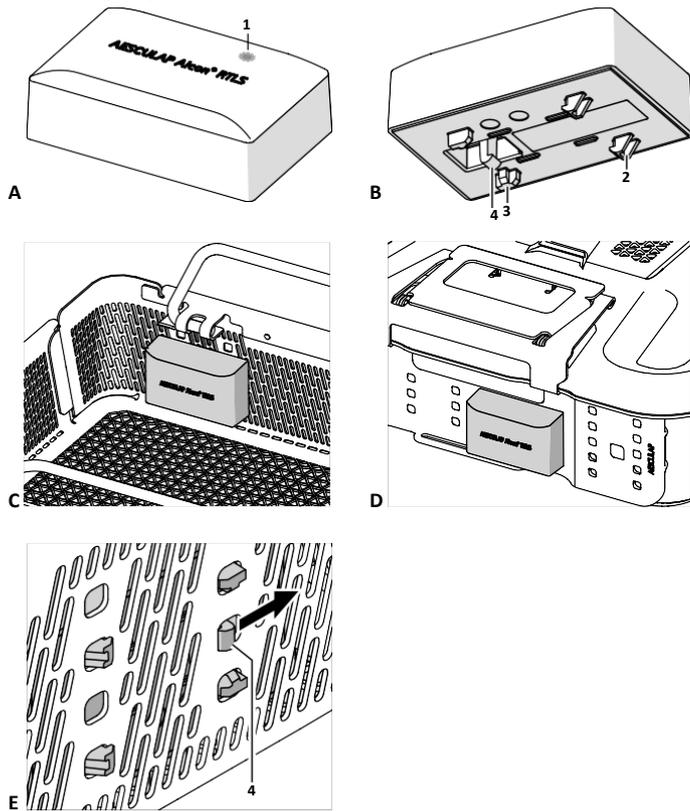
REVIEW - AESCULAP Aicon[®] RTLS

Document information

Document No	TA016560
Change No	
Revision	2024-10
Document Type	User Manual
Product	Aesculap Sterile Goods Management Sterilcontainersystem Aicon
	  eifu.bbraun.com
TIM ID	0000001408
TIM Version	001
Language	EN
TIM Title	TA016560 - AESCULAP Aicon - RTLS beacon

B BRAUN

Cover graphic



AESULAP Aicon[®] RTLS

Beacon

Variant: Content: Foldout and Legend

Legend

ID: 0000036703-001

- A** Top side of beacon
- B** Bottom side of beacon
- C** Beacon mounted inside basket on front side
- D** Beacon mounted on container face plate
- E** Removing the beacon
- 1** LED
- 2** Fixed hooks
- 3** Positioning pins
- 4** Snap hook

1 About this document

1.1 Scope

This document applies to the following products:

REF no.	Designation
J660	AESULAP Aicon RTLS beacon

Note

Instructions for use and further information about B. Braun / AESULAP products can be found on the B. Braun eIFU website at eifu.bbraun.com

1.2 Safety messages

Safety messages make clear the dangers to patient, user and/or product that could arise during the use of the product. Safety messages are labeled as follows:

WARNING

Indicates a possible threat of danger. If not avoided, minor or moderate injury may result.

CAUTION

Indicates a possible threat of material damage. If not avoided, the product may be damaged.

2 Clinical use

2.1 Product description

Note

The product is not a medical device.

The AESULAP Aicon RTLS beacon is a device that can be placed either on the basket (tray), on the sterile goods container, or on a cart. Its purpose is to enable localization in combination with RTLS software and infrastructure.

The AESULAP Aicon RTLS beacon can be used for tracking assets during the processing procedure (cleaning and sterilization).

The AESULAP Aicon RTLS beacon is intended to be used with AESULAP Aicon products. The AESULAP Aicon RTLS beacon can also be used in combination with different 3rd party RTLS solution providers.

► Contact B. Braun / AESULAP agency for more information regarding compatibility.

The AESULAP Aicon RTLS beacon has an integrated LED to visually identify sets. This function needs to be available in the 3rd party RTLS software in combination with AESULAP Aicon RTLS.

- ▶ Contact the RTLS service provider for more information.

2.2 Safety information

2.2.1 Clinical user

General safety information

To prevent damage caused by improper setup or use and to avoid compromising manufacturer warranty and liability:

- ▶ Use the product only according to this document.
- ▶ Follow the safety and maintenance information.
- ▶ Ensure that the product and its accessories are only operated and used by qualified personnel.
- ▶ Store any new or unused products in a dry, clean, and safe place.
- ▶ Prior to use, check that the product is in good working order.
- ▶ Keep this document accessible to the user.

2.2.2 Product-specific safety information

- ▶ Only combine AESCULAP products with each other.
- ▶ Always adhere to applicable standards.

2.2.3 Sterility

The product is supplied non-sterile and intended to be used in the processing cycle.

- ▶ Clean the new product after removing its transport packaging and prior to its initial sterilization.

2.3 Preparation

The AESCULAP Aicon RTLS beacon can be mounted on the click-in area for labeling elements on the front side of AESCULAP Aicon baskets (see Fig. C) or on the face plate of AESCULAP Aicon containers (see Fig. D).

2.3.1 Mounting

- ▶ Hold the beacon with the bottom side facing the inside of the basket front side or the container face plate.
- ▶ Insert the fixed hooks **1** the edge of the basket front side or container face plate.
- ▶ Lower the other side until the positioning pins **2** align with the basket click-in area or container face plate.
- ▶ Press the beacon onto the basket click-in area or container face plate until the snap hook **3** snaps into place.

2.3.2 Removing

- ▶ Press the snap hook **3** outward from the underside of the beacon, see Fig. E.
- ▶ Lift the beacon and remove it from the basket or container.

2.4 Application

- ▶ For information regarding the RTLS software, please refer to the separate landing page (link to be provided).

While being mounted on a basket containing medical devices to be processed, the AESCULAP Aicon RTLS beacon can be processed with the same process used by the medical devices, as long as the following information is observed:

- Automatic neutral, mild alkaline, or alkaline cleaning
- Steam sterilization

- ▶ Do not immerse beacon in an ultrasonic cleaning bath.

Hot temperatures or long holding times during sterilization negatively impact the lifetime of the battery.

- ▶ Do not exceed 140 °C at any point of the processing procedure.
- ▶ During sterilization, keep holding times as short as possible.

3 Processing

3.1 Safety information

Successful processing can only be assured if the processing method has been validated in advance. This is the responsibility of the operator / sterile processing technician.

The cleaning and disinfecting agents listed were used for validation. The validated steam sterilization process was performed in [AESCULAP](#) sterile container systems.

- ▶ Follow national regulatory requirements, national and international standards and guidelines, and local clinical hygiene instructions for sterile processing.
- ▶ For patients with Creutzfeldt-Jakob Disease (CJD), suspected CJD or possible variants of CJD, comply with relevant national regulations for processing of products.
- ▶ For products with manual (without washer-disinfector) and automatic validated cleaning procedures, prefer the automatic cleaning procedure whenever possible for more standardized and reproducible results.
- ▶ For the most up-to-date information on processing and material compatibility, visit the B. Braun eIFU website at <https://eifu.bbraun.com>.

For stainless steel products, residues containing chlorine or chlorides, such as surgical residues, medications, saline solutions and process water used for cleaning, disinfection and sterilization, will cause corrosion damage (pitting, stress corrosion) and destruction.

- ▶ Remove residues containing chlorine or chlorides by thoroughly rinsing with demineralized water followed by drying.
- ▶ Do not use pre-cleaning temperatures > 45 °C or disinfectants with aldehydes or alcohols as their active ingredient.

Only tested and approved process chemicals (e.g., VAH or FDA approval or CE mark) that are compatible with the materials of the product according to with the recommendations of the chemical manufacturer may be used for processing the product. Otherwise, the following problems may occur:

- Visual changes in materials, such as fading or discoloration of titanium or aluminum. In the case of aluminum, an application / processing solution with a pH value > 8 may cause visible surface changes.
- Material damage such as corrosion, cracking, fracturing, premature aging or swelling
- ▶ Strictly follow all application specifications of the chemical manufacturer.

Metal cleaning brushes or other abrasives can damage the product surfaces and cause corrosion.

- ▶ Do not use metal cleaning brushes or other abrasives.

Note

More detailed information on hygienically safe, material- and value-conserving processing can be found in the "Red Brochure" at <https://www.a-k-i.org>.

3.2 Service life

Materials for reusable surgical instruments are generally chosen to be suitable for repeated processing. However, it should be noted that each mechanical, chemical and thermal treatment can lead to stress and thus to aging of the material.

The service life of the product is limited by damage, normal wear, type and duration of use, as well as by handling, storage and transport of the product.

Influences of processing using the validated procedure that lead to damage to the product are not known.

Careful visual and functional inspection before each use is the best way to detect a product that is no longer functional, see Visual inspection and see Functional test.

3.3 Initial treatment and disposal at the point of use

This section is detailed in the separate brochure "Validated Processing Procedures" (AVA-V7) C63402.

- ▶ Remove coarse contamination and visible surgical residues immediately after use while still in the operating room, e.g., with a damp, lint-free cloth.
- ▶ If applicable, rinse non-visible surfaces (preferably with deionized water), e.g., with a disposable syringe. Dried or adhering surgical residues can make cleaning more difficult or ineffective and may cause corrosion.
- ▶ Keep the time between disposal and processing as short as possible.

- ▶ Transport products as dry as possible in closed disposal containers for cleaning and disinfection.
- ▶ Visibly mark processable products that are detected to be defective during use.
- ▶ If defective products are returned for repair, process those products as well.

3.4 Preparation before cleaning

- ▶ Remove coarse contamination by rinsing and flushing with cold, clean water.

3.5 Cleaning, disinfecting and drying

3.5.1 Product-specific safety information on the processing procedure

Damage to or destruction of the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- ▶ Use cleaning and disinfecting agents according to the manufacturer's instructions.
- ▶ Observe specifications regarding concentration, temperature and exposure time.
- ▶ Do not exceed the maximum allowable disinfection temperature of 95 °C.

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While being mounted on a container or basket to be processed, the AESCULAP Aicon RTLS beacon can be processed with the same process used by the container or basket, as long as the following information is observed:

- Automatic neutral, mild alkaline, or alkaline cleaning
- Steam sterilization

- ▶ Do not immerse beacon in an ultrasonic cleaning bath.

Hot temperatures or long holding times during sterilization negatively impact the lifetime of the battery.

- ▶ Do not exceed 140 °C at any point of the processing procedure.
- ▶ During sterilization, keep holding times as short as possible.

3.5.2 Validated cleaning procedure

Note

The following procedures are meant to be used if the beacon must be processed removed from a basket or container.

Validated procedure	Short description	Characteristics/requirements
<p>Manual cleaning and wipe disinfection</p> <p>see Cleaning without washer-disinfector and subsection:</p> <ul style="list-style-type: none"> • see Manual cleaning with immersion and wipe disinfection 	<ul style="list-style-type: none"> • Preparation before cleaning • Cleaning • Drying • Wipe disinfection 	–
<p>Automatic neutral or mild alkaline cleaning</p> <p>see Automatic cleaning and subsections:</p> <ul style="list-style-type: none"> • see Preparation before cleaning • see Automatic neutral or mild alkaline cleaning 	<ul style="list-style-type: none"> • Preparation before cleaning • Washer-disinfector: Neutral or mild alkaline process 	–

3.6 Cleaning without washer-disinfector

3.6.1 Manual cleaning with immersion and wipe disinfection

Applies to: Master V7

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	Preparation before cleaning	< 25/77	–	D-W	–
II	Cleaning	< 25/77	≥ 5	D-W	Aldehyde-, phenol- and QAC-free, pH ≈ 9
III	Drying	–	–	–	–
IV	Wipe disinfection	–	≥ 1*	–	Alcohol(s) ≤ 70 %, quaternary ammonium compound(s) ≤ 2 %

Applies to: Master V7

*	Appropriate exposure time according to the manufacturer's specification
D-W	Drinking water

Notes on the processing procedure

- The following cleaning/disinfection agents were used for validation:
- B. Braun Stabimed fresh
- B. Braun Meliseptol Wipes sensitive
- Steps marked with an asterisk (*) are required if the product has the corresponding characteristics or cleaning requirements, see Validated cleaning procedure.

Phase I: Preparation before cleaning

- ▶ *Disassemble the product.
- ▶ Remove coarse contamination by rinsing the product with cold, clean water.
- ▶ *Mobilize movable parts, such as set screws or joints, during rinsing.

Phase II: Cleaning

- ▶ Fully immerse the product in the cleaning solution for at least 5 minutes. Make sure all accessible surfaces are wet.
- ▶ Clean the product in the cleaning solution with a suitable cleaning brush until no residue is visible on the surface.
- ▶ *Mobilize movable parts during cleaning.
- ▶ *Non-visible surfaces:
 - Brush non-visible surfaces, such as lumina, channels, undercuts or cavities, at least five times (back and forth = 1 time) with an appropriate cleaning brush.
 - Thoroughly flush non-visible surfaces with the cleaning solution at least five times using a disposable syringe (10 ml to 50 ml depending on the product).

Phase III: Drying

- ▶ Dry the product with appropriate equipment (e.g., cloth, compressed air).

Phase IV: Wipe disinfection

- ▶ Wipe all surfaces of the visually clean product with a lint-free, disposable disinfectant wipe for at least 1 minute.

3.7 Automatic cleaning

3.7.1 Preparation before cleaning

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	Preparation before cleaning	< 25/77	–	D-W	Preparation before cleaning may be part of manual pre-cleaning.

D-W	Drinking water
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Notes on the processing procedure

- Steps marked with an asterisk (*) are required if the product has the corresponding characteristics or cleaning requirements, see Validated cleaning procedure.

Phase I: Preparation before cleaning

- ▶ *Disassemble the product.
- ▶ Remove coarse contamination by rinsing the product with cold, clean water.
- ▶ *Mobilize movable parts, such as set screws or joints, during rinsing.

3.7.2 Automatic neutral or mild alkaline cleaning

Applies to: Master V7

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	Pre-rinse	< 25/77	3	D-W	–
II _n	Cleaning	55/131	10	D-W*	Aldehyde-, phenol- and QAC-free, pH 7 to 10,5
III	Intermediate rinse	> 10/50	> 1	FD-W	–
IV	Thermal disinfection	90/194	5	FD-W	–
V	Drying	–	–	–	Recommended: 10 min at 100 °C

Applies to: Master V7

*	Appropriate water quality according to the manufacturer's specification
D-W	Drinking water
FD-W	Fully demineralized water (low-germ, max. 10 CFU / 100 ml, as well as low endotoxin contamination, max. 0,25 endotoxin units/ml)

Notes on the processing procedure

- The following cleaning agent was used for validation: B. Braun Helimatic Cleaner neutral, 0,5 % working solution
- An established standard process has been chosen for machine cleaning in the washer-disinfector (machine type: single-chamber cleaning/disinfection device without ultrasonic).
- The automatic cleaning device must be tested and approved for effectiveness (e.g., a washer-disinfector in compliance with ISO 15883) and must be serviced and checked at regular intervals.
- Alternatively, or when using cleaners other than those validated, a second intermediate rinse and/or neutralization may be required in the process sequence.
- Steps marked with an asterisk (*) are required if the product has the corresponding characteristics or cleaning requirements, see Validated cleaning procedure.

Before automatic cleaning cycle

- ▶ *Mount jaws protection on the product.
- ▶ *Insert the product in the proper position in its holder.
- ▶ Place the product on a storage device that is suitable for cleaning (avoid rinse residue).
- ▶ *Fix the product in the machine or on storage devices so that it can be thoroughly cleaned.
- ▶ *Connect either the product or the holder / rinsing device to the injector cart using a flushing connector, flushing sleeve, or injector nozzle.
- ▶ *Ensure that working ends and movable parts, such as set screws or joints, are open and remain accessible during automatic cleaning cycle. If necessary, use cleaning aids.

After automatic cleaning cycle

- ▶ Inspect visible surfaces for residue.
- ▶ If necessary, dry the product again, e.g., with compressed air.

3.8 Inspection

- ▶ Allow the product to cool down to room temperature.
- ▶ Dry the product if it is wet or damp.

3.8.1 Visual inspection

- ▶ Make sure that all soiling has been removed. In particular, pay attention to mating surfaces, recessed areas.
- ▶ If the product is still dirty: Repeat the cleaning and disinfection process.
- ▶ Check the product for damage, e.g., insulation or corroded, loose, bent, broken, cracked, worn or severely scratched and fractured components.
- ▶ Check the product for missing or faded labels.
- ▶ Check the surfaces for rough spots.
- ▶ Check the product for burrs that could damage tissue or surgical gloves.
- ▶ Check the product for loose or missing parts.
- ▶ Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

3.8.2 Functional test

- ▶ Check that the product functions correctly.
- ▶ Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

4 Technical service

⚠ CAUTION

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

- ▶ **Do not modify the product.**
- ▶ **For service and repairs, contact the national B. Braun / AESCULAP agency.**

Service address

Aesculap Technischer Service

Am Aesculap-Platz

78532 Tuttlingen / Germany

Phone:+49 7461 95-1601

Fax: +49 7461 16-2887

E-Mail: ats@aesculap.de

Other service addresses can be obtained from the address indicated above.

5 Disposal

⚠ WARNING

Risk of infection due to contaminated products!

- ▶ **Adhere to national regulations when disposing of or recycling the product, its components and its packaging.**

ID

Note

The user institution is obliged to process the product before its disposal, see *Processing*.

► Detailed information concerning the disposal of the product is available through the national B. Braun / AESCULAP agency, see Technical service.

	<p>The recycling passport can be downloaded from the B. Braun eIFU website at eifu.bbraun.com as a PDF document by entering the respective article number. (The recycling passport includes disassembling instructions for the product as well as information for proper disposal of components harmful to the environment.)</p> <p>Products carrying this symbol are subject to separate collection of electrical and electronic devices. Within the European Union, disposal is taken care of by the manufacturer as a free-of-charge service.</p>
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6 FCC statements

	<p>This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:</p> <ul style="list-style-type: none"> • (1) This device may not cause harmful interference. • (2) This device must accept any interference received, including interference that may cause undesired operation of the device.
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FCC ID: 2BBC6-JJ660

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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

7 IC statements

IC: 30643-JJ660

Model/HVIN: 4000-002

Compliance Label: CAN ICES-003 (A) / NMB-003 (A)

- English:

This device complies with ISED's licence-exempt RSSs. 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.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be chosen so that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

- French:

Le présent appareil est conforme aux CNR d'ISED applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. le dispositif ne doit pas produire de brouillage préjudiciable, et
2. ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radio électrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

The radiated output power of the device is far below the FCC and ISED radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact during normal operation is minimized.