Embedded Systems for Telemedicine in Germany

‘Practical market insights on your product’

Currently still in the development stage, telemedicine in Germany is seen as a segment with high potential, driving the demand for more complex embedded solutions. Driven by a large number of projects, the acceptance of telemedicine is growing, but the large scale growth of telemedicine will not happen in the short term. The international trade with embedded systems is expected to benefit from the trend of software and hardware separation and the currently increasing shift to outsourcing hardware production.

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 85421966), digital signal processors (HS-code 8541500), peripheral systems (HS-code 85422161), network subsystems (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 Germany are Advantech, Intel, Kontron, DATA MODUL, Micron Technology, Congatec, Emerson Networks among others. Software and service providers specifically for e-Health in Germany are CGM CompuGroup Medical Deutschland and its subsidiaries Albis, Medistar, Systema, Turbomed, Compumed, and Data Vital, as well as Medavis, Protec, Bayerische TelemedAllianz, Neat, Ascom, Deister Electronic.
Product specifications

Quality:
High product quality and compliance with international and European standards on safety, as well as national legislation and practices, are key to 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"), German 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 Germany must be labelled in accordance with EU requirements and must provide product information listed below.

The label information must also be electronically readable. Examples of suitable label technologies include:
- Bar Codes
- 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 from possible injuries by avoiding the use of prohibited chemicals or materials.
- Packaging for products marketed in Germany must meet certain EU requirements. Make sure that your packaging:
  - has minimal weight and volume;
  - has low levels of hazardous substances and materials in the packaging material;
  - 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 the 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 Germany.
- 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.
2. Chemicals

- 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 Germany, 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 Germany, 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 customer needs. Compliance with VDE (a European standard with several variations) is often also required by German buyers.

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

- **Corporate Social Responsibility (CSR).** German 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 the 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 Germany.
- 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 embedded systems can be sold under ecolabels to a third party, such as the "Blaue Engel" in Germany.

**Considerations for action:** Familiarise yourself with the ecolabel "Blaue Engel" or other European ecolabels. See if it is worth having your products labelled, or selling your components to manufacturers of ecolabelled products.

Macro-Economic Statistics

When cooperating with German companies, DC exporters can mitigate the financial risks in the investments via partnerships. Germany is one of the leading economies in Europe with strong historic development and growth forecasts above the European level.

Germany is expected to have a Compound Annual Growth Rate (CAGR) of 4.7% in 2014-2018 and is forecast to see year-on-year growth of 6.6% in 2014 outperforming Europe, which is set to grow 6.2% in 2014.
Germany is the largest market in Europe with a 21% share of total GDP and 30% share of total manufacturing, respectively.

The population of the EU was estimated at 506 million in 2013, and Germany contributes 16% to the total EU population (approximately 81 million).

**Trade Statistics**

**Production and consumption**

After a dip in the embedded systems market in 2012, the industry is expected to pick up on growth, driven by the recovering key application industries. Besides major industries, emerging applications such as telemedicine are also expected to foster market growth.

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

Source: Eurostat Prodcom (June 2014)

- Germany is the leading producer and consumer of embedded systems in Europe. The market accounts for nearly 30% of embedded systems.
manufactured Europe-wide and 20% of the European consumption of embedded systems. In 2008-2012, the production of embedded systems was growing at a Compound Annual Growth Rate (CAGR) of 103%, while consumption was growing at a slower pace (2.7% CAGR between 2009 and 2012). In 2012, Germany saw a dip in the market’s production and consumption of embedded systems, caused by the economic slowdown. With the recovery of the key embedded systems application industries (e.g. automotive), in-country production and consumption will pick up on the growing trend.

**Considerations for action:** Target Germany as the leading market for embedded systems for various industrial applications. Consider a go-to-market approach through an alliance with local manufacturers of embedded systems (software or hardware) in Germany. Find out who are the leading market players through local directories or associations such as ZVEI.

**Figure 4: Apparent Consumption of embedded systems from Germany, value in € million**

![Graph showing the apparent consumption of embedded systems from Germany, France, UK, and Europe from 2009 to 2012.](image)

*Apparent consumption (Production + Imports – Exports)*

*Source: Eurostat Prodcom (June 2014)*

- 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, start off by targeting companies that are active in telemedicine. Carry out internet research and find out what companies are supplying to this emerging industry and consider offering your products and/or services to them. Look for this information through specialised associations (for example, Spectaris) in Germany or tradeshows (for example, Medica).

**Import and export**

After less favourable market development in 2012 and 2013, the international trade with embedded systems is expected to benefit from the trend of software and hardware separation and the currently increasing shift towards outsourcing the production of hardware. However, in the long-term the expected shift to reshoring may have a marginally negative impact on the segment development.
The share of imports of embedded systems from DCs is 11% (2013), while nearly 70% of embedded systems are imported from other European countries to Germany. Imports from DCs saw stronger growth in 2009-2013 compared to imports from Europe, 15% CAGR and nearly 12% CAGR respectively. The trend of separating software and hardware and increasingly outsourcing the production of hardware overseas will elevate the importance of DCs in the supply chain even further. In 2012 and 2013, total imports of embedded systems were hit by a slowing demand in Germany and the weakening economy. In the long term, the re-shoring trend in embedded systems may cause a slowdown in international trade.

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, Malaysia, the Philippines, Ukraine, Thailand, Indonesia are the key importers of embedded systems. Imports from Morocco, Ukraine and Indonesia saw the strongest growth in imports of embedded systems in 2009-2013, most probably benefiting from strong experience in this product group and availability of skilled people, but also from the geographical situation and the proximity to Europe (in case of Ukraine and Morocco).

Considerations for action: DC exporters that are located close to Europe will probably have geographical advantages, however exporters with the technical background and good reputation in the production of embedded systems have more significant advantages. Thus, regardless of your geographical position, continuously work on quality improvement - this is particularly critical in the telemedicine application.
Germany exports about 73% (of total exports) of embedded systems to the EU+EFTA. Exports to EU+EFTA declined by CAGR 2.1 in 2009-2013, but Germany was able to record a 12% year-on-year growth in 2013. Exports of embedded systems to the Netherlands, Czech Republic, Denmark and France developed most during 2009-2013, mainly driven by a significant growth of production activities in relevant application industries such as automotive, medicine and other.

**Considerations for action:** Through the cooperation with German suppliers of embedded systems, you will indirectly be able to reach out to other significant European markets that are supplied by German manufacturers.

**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 the telemedicine service, including the interaction between doctors and patients, is an opportunity both for patients and manufacturers in related industries. (Source: European Commission)

In Germany, the use of Information and Communications Technology (ICT), including embedded systems, is above the European average:

- All healthcare practices are equipped with computers, and nearly 2/3 are equipped with internet access;
- The use of computers during consultations is above-average;
- Electronic Medical Data Storage is above-average;
- The use of ICT for decision support is above-average;
- The exchange of medical data is rare;
- The exchange of administrative data with reimbursing bodies is rare;
- The electronic transfer of laboratory results is slightly more frequent than in Europe.
The preliminary results of the project "Empowerment of citizens with chronic heart disease through lifelong learning and self-monitoring. The Baltic Heart Trial" indicate that about 20% of patients in Germany would like to use telemedicine, which is a good acceptance overall. In Norway, telemedicine acceptance is 100%, in Finland – 50%, in Sweden – 30%, while the average acceptance of European patients is 22%. The acceptance of telemedicine is expected to grow with increasing internet access. (Source: ICT for Health)

Source: empirica, Pilot on eHealth Indicators, 2007 (link)
There are some challenges in promoting telemedicine in Germany:

- **Regulatory**: the German code of conduct for doctors hinders remote treatment unless the doctor has seen the patient at least once in person.
- **Technical**: The quality of the internet connection in some areas is lagging.
- **Information**: Lack of knowledge of telemedicine advantages and possibilities.

Numerous European and German projects have been set up to further raise the acceptance of telemedicine and work on the limitation of other challenges in telemedicine solutions. There are 240 identified telemedicine projects in 100 cities and communities in Germany, suggesting that the acceptance of telemedicine is continuously growing. More information on telemedicine projects can be found [here](#).

**Considerations for action:**

- Pursue the opportunities within the growing acceptance of telemedicine in Germany through a value proposition to local manufacturers of telemedicine devices such as CGM CompuGroup Medical Deutschland, Medavis, Protec, Bayerische TelemedAllianz, Neat, and others.
- Approach the local manufacturers of Telemedicine devices at international trade-fairs (e.g., Medica) or other venues.
- Consider sharing your knowledge and taking part in pilot projects. Check buyers’ websites to find out 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. Germany has launched an EMS initiative supporting local EMS companies. 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 Germany. Look for local EMS suppliers in Germany through local directories, tradeshows such as Medica and EmbeddedWorld (look for lists of participants) or specialised associations (for example, ZVEI).

- 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. They provide a space within an intelligence centre to showcase your company, innovations and 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.

<table>
<thead>
<tr>
<th>Embedded Systems</th>
<th>OEM volume price range, €</th>
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<tbody>
<tr>
<td>Motherboards</td>
<td>50-150</td>
</tr>
<tr>
<td>Single board computer</td>
<td>75-900</td>
</tr>
<tr>
<td>System on module</td>
<td>250-1300</td>
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</tbody>
</table>

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 own costs, liabilities and responsibilities, and analyse product market price levels.

Considerations for action:
- Strive to keep overall production costs significantly lower than in Germany in order 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 Germany does not differ significantly from this general overview.

Main Sources

- Eurostat, URL: http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home
- Organisation for Economic Co-operation and Development (OECD), URL: http://www.oecd.org
- ZVEI (German association of electronic industry), URL: http://www.zvei.org
- German Association for Electrical, Electronic & Information Technologies VDE, URL: http://www.vde.com
- Medica - International Trade Fair for medicine, URL: http://www.medica.de/
- Embedded World – International Trade Fair for embedded solutions and services, URL: http://www.embedded-world.de/
- German Society for Telemedicine, URL: http://www.dgtelemed.de/
- ICT for Health, URL: http://www.ictforhealth.net/
- European Health Telematics Association, URL: http://www.ehtel.eu/

More information

CBI market information: Promising EU export markets.
Several queries are possible. For trade, choose ‘EU27 Trade Since 1995 By CN8’. Use the guide ‘Understanding Eurostat: Quick guide to easy comext’ (http://epp.eurostat.ec.europa.eu/newxtwweb/downloadobject.do?keepsessionkey=true&filenameOut=User_guide_EASY_Comext_EN_2_0_1.pdf&mimeType=application/pdf&objectId=2567&objectType=LOB&disposition=attachment) for instructions.
International Trade Statistics - http://www.trademap.org - you have to register

This survey was compiled for CBI by Global Intelligence Alliance in collaboration with CBI sector expert Günther Fandrich

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