



Ecos™ Bowie & Dick Type Test Pack for Prevacuum Sterilizers

Complies with ANSI/AAMI/ISO 11140-1:2014, Type 2

Complies with ANSI/AAMI/ISO 11140-5:2007

Reorder Number: 26630400

Ecos™ ANSI/AAMI/ISO Compliant Performance

Ecos™ is a lead free, heavy metal free, and toxic metal free Bowie and Dick test pack that meets the stringent requirements stated in both ANSI/AAMI/ISO 11140-1:2014 and ANSI/AAMI/ISO 11140-5:2007.¹⁻² Bowie and Dick test packs that meet the requirements of these standards, such as Ecos™, are classified as Type 2 chemical indicators. A Type 2 indicator is an indicator and test system that is used to evaluate the effectiveness of air removal during the pre-vacuum phase of steam sterilization cycles.

By complying with ANSI/AAMI/ISO 11140-5, Ecos™ is proven to be equivalent to the standard towel test pack (construction of the standard test pack is described in Annex E of ANSI/AAMI/ISO 11140-5). Thus, Ecos™ is confirmed to be as effective as the standard towel pack as an air removal test when used to evaluate the efficacy of air removal during vacuum phases and the presence of noncondensable gases.

The ANSI/AAMI/ISO 11140 standards refer only to the effectiveness regarding air removal and noncondensable gases and have no requirements for the detection of super-heated or wet steam. The Ecos™ test pack is able to detect both super-heated and wet steam: this is an added feature that is above and beyond the requirements of these standards and is something not seen with a standard Bowie and Dick test.

Advanced Indicator Ink Formulation

Ecos™ makes use of one of the latest advances in steam indicator ink: the Blu™ ink technology. The advanced formulation of Ecos™ allows for increased sensitivity to air, insufficient temperature, and wet steam, and is designed specifically so that the test sheet results can be read clearly. In addition to the increased sensitivity, the Blu™ ink technology is completely free of latex, natural rubber, lead and other toxic or heavy metals that may be hazardous to the environment or the user. While being “lead free” is rather straightforward, being “toxic metal free”, “heavy metal free”, or even “toxic heavy metal free” is much less so. The following section will show how these descriptions can change based on the source material referenced.

Lead and Other Heavy Metal Content

Neither lead nor heavy metals were used as a component in the making of the Ecos™ test sheet; however, most available Bowie and Dick type tests use some form of lead or other heavy metal in the formulation of their indicator ink. One issue with the current generation of Bowie and Dick type tests is that terms like “heavy metal free” or “toxic metal free” are used without explaining just what these terms mean.

¹ ISO 11140-1:2014 Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements

² ISO 11140-5:2007 Sterilization of Health Care Products – Chemical Indicators – Part 5: Type 2 indicators for Bowie and Dick air removal test sheets and packs

Heavy Metals

There are several means of defining and classifying heavy metals. One such classification is that heavy metals are elements that have a specific gravity that is more than 5 times that of water. From this definition, the heavy metals that people are commonly exposed to are antimony, arsenic, bismuth, cadmium, cerium, chromium, cobalt, copper, gallium, gold, iron, lead, manganese, mercury, nickel, platinum, silver, tellurium, thallium, tin, uranium, vanadium, and zinc. However, missing from this list are metals, such as beryllium and barium, that are sometimes referred to as toxic. For example, both beryllium and barium are listed as the SARA (Superfund Amendments and Reauthorization Act) federal regulation for toxic emission reporting. In fact, beryllium is listed by the Occupational Safety and Health Administration (OSHA) as a toxic metal and does not appear on the above list of heavy metals.

Another such definition of heavy metals is elements of a high atomic weight; however, beryllium has the fourth lowest atomic weight and is again excluded. Rather than classifying metals based on weight or density, attempts have been made to classify them according to chemical properties such as toxicity; however, different types of legislation often utilize diverse definitions of toxicity.

Toxic Metals

In the United States, state legislation based upon the Coalition of Northeastern Governors (CONEG) model regulates heavy metals used in packaging materials. CONEG based legislation lists cadmium, hexavalent chromium, mercury and lead as toxic heavy metals that were regulated in packaging.³

OSHA lists six elements as toxic metals: arsenic, beryllium, cadmium, hexavalent chromium, lead, and mercury.⁴

The voluntary ANSI Z66.1/ASTM F953 standard sets guidelines for the use of toxic metals in toy manufacture.⁵ It includes cadmium, hexavalent chromium, mercury, lead, antimony, arsenic, barium, and selenium. The federal Resource Conservation and Recovery act (RCRA) includes these elements and adds silver to the list. The previously mentioned SARA regulation includes the RCRA elements and adds beryllium, cobalt, copper, manganese, nickel, thallium, and zinc.

In the European Union, the Restriction of Hazardous Substance (RoHS) directive restricts the use of hazardous materials in the manufacture of electronic devices, and includes cadmium, hexavalent chromium, lead, and mercury.⁶ The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation of the European Union describes a list of substances of very high concern (SVHC).⁷ The European Chemicals Agency (ECHA) maintains this list, which includes chemical compounds that contain arsenic, cobalt, and lead.

Depending on the source or legislation, the definition of toxic or heavy metals varies greatly. Ecos™ removes the need to be concerned about choosing specific definitions or worrying about future legislation changes, as **no toxic or heavy metals** (including lead) were used as components in the making of the Ecos™ test sheet. Through the innovative Blu™ ink technology, Ecos™ is future safeguarded against any legislation regulating the use or disposal of any heavy or toxic metal.

In addition to the environmentally friendly design, the Ecos™ test pack meets the AAMI and ISO requirements for a Bowie and Dick type test. Oftentimes, products are stated to meet these requirements without any insight into what these requirements are. The following section briefly describes what it means for Ecos™ to be compliant with both 11140-5:2007 and the Type 2 requirements of AAMI/ISO 11140-1.

³ Coalition of Northeastern Governors. Reduction of Toxins in Packaging. 8/6/09.

⁴ a) <http://www.osha.gov/SLTC/metalsheavy/index.html>. 2009.

b) Occupational Safety and Health Standards 1910.1200.

c) Occupational Safety and Health Standards 1915 subpart Z.

⁵ a) American National Standard Specifications to Minimize Hazards to Children from Residual Surface Coating Materials: ANSI Z66.1-1964 (R1972).

b) Standard Consumer Safety Specification on Toy Safety, ASTM F963-86. 1986.

⁶ Directive 2002/95/EC Official Journal L 037 , 13/02/2003 P. 0019 - 0023

⁷ Regulation (EC) No 1907/2006. OJEC L396, 30.12.2006, pp. 1–849. 2006.

ANSI/AAMI/ISO 11140-5:2007 Requirements

Ecos™ meets every requirement of the ISO performance standard for the Bowie and Dick type test: AAMI/ISO 11140-5:2007, as well as all the Type 2 requirements of AAMI/ISO 111401-1.¹⁻² By complying with these standards, Ecos™ is recognized as a Bowie and Dick type test that is proven to be equivalent to the standard towel test pack. Thus, Ecos™ is as effective as the historically proven standard towel pack based Bowie and Dick test in evaluating the efficacy of air removal during the pre-vacuum phase of a pre-vacuum sterilization cycle or the presence of noncondensable gases during the pulsing stage of positive pulsing cycles.

AAMI/ISO 11140-5 contains many performance, quality, and sensitivity requirements. One such sensitivity requirement is that a densitometer is used in the product validation phase to measure the difference in color between the changed and unchanged indicator sheets. This is done in order to quantify the efficacy of the color change. Some additional requirements are

Pass Cycles. The indicator must show a uniform change after exposed to saturated steam at 134°C (273°F) for 3.5 minutes.

Fail Cycles. The indicator must show a non-uniform change when the temperature in the center of the pack is 2°C lower than the exposure temperature after 2.5 minutes (71%) of the 3.5 minute exposure phase has been completed. This represents a commonly seen fault condition generated by inadequate air removal.

Dry Heat. The indicator shall not react when exposed to dry heat at 140°C for 30 minutes. This requirement ensures that the indicator only changes when all of the critical parameters of the steam sterilization cycle (time, temperature and saturated steam) are present.

Ink Coverage. The indicator ink should cover at least 30% of the test sheet substrate. This is required so that even the slightest fails can still be detected. Ecos™ offers extra security by having ink on significantly more of the surface than is required by the standard.

Permeability. The test sheet and paper used in the pack construction should have an air porosity that is greater than 1.7 $\mu\text{m}/\text{Pa}\cdot\text{s}$. This is to ensure that steam fully penetrates the entire pack during the sterilization cycle in a manner that is analogous to what occurs when the standard AAMI towel pack is sterilized.

Ink Transfer. The indicator ink shall not transfer to adjacent material of the test pack. This requirement ensures that the indicator region will not be compromised by the loss of the indicator agent, which could potentially interfere with the proper evaluation of the test sheet result.

Summary

Ecos™ is a lead free, heavy metal free, and toxic metal free Bowie and Dick test pack that uses the latest in indicator ink technology. Ecos™ is compliant with both ANSI/AAMI/ISO 11140-1:2014 and ANSI/AAMI/ISO 11140-5:2007.

Product Description

Ecos™ is a Bowie and Dick type test designed for the daily monitoring of pre-vacuum steam sterilizers. Ecos™ will detect air leaks, inadequate steam penetration, vacuum pump failures, low exposure temperatures, and wet steam. The test pack is placed in the most difficult to sterilization location and run in a sterilization cycle of 3.5 minutes at 134°C. If the sterilizer is properly functioning, the steam will full penetrate the pack and the test sheet will turn a uniform pink color. If a small amount of air is present, such that the temperature is 2°C lower than the set temperature after 2.5 minutes (71%) of the 3.5 minute exposure phase has been completed, then the air will localize in the test pack turning the sheet a non-uniform dark purple or blue color.

Color Change

Blue to Pink for complete cycles with no air leak and sufficient vacuum.

Purple or Blue area in the center of the pack in the presence of air.

Physical Characteristics

Dimensions: 4" by 3.25"

Quantity/Case: 30

Reorder Number: 26630400

Shelf-life: 30 months from the date of manufacture.

Storage Conditions

A relative humidity between 30% and 70%, and a temperature between 10°C and 30°C.

Standard Compliances and Classifications

ANSI/AAMI/ISO 11140-1:2014, Type 2

ANSI/AAMI/ISO 11140-5:2007