

## Eucomed Position Paper on Bar Coding for Medical Devices

Scope: Although other auto-ID technologies such as radio-frequency identification can be used today, this position paper reflects the position on Bar Coding only.

### **RECOMMENDATIONS:**

- Eucomed recommends that all parties involved in the manufacture of, and use of medical devices should implement bar code technology to improve patient safety and provide quality data whilst minimising supply chain costs.
- Eucomed recommends selecting one of the industry standard bar codes:
  - UCC/EAN
  - HIBC

These standards are approved by CEN and endorsed by AIM.

### **BACKGROUND TO RECOMMENDATIONS:**

**Applying bar codes to medical devices has a two-fold impact: it increases patient safety and makes the supply chain more efficient for everybody.**

- Using bar codes to identify products makes the whole supply chain more efficient, from manufacturing through to distribution and medical use in hospitals.
- Bar codes can form part of the data capture system, in conjunction with bar code scanners and computerized databases that enable health care professionals and relevant hospital personnel to verify whether the right device was used on the right patient and to track the device before, during and after medical intervention, thereby improving patient safety.
- They make the recording of the movement of products easier (for example, less labour intensive) and much more accurate. They have synergies with electronic trade for further efficiency. Together, bar code data capture and electronic sending of information make the tracing of products and product batches feasible.
- Manufacturing, as the first stage of the supply chain, is the most efficient point at which to apply bar codes. Any additional or later (re)labelling brings increased costs and potential inaccuracy that reduces the overall benefit.

**There are two bar codes already in substantial use for medical devices.**

- Bar codes have been applied to medical devices for decades. Two different standards, EAN and HIBC are in substantial use. Both give adequate functionality.
- Reading both bar codes in parallel poses no problem for modern bar code readers but may require some additional investment in in-house software.

**Reading both codes brings advantages to hospitals.**

- If hospitals can read and use both codes, they will have instant access to bar codes on a much larger number of products used and the supply chain will avoid the additional cost of re-labelling.
- Thus, it is recommended that hospitals and healthcare logistics organisations make arrangements for the handling of both codes.

**BAR CODE SELECTION:**

- Choosing which bar code to use involves many factors, such as functionality, customer preferences, use in related trades, on-site support for the manufacturer, and future developments.
- For the European manufacturer of medical devices a [decision tree](#) is appended to help in this choice by showing where product identifier conversions may be needed.

Note: Within a total hospital facility, other bar codes are used for specific technical applications.

**Technical questions on the subject should be addressed to the following organisations:**

AIM Europe: (International Association of Manufacturers and Suppliers of Automatic Data Capture Products and Services)

The Old Vicarage  
Haley Hill  
Halifax  
HX3 6DR  
England

Tel. 00 44 1422 368 368 Fax. 00 44 1422 355 604

EAN International: Rue Royale 145  
1000 Brussels  
Belgium

Tel. 00 32 2 227 10 24 Fax. 00 32 2 227 1021

EHIBCC: Jozef Israëlslaan 3  
2596 AM The Hague  
The Netherlands

Tel. 00 31 70 324 47 54 Fax. 00 31 70 324 25 22

**Eucomed**, the European Medical Technology Industry Association, represents directly and indirectly more than 3.500 business entities in Europe and beyond. Members include national trade and pan-European product associations, internationally active manufacturers of all types of medical technology products, smaller companies and start-ups in areas such as tissue engineering or new materials.

The **Eucomed** mission is to create and maintain a suitable framework enabling the manufacturers of medical technology and other relevant economic actors to operate, innovate and market in an open, predictable and competitive market place, with the ultimate objective of contributing towards ensuring clinicians and patients have equitable access to medical technology.

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**Appendix 1**  
**Decision Tree for Determination of Which Bar Code to Use**

