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Kurt Hornschild (project director)*
Stephan Raab*
Jörg-Peter Weiss*

With papers by:

Markus Wilkens, VDI Technologiezentrum Düsseldorf**
Klaus-Dirk Henke, Technische Universität Berlin***

Research Assistants:

Jasmin John
Kristina Meier
Hella Steinke

Medical Technology in Germany – Opportunities and Risks through Technological Innovation Repercussions of and for the National Health System, as well as Potential Growth Markets Abroad

- Summary -

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* DIW Berlin, Department Innovation, Manufacturing, Industry. khornschild@diw.de; sraab@diw.de; jweiss@diw.de.

** wilkens@vdi.de.

*** khenke@finance.ww.tu-berlin.de.

Editorial Details

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DIW Berlin
German Institute for Economic Research
Königin-Luise-Str. 5
14195 Berlin
Phone +49 (30) 897 89-0
Fax +49 (30) 897 89-200
www.diw.de

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Preface

The study at hand focuses on the prospects of medical technology in Germany. In tackling this extremely extensive object of investigation, we have cooperated with Markus Wilkens, VDI Technologiezentrum Düsseldorf, and Klaus-Dirk Henke, Technical University Berlin. Their contributions are published in chapters 6 and 7 of the full edition of the final report, respectively. The results of the study were discussed with economic and financial policy experts before the final report was completed.

The associations of enterprises in the medical technology area „Bundesverband Medizintechnologie e. V. (BVMED)“, „Spectaris – Deutscher Industrieverband für optische, medizinische und mechatronische Technologie e. V.“, „Fachverband Elektromedizinische Technik im ZVEI“ and „Verband der Diagnostica Industrie e. V. (VDGH)“ supported us in the preparation and implementation of the survey targeting businesses in the area of medical devices in Germany.

Special thanks go to the experts who participated in the workshops or served as interview partners, the companies that answered the questionnaire, the medical technology organisations, and the contractor who supported our work throughout.

Dr. Kurt Hornschild

Project director

1 Objective of the Study

The central question of the analysis at hand is: „Which productions in the area of medical devices have a stake in the future at German location and what has to be done to improve Germany’s locational competitiveness for research and development (R&D) as well as high quality production in this field?“ The location is shaped by technological developments on the one hand and the development of national health systems on the other: The demand for health services and—derived from this—for clinical equipment and products is crucially influenced by state regulations. Moreover, the research considers the development of foreign trade with medical devices, with a focus on its distribution respective regions and products.

Regarding the future development of medical devices industry in Germany there are the following central challenges:

- Reforms in the national health systems.
- Increased competition through intensifying international trade, which on the one hand opens new markets, on the other hand—with new competitors emerging on the markets—forces traditional medical devices locations like Germany to newly stand their ground.
- The rapid advancement of new technologies such as microelectronics, information and communication technology, materials research, optical technologies, microcomputer-based systems, nanotechnology, or biotechnology within medical technology.

2 Classification and Data

Due to various statistical classifications a distinction has to be made between medical technology in a narrow sense and medical technology in a broader sense. The study follows the definition and classification of medical technology in the study of the BMBF consortium,¹ which uses the definition of medical products in the medical products law (Medizinproduktegesetz, MPG). Medical technology in the narrow sense includes clinical and orthopaedic

¹ Cf. Situation der Medizintechnik in Deutschland im internationalen Vergleich, study on behalf of the Federal Ministry for Education and Research (BMBF), carried out by a consortium under the leadership of Aachener Kompetenzzentrums Medizintechnik and Deutsche Gesellschaft für Biomedizinische Technik, Aachen – Frankfurt/Main, 2005.

URL: <http://gesundheitsforschung.bmbf.de/de/921.php>.

products (product class 33.10 of the European classification of products for the census of production). Medical devices in the broader sense furthermore include goods which are covered by the medical products law, but belong to another class of products. Examples are optical products, vehicle construction such as lifts for invalids, wheel chairs, dressing material and diagnostics, textiles, medical plastics and rubber products.

The quantitative statements of this study are based on data from national statistics offices as well as from Eurostat and the OECD regarding the production and foreign trade of medical devices, turnover, added value, employment and cost structures of enterprises in the field of medical engineering.

Germany as a location for enterprises can not be adequately judged by these official, aggregated data. Therefore, a survey targeting businesses in the area of medical devices in Germany was carried out by mail questionnaires. The objective of the survey was to receive information on how enterprises in the field assess their position on the market and with which strategies they intend to meet new challenges in their markets. Since the markets for products regarding medical technology and also the conditions for competition are very heterogeneous, the study differentiates between capital goods and consumer goods.

3 Procedure of the study

The study at hand tries to account for the competitiveness and perspectives of medical devices industry located in Germany using a special approach, in which market structures and enterprise behaviour can be seen as central explanatory parameters. A glance at the supply side of the market already shows that there is no such thing as the market for medical devices. Apart from some businesses belonging to big corporate groups, which partly dominate the market, the supply side of the medical devices market is characterised by small enterprises. Medical devices feature a broad range of products regarding medical diagnostics and therapy. On the demand side there are the end-consumers—patients who use medical products such as dressings, walking frames, wheel chairs, hearing devices, heart pacemakers etc.—as well as medical practices, hospitals and other medical institutions that apply medical devices partly as capital equipment and partly as consumer goods.

The approach taken here is reflected in the design of the analysis:

Departing from the present situation, the study starts with an analysis of the perspectives concerning the development of the *sector* (chapter 3 of the study) followed by the competitive position of *enterprises* (chapters 4-6), their expectations as well as their strategies. The enterprise-related analysis focuses on two main points. After describing the *conceptual design of the survey* by mail questionnaire (chapter 4), the question of the competitive position of German medical engineering enterprises is raised (chapter 5). The issue of *innovative behaviour and innovative potential* is considered in chapter 6 (Markus Wilkens, VDI Technologiezentrum, Düsseldorf). Chapter 7 analyses *Germany's national health policy* from the perspective of the location of the medical devices industry in Germany (Klaus-Dirk Henke, Technical University Berlin). Subsequently, the *analytical results* are reviewed in a summary (chapter 8). By means of *scenarios* (chapter 9), we present deliberations of what the medical devices market might look like in the more distant future. In the final chapter, the results of the analysis are summarized in the form of *economic policy recommendations*.

4 Results

Medical devices market

Worldwide, Germany comes in third regarding the production and volume of the market for medical devices. In 2004, Germany's outlet on production of medical technology in the broad sense amounted to € 15,1 billion. This included medical devices in the narrow sense of € 11,7 billion. The following table offers information about the scope and the dynamics of the three most important national markets for medical products.

Medical devices in the broader sense: Home market and production of medical products (2002)

	USA	Japan	Germany ¹	USA	Japan	Germany
	in Bill. Euro			Average annual change 1998-2002 in %		
Production	86,6	15,3	13,2	5,6	1,7	6,1
Import	17,9	6,3	7,3	15,3	5,6	10,6
Export	21,3	3,5	10,8	7,6	-1,2	12,4
Domestic market	83,2	18,1	9,7	6,8	3,6	3,3

¹ Excluding „Special equipment for hospitals and clinical practices“.

Sources: USCB, METI, Statistisches Bundesamt, calculations of DIW Berlin.

In the period from 1998 to 2002—for these years there is comparable information available—Germany outperformed the USA in growth of production and export. However, the market development was—similarly to Japan—distinctly weaker. Germany, as well as the USA, showed export surpluses amounting to about € 3,5 billions, while Japanese external trade displayed import surpluses.

Medical devices industry location

Medical devices industry in Germany has asserted itself well in the competition. The development of production within the field has been above the average of German manufacturing industry. The number of employees and the export quotas increased. Good market position and technological leading positions especially with visual systems like computertomographs, X-ray equipment for radiography and magnetic resonance devices, many small enterprises that, as specialists, have strong market positions with high quality products, and finally the decision of General Electric to build up capacities here, leads to a good attestation regarding the German location for medical devices industry, and are proof of the competitiveness in this sector.

Medical devices as technology sector

The medical devices industry belongs to the high technology sectors. In Germany, the sector spends approximately 8 % of turnover on research and development (R&D). This portion is more than double compared to the portion of the manufacturing industry as a whole.

Medical devices show six basic technological development trends. These trends can be associated with the following key technologies: Biotechnology/cell technologies, optical technologies/laser technology, microcomputer-based systems, electronics/microelectronics, information and telecommunication technologies, nanotechnology, mechatronics (robotics), materials science/bio-materials and production technologies.

Established key technologies such as information and communication technologies, electronics/microelectronics and production technologies are already increasingly used by companies investing in R&D in Germany. The application of „young“ key technologies such as biotechnology and cell technologies or nanotechnology plays a significant role with start-up enterprises.

Health policy in Germany

The reform legislation in health policy, especially the law on the modernization of the state health care, also impacts the field of medical devices. To name in this respect are the introduction of the DRG system of the in-patient medical supply, the new refund rules in the ambulatory health care (EBM 2000plus), the fixed amount rules in the area of medical aids and—last but not least—also the new codes of procedure of the Common Federal Board for the admission of medical innovations in the catalogue of benefits of the GKV, which newly also asks for evidence proofs of the highest category in innovations in the stationary sector.

The recent reforms (especially the introduction of the DRG systems by means of the diagnosis related groups law and the new possibilities for integral provisioning) belong to a superordinate context of the implementation of free market economy structures in the German health system. In the three competition areas integrated (market for health services, market for insurance contracts and market for provisioning contracts), decentralized new forms of cross-sector care can thus emerge.

The introduction of the DRG system in the stationary care is a severe change in the hospital system of the Federal Republic of Germany, which brings about substantial changes for the various parties entitled to claim. For the hospital system in general, there will be severe structural changes; municipal hospitals will close down or be taken over by other institutions in order to reduce excess capacities. For the individual hospital, there is a necessity for more specialization and a rising cost pressure because of the new transparency in cost and quality

introduced by the DRG system. The future will show if the introduction of the DRGs in the stationary sector turns out to be a hindrance for innovations in the medical products industry.

The DRG implementation could also be a first step towards a monistic hospital funding. However, the DRG would have to include lump sum compensation for amortisation, so that a hospital is able to decide on its own about the volume and form of its investments. A monistic hospital finance would bring about chances (closing the investment gap) as well as challenges (introduction of new forms of finance such as leasing and licence agreements) for the area of medical technology.

Perspectives of Germany as location for the medical device industry

Due to spending cuts and rationalization in public health systems in Germany and other European countries during the upcoming years there will only be a restrained demand for medical products on the domestic and the neighbouring markets.

On the whole, Germany offers good preconditions for medical devices at highest technological level. This is especially true for R&D and for the production of high quality products. Nevertheless, this study argues for a differentiated and altogether careful assessment of the perspectives of the sector in Germany.

For a long period the sector received important impulses from the domestic market. Such a stimulating function from the domestic market will be missing for the foreseeable future.

As to the future technological competitiveness, the companies should be alarmed by the unfavourable assessment of R&D conditions. In the survey, the companies in the categories consumer goods and capital goods consider their position regarding the costs for research and development, proximity to research institutions and medical clinics, and the reservoir of own patents as merely satisfactory. Only in terms of their supply of innovative products they assume to have a good position. The public support is generally criticised by the enterprises.

As the demand in the European neighbouring countries will likewise develop in a restrained way, medical engineering companies should make more efforts aiming at overseas markets and open up new business segments in order to expand their production. However, small businesses often neither have the necessary capacities for distribution and services, nor the required capital.

The „medical devices location Germany“ could get between two millstones.

- In the area of high quality medical devices the competition increases—especially from the USA. In the USA the high technological potential, the large market and—compared to Europe—a market that is growing faster and more open for innovations, offer advantages for medical devices businesses. Apart from that, there are also the technologically catching up economies in Asia.
- For productions in which the costs are the crucial factor for competition, the large number of low costs countries offer opportunities. Of these countries, countries in Eastern Europe—having entered or being on the brink of entering the European Union—as well as China are especially interesting locations.

5 Two scenarios

Two scenarios with a time horizon beyond the year 2020 are presented to assess the possible future of the markets for medical devices, and the role that medical devices industry plays in Germany.

Scenario 1, „*scenario status quo*“, assumes that the existing policy in the areas of health, economy and technology will be continued. This scenario appears more real, but it describes a lower development path for the medical technology in Germany. „Scenario 2“, named „*scenario of radical change*“, breaks new ground regarding the cooperation between politics and economics—with serious effects on the development of medical devices industry. Regarding the exploitation of the potentials of medical devices industry in Germany, this scenario is located at the upper limit of conceivable developments.

Scenario 1

In the policy fields of health, economics and technology, the paths already taken will be pursued.

Medical engineering follows the development pattern of most industries. Compared with the starting point, the production profile will subsequently be narrowed down further. Germany has its strengths in research-intensive medical devices areas, especially imaging methods like magnetic resonance imaging or computer tomography, acute medication, high quality hospital equipment, sophisticated implants and prostheses. The already high export ratios of domestic

manufacturing firms will increase further.

On the whole, however, Germany will not be able to compensate lost workplaces by the creation of new jobs. In this scenario medical technology is not a motor for employment and growth in Germany.

Scenario 2 „scenario of radical change“

This scenario is based on a paradigm shift in the national health policy.

In Germany, politics regards „health care“ as a key sector and strives to develop the economy into a location featuring a modern, technologically outstanding and efficient health care system. It faces the problem that the technological progress in medicine offers medical care that can hardly be financed in the familiar way. Politics accounts for this through a guaranteed primary health care, complemented by health care largely following the rules of the market. States formerly offering services turn into states now offering warrantees, which guarantee quality standards and basic health care services.

The thus triggered impulses are manifold and broadly outreach the medical devices industry in the narrow sense. All big medical devices enterprises focusing research are engaged in Germany in R&D and often in the production. The environment is open for innovation—supported by public support programmes—and induces new, innovative medical devices enterprises to enter the market. The competence of Germany as a location for high quality services in the health sector attracts businesses to invest in hospitals and medical practices here. Regarding the evolution of domestic demand, thus Germany ties up to the development of the past years.

6 Economic policy recommendations

A central prerequisite for a positive development in medical engineering is the deregulation of health service markets. We do not advocate a complete system change in national health care; however, fundamental changes must come about. Maintaining the status quo in health care sector leads into a dead-end street.

A policy aiming to turn Germany into a *premium location* for health care would be especially advantageous for the development of the sector. This would include the provision of efficient, technologically sophisticated health care systems for the broad population, as well as the pre-

condition that state-of-the-art technological knowledge in diagnoses and therapy is being applied. Under these circumstances, Germany would continue to be at the forefront in medical devices industry internationally.

For both scenarios measures in the following policy areas are recommended:

- Promotion of technological advancements
- Health system
- Start-up enterprises; innovative small and medium-sized enterprises

Further measures are connected with system revisions by opening of markets—scenario 2:

With the opening of the markets for health care and the inflow of additional private capital, structures will be developed that see a range of differentiated offers alongside equally differentiated demand. Medical devices companies in Germany would particularly benefit from this. With the inflow of additional private capital the medical devices sector in Germany would again find similarly good demand conditions as in the past. Together with the already existing technological potential this would be stimulate competitiveness and growth in the sector.

Besides a special promoting policy for medical devices the state has to guarantee the compliance with quality standards and competition, and it has to provide efficient health care provisioning for all. This includes in the first instance the elaboration of concepts for

- rules of competition for deregulated markets in the area of health services,
- a system that combines state guaranteed primary health care with private health care services
- arrangements for the transition period including the applied instruments, the time frame and the administrative responsibilities.

Out of this comes the postulation: Reforms of the health system should be conducted with regard to factors of macroeconomic efficiency, while taking economic and technological aspects into account.