matachana

Infection Control

A_0 Indicator

(100 units / box)

WASH

TECHNICAL - COMMERCIAL DESCRIPTION – Ref. 85666.3/85667

1. PRESENTATION AND CERTIFICATIONS

INDICATOR FOR RUTINE CONTROL OF MEDICAL DEVICE REPROCESSING WHICH GIVES ADDED VALUE TO QUALITY CONTROL OF RUMEDs.

The A_0 Indicator allows the evaluation of the automatic washing and disinfection processes allowing an adequate **routine control** to increase the quality control of the medical device reprocessing units (RUMED).

INDICATOR CERTIFIED BY ACCREDITED LABORATORIES

The A_0 Indicator is composed of three indicators in one, designed with a polypropylene substrate (indicator strip):

1.- Indicator 1 has a dirt that is integrated into this strip (**Integrated dirt or *test soil***) in accordance with the current technical specification **ISO/TS 15883-5.**

2.- Indicator 2 is a specific temperature and time Indicator for the thermodisinfection phase.

3.- Indicator 3 is a specific temperature and time Indicator for the drying phase.

SPECIFIC INDICATOR FOR MONITORING WASHING CONDITIONS IN CONTACT WITH MEDICAL DEVICES

Its **laminated polypropylene** substrate allows to simulate the surface of plastic medical device and its **integrated dirt composition (*Test Soil*)** is equivalent to that found in surgical instruments for rigid endoscopy, anaesthesia, wedges or bottles. The temperature indicators provide **additional information on the A_0** of the washing and thermodisinfection process, as well as the temperature and time used in the drying phase.

INDICATOR THAT ALLOWS TO VERIFY IN A SIMPLE AND PRACTICAL WAY THE DEGREE OF HYGIENE OF THE PROCESS AND THE THERMODISINFECTION

The operating principle of the **A_0 Indicator** consists of the **removal** or total **decontamination** of the integrated dirt or *soil test* located in the first oval of the indicator by the washing process to be evaluated. In addition, the other two ovals are used for the approximate evaluation of **the temperature and time** of both the thermodisinfection and drying phases.

INDICATOR SET TO DETECT DETERGENT DOSAGES OF DIFFERENT BRANDS

Its simplicity as a washing test allows to introduce it as part of the standardized procedures of a sterilization central (RUMED) to detect variations during the washing process and thermodisinfection very useful as:

- Detects variations in optimal temperatures of the detergent.
- Detects the determined and established dosages of alkaline, alkaline-enzymatic or enzymatic detergents according to the purity of the water.
- Detects the correct pressure of the water spray arms during the process.
- Detects the determined and established time of exposure to the detergent.
- Detects the thermodisinfection temperature as a function of time, making a clear distinction between A_0 60 and A_0 1000 – 3000.
- Detects the drying temperature by distinguishing between prolonged periods of time.

EASY TO USE AND INTERPRET INDICATOR

The A_0 Indicator should be placed together with the metal basket (code 85667) which allows it to be placed in a single central position in the automatic washing machine chamber and in the most challenging places in front of the washing process such as: in the corners of the chamber and right in the center under the spray arms. Always observe the usage guidelines according to the **Product Safety Note C_MKT_A0indicatorFieldSafetyNote_00_00.**

Its mode of use is described in the **Instructions for Use (IU_MON_WASH_85666_3_00_00_arx.)** which can be consulted through the QR code on the A_0 Indicator packaging.

This document has the Results Interpretation Guide that takes into account the reasons for possible incidents in washing-disinfection machines and the actions to be taken and considered.

2. TECHNICAL CHARACTERISTICS

	Technical Characteristics
What is it used for?	For the evaluation of washing efficiency and obtaining additional information on the A_0 of the process and drying phase in Automatic Washer-Disinfectors
Substrate Composition	Polypropylene laminate to simulate a medical device made of polypropylene or other plastics
Integrated Dirt Composition (*Soil Test*)	Equivalent to the mixture of: 1.) Sheep's blood without fibrin 2.) *Enterococcus faecium* ATCC 6057 3.) Skimmed milk powder 4.) Butter 5.) Sugars 6.)) Semolina (durum wheat flour) 7.) Tap water 8.) Egg yolk 9.) Peptone from casein digestion
Integrated Dirt Surface 3 ovals	1,5 cm^2 of total area for washing evaluation
Thermodisinfection temperature indicator surface	1,5 cm^2 of total area for temperature evaluation as a function of time of the thermodisinfection phase and integrates part of the washing phase
Drying temperature indicator surface	1,5 cm^2 of total area for temperature evaluation as a function of the time of the drying phase

	Technical Characteristics
How often should it be used?	It is recommended to use it frequently per cycle and in different positions because it will simulate the dirt in the proximity of the medical device itself that is being processed giving information of the correct washing process in that position of the chamber.
What is its useful life? **Period of useful life**	After 3 years the loss of stability begins
ISO Standard Compliance	ISO/TD 15883-5 (Annex P and G)
AAMI and AORN compliance	AAMI ST70:2017 Processing of health care products-Quality Management systems for processing in health care facilities
Compliance with ASTM standard	Guide D7225 ASTM
Storage and Transport (conditions must be kept within the described margins)	10 - 30 °C (Temperature controlled storage) Additionally it can be stored at 4 °C. 30 – 70% (Controlled relative humidity)
Indicator dimensions	7,7 cm x 3,3 cm x 0,25 mm
Weight	87 g/box
EAN 13 (consumption unit)	8435275806293
EAN 14 (sales unit)	8435275807603