Embedded Systems for Telemedicine in the Netherlands

‘Practical market insights on your product’

The Netherlands is one of the frontrunners in telemedicine. The development of telemedicine and the broader use of Information and Communications Technology (ICT) in healthcare is supported by the Dutch national infrastructure AORTA and by international pilot projects. Thousands of Dutch companies use embedded systems in production processes. The share of embedded systems used in telemedicine is small compared to other industrial applications. Nevertheless telemedicine is seen as a high-potential segment and is expected to drive the demand for more complex embedded systems.

Product definition

In Telemedicine or e-Health the typical embedded systems used are: motherboards, single board computers and system on module. The product range includes microprocessors (HS-code 85421355), microcontrollers (HS-code 85421360), microcomputers (HS-code 85421366), digital signal processors (HS-code 8541500), peripheral systems (HS-code 85422161), network sub-systems (HS-code 85421200), interfaces (HS-code 85422970), memories and memory peripherals (HS-code 8542320), memories for other uses (HS-code 85421940) and other system solutions (HS-code 8542500). In most cases, the embedded software is an integral part of the embedded hardware and is sold as one product.

Embedded systems are used in many applications, including Telemedicine or e-Health. The typical functions of embedded systems in Telemedicine include storage of administrative and medical patient data, use of computers during consultations, the transfer of administrative patient data to reimbursing bodies, transfer of lab results from the laboratory, transfer of medical patient data to other carers and e-Prescribing. However, telemedicine is getting more complex every day. The new generation/evolving functions of embedded systems in telemedicine are real-time communication, adaptive scheduling, resource management, multitasking, and the transfer of data from sensor to destination.

The major suppliers of embedded systems in Europe and in the Netherlands are Advantech, Intel, Kontron, DATA MODUL, Micron Technology, Congatec, Emerson Networks among others. Software and service providers specifically for e-Health in the Netherlands are TOPIC Embedded Systems, Alphatron Medical Innovations B.V., Man & Machine Europe, and Purekeys among others.
**Product specifications**

**Quality:**
High product quality and compliance with international and European standards on safety, as well as national legislation and practices, are key for European companies. Product safety is essential, since in many cases people's lives depend on the system, in particular in the e-Health application.

In addition to ISO 9001, RoHS and REACH standards (see "Buyer requirements"), Dutch customers expect a high level of reliability in embedded systems. They require product testing to be conducted by the supplier; Automated Optical Inspections (AOI) and In-Circuit Tests (ICT) are the most common tests although more sophisticated testing methods are also used.

Although defect rates of 500 ppm might be acceptable for non-critical applications, defect rates of 50 ppm or less are expected for higher quality suppliers. As these requirements are influenced by different factors each supplier must negotiate the specific requirements with the customer.

Embedded systems are characterised by the interface, platform, peripherals, and other tools. Embedded systems may also vary in terms of system complexity. Complex embedded systems may include connectivity to a network, a touch screen, real time computing, etc. New generation telemedicine requires real time communication and adaptive scheduling.

Embedded systems are used in highly innovative environments/industries. The ability to offer a customised product design is a key driver in this product category. Customised solutions are required in telemedicine. Customisation may include integration or development of software for existing hardware assemblies, presenting cost benefits for DC exporters because of easier/no shipping.

**Labelling:**
Products marketed in the Netherlands must be labelled in accordance with EU requirements and must provide product information as listed below. The label information must also be electronically readable. Examples of suitable label technologies include:

- Bar Codes

Source: CBI Market Information Database  •  URL: [www.cbi.eu](http://www.cbi.eu)  •  Contact: marketintel@cbi.eu  •  [www.cbi.eu/disclaimer](http://www.cbi.eu/disclaimer)
• Data Matrices
• Radio Frequency ID

Embedded systems are typically labelled with the description of content, including the following types of information:
• type of product,
• model type,
• quantity,
• net and gross weight (in kilograms),
• supplier/manufacturer name
• supplier/manufacturer location,
• serial number,
• various environmental logos,
• country of origin based on assembly.

Packaging:
• Typically the buyer defines the preferred type of packaging
• Packaging must protect products from damage and protect consumers’ possible injuries by avoiding the use of prohibited chemicals or materials.
• Packaging for products marketed in the Netherlands, must meet certain EU requirements. Make sure that your packaging:
  o has minimal weight and volume;
  o has low levels of hazardous substances and materials in the packaging material;
  o is recyclable.
• Embedded systems are typically packaged in plastic bags and cardboard boxes.

Buyer Requirements

To assure durability and safety, products must comply with relevant EU regulations and standards. Compliance with 1) must requirements, 2) common requirements and 3) niche requirements, is a basic necessity for all exporters in the electronics and electrical engineering sector. Below you will find all standards that apply to embedded systems. Familiarise yourself with guidelines on the application of all must, common, and niche requirements.

Requirements you must meet

1. CE marking
• For intra-European trade, all embedded systems must be marked with the CE mark. This shows that the product was assessed before commercialisation and that it meets EU safety, health and environmental protection requirements. For embedded systems, the most important Directives on CE marking are:
  • Low voltage equipment (LVD 2006/95/EC),
  • Ecodesign for energy-related products (Directive 2009/125/EC), which are not standards but implementing measures,
  • RoHS (see below).
For software used in medical devices, the following Directive on CE marking is important:
• Medical devices Directive (93/42/EEC)
Considerations for action:

- Apply for CE marking for all your products, before approaching potential customers in the Netherlands.
- The European Commission page on CE marking is a useful starting point to find out how the legislation on CE marking is relevant to you; it illustrates the key steps you need to take in order to comply with and have your products CE marked.
- Check the information for relevant standards and guidelines on the application of LVD, EMC and Ecodesign in the Buyer Requirements section on CBI’s Market Intelligence platform.
- Familiarise yourself with standards that apply for embedded systems here (LVD) and here (EMC)
- Familiarise yourself with implementing measures on ecodesign here
- Read more about CE marking for low voltage equipment and electromagnetic compatibility in the EU Export Helpdesk
- If your target customer industry is medical devices, check the conformity of your products with the Directive here and at The European Commission page here. Apply for the CE marking for software that is used in medical devices.

2. Chemicals

- The use of certain chemicals is restricted by the EU and is regulated through several Directives and Regulations.

Considerations for action: Exporters of electronics and electronic components have to meet the requirements under both RoHS and REACH.

- Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS). The Directive sets maximum levels for lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE) in electronic equipment (0.01% by weight for cadmium and 0.1% for the other substances). The Directive covers all embedded systems, with the exception of the products mentioned in Annex III to the Directive. Since 2013, CE marking has been required in relation to RoHS compliance of final products. This includes technical documentation and a declaration of conformity.

Considerations for action:
- Make sure that you provide the EU buyer with all information required in relation to chemicals used in embedded systems. Fill out this information in the form required by your EU buyer, e.g., by providing information in Material Safety Data Sheets (MSDS) or software in which you declare the chemical content of your product (e.g. BOMcheck – a collective data system developed by a group of large electronics companies to collect chemical composition information from suppliers).
- Provide the EU buyer with technical documentation and a declaration of conformity for the products supplied.
- REACH Regulation. This legislation restricts the use of certain dangerous chemicals (as per Annex XVII of the Regulation) and sets requirements on indicating information about the chemicals used. Manufacturers are required to provide information on the properties of chemical substances used to their buyers.

Considerations for action: List all chemicals, including raw materials and additional materials, used in your production process. Check the candidate list of Substances of Very High Concern.

- Waste of Electrical and Electronic Equipment (WEEE). If you want to export embedded systems to the Netherlands, be aware that your EU producers are obliged to participate in product take-back schemes. This does not directly affect exporters from developing countries, but specific requirements on the design may be set in order to facilitate the reuse and recycling set out by WEEE.

Considerations for action: To have a better understanding of WEEE requirements, familiarise yourself with information published in the EU Export Helpdesk.
Common Buyer Requirements

- **Quality management systems (QMS).** If you plan to export to the Netherlands, all products must meet buyers’ quality demands. ISO 9001 and 14001 are designed to make sure that the manufactured and/or exported products to Europe meet needs of customers. Compliance with **VDE** (a European standard with several variations) is often also required by Dutch buyers.

**Considerations for action:**
- Apply for ISO 9001 as quickly as possible and plan for ISO 14001.
- Familiarise yourself with VDE requirements.
- Consider forming a Quality Assurance team within your company that will assure the high product quality required by EU buyers.

- **Corporate Social Responsibility (CSR).** Dutch buyers increasingly look for products that have been manufactured with due respect for human rights, labour conditions and the environment. Bigger EU companies even develop their own CSR policies and require suppliers to conform to these requirements. In particular, workers’ health and safety are sensitive topics in Europe, and buyers want to avoid reputation loss.

**Considerations for action:**
- Understand what CSR policies are required by your customers by checking websites of electronic companies in the Netherlands.
- An important initiative for the electronics sector is the **EICC Code of Conduct**. Most large electronics companies have implemented this code and require their suppliers to act in accordance with it.
- **SA 8000** is a certification standard for social conditions. Although this certification is not a requirement, the standard is publicly available, so you may want to be aware of the most important issues.
- Consider implementing **OHS - Occupational Health and Safety** - that deals with aspects related to labour conditions. These requirements are not mandatory, but they will definitely give you an advantage over other DC exporters.

Niche Buyer Requirements

Ecolabels

- There is a growing niche market for environmentally friendlier/greener electronics. Green electronic assemblies can be sold under ecolabels to a third party, such as the "**EU Ecolabel**".

**Considerations for action:** Familiarise yourself with the "**EU Ecolabel**" or other European ecolabels. See if your customers need to have your products labelled. Consider selling your components to the manufacturers of ecolabelled products.

Macro-Economic Statistics

The Netherlands is a small European country, but it has a strong economy. The Netherlands has demonstrated solid historic development (except for the economic slowdown in 2012 across most European countries) and positive growth forecasts.

The Netherlands is expected to have a Compound Annual Growth Rate (CAGR) of 4.5% in 2014-2018 and is forecast to see year-on-year growth of 4.8% in 2014, while Europe is set to grow 6.2% in 2014.
The Netherlands holds a 5% share of total GDP and 4% share of total manufacturing, respectively. The population of the EU was estimated at 506 million in 2013, and the Netherlands contributes 3% to the total EU population, this is approximately 17 million.

**Figure 2: Key 2013 macroeconomic indicators for the Netherlands, the EU and selected countries, in € billions (population in millions)**

**Source:** IMF and OECD 2014

**Trade Statistics**

**Production and consumption**

Despite the low production volume of embedded systems in the Netherlands compared to other EU countries, thousands of Dutch companies are using embedded systems in their production processes. Emerging applications such as telemedicine are expected to foster market growth and open up more opportunities for hi-tech hardware and software suppliers.

**Figure 3: Production of embedded systems in the Netherlands, value in € million**

**Source:** Eurostat Prodcom (June 2014)
• Production of embedded systems is not very strong (€ 25 million in 2012) in the Netherlands compared to other countries. There are around 80 Dutch companies that specialise in the development of embedded systems, while for another 150 companies embedded systems are an integral part of their business. (Source: Holland high Tech) These 250 companies can function as the 'door-openers' to many embedded system users across Europe. The Netherlands is exceptionally strong in innovation. The country was ranked 4th in the WIPO Global Innovation Index 2013. Key R&D spending areas are various industries, including hi-tech.

**Considerations for action:** The low production volume of embedded systems in the Netherlands opens up opportunities to DC exporters, as the demand for hi-tech embedded solutions is strong. Consider a go-to-market approach through an alliance with local developers of embedded systems in the Netherlands. Find out who are the leading market players through local directories or associations such as [Embedded Systems Innovation](#).

• Currently, the share of embedded systems used in telemedicine is small, but the importance of this application is growing. The telemedicine application requires more complex solutions, often with two processors in one interface. Telemedicine is seen as a segment with high potential, driving the demand for more complex embedded solutions.

**Considerations for action:** Depending on your product offering, initially target the companies that are active in telemedicine. Carry out research on the internet and find out what companies are supplying this emerging industry, and consider offering your products and/or services to them. Look for this information through specialised associations (for example, [Nictiz](#) or [NVEH](#)) in the Netherlands or international tradeshows (for example, [Medica](#)).

### Import and export

According to market experts, the ongoing trend of software and hardware separation and an increasing shift towards outsourcing the production of hardware will elevate the significance of the international trend. DC exporters will also benefit from the positioning of the Netherlands as a European trade hub.

**Figure 4: Imports of embedded systems to the Netherlands, value in € million**

![Graph of imports of embedded systems to the Netherlands from 2009 to 2013](#)

*Source: Eurostat (June 2014)*
The share of imports of embedded systems from DCs is 12% (2013), while nearly 70% of embedded systems are imported from other European countries. Imports from DCs recorded marginal growth of 2.5% CAGR in 2009-2013, while imports from Europe saw more significant growth over the last 5 years (34.3% CAGR). The experts foresee that the trend of separating software and hardware and an increasing shift towards outsourcing the production of hardware overseas will elevate the importance of DCs in the supply chain.

**Considerations for action:** Work on minimising the entry barriers and maximising your competitiveness. To achieve this, ensure that you have:

- a value proposition,
- a product that answers the European quality standards,
- knowledge of the local language and/or outstanding business English,
- good understanding of European business culture.

Besides China, the Philippines, Malaysia, Thailand, and India are some of the key importers of embedded systems. Imports from Thailand, India, and the Philippines saw the strongest growth in 2009-2013, probably benefiting from strong experience in embedded systems and the availability of skilled people in the countries.

**Considerations for action:** Regardless of geographical position, exporters with strong technical backgrounds and good reputations in the production of embedded systems have significant advantages. Work on continuous quality improvement, which is particularly critical in the telemedicine application.

Figure 5: Exports of embedded systems from the Netherlands, value in € million

Source: Eurostat (June 2014)

- The Netherlands is an important trade hub, but it has been losing the position due to the recent economic slowdown. It exports over 90% (of total exports) of embedded systems to the EU+EFTA. Exports of embedded systems to Belgium, Sweden, Poland and Estonia developed most significantly in 2009-2013, driven by a strong growth of production activities in the relevant application industries. However, total exports of embedded systems from the Netherlands declined by a CAGR 14.3% in 2009-2013.

**Considerations for action:** Through the cooperation with Dutch suppliers of embedded systems, you will be indirectly able to reach out to other significant European markets that are supplied through the trade hub.
**Trends**

The European telemedicine market is expected to be worth over € 5 billion per year by 2015. However, the market is not yet developing on a large scale and there are only a few good examples of solutions transfer across healthcare centres. The growing usage of telemedicine services, including the interaction between doctors and patients, is an opportunity both for patients and manufacturers in related industries. (Source: European Commission)

The Netherlands is one of the frontrunners in the use of Information and Communications Technology (ICT), including embedded systems. ICT in the following services is particularly strong:
- Storage of administrative and medical patient data,
- Use of a computer during consultation,
- Use of a Decision Support System,
- Transfer of lab results from the laboratory, and
- E-Prescribing.

**Figure 6: eHealth use in the Netherlands and in Europe**

Source: empirica, Pilot on eHealth Indicators, 2007  

The acceptance of eHealth in the Netherlands is very high, driven by the national eHealth strategy that is focused on improving the affordability, accessibility and quality of healthcare through an optimal usage of ICT. The Netherlands uses keystone technologies such as the Electronic Health Record (EHR) to promote broader use of ICT in healthcare. The Dutch national infrastructure AORTA has been introduced to support a better exchange of data between healthcare providers. AORTA contains an eID authentication system and allows the safe, controlled transfer of health data across the Netherlands through a central hub. The electronic exchange of information is strictly regulated, and AORTA hub guarantees privacy and encompasses a comprehensive access-rights management framework. (Source: epSOS)
Aside from the national efforts, large-scale pilots have also contributed to the growing acceptance of telemedicine in recent years and in to the introduction of EHR and other eHealth solutions.

**Considerations for action:**
- Pursue the opportunities in the telemedicine segment in the Netherlands – one of the frontrunners in eHealth Europe - through a value proposition to local manufacturers of telemedicine devices.
- Approach the local manufacturers of Telemedicine devices at international trade fairs (e.g., Medica) or other venues.
- Consider sharing your knowledge and take part in pilot projects. Check the buyers’ websites to see which projects they are currently working on. In addition, familiarise yourself with the current telemedicine projects here and consider offering your support, if the relevant experience and capacity are in place.

For more information on market trends, please refer to CBI Trendmapping for Electronics and Electrical Engineering.

**Market Channels and Segments**
- The importance of authorised distributors is growing in Europe. OEMs are increasingly shifting the multi-partner cooperation approach to a single-provider/EMS. An EMS supplier typically provides value-added services that include:
  - resolving complex logistics problems,
  - providing local support services,
  - sourcing hard-to-find components,
  - providing small volume procurement,
  - minimising costs and saving time for OEMs/ODMs.

**Considerations for action:**
As an alternative to the direct contact with manufacturers of telemedicine devices, consider supplying EMS providers in the Netherlands. Look for local EMS suppliers through local directories and international tradeshows such as Medica and EmbeddedWorld (look for lists of participants).

- Internet blogs are a new sales channel for embedded systems suppliers who want to attract high-end customers. Manufacturers use the blog to showcase their expertise by posting technical topics and discussing them. This enables direct interaction with a customer’s design team. This approach has proven successful in many markets.

**Considerations for action:** Consider specialised internet blogs in demonstrating your professional skills and experience. As an added benefit, use these intelligence centres in order to introduce your company and your ideas.

For more information on market channels and segments, please refer to CBI Channels and Segments for Electronics for Electronics and Electrical Engineering.

**Price**

Embedded systems have a wide price range - from €50 to €1300 in Europe, depending on the specifications and application. Suppliers that are present in several European countries have harmonised their prices; any differences in pricing may occur because of the different logistics, taxes and other local costs.
Be aware of different costs and value chain margins that add up to the product price. Production and administration costs of the manufacturer usually make up 47-54% of the end price (OEM volume price). Production and administration costs should include all raw material costs, development, labour, and other fixed and administration costs. To develop a unique selling proposition, DC exporters will have to understand their own costs, liabilities and responsibilities, and analyse product market price levels.

**Considerations for action:**
- Strive to keep overall production costs significantly lower than in the Netherlands, to compete with domestic manufacturers.
- Work on production process optimisation and delivery time reduction.
- Make the production process more efficient and flexible by introducing a modular production approach and using different technologies.
- Minimise the risk of damage during production and meet customer requirements in terms of product quality and delivery time.

**Field of Competition**
See CBI Market Competitiveness for Electronics and Electrical Engineering and CBI Buyers’ Black Box, as the market competitiveness of embedded systems in the Netherlands does not differ significantly from this general overview.

**Main Sources**
- epSOS – European Patients Smart Open Services, URL: [http://www.epsos.eu](http://www.epsos.eu)
• Embedded Systems innovation, URL: http://www.esi.nl/
• Holland High Tech, URL: www.hollandhightech.nl/
• Dutch Association of eHealth, URL: http://www.nveh.nl
• European Health Telematics Association, URL: http://www.ehtel.eu/

More information
CBI market information: Promising EU export markets.
International Trade Statistics - http://www.trademap.org - you have to register

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