Medical Devices in Sweden

Industrial structure, production and foreign trade 1985-2002

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Before I started this study, I couldn't understand why somebody hadn't already done it. Now I do.

Abstract

Medical Devices in Sweden:
Industrial structure, production and foreign trade 1985-2002

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This licentiate thesis uses descriptive, mainly official, Swedish statistics to analyse industrial structure, production and foreign trade in an industry that is traditionally difficult to describe in numbers, that of medical devices. For the purposes of the thesis, the Swedish Medical Device industry is defined as companies classified in the SE-SIC manufacturing codes 33101 (medical equipment and instruments, etc), 33102 (dental products) and 35430 (invalid vehicles). Also other branches contribute, notably *parts* of SIC 51460 (wholesale in medical equipment and pharmaceutical goods) and 73103 (medical research and development) although their medical device volume cannot be specified. Additional items have been identified in terms of specific product groups rather than as "belonging" to a specific SIC industrial code.

Taken together, this is considered to correspond reasonably well to the scope of the field as defined by the Global Medical Device Nomenclature (GMDN), a new European standard for classifying medical devices in a more generic way than do the European Medical Device Directives (or other pieces of legislation). No quantification according to GMDN can be made as yet, however, as that requires changing reporting habits in industry as well as in official statistical classification and nomenclature regimes.

With the manufacturing code SE-SIC 33101 as main object, the study for the first time presents data on the regional distribution, size classes of employment, company starting time and company dynamics, in the form of entries to and exits from the code, over a six-year period. The latter analysis includes a follow-up of the "exits", some firms reappearing in other parts of industry and others disappearing – surprisingly few among them being limited companies. Although this industry is comparatively mature, considerable mobility among the mid-sized companies is indicated for reasons of real changes or (to some degree) factors inherent in the industrial classification system. Some structural changes in companies in the ≥50 employees bracket are identified. It is noted that American actors, directly or indirectly, are increasingly involved with the medical device industry in Sweden, and that a number of technology-based companies that were started mostly in the early eighties have recently reached the 50+ employee level.

The analysis of identifiable production and international trade in medical devices spans a period of 17 years based on official statistics following the HS/CN nomenclatures. A database has been built, bottom-up, from the 8-digit CN level with production, exports and imports values for close to 100 items collected in 12 product groups, for presentation purposes grouped under three main headings. Compound annual growth rates for the latter are presented for three five-year periods 1985-2000, showing that Swedish production and exports have had an overall growth of 10 per cent p.a. This has kept Sweden ahead of the international overall growth of 6-7 per cent p.a. in recent years, products in the main group "Aids & Implants" growing more than 20 per cent p.a. Growth rates in the most recent five-year period are lower, however. Healthy net exports figures are presented, the figure for 2002 *nominally* representing 40 per cent of the production value in current as well as constant prices.

Production figures are given at industry (local unit) level as well as at product group level. The product-based figures identified for *Production* 2001 are estimated to SEK 13,3 billion, *Exports* to SEK 13,7 billion and *Imports* to SEK 9,7 billion. Figures for the *Apparent Domestic Market* are calculated for the corresponding entities. It is obvious, however, that the statistics do not capture the real production value as exports exceed production both at overall level and in major product groups, particularly those on a high systems technology level. The situation is not uncommon for a number of reasons; further, cases in the statistics methodology literature confirm that medical instrument-related codes are liable to this phenomenon. Corrections, including adjustments of both production and exports values, are possible but demanding already at *one* individual 4-digit HS/CN level. This, therefore, must be considered outside the scope of an academic study.

The basic tablework developed for this thesis will be made freely available to external parties for their own use provided the author, with contact details, is named as the source. (Processing for commercial purposes is not expected, however.) Any suggestions for improvements are welcomed.

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Table 1-1 Codes, terms, abbreviations, etc, used in this thesis

Industry Classification Code	English	Swedish	Author's comments
SE-SIC 92	Swedish Standard Industrial Classification of 1992	SNI 92, Svensk närings-grensindelning	
(SE-SIC 2002)	Somewhat modified version applied from 2003 on	Något modifierad version som används fr o m 2003	
SE-SIC 33101 as an activity	Manufacture of medical and surgical equipment and orthopaedic appliances except artificial teeth, dentures etc.	Tillverkning av medicinsk utrustning och instrument (även delar, installation, reparation och underhåll, ej termometrar)	Main object of chapter on structure; used throughout the thesis Names not symmetrical
SE-SIC 33101 as a branch	Industry for medical and surgical equipment	Industri för medicinsk utrustning och instrument	Names not symmetrical
SE-SIC 33102 as an activity	Manufacture of artificial teeth, dentures, dental plates etc.	Tillverkning av tandproteser (även delar och reparation, ej tandfyllningsmedel)	
SE-SIC 33102 as a branch	Dental laboratories	Tandteknikerlaboratorier	
SE-SIC 331, i.e., 3-digit level = 33101+ 33102	Manufacture of medical and surgical equipment and orthopaedic appliances	Industri för medicinsk, kirurgisk och ortopedisk utrustning	Both names confusing as they do not mention *dental*
SE-SIC 35430 (=3543 when 4-digit only) as an activity	Manufacture of invalid carriages	Tillverkning av invalid-fordon (med eller utan motor, även delar och tillbehör)	
SE-SIC 35430 as a branch	Invalid carriages industry	Invalidfordonsindustri	
SE-SIC 51460 as a branch and an activity	Wholesale of pharmaceutical goods	Partihandel med medicinsk utrustning och apoteksvaror	English name misses the medical device part that is present in Swedish
SE-SIC 73103 in SIC 92	Research and development on medical sciences	Medicinsk forskning och utveckling	Medical devices, medical technology & biomedical engineering not visible in name, even less so from 2002!
(SE-SIC 73103 in SIC 2002)	Research and development on medical *and pharmaceutical* sciences	Medicinsk *och farmaceutisk* forskning och utveckling	

Term	English	Swedish	Author's comments
AB	Limited company	aktiebolag	legal form of company
Basfakta (SCB) from Företagsstatistik	Basic figures on 2-5 digit level SE-SIC codes from SCB Structural Business Statistics		Accessible on the Internet via Sweden's Statistical Databases (SSD)
CAGR	Compound Annual Growth Rate	årlig real tillväxt	
CN (Engl) / KN (Swed)	Combined Nomenclature that builds on HS	Kombinerad nomenklatur som bygger på HS-systemet	For classification of industrial goods in foreign trade (4,6, 8-digit)
Company level in statistics	*institutional* unit of observation	"företagsekonomisk" redovisning av "AB Sverige"	Chapter 2, 4
ExPI	Exports Price Index	Importprisindex	See Chapter 4
Foreign Trade Statistics	Foreign Trade Statistics	Utrikeshandelsstatistik	See Chapter 4
GMDN	Global Medical Device Nomenclature Standard EN ISO 15225	Svensk Standard SS-EN ISO 15225	First ever standard for classification of products See Appendix 3
HB/KB	Partnerships	handels/kommanditbolag	legal form of company
HS	Harmonised Commodity Description and Coding System		For classification of industrial goods in foreign trade (4,6,7-digit)
ImPI	Imports Price Index	Exportprisindex	See Chapter 4

Term	English	Swedish	Author's comments
ISIC (UN)	International Standard Industrial Classification of All Economic Activities	Av FN institutionaliserad nomenklatur som dels kan kopplas till EUs, dels till den nya nordamer. NAICS	See Chapter 4
IVP	Statistics on Production of commodities and industrial services, IVP	Industrins varuproduktion (SCB)	See Chapter 4
Local unit (or *Activity*) level in statistics	*functional* unit of observation	"nationalekonomisk" redovisning av "AB Sverige"	Chapter 2, 4
NACE (EU)	Nomenclature Géneral des Activités Economiques dans les Communautés Européennes	Europeisk nomenklatur för näringsgrensindelning som är anpassad till internationell genom FN, jfr nedan	See Chapter 4
P1	Denotes main activity in a company or local unit from a classification point of view	Den huvudaktivitet som bestämmer företagets (el arbetsställets) branschkod	Chapter 2
P2, P3 or P2-3	Denotes any secondary activities (see above)	Ev andra aktiviteter som företaget/arbetstället bedrive	Chapter 2 (& 4)
PPI	Production Price Index	Produktionsprisindex	See Chapter 4
Production value (in Structural Business Statistics)	Note difference between production value and (net) turnover	OBS skillnaden mellan produktionsvärde och omsättning m fl mått	See Definitions in Chapter 4
SCB	Statistics Sweden	Statistiska Centralbyrån	
SPsh	Sole proprietorship	Enskild firma (fysisk person	legal form of company
SSD	Sweden's Statistical Databases	Sveriges statistiska databaser	Homepage www.scb.databaser /makro/start.asp
Structural Business Statistics	Structural Business Statistics	Företagsstatistik (SCB)	"Corporate accounts for the domestic economy" See Chapter 4
Value Added (at different levels)	Contribution to GDP from an industry (+ analoguous at company/branch level)		See Definitions in Chapter 4

1 Introduction

1.1 Background: What's in a name?[1]

1.1.1 On "Medical Technology"

The term "Medical technology" has several connotations in English. The same is true in Swedish, where the most frequent term "*medicinsk teknik*" has several more or less distinct meanings. Regardless of language it could mean:

1. a field of knowledge, one of societal importance
2. an academic subject, including research and education
3. an entrepreneurial activity at the interface of research and industry
4. an industrial manufacturing activity
5. a collective term for various products embodying medical technology, *and*
6. a collective term for products used in a medical/healthcare setting[2]
7. a healthcare/hospital activity at the service of other healthcare professionals as well as a speciality on its own merits.

If one adds the somewhat more generalised term, "Healthcare technology", which today is more common in international English than its literal translation is in Swedish (*sjukvårdsteknik*), the situation often gets even more confusing. Even so, there are yet other, partially overlapping terms for the area as such. Since they are based on very diverse sets of knowledge and combinations thereof – including frontline bioscience as well as advanced engineering and production methods that are *not* rooted in "research" – also the industrial products related to medical technology are subject to this tendency of multiplicity and overlapping. Taken together, this makes it difficult to build an overview of the area in order to describe its industrial structure and types of products, and to determine its value to society in creating jobs and economic value.

These features were documented already in 1988 in a study made by the Royal Swedish Academy of Engineering Sciences (IVA), the "Definitions" chapter of which occupied several pages. Its topic was the interaction between industry, healthcare and society in the field of medical devices, with the present author as main contributor (IVA 1988[3]). Being the first of its kind in Sweden to present a reasonably comprehensive picture of the field, it analysed, partly in international comparison, aspects of the healthcare sector as a cooperation partner, user and buyer, forces affecting innovation and product and industrial development, supporting structures

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[1] "What's in a name? that which we call a rose / By any other name would smell as sweet"
Shakespeare, Romeo and Juliet, 1595
"Vad gör väl namnet? Det som ros vi kalla / med annat namn dock lika ljuvligt doftar"
Swedish translation 1850 by *CA Hagberg.*
Although not in the international literature, there is in Swedish also the saying, "A dear child has many names"

[2] not including administrative and "hotel" functions

[3] The study is in Swedish, but its chapter on Definitions is provided in Appendix 3 and a translation of its Introduction in Appendix 4 for reference

in the public sector, etc. It also made a first attempt to quantify the role of the medical technology industry in the Swedish economy. No follow-up has been made since.

In fact there is a general lack of data on current economic aspects of the field, despite the fact that a successful industry interacts with, underpins and contributes to the activities of the other stakeholders in medical technology. This situation is similar in many other countries, in large part due to the fragmented nature of the field as expressed in highly different core technologies (and competencies in a wider sense) as well as types of products. With all due respect to innovators and entrepreneurs, there is also a relative lack of *strong* actors pioneering the field in the *domestic, industrial* (and industrial policy) landscape, even though they might be wellknown internationally and successful exporters. Further there may exist a perception that medical technology is too "small" to merit attention from general policymakers or industrial leaders. Thus few people know that medical technology in an overall sense is estimated to represent a global market of some USD 180-200 billion, that is, almost half of the pharmaceutical industry (2000). Yet medical technology has often been "obscured", as an industrial undertaking mostly by pharmaceuticals and as a research and entrepreneurial activity, by biotechnology.

However, during the last few years in several countries there has been a movement to focus on medical technology, emphasising its importance to society not only from an intellectual or health policy but also from an industrial and economic point of view (Foote 1992, DOH-ABHI 1997, SNITEM 1999, HIMA 2000, BVMed 2000). Thus studies have been presented in the United States, the United Kingdom, France and Germany that analyse the field from several perspectives, quantifying its role to their national economies in different ways, all of them concentrating on medical technology in the form of *medical devices* although the British traditionally seem to prefer the term, "medical equipment". The present study aims to fill on of the gaps in the Swedish setting, providing figures and facts on Swedish industry as a producer of medical devices, that is, on items 4, 5 and 6 in the list above.

1.1.2 On "Medical Devices" as products

The Academy study (IVA 1988) helped diffuse the new term "*medicinteknisk produkt*" to a somewhat wider audience. Literally meaning "medical technology product", this *de facto* translation of "medical device" before then was known only to those who coined it and to a select group of company and industry executives in Sweden. The occasion was the preparation of background material for Sweden to comply with the first of the European Union's *Medical Devices Directives*[4] that would come into force in 1990[5]. A corresponding effort took place in,

[4] The "chief engineer" of those regulatory preparations and the person who coined the term "medicinteknisk product" was *Göran Liedström*, then in charge of Medical Technology at the Swedish Board for Health and Social Welfare.

e.g. Germany and the United Kingdom, choosing the similar terms "medical product" and "*Medizinprodukt*" for official needs. France however chose "*dispositif medical*", the first word meaning precisely "device, appliance". In contrast to Sweden and France, the first two thus did not specifically note the "technical" aspect that is inherent in the word "device". On the other hand, the "device" concept may not be optimal for some types of products, a situation that the slightly wider Anglo-German terms may have been designed to avoid.

In honesty, the term "*medicinteknisk produkt*" has not been a great success in ordinary language in Sweden. Thus most people inside as well as outside the industry still say "medical equipment" or "medical instruments" or related, simply making their own picture of what it includes, or for that part, what the medical equipment *market* could include[6]. In this study, we will mostly use "medical device(s)" as a *general* term for the products of the medical technology industry[7]. This is for three reasons:

- ⊗ the main focus of the study is the production of medical technology expressed as physical goods, bottom-up so to speak, and on the structure of the industry that produces them
- ⊗ the term is well understood in "international English" (even though domestic language habits will continue to vary), while because of the EU directives it also has somewhat of a "uniting" role, creating some coherence to a fragmented industry at the European level
- ⊗ the term was first coined in, and is often used in industrial as well as official circles in the world's by far largest actor in the field, the United States.

The identity of medical devices as a "field" for certain has been shaped by legislation also in the United States, only that they started 20 years earlier. Thus although the term existed before that, it was the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act that were the first to establish a risk-based classification for all medical devices and to provide a set of general controls for all medical devices. A further boost in making the term medical device more widely disseminated – while promoting medical technology as an important area of knowledge as well as of industrial activity - was the publication in 1984 of "Federal Policies and the Medial Devices Industry" (OTA 1984). It was published by the (later dissolved) Office of Technology Assessment of the US Congress, referred to in (IVA 1988); see also (Foote 1992) for an extensive background.

Although Sweden had not yet discovered it would become a member of the EU, the Directive (and its two later sister directives) by design would cover the entire European Economic Area, including non-EU members as well.

[5] European Directives No. 90/385 on Active Implantable Medical Devices of 1990 (AIMD), later No. 93/42 on Medical Devices of 1993 (MDD) and No. 98/79 In-vitro Diagnostic Medical Device Directive of 1998 (IVDD) All three are found at http://europa.eu.int/comm/enterprise/medical_devices/. The Swedish laws corresponding to the two first directives are Lagen om medicintekniska produkter 1993:584 and 1994:860, respectively.

[6] In a presentation on the "World Market" in "Medical Technology" in 1995, the executive director of Siemens-Elema AB, the largest MT company in Sweden, did not include pacemakers. Siemens then had recently divested their cardiac pacing activities, originally a Swedish jewel in their crown. The example shows the importance of asking "*whose* market is it – the world's or the company's?"

[7] However the following analysis, for obvious reasons, also must refer to official names of the various industries and product nomenclatures (from *calare*, *to call out*; thus "nomenclature" means "to call by name").

Below one may note the relative similarity between the "portal paragraphs" quoted from the respective pieces of legislation and that of the US cited first:

Figure 1-1 Definitions of "Medical Device" in the US and EU regulatory frameworks

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmaco poeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

(http://www.fda.gov/cdrh/devadvice/312.html - link_2)

"(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;"

(http://europa.eu.int/comm/enterprise/medical_devices/communitywidelegalframework.htm).

The last part of both definitions is important: It is the expression "… which is/does *not* …" (author's italics) that defines the border between the regulation of medical devices from that of other medical products. Thus, simplistically speaking, if a product *does* work through chemical or pharmacological or metabolic action, then it should be subject to other regulation – normally pharmaceutical[8], even though the product might have partial character of a device.

As is easily seen, these examples of regulatory texts meet high demands for lack of specificity as to what the concrete products really could be. In fact the same situation prevailed also in the United States some ten years ago, when (Foote 1992), a well-known academic and policy analyst in the field in a major study on public policy and medical device innovation wrote, "The products of the medical device industry are probably more familiar to readers than the term *medical device* might convey". Thus many of the bodies dealing with medical devices from a promotion perspective – such as industry associations that exist on domestic or European level – but also bodies conducting practical work associated with the regulatory framework – tend to "define" by *examples*. These often drastically illustrate the wide spectrum that medical devices

[8] A new EU directive covering products based on human tissue, cells, etc is presently in the making; and combinatory regimes exist both in the US and the EU

represent, ranging from simple bandages, dentures and corrective eyeglasses to advanced implants, infusion systems, operating theatres, functional sensory aids, etc, all the way up to highly sophisticated imaging and radiation treatment equipment.

With the increasing complexity and multitude of the products, and in view of safety aspects as well as in order to facilitate procurement in hospitals etc, there is a need to characterise and systematize medical devices more operationally than the above "definitions" do. To allude to the heading of this chapter on *what's in a name*, not only Shakespeare but also Linnaeus was a lover of roses. Referring to Isadorus of Sevilla, Linnaeus said "*Nomina si nescis, perit et cognitio rerum*"[9], which in a very informal translation would read something like "If you don't know their name, your knowledge of things will be lost".

Thus there exists since 2001 a standard, the *Global Medical Device Nomenclature* (GMDN), which on a generic basis will classify some 7000 types of medical devices into 12 major product groups (See Appendix 3 for a short presentation of the 12 groups). The explicit intention of those involved is to develop this list, with its associated protocols, into a strong but "living" framework for all those who work in the field, whether on the manufacturing or healthcare or inspection side of the medical device actors' network. Although the standard has a European number, the ambition is for GMDN to be adhered to by US actors as well, since the generic system is developed together with, and to a good extent based on, an earlier nomenclature from ECRI. Formerly called the Emergency Care Research Institute, this is an independent non-profit health services research agency focusing on healthcare technology, healthcare risk and quality management. Based in the US, it has offices in the UK and Asia.

Table 1-1 The Global Medical Device Nomenclature (GMDN) Product Groups

Code 01 Term: Active Implantable Devices
Code 02 Term: Anaesthetic and Respiratory Devices
Code 03 Term: Dental Devices
Code 04 Term: Electro mechanical medical devices
Code 05 Term: Hospital hardware
Code 06 Term: In vitro diagnostic devices
Code 07 Term: Nonactive implantable devices
Code 08 Term: Opthalmic and optical devices
Code 09 Term: Reusable instruments
Code 10 Term: Single use devices
Code 11 Term: Technical aids for disabled persons
Code 12 Term: Diagnostic and therapeutic radiation devices

Source: http://www.gmdn.org/GMDN_user_guide.pdf (per 2003-03-17)

[9] *C. von Linné,* Critica botanica 1, 1737, quoted in *Pelle Holms Bevingade ord, 15th revised edition 1989*

1.1.3 On the Medical Technology/Device Industry

Relevant parts of industrial *classification* principles for statistical purposes will be treated in Chapter 2 on industrial structure and Chapter 3 on methodology. However a brief overview is in order to somewhat indicate the "nature" of companies in medical technology and devices, or perhaps we should say "natures". As a more detailed look at the structural analysis would reveal to an observer with some knowledge of the field, the categories of companies involved with medical devices look very different, one is tempted to say *extremely* different. To a considerable extent they all work with their own sets of knowledge, generic and specific technologies, production methods, etc. The ways of interaction with users/buyers/customers differ, depending on the medical and other professions involved in using, prescribing and recommending medical devices, those formulating procurement regimes and the like.

Further the companies, or sub-industries, work under very differing conditions of *competition* domestically and internationally, and in their degree of dependence on *research*. The latter here must not be confused with *technology* or *engineering* in a fundamentally generic sens*e*, which is very important to *almost all* companies in medical devices. This is partly inherent because medical devices frequently are products of *systems technology* (with or without research), which means that renewal comes in small parcels, developing over partially very long time periods. The role of technology and systems is further underscored by the strict regulatory regimes for medical devices, as expressed in particular in the United States, but also through the EU directives, forcing manufacturers e.g. to *document* their manufacturing processes and raw materials extremely well.

Let us thus look briefly at some different categories of medical device companies. The list is not a "scientific" product but intended to filter out some topical examples. The size varies greatly between countries, of course, but in general the size indications here – from "XXL" to "XXS", so to speak – generally hold true even though the absolute unit size varies considerably.

1. Very large companies, traditionally based in electrical engineering and electronics, producing heavy, big-ticket, complex systems, mainly but not exclusively in imaging and other physics-based diagnostic technologies – examples include General Electric (US), Siemens (DE), Philips (NL), Toshiba (JP), Thomson (FR). These incorporate considerable R&D activities, not least in information technology

2. Large to very large, multi-product device companies, often also including consumer goods, an example being Johnson & Johnson (the largest publicly traded U S company active in medical devices). R&D shares high in *niche* segments, lower in other, more mature segments of singe-use products, etc

3. Medium to large firms specialising in one or a few large product segments relating to specific medical needs - orthopaedics, renal, dental products, etc. R&D intensity varies

from medium in some mature segments as dialysis products or standard implants, etc – examples are Gambro AB and Nobel Biocare AB, and Instrumentarium OY – to high or very high very high in e.g. wound management with Smith & Nephew or Swedish Mölnlycke Health Care[10], etc, and cardiovascular implants made by, e.g. Boston Scientific and others

4. Medium to large companies manufacturing high volume single-use products from different materials (synthetic polymers, cellulose fibres, etc). All these, also some smaller ones, to a large extent depend on advanced production technologies, a major example being Swedish SCA AB with its incontinence products. Although the products in this category may not seem "high-tech", devices in these categories often build on advanced generic research components (coatings, absorbents, etc)

5. Small to very small, highly research-intensive entrepreneurships specialising in a certain core technology, e.g. microsystems for biomedical measurements, advanced biomaterials, small systems for bioimaging, etc, some Swedish examples being Radi Medical AB (cardiovascular), Entific AB (implanted hearing aids), Mamea AB (mammography)

6. Small to very small firms in specific areas as surgical instruments, rehabilitation aids, etc produced in e.g. mechanical workshops and other materials-processing settings, sometimes operating outside the manufacturing industry proper. These very seldom are visible (or even detectable) in contexts associating even to the "D" in "R&D". In fact, however, they make up a highly competent type of firms, managing in their own ways to survive and make a living[11]

7. *Distributors* of medical devices come in all sizes, the large ones often dealing also with pharmaceutical goods. Sweden's major firms in this segment are Tamro AB (Finnish) and Kronans Droghandel AB. Wholesaling firms may include some manufacturing of their own. Distributors play an important role in many high-volume products for healthcare including dental care. These will not be dealt with here, however.

Other types of companies who are manufacturers or suppliers of products to the healthcare sector exist, of course; we have here only indicated some major categories that make up the bulk of *medical device* companies in relative symmetry with the concept as treated in Chapter 2.

1.2 Global glimpses of medical devices

Below we reproduce a table (Table 1-3) from a recently issue report on the functioning of the European Medical Device Directive (EU-MDEG 2002). The note below the table deserves noting, as it says one should add "another" 17 per cent of the World total to capture also the *in-vitro* diagnostics (IVD) devices market, adding the world market up to some USD 180 billion. This is because the original source of the European figures, the European Medical Technology Industry Association (EUCOMED) does not cover IVDs. The latter products are instead

[10] Before 1998, SCA owned the "old" Mölnlycke AB, the latter producing incontinence as well as other fibre-based medical products as hospital gowns, etc. The latter part was divested by SCA and merged with a Finnish firm by a consortium starting the "new" Mölnlycke Health Care AB

[11] Maybe these firms symbolise what might be called "*the Front Lines of 'LowTechnology'*" to borrow from the title of a 1996 paper by Staffan Laestadius of Industrial Economics, KTH (the paper not being studied as such)

represented by another organisation (European Diagnostics Manufacturers Association, EDMA)[12].

Table 1-2 Global regional distribution of the medical device market and associated metrics

Country	Market Size 2000 billion	% of World Market 2000	Health Expenditure % GDP	Medical Devices per capita	Growth Rate 2000
EU	41*	25.6%	5.7%*	66	5.5%
USA	60*	41.5%	13.9%*	125	7%
Japan	24.5*	15%	7.1%*	116	4%
Rest of World	34.5*	18%	-	-	15%
World	160*	100%	-	-	6%

Source EUCOMED and ADVAMED (formerly HIMA) 2000, World Bank 2000 World Development Indicators (Market size figures indicated exclude In-vitro Diagnostic devices (IVDs) which are up to 17% of the overall market value)

Source: EU-MDEG 2002

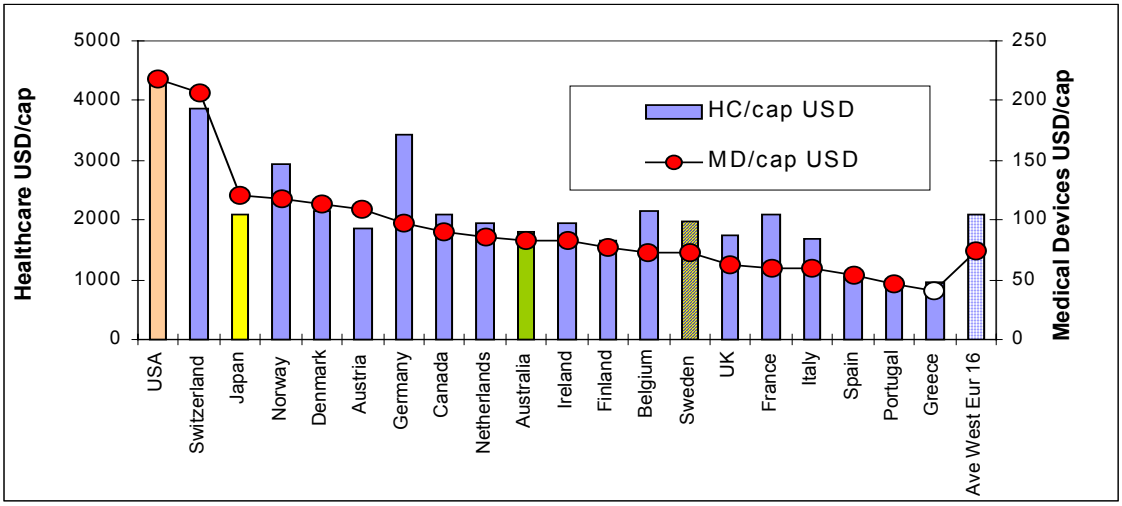
To qualify the figures somewhat, a diagram is shown below (Figure 2), giving healthcare expenditure as well as medical device expenditure on a *per capita basis* for several countries. It must be noted that all these figures represent a special form of "medical measurement technology", since the present study only too well has confirmed the inherent difficulties in characterising this field in numbers[13]. Having said this, however, the gross figures given above appear comparatively often. That is not the case with the diagram below that has been compiled by the author from the first pages of a number of so-called market intelligence reports taken from the Internet (one source for every country, the actual contents of the reports only being for paying customers). In this diagram, if the dots representing Medical device expenditure per capita are "lower" than the corresponding bars for Healthcare expenditure per capita, then that implies that the country in question invests relatively less in medical devices as a proportion of healthcare costs than do countries whose measures are aligned. This, as we can see, seems to be the case with Sweden as well as several other countries in Europe. The German bar for healthcare per capita however is curious; in contrast to almost all the other countries this figure is quite out of line with the otherwise often quoted OECD Health Data figures[14].

[12] In analogy, there are separate organisations in Sweden for medical devices in general and IVDs, respectively, the first and larger being the Swedish Association of Suppliers of Medical Devices (SLF) and SINDIF. The American industry association supplying the US figures in Table 3, AdvaMed, on the other hand represents manufacturers of IVDs as well as all other groups of medical devices as implied in the GMDN.

[13] In fact, the basic report (EUCOMED 2000) underlying the European figures given above, shows several inconsistencies noted by this author and communicated to SLF as its Swedish member organisation. However, most people involved recognise that precision is impossible

[14] Sweden is somewhat out of line also in that as late as *per August 2002*, there were no figures more recent than *1998* for Sweden's Healthcare/GDP in the OECD figures, whereas most other countries had figures for at least 2000.

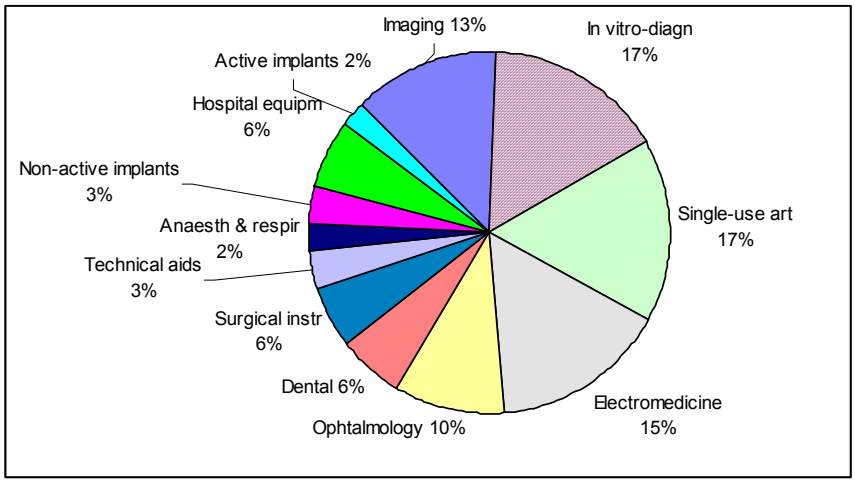
Figure 1-2 Per capita Expenditure of Healthcare vs. Medical Devices, mainly years 2000-2001



Source: ESPICOM, own calculations

To give a hint as to the proportions of different types of medical devices on a world market basis, we will have to use old figures, as there are very few even "semi-accessible" sources available that try to estimate these shares at one and the same occasion (or place). Thus this concluding diagram builds upon tables in a commissioned study, which was made for medical device officials in the EU by a Belgian consulting firm (LEK Partnership) and published in 1996. The figures may be older, however, some dating from as far back as 1993 (at which time the world market was estimated at some ECU 80 billion in that report, and according to US sources, some USD 95 billion. Thus with the above estimates of some USD 180-200 billion today, it would imply a doubling of the global medical device market in ten years (in current prices). The division into 12 pieces of the medical device "cake" below is closely related to the GMDN categories referred to (Appendix 3), knowingly the first time they were published in a "semi-public" connection.

Figure 1-3 Distribution of world market by product group from a 1996 source



Source: EU-LEK 1996, own calculations
Note: See text regarding age of figures!

1.3 Research questions

In the period that has passed since the publication of (IVA 1988), no actor has made an effort to update the information on the production of medical devices in Sweden and therewith associated foreign trade, etc. Over the years since, medical technology and the young medical device industry have attracted considerable interest from various actors in Sweden. This was fuelled partly by the surge in companies introduced on the stock market (both older and start-ups) that occurred in the mid-nineties. Another reason is that the "high end" of medical technology is situated at the crossroads of exciting developments in several areas of science and technology, drawing upon advances in the life sciences as well as the physical sciences, engineering and information technology. In fact, medical (device) technology frequently has been seen as the first potential recipient or application area for a whole spectrum of new technologies. Not surprisingly, however, public, and public policy, interest mainly has focused on individual examples of new developments in medical technology, and on individual start-up companies – or entrepreneurs – rather than on the *industry* as such.

On the other hand, several representatives of the Swedish "medical technology network" have an interest in also monitoring industry and its development. For example there is a curiosity to see whether some of the early investments made by the former National Board for Technical Development (STU) and its successor NUTEK[15] in new medical technology and new companies from the mid-eighties and forward have borne fruit in economic terms. Officials representing Swedish trade circles both in Sweden and abroad[16] likewise have asked, are we doing well in exports? - which product areas are the most successful ones, etc. The Swedish Association of Suppliers of Medical Devices (SLF), in turn, wants to be able to present facts and figures on their industry, i.e. not only of their own members – but everybody realises that it is a difficult undertaking.

At the same time, there are actors who participate in defining the framework for the medical device industry in Sweden, who – with a somewhat pointed expression – seemingly rather seldom take an interest in the health of this industry– that is, healthcare policymakers[17]. However, in a recent report on healthcare as a driver for regional development from the two

[15] Following a reorganisation of the Swedish research system, the R&D-supporting role of NUTEK in 2001 has been transferred to the new VINNOVA, the Swedish Agency for Innovation Systems

[16] In fact, Swedish official representatives in Germany were referred to the author to get some data on the Swedish-German trade relations

[17] This expression, that the health authorities also to some extent are responsible for the health of their medical equipment suppliers, is borrowed from a UK government commission in a report from 1987 (cited in IVA 1988). See also next section on, e.g. the British Department of Health together with the UK medical devices association commissioning a very comprehensive survey on the British medical systems industry

cooperative organisations for employers in charge of healthcare and elderly care provision in Sweden, *Landstingsförbundet* and Svenska *Kommunförbundet* (LF-SK 2002), there is a discussion on opportunities for improved interaction with industry – on the local level, as it emerges. The main reason for referring to this report here, however, is that it clearly states that nobody knows the economic value of procurement in the Swedish healthcare sector. The statistics kept by *Landstingsförbundet* is very scant, the authors say, referring mostly to "supplies" like single-use articles, etc, and as for investments, medical equipment is co-documented with that of investments in ordinary computers, machines, etc. The authors also state, "…information on location of (industrial) production, regional distribution of value added, etc, are believed to be difficult to compile".

The indications presented all point to a need for more concrete data, spanning from regional structure of companies, via product areas to the size and distribution of exports and the contribution of the industry at large to the national economy. The following research questions have been formulated in response to the "white patches" that the author has observed through own contacts in the field from the Academy study (IVA 1988) and forward, taking part of discussions on related topics in the analysis of other industries, reading, etc:

1. W
   hat does the medical device industry *look* like in terms of structure? How many companies are there, where are they located, how many do the employ, how old are the firms, can one say anything about the dynamics as expressed in firm entry and exits? Are there any aggregate measures to illustrate the contribution of the "Swedish Medical Device Division" to the "mother company", "Sweden, Ltd"?

2. W
   hat do the relevant parts of Swedish industry *do*, in aggregate terms? Which medical device products groups are manufactured in Sweden, what economic values does this production represent? How does exports develop, what is being exported and to what receiving countries, can we finance our imports from own exports? Attempting to quantify the overall production, exports and imports – what can we tell about the size of the apparent domestic market, i.e. that will give a proxy measure of aggregate supply to the healthcare sector? This is a question that no national healthcare providers, even in the best of worlds, really can answer for themselves.

These questions are being treated in Chapters 2 and 3, one for each cluster of questions. The structural analysis spans a period of six years in "real-time". The production and foreign trade

analysis covers the time from 1985 onwards, i.e. in effect from the base year for the quantitative parts of the (IVA 1988) study up to the present, giving preliminary trade data even for 2002. It should be noted that the second question by necessity has generated a large amount of data at *detailed* product level that may not prove very interesting to the *general* reader. In order not to drown her or him in even more data and diagrams than Chapter 2 and 3 will present, further data are provided in an Appendix (2 A-C) to Chapter 3. Also the full data set on production, exports and imports of goods will be made available electronically for those interested.

1.4 Earlier work

The year 1985 was chosen as the point of departure for the present study because this was in effect the base year for the quantitative part of the first Swedish report ever to present a reasonably comprehensive study of the field of medical devices proper – and the interaction between this industry and healthcare and society at large – published by the Royal Swedish Academy of Engineering Sciences (IVA, 1988). The present author was main author at that time, although an independent expert was commissioned to do the statistics sub-project. The report includes an extensive review of the mostly "grey" literature on medical devices in healthcare, industry and society that had been identified until the late eighties in Sweden and major industrial countries.

On the international scene, the field and its industry have been subject to considerable attention and debate because of the importance of medical devices to society in helping ensure a high-quality and effective healthcare sector. Associated with that aspect is the close tie between medical devices and the regulatory framework. One of the rather few more widely disseminated *academic* works on this combination theme – devices, regulation *and* industry – is that of the device policy analyst Susan Bartlett Foote (Foote 1992)

This latter aspect has not been visible to the same extent in the Swedish setting. Despite being as important a factor in the production of healthcare, medical devices are much less noticed (publicly) and studied (by academics) in Sweden than are the area's "siblings" pharmaceuticals and biotechnology, and their respective industries, on the other. Several possible explanations may be identified, for example

- scientific discoveries expressed in cells, molecules and eventually pills are seen as more "thrilling" in addressing human needs than new instruments or materials, etc, which in order to become useful requires integration often at quite high systems levels

- unlike biotechnology, and to some extent pharmaceuticals, medical devices have no strong and/or publicly known opinion leaders or similar acting as "champions", whether in industry, healthcare or government
- The fact that biotechnology is an important *core science* in the development of new medical technologies often obscures the fact that the final *products* are medical devices, produced by companies that have to adhere to regulatory framework for medical devices whether in the United States or the European Union.

Yet as has been noted, the global size of the medical device industry is estimated to some USD 180-200 billion per year (AdvaMed 2000, EUMDEG 2002) was close to half that of the pharmaceutical industry (2000) – and thought to increase to some 260 billion by 2006 (EUCOMED 2000).

However, in line with policies stimulating innovation and industrial renewal there are some Swedish studies on, or including (parts of) the medical device industry, often of a qualitative nature with quantitative parts and almost entirely devoted to various aspects of medical devices and innovation and/or entrepreneurship. These include, e.g., two studies commissioned by NUTEK, the former Swedish National Agency for Industrial and Technical Development, by Jens Laage-Hellman - one on research-based entrepreneurship in medical devices (NUTEK 1993) and the other on the "biomedical industry" in Sweden (NUTEK 1998) The latter is built upon a survey to Swedish companies in pharmaceuticals and diagnostics, medical devices (in turn comprising equipment, supplies, rehabilitation aids), biotech supply and healthcare services. Both include highly interesting case studies, but quantitative data in the first one are limited to starting year, employment, and turnover and export share for 1993 in the 34 companies studied (turnover for 1988 and 1992). The second study reports data on employment and turnover (globally and in Sweden), ownership, etc for a total of some 100 companies in 1996, for part of them also illustrating changes since 1988. As will be commented in Chapter 3, some of the "case" companies in Laage-Hellman's analyses have now grown to the over the ≥50 employee size bracket in SE-33101, i.e. the main industry studied in this thesis.

In a recent doctoral thesis in industrial economics on dynamics and growth in the healthcare industry, Ann-Charlotte Fridh (Fridh 2002) devotes a chapter to an analysis of statistics of the Swedish healthcare industry structure at the macro level, based on official statistics from SCB. Under the title, "The size and statistical development of the healthcare industry in Sweden", this chapter presents structural data in the form of the number of firms, local establishments[18] and employment, respectively, in 25 industrial classification codes for 1993 and 2001 (for codes being cited here, see Table 1-1 on explanations and Chapter 4 on Methodology). The analysis

[18] The term "establishment" for "arbetsställe" is used in the economic literature and in OECD and North American statistics. In EU language it is called "local unit"

does not look inside the "black box" of the various codes to see what products or economic values the industries in question represent.

As to coverage of different industries, the author has chosen a very wide definition of the healthcare industry as comprising

> " i) the pharmaceutical industry, ii) the industry for medical instruments and laboratory equipment, iii) care - covering everything from dispensing chemists shops to hospital care, iv) research and development in medical science, v) education for health occupations, (vi) administration in the pharmaceutical and medical technology industry and vii) the business of insurance i.e. the social security offices. Thus we have identified seven different sectors that make up the whole health care industry, using the SNI codes from Statistics Sweden (SCB). /…/ The definition presented /…/ in fact, is even broader than that of Eliasson (2002). Research, education and administration in the health care industry are part of our definition. The insurance sector is probably overestimated, since it is hard to know how large a part of the sector that is related to health or health care."
> (Fridh 2002, p 37)

In a preceding paragraph, Fridh states that

> " Eliasson (2002), defines the health care industry as hospital care and medical treatment, pharmaceuticals, medical instruments (devices and other supplies), biotechnology as a technological support industry for pharmaceutical industry, laboratory equipment and health insurance. This definition is difficult to use for statistical analyses. One problem is that the statistics do not separate out the biotechnological industry."
> (Fridh (2002); the latter quote preceding the first quote above.)

In two other chapters, Fridh uses the industry data gathered at national level as a quantitative background for an econometric analysis one the one hand of changes occurring at the regional level in Uppsala with surroundings as a result of Pharmacia phasing out its activities there, and on the other, to study the effects of turnover of establishments on regional growth.

Three of the branches included in Fridh's study coincide with objects treated in different degrees of detail in the present study, viz. two of the manufacturing branches and one in services. These are SE-SIC 33101 Industry for Medical equipment and instruments, 33102 Dental laboratories, the third one being 73103, Research and development on medical sciences. The analysis does not include two further industries that in this author's opinion would deserve consideration in view of the statement cited above, that the industries chosen should "… make up *the whole* health care industry …" (this author's italics). The "missing" ones are both entirely associated to the healthcare sector, one in manufacturing (SIC 35430, Industry for invalid carriages) and one large in the service industry that represents a mixture of drugs, devices and other supplies for healthcare (51460, Wholesale in Medical equipment and pharmaceutical goods[19]).

[19] This author's translation, since SCB in the English version of SE-SIC 51460 for some reason only mentions "…pharmaceutical goods" despite the Swedish version explicitly naming starting with "*Medical equipment and…*"

Partly in the same vein as (parts of) Fridh's thesis, a PhD project in cultural and economic geography goes on in Lund, examining the geographical base for innovation and competitiveness with medical device-related branches of industry as his point of departure. The project is not yet finished yet, but in a pre-study (Jonsson, Persson and Silbersky 2000) use three medical device-related industries for a semi-quantitative analysis of innovativeness in a Swedish regional context. Ulf Silbersky here looks at the distribution of these industries in terms of numbers of companies and employment within the 70 administratively defined, so-called Labour market regions in Sweden based on SCB Business Register data on the one hand, and different measures of "innovativeness" (relating to new or improved products) collected from own company surveys on the other. This work includes one manufacturing and two service branches, namely SE-SIC92 33101 (Industry for medical equipment and instruments), 51460 (Wholesaling in pharmacy goods and medical equipment), and 73103 Medical research and development, respectively.

Before leaving recent Swedish studies that devote main attention to the medical device industry in an innovation perspective, two more PhD theses in industrial economics deserve mentioning, (Hidefjäll 1997) on "The Pace of Innovation", dealing with the development of the pacemaker industry in Sweden and internationally, and (Rickne 2000) on biomaterials-based entrepreneurship in Sweden and the United States. One might perhaps also note (Bonair 1990), who is the one author referred to here who comes from the healthcare sector. Her PhD thesis is written mainly in a sociological tradition, dealing with technological change and the diffusion of new technologies for haemodialysis. Although the thesis does not involve industrial aspects, its topic is the area on which Sweden's largest, today highly international medical technology company Gambro was founded close to 40 years ago.

The one Swedish work that is similar to the present study is a series of reports produced by NUTEK together with Statistics Sweden itself on the Electronics industry and IT-related service companies in Sweden, the first being (NUTEK R 1999:15 in Swedish, translated into English as NUTEK R 2000:4). Two later versions refer to the situation in 1999 and 2000 respectively (ITPS S2001:014 and ITPS S2003:003, both in Swedish only). The resemblance lies perhaps more in method than in contents, but for an important product group of the Swedish medical device industry, viz. medical electronics, the reports also give official statistical data on production, exports and imports. Taken together they do this for the reference years 1996-1999, breaking figures down on individual product groups that are directly comparable with part of the results presented below. A detail is that pacemakers have "disappeared[20]" in the NUTEK-SCB figures for1997, something that has not been corrected in later versions despite the figure

[20] The "disappearance" of pacemakers in the raw data for *1995* in the present study still holds, however

existing. As a result, the calculated relative share of medical electronics to all electronics is distorted for 1997. Regarding aggregate foreign trade (but not production) the NUTEK/ITPS reports also give data for (e.g.) medical electronics from as far back as *1975*. A valuable feature is that the share of medical electronics in production and export/import values compared to other branches of the electronics industry are given. In the latest report of the three, which looks a little different from the two preceding ones, also receiving countries for exports are documented.

As to *differences*, the NUTEK/ITPS reports of course are much more comprehensive, covering a large number of important industrial branches. Together these represent a very major share of Sweden's industry and exports at large, which dwarfs the medical electronics contribution of between 6 and 2 per cent on the production side from 1994 to 1999, the reduced share entirely depending on the extremely rapidly increasing denominator, i.e. totals, during that period. (After the decreases in the grand totals after the reference year 1999 due to the crisis in the telecom industry, and given the continued increase in the less sensitive market segment of medical electronics, the share of the latter will thus likely increase in reference years 2000 to 2002 – coming reports on the electronics and IT industry will have to be checked for that.) Further, in view of their very comprehensive scope, these reports deal not only with company but also company group structure; further they go much deeper into employment and education levels, etc, using official registers that have not at all been consulted for the present study. This also goes for research and development aspects, which would seem natural to address also here (see chapter on Methodology).

A completely new report on the Swedish biotechnology industry has been presented by IVA and VINNOVA in April 2003, giving an interesting analysis of developments over the last four years including measures on company turnover in both meanings of that expression. Although that part of the analysis does not contain much medical technology or devices from the present perspective, it includes an analysis of US patents with a Swedish inventor or assignee. That database includes medical technology and devices in the two patent categories "Medical electronics" and "Medical equipment", respectively, which together in fact outnumber those related to Swedish pharmaceuticals and biotech.

Before leaving the Swedish arena, a survey on manufacturers of functional aids (HI 1996a,b) should be mentioned. Made by Johan Arnell, this is a combination of a "resource catalogue" describing the capabilities of the companies, and a questionnaire survey to the firms to identify their main features, including their turnover measured as within certain brackets.

As to quantitative studies from the international literature, there are comparatively few studies and two different kinds may be identified: One is made in an academic setting and one largely includes studies commissioned by industrial interests and conducted by academics, other times by consulting firms specialising in medical technology and devices. Two studies at the individual state level in the US have been identified; (MassMEDIC 2001) on medical devices in Massachusetts (i.a. calculating "exports" to the US from MA) and (Haney et al 1997) on Ohio; the latter one indicating there may be more examples of that kind. One of the co-authors of the latter report later has co-authored a study with Laage-Hellman (Cetindamar & Laage-Hellman 2002) on micro-level analysis of biomedical firms in Ohio and Sweden.

Representing the second kind are three studies from the three largest EU countries, with one aiming at creating reliable metrics for the UK medical systems industries being the first (DOH-ABHI 1997). Interestingly, this study is published by the UK Department of Health and carried out on behalf jointly of the British Association of Healthcare Industries and the Department of Health. Being quite extensive, ranging from detailed background data collection and engaging a consulting firm to carry out interviews with a large number of company executives, it combines official statistics and first-hand sources. In the process it also involves a modelling exercise with the UK mechanical industry as a proxy to compensate for missing links in the survey conducted. Their trade analysis clearly showed that there is room for improvement in matching what must have been an early trial version of the new generic product nomenclature (GMDN, see above) to the Intrastat nomenclature, i.e. that used for inter-EU movements of goods. However it deserves noting that this was a trial five years ago.

All three reminding a somewhat of the two others, there is a series of studies commissioned by the medical device industry associations of France, Germany and the US (SNITEM 1999, BVMed 2000, AdvaMed 2000) with some American participation also in the two others. Having the topic "value of medical devices" to society as a common thread, they are all quite comprehensive. The two European ones plough deeply into their respective healthcare system to argue for changes that are perceived as necessary for society fully to benefit from the advantage of using more, and more advanced medical devices. The American association has had this profile for a number of years, all three urging, e.g. for changes in the reimbursement system so as to lift barriers to using new kinds of medical devices.

Most international studies cited present mainly aggregate figures, i.e. without giving any detailed product groups. There do exist two other kinds of material addressing the issue in more or less detail, however. One kind is market reports and similar compiled by commercial actors in industrial intelligence. These are sold at a high cost (not seldom at least USD 2000) and often

give rather limited *substantial* information on definitions and/or the methodology applied, thus considerably reducing usability and reproducibility in an academic context. Besides, and for understandable reasons, they more often rely on contacts with established actors in industry – perhaps in other countries than the one studied – than on actual analysis of official statistics, or other third-party data (should there be any). The reliability of market intelligence reports therefore is varying and often difficult to evaluate for a non-trained observer– whether a potential foreign[21] investor or entrepreneurs in newly started companies - otherwise one may think that knowledgeable persons would go about it other ways.

1.5 Method and data

As the research questions are formulated above, and in view of what was known about the fragmented industrial structure in medical devices at large, few other methods seemed feasible but using some kind of statistical resources. Although the (recently retired) Managing Director of the Swedish Medical Device Suppliers Association (SLF) kindly has made informal material available and acted as an interested discussion partner along the course of this study, SLF does not keep any records of the kind addressed here, only some very basic sales data for its around 130 member companies.

A questionnaire survey was considered in the preparations for the project. However, in 1996 there was a large number of companies already in the main industrial code for this area, "Manufacturing of medical and surgical equipment and orthopaedic appliances" (SE-SIC 33101), some 400, and this *before* considering any related industrial branches. In view of only 25 per cent response rate[22] in a questionnaire study targeted to the same industry code within another project (an unpublished candidate degree paper in spring 1997 from Södertörns högskola), it was decided not to choose a survey of this kind. Other aspects supporting this stand include:

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[21] As an example it may be mentioned that a recent report on the hospital market in Scandinavia from a well-known US market intelligence company, in a passage on the Swedish healthcare system states that *in 1999* "healthcare responsibilities were divested to county councils and municipalities from the Swedish Institute for Health Services Development (SPRI)". In fact this responsibility has rested with the county councils since 1928 when a special hospital law was introduced (http://www.landstingsvarlden.com/ltregrad/LTR_historia.asp), and in a law from 1990 the municipalities were given financial responsibility for the care of elderly.. It was in connection with the disbanding of SPRI in 1999/2000 that some of its tasks – as a cooperative organisation between the central government and the county councils as regional healthcare principals – were divested to other bodies.

[22] Although that survey was rather comprehensive, it was based on much more qualitative questions, not generally requiring quantitative data on a more detailed level than a managing director – given an interest in participating at all – would be able to ask one or two associates to supply.

- The existence of but few well known companies and a very large majority of small ones, nobody knowing what "volumes" the latter represent, only that at times they are high
- reliable and *comparable* data, especially on production, but also on exports and imports, are difficult to obtain from *one* reasonable "target person" in a large company
- small companies may not even have the time to attend to the questionnaire (and/or finding it too "bureaucratic" or "academic"; the author largely sympathises)
- to capture data on a differentiated product group level as well as, for exports, on a geographical level is even more difficult, touching on the impossible
- the strange habit of people in the "real world" of defining everything from product name to number of employees in their own way.

On the other hand, official statistics have disadvantages as well, mainly that of being difficult to use and interpret without some training; also it might be a rather blunt sword where you would perhaps need a scalpel to dissect some of the finer tissue. And although the official *statistics descriptions* or survey forms may have clear-cut definitions, these, too, are to be filled out by people in the real world…

Method and data are intimately associated in this study, the raw material being official Swedish statistics from a number of sources within Statistics Sweden (SCB). This has been obtained in either of four ways: a) "Physically" as loans or copies from the library of SCB, b) via personal contacts with a large number of helpful persons who have kindly supplied data as well as advise, c) data commissioned specifically for the present study, and d) complementary data downloaded from Sweden's Statistical Databases. Now that this study is concluded, the latter are easily accessible on the Internet, but mainly only for later years, especially from 1997 when several changes came into force. Material from before 1990, and also certain data from the early nineties are not accessible that way, however, only at request.

As hinted, learning to work with official statistics takes some time to train if the data is not to seem like an endless series of "black boxes" only; yet that is often the case in studies at the macro level. A reaction from somebody who is trained in identifying and explaining odd spots in, e.g. a series of physical experiments, and also is used to put together material from a diverse set of investigations with the aim of synthesising it, makes statistics work sometimes a rather frustrating exercise. There is no lack of knowledgeable persons to ask about one *specific* set of statistics including its limitations, but there is very little in the way of overarching "*learning* material" to take part of, not to speak of any "model designs" for how to conduct an analysis of a kind similar to the one utilised here, which takes the method of the statistics part of the Academy study (IVA 1988) several steps further.

At times, therefore, one was tempted to ask the question, is this a study on the medical device industry by way of an analysis of statistics, or is it an exercise in statistics using the medical device industry as a case? Because of this, and in order to perhaps somewhat facilitate for others who might want to try something similar, there is a full chapter (3) on methodological aspects and the statistical sources used. It is written duly acknowledging a study carried out by SCB on behalf of NUTEK in 1999 (NUTEK 1999) that turned out to employ roughly the same method in an analysis of the much larger electronics (and IT) industry. Maybe it is symptomatic that it proved impossible to identify even *one* person with enough overview to respond to more than one or two of the twenty or so follow-up questions raised as to the methods employed.

1.6 Summary and conclusions

Medical technology is an area of considerable societal interest from an innovation point of view while at the same time it makes up an important precondition for the delivery of high-quality healthcare. In the absence of quantitative data on those parts of Swedish industry that manufacture medical devices, i.e. products of and for medical technology, a study has been undertaken to redress this imbalance. Using data from several sources in official Swedish statistics as a basis, a picture of the industry, or - as it is shown from a statistical classification point of view – the *industries* concerned, is built up.

1.6.1 Industry structure

With SE-SIC 33101, "Manufacture of medical equipment and instruments" as its main object the study illustrates the number and location of companies, their distribution by size class of employment, company age and movements in and out of this code over six years. This immediately shows the great imbalance between smaller and larger companies in this area, there being only about 4 per cent of the 550 companies in this code in 2002 having more than 50 employees, and half of them having no employees at all. At first, one gets an impression of a considerable element of stability – many companies being founded comparatively long ago and being present in the code at all three measurement points in 1996, 1999 and 2002 respectively.

On the other hand it is demonstrated that numerous firms are crossing the boundary between the code studied and other areas of industrial activity or, in comparatively few cases, leaving the industry altogether. There is also an inflow of companies comprising new ones as well as

"immigrants" from other codes, all this together resulting in a much more complicated pattern of movements than a simple comparison of numbers of companies at different points of time would reveal. There is an indication that the number of young companies, here defined as less than three years old, has decreased in the inflows to the 33101 code in the later three-year period.

As to geographic distribution, it is shown that "South Sweden", a statistical region comprising Southern as well as Western Sweden, as well as Northern Sweden have increased there share of medical device companies during the six-year period studied at the expense of Mid-Sweden i.e. mainly the Stockholm area. In an accompanying analysis of number of *local units* (close to, but not identical to *companies* here) and measures of employment there is a trend for employment in the two largest size brackets (>500 employees) to taper off after year 2000.

1.6.2 Economic measures at industry level

In a somewhat wider analysis, the manufacturing codes 33102, comprising dental products, and 35430, meaning invalid vehicles, are taken into account. It is shown in all three codes that individual companies, if large enough, will have a decisive influence on the development of employment, accompanied by detectable changes in the corresponding economic measures if one of them "moves", as a complementary study of the Business Structural Statistics shows. The aggregate, and aggregated, 3-code economic analysis (including operating income, operating costs and value added), shows that medical devices in the manufacturing industry represents some SEK 17 billion in income, 9300 employees distributed among 1270 local units and SEK 4,7 billion in value added.

On a per capita basis, this means that income per employee is around SEK 1,8 million. Value added per employee, the so-called labour productivity, is SEK 0,5 million per employee. These figures are calculated for local units in companies of *all* sizes from 0 employed up. If one looks at those with *at least ten* employees only, the corresponding absolute figures are lowered by on average 10 % while the per capita relations conversely increase by 5-8 per cent. Looking at the share of the three industries involved in these money measures, the medical equipment and instruments share of the totals is 75-80 %, that of invalid vehicles around 8-10 %, and the share of dental industry 15-20 %, the latter having the lowest income per employee as well as value added per employee.

1.6.3 Production and foreign trade at product level

Again using official statistics, the development of Swedish production, exports and imports of medical devices at *individual product (group) level* is analysed over a 17-year period, resulting in a valuable database that starts from the most disaggregated data possible and includes close to 100 different product items. This part of the analysis shows that Swedish industrial production and exports over the period have managed to grow quite healthily, here defined as more – or in some segments, much more - than the international average growth rates of 5-6 per cent per annum in current prices. There is a tendency to lower growth rates in the latter part of the three five-year periods studied, than in the 1985-1995 periods.

From this set of product-based data, it is calculated that Sweden in *year 2001* – the latest year for which *production* figures are available as yet – had a production value of SEK 13,3 billion, exports of SEK 13,7 billion and imports of some SEK 9,7 billion. For 2002 preliminary foreign trade data exist, however. Calculating exports minus imports over the entire period, the resulting net exports have increased from 3,9 to 4,7 billion between 2001 and 2002 only, resulting in net exports in 2002 representing close to 40 % of production value in current as well as constant prices.

1.6.4 Exports > Production makes domestic market difficult to calculate…

Calculating the *Apparent Domestic Market* as Production plus Imports minus Exports reveals several instances of uncertainties in the data at the detailed levels, in particular for those of Swedish production (or shipments). A major reason is that production data are collected in a different way than foreign trade data, other contributions being that manufacturing also takes place outside the codes studied as well as in sectors not covered by ordinary production statistics, and that smaller companies are not well covered in statistics at detailed product level.

The general difficulty of using a calculated domestic market is cautioned against on the part of Statistics Sweden, not in any ordinary statistics descriptions that the author has managed to retrieve from SCB itself, but identified in the (NUTEK 1999) electronics industry study referred to. Thus the results obtained in the present study show that Exports have "outgrown" Production at the aggregate level as well as in several economically important product groups. This should *not* be the case according to textbooks in economics – if the parameters are correct, i.e. adjusted so as to enable comparison on reasonably symmetrical terms.

With reference to a Canadian source in statistics methodology (StatCan 2000), it is confirmed that (i.a.) *medical instruments* tend to show this kind of asymmetric production vs. international trade behaviour. A method, in principle, to redress such a situation is indicated. As it is very demanding computationally and manually, it is clearly out of reach for an academic work, but in the author's opinion, stakeholders should consider this problem, that is, the medical device industry itself and perhaps also statistics people in connection with reforms in classification and coding systems. The corresponding calculations made on product group level for the product groups where Exports > Production could be used to identify *probable gaps in the reporting habits* from companies manufacturing the items in question.

1.6.5 …but an attempt is made

Having said this does not necessarily mean that one could not do *some* comparison between production and foreign trade at the aggregate level, as long as the problems are identified and clearly stated. Taking account of the comparatively many product groups under study here, it is believed that an aggregate "helicopter view" might be reasonable here. In that case, the "*arithmetic" Apparent Domestic Market* would be in the *order of size of SEK 9 billion for 2001*, counted conservatively from the gross Production, Exports and Imports figures given above. On the other hand, a rough calculation exercise could be made with some of the "generic" adjustment factors identified in the Canadian source mentioned (some percentages being given in section 3.7.3 below). Such an exercise seems to indicate that perhaps up to 20-25 per cent of the shipments value is not captured by the statistics, while on the other hand exports, and to some degree imports, may be underestimated.

Taking 15 per cent as a more modest *example*, this would indicate a *Swedish production value of somewhat more than SEK 15 billion* while after correction for re-exports, the *Swedish export* value would be somewhat below *SEK 13 billion*. With some adjustment also on the import side this, speculatively speaking would imply that the supply to the domestic market of medical devices would be around SEK 10,5 billion. Already the "documented" rough figure of SEK 9 billion is high, however, in comparison to the value for the medical device market conveyed by Figure 1-2 above, which is some USD 655 million (i.e. only between SEK 5,5-6,5 billion depending on currency conversion rate). This further demonstrates the elusive nature of the topic for this thesis.

1.6.6 Trends in exports and production

Figures on each of production, exports and imports and CAGR in five-year intervals have been produced for a complete set of the product groups studied, enabling closer inspection and analysis by those interested in specific larger or smaller segments. Further, export trends have been analysed by receiving country and per product group during the period 1995-2001, in some case also including 2002. It is demonstrated that Germany is the largest single receiving country, in 2001 representing 14 % of total export value in the two major of the three main product groups covered in this thesis (the latter covering SEK 12,5 billion out of the total exports of 13,7 billion). Although fairly constant in (current) economic terms, the relative share of Germany is decreasing over the most recent six years. Exports to the US, however, are increasing in absolute as well as relative terms with a share of 11 % in 2001, compensating for some of the "losses" due to Germany. Norway and Japan come as No.3 and 4 with some 7 % each of the major high-value exports.

As to the product groups dominating exports in 2001, the largest one is the family of products in the 9018 HS/CN code, officially called "Instruments and appliances for medical, surgical, dental or veterinary use". For simplicity often called "Medical instruments…" this product group represents a broad mixture of products that accounts for 38 % of overall production value and 43 % of exports in the two major main groups. It is followed by the product group "orthopaedic articles and implants" (the HS/CN 9021 family), with 28 % of overall production value and 27 % of exports in the two major main groups. Invalid carriages, X-ray apparatus and Respiration apparatus, respectively, follow in production, the two latter in exports, with some 8-9 % shares of each.

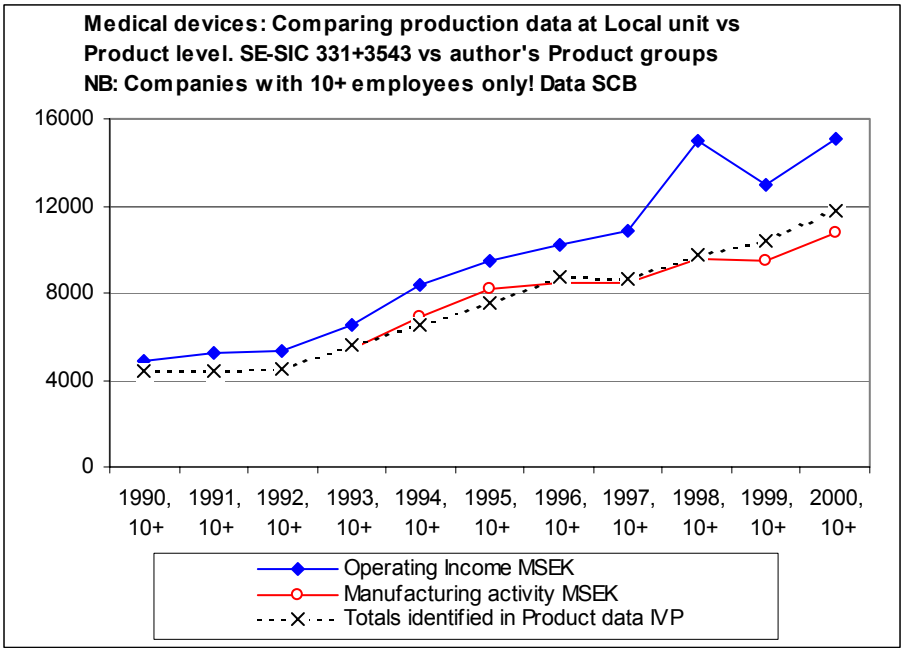
The overall growth rates (in current prices) in exports and production have been upheld mainly by the strong growth in the main group "Aids and Implants" (consisting of product groups Invalid carriages & Orthopaedic appliances, etc) over the period. Growth in the main group "Medical equipment and instruments" has been weaker, especially in the most recent five-year period studied, i.e. 1995-2000.

1.6.7 Comparison of production at industry and product level

A "control" series of data has been designed, aimed at comparing economic measures resulting from the study on the *aggregate* industry (branch) level in Chapter 2 and the data extracted from *product levels* in Chapter 3. The comparison only works for the period from 1993 and onwards, because that is the earliest point in time from which values for the "industrial", i.e. *manufac-*

turing activity are available as an identifiable part of total operating income of an industry as defined in the SE-SIC 92 system. Furthermore, the comparison can be made for (local units in) companies with a *minimum of 10 employees* only, i.e. data for companies smaller than that are not possible to capture in this particular comparison. Based on data from Chapters 2 and 3 the following picture emerges, based on the three industrial codes for medical and surgical equipment including dental firms (= SE-SIC 331 = 33101 + 33102) and SE-SIC 35430, Invalid carriages.

Figure 1-4 Comparison of production data on Local unit vs. Product level



Source: Statistics Sweden, own calculations

As may be seen from the two lower curves, there is good correspondence, confirming that the products investigated in Chapter 3 – summed up in the dashed curve – are representative of the industries studied at the overall level in Chapter 2. In fact they should be, but it is always interesting to see whether top-down and bottom-up processes converge. Moreover, Figure 1-4 above demonstrates that the difference between operating income and the part of the latter that comes from *manufacturing* tends to widen over the period. Thus other sources of income, including *trade*, seem to be taking a larger share of total income for these three industries in later years taken together. The "leap" for 1998 is due to an extraordinary income of a specific company, a special case that is commented in section 2.3 below. The top curve illustrates the difficulty in comparing statistical and "real" measures of income, etc – be it turnover, or production or shipment values, etc. That also explains why it is hard to take statistical figures and "complement" them with individual micro-data for certain companies, for example.

1.6.8 Conclusions

- ⊗ In the way this study has been conducted, official statistics *can* be used for analysing industries of a reasonably well-identified kind and provided there are not too many companies involved (500 being an upper limit without requiring computer programming)
- ⊗ The structural analysis rests on the assumption that the industrial classification in SE-SIC codes is made "correctly", but in a majority of cases this is difficult to test. There are instances of the share of mis-classified firms being as high as 30 per cent in other studies (SIKA 2001) without the reasons being analysed
- ⊗ Known difficulties in comparing different kinds of statistical sources have been confirmed. This does not necessarily mean that the resulting data cannot be used productively at aggregate level, provided the uncertainties are noted
- ⊗ The figure calculated for the Apparent Domestic Market, which per definition cannot be "measured" as such, is uncertain but in the order of size of *at least SEK 9 billion* for the year 2001. In view of potential adjustments that can be made of the material at hand on statistical grounds as well as of some data on *de facto* medical device products not being available at the time of publication, the figure under certain conditions may be estimated to be possibly 15-20 per cent higher.

1.6.9 Contributions made

There now exist data not at all known before, and partially in a long time trend series, for an industry that in Sweden has been subject to a general "under-coverage", to borrow a statistical term – namely that of Medical Devices. Thus there now exists a description of its structure with several industrial classifications as points of departure, as well as key economic data on the aggregate and product group levels, including export patterns, etc. This material is of a generic nature, being applicable to other not too complicated industries as well.

Part of these data, the exit - entry analysis, is processed with methods that although not unique, seldom are described in any detail in the type of background material that has been available, most studies being entirely on the macro level treating the companies as "black boxes". Here combining trends in aggregate data on the one hand, and adding certain "micro-information" on the other, although partially of a somewhat "soft" nature, enables the author to identify and explain certain oddities in the statistics presented, associating them to some large industrial actors in the field.

The lion share of the data will be made available for use by other researchers or industrial actors.

1.6.10 Issues for further research

The work almost "by itself" has identified several points of potential improvement that, *at first*, may seem to be for statistics purposes only. One of these is the *industrial classification* system and also how it really *works* – who decides about the coding, etc, is not crystal clear to judge from many "real life" examples in the author's rather considerable network. The effects of this issue are of importance to many users of statistics stretching far outside the "methodology" community – this is an experience from the author's ordinary job, which includes, e.g. analysing R&D statistics. As a major revision in the EU industrial classification system is foreseen for 2007, parts of this study may be relevant to those in the medical device industry – including its industrial association, SLF – to suggest some improvements.

The author would tentatively like to think in terms of a system that – without disturbing the basic international "skeleton" of the coding, of course – would enable firms in ALL healthcare-related codes in *manufacturing*, *wholesale* and *research and development* to be classified in a way that would enable analysis of their actual production, etc, distributed by EACH of the three "components" Pharmaceuticals, Medical devices and Biotechnology, respectively. The issue of how to handle Biotechnology in official Swedish statistics is under discussion; and although there are certain factors that are rather particular to that field, a somewhat wider perspective might prove valuable.

She would also like to think in terms of identifying actors in other industries, including the "grey zone" that makes figures of Production seem small in comparison to Exports. Although other factors contribute, two main reasons for the discrepancy generally are believed to be that production is not "visible" from companies that are not classified in "industry" at all, and that manufacturing takes place within wholesale companies whose products are not classified in a comparable way at the product level. For example a study of the medical device companies in the SE-SIC 51460 code would be merited, "*Wholesale of medical equipment and pharmaceutical goods*". With over 800 limited companies in this code, employing some 9000 persons, the author would venture that at least 25 per cent of the companies are involved with

medical devices. Of the 150 with the largest (net) turnover, 50 have easily been identified as medical device companies, some definitely engaged in manufacturing. These 50 companies together represent a net turnover of SEK 9000 million in 2001 (a doubling since 1998, although some acquisitions have taken place) and six (sic) of the 50 have R&D expenses between them of SEK 140 million (almost 3 times the 1998 value). Employment in the group of 50 has grown with 40 % since 1998, all according to

Finally, as has been explained in the Chapter 4, the official R&D statistics were not used for this study because of problems perceived in reflecting only the "very largest" companies on the one hand, and a set of companies somewhat larger than ≥50 employees which is *highly variable* according to the structural analysis carried out here. Although there have been studies on R&D in companies in the <50 bracket, these in their published form were not distributed by the 5-, or even 3-digit SE-SIC level. It would be an interesting aspect to follow-up, if it were possible to direct a survey to healthcare- and biotechnology companies jointly as there are several trends that lead to the convergence, or at least co-operation, of biotechnology as one generic core science with medical devices as "beneficiaries" as well as in themselves contributing other core technologies that may be beneficial to biotechnology.

2 Structure and aggregate data of the medical device industry in Sweden

This chapter will deal with three different manufacturing branches of the medical device industry, in particular the one called SE-SIC 33101 but to a certain extent also with SIC 33102 and SIC 35430. Along the way it will give glimpses of two related service industries, on the one hand SIC 51460 and on the other SIC 73103. The reader is recommended to take part of the chapter on methodology and/or the list of codes and concepts, etc, in Table 1-1 as a preparation.

The chapter will end with a short section on research and development. Although it is based on micro-data from MM Partner only and not on aggregated data from Statistics Sweden (see chapter on methodology for explanation), it will give an indication of the volumes of research and development in the codes studied and main R&D conducting companies will be identified.

The official code names used in this presentation are as follows:

Table 2-1 Industries (branches) related to Medical Devices and their SE-SIC 92 codes

33101	Manufacture of medical and surgical equipment and orthopaedic appliances except artificial teeth, dentures etc.
33102	Manufacture of artificial teeth, dentures, dental plates etc.
35430	Manufacture of invalid carriages
51460	Wholesale of pharmaceutical goods (briefly)
73103	Research and development on medical sciences (briefly)

2.1 SIC 33101: Medical and surgical equipment, orthopaedic appliances

Based on three runs commissioned by the author from the Business Register of Statistics Sweden (SCB), lists of the companies included in SE-SIC 33101 per 30 June each of the years 1996, 1999 and 2002 have been analysed.

2.1.1 Number of companies, primary activity, legal form, etc

In the following, "P1" symbolises that SIC 33101 is the primary (Priority 1) activity of the company. This means that the activity in question represents the largest economic value among the areas in which the company has been active a given year. Companies that are active in SIC 33101 as secondary or tertiary branch are denoted by "P2" and "P3", or together "P2-3" in the following. For other explanations, see Table 1-1

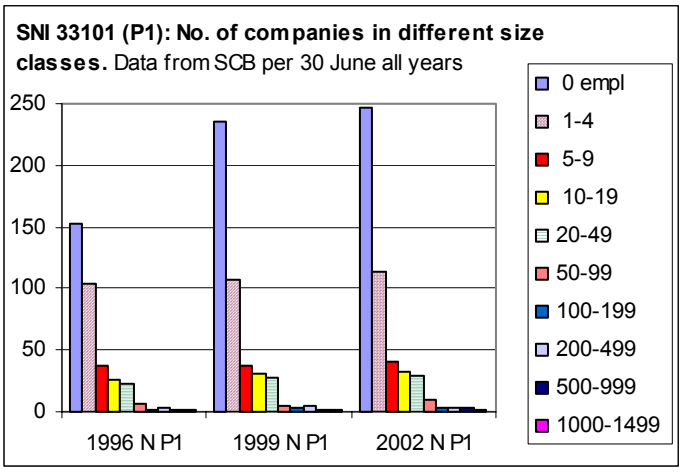
Table 2-2 Number of companies and legal form in SE-SIC 33101 at three points in time

	1996 tot	1996 P1	1996 P2-3	1999 tot	1999 P1	1999 P2-3	2002 tot	2002 P1	2002 P2-3
AB - Limited comp	291	256	35	341	298	43	366	315	51
HB/KB – Partnersh	57	53	4	66	62	4	70	64	6
Ensk firma - SPsh	52	47	5	100	93	7	116	102	14
Other legal forms	3	2	1	2	1	1	1	1	0
Total No. Companies	403	356	47	507	453	54	552	481	71
Total No. Local units	*436*			*542*			*593*		

Source: Statistics Sweden and own calculations

A look at the totals in Table 2-2 above reveals that there were some 400 companies in mid-1996, increasing to some 500 three years later (nominally with 26 % over three years) and then increasing to around 550 another three years later, in mid-2002 (nominally with only 9 % growth over three years). About two thirds of the companies are limited companies (AB) and up to 15 per cent are partnerships (HB/KB). Some 15-20 per cent are sole proprietorships (physical persons), increasing in absolute as well as relative terms over the period studied here. The share of companies whose main activity *outside* SIC 33101 is 12-13 per cent, the remaining close to 90 per cent having manufacture of medical equipment, etc, as their main activity.

Figure 2-1 Number of companies in different size classes with 33101 as primary activity



Source: Statistics Sweden and own calculations

As to the distribution of sizes, see Figure 2-1 above, most of the companies are very small. More than 80 per cent have less than 10 employees, the share with no employees at all making up more than half from (the measurement in) 1999 onwards. Only 15-20 companies have more than 50 employees among those with 33101 as their main activity (P1) as illustrated in the figure. The number of "really" big companies, with more than 500 employees, is only three, two and four in 1996, 1999 and 2002, respectively, with only one in the top bracket above 1000 persons continuously. One reason for showing only P1 companies here is that there are another two very large companies with SIC 33101 as secondary and tertiary activity. None of the latter

is dealing with what is meant by medical devices for the purposes of this thesis (see section on P2 and P3 companies below).

The great majority of the companies have only one local unit, the "average" being around 1,08 units per company in the code. Companies with more than two local units (the maximum being ten in any one year) quite frequently are firms in orthopaedic appliances and rehabilitation aids, implying regional distribution of a number of workshops for prostheses, etc (partially former hospital workshops).

2.1.2 Changes in SIC 33103 between 1996 and 2002

2.1.2.1 Methodology to analyse entries to and exits from the code

At first sight, the change in the number of companies referred to above, from 403 in 1996 to 509 in 1999 and further to 553 in 2002, implies that some 103 new entrants appeared in the code by 1999 and another 44 until 2000. Thus in the formula,

$$N_{96} + \Delta_{96\text{-}99} + \Delta_{99\text{-}02} = N_{02}$$

where Δ is the difference in number of companies between two consecutive measurements (i.e. three years),

$$\Delta_{96\text{-}99} = 106 \text{ and } \Delta_{99\text{-}02} = 44$$

A closer look reveals a much more complicated pattern, however. To analyse the internal changes between the years, the lists from the Business Register have been compared in detail – a manual task, as there are no shortcuts available. Thus all entities in the lists for each of the three years (of measurement) have been analysed for changes in name and/or in their 10-digit organisation number. The latter is as unique to a company (or other officially registered organisation) as personal numbers are to physical persons in Sweden; in fact the organisation number for the legal form of Sole proprietorship is also often that person's personal number.

In this way a number of changes *within* the boundaries of the code SIC 33101 have been detected between the first and the second points of measurement (1996-1999) as well as between the second and the third (1999-2002). Some company have changed their names, perhaps in connection with a change of ownership[23]; others their legal form, for example in connection with the requirement for limited companies to increase their stock capital between 1996 and 1999. The latter resulted in some switching to partnerships or sole proprietorships

[23] Ownership changes cannot be detected through the Business Register *per se*, and have not been pursued otherwise

instead. Some have SIC 33101 as a lower or higher priority than the previous time, etc. Yet other changes have taken place, the most obvious one being that "new" companies were found in the lists for 1999 and 2002 as compared to the situation at the previous point of time, and in analogy, that others were missing at the next consecutive measurement.

Before going further, combinatory reasoning will explain the various sub-groups among which we have distributed the total number of entries (arithmetically speaking) in the three lists from the SCB Business Register. This total number was the sum of the companies from each separate list = 403 + 509 + 553 = 1465. Now all companies from the list of 1996 was marked with an "x", each from the list in 1999 with a "y" and each on the list for 2002 with a "z". A company appearing in all three years was thus given the code "zyx", while one that appeared in two (but not three) of the years was given the corresponding combination, i.e. "zy" or "yx" or in fact "zx". Since the names and organisation numbers had now been checked for any duplicates (including change of legal forms within the code, other identifying factors such as address being constant), it follows that companies with *only one* letter in the *first two* rounds, i.e. "x" for 1996 only and "y" for 1999 only, *must have left* the code 33101 in the following three-year period. Further, the companies in the sub-group "yx" also must have left the code by 2002, at least for the time being. In this way we get the following situation:

Table 2-3 Aggregate changes in SE-SIC 33101 between 1996 and 2002

Stock 1996: (30 June)	**403**	**Changes 1996-1999**	**Stock 1999: (30 June)**	**509**	**Changes 1999-2002**	**Stock 2002: (30 June)**	**553**
of which			**of which**			**of which**	
x: 96 only	79	**exits from 33101:**					
zx: 96 and 02	5	-84			**entries to 33101:**	zx: from 96	5
					141	z: "new" 02	136
		entries to 33101:	zy: 99 and 02	140		zy: 99 and 02	140
		190	y: 99 only	50	**exits from 33101:**		
yx: 96 and 99	47		yx: 96 and 99	47	-97		
zyx: 96, 99, 02	272		zyx: 96, 99, 02	272		zyx: 96, 99, 02	272
control	403	**106**	control	509	**44**	control	553
		net change			**net change**		

Source: Statistics Sweden, own calculations

The colours are to further clarify which sub-group of companies end up where, but as each group has its own line the table will be legible anyway. The "xyz's" from above have been complemented with the real years to further elucidate the situation.

It now is clear that we are dealing with a total number of 729 individual companies, or the sum of the individual sub-groups – x, yx, zx, y, zy, z and zyx – over the six-year period. Out of these, *272 companies are present all the way*, 84 left after 1996 (5 of which to reappear in 2002)

and 47 went on from 1996 to 1999 but then left the code before 2002. Taken together, these sub-groups make up the *stock from 1996* of 403 companies. Further, of the 190 companies that entered the scene, or rather the code, in 1999, 50 were there in 1999 only, while the remaining 140 went on to 2002. The latter there joined the 272 already existing ones together with 136 "new" entrants and the 5 from 1996, summing up to the stock in 2002 of 553 companies that our series ends with. As seen from the boxes for entry and exit from the code in the two interim columns in Table 2-3, this leads to the following qualification of the original "Eq.1" above:

$$403 + (190-84) = 509 \quad \text{and} \quad 509 + (141 - 97) = 553 \qquad \text{("Eq. 2")}$$

or that

$\Delta_{96\text{-}99}$ = 106 = the net effect of 190 entries *to the code* and 84 exits, and that

$\Delta_{99\text{-}02}$ = 44 = the net effect of 141 entries and 97 exists.

So far, when speaking of "entry" and "exit" *here*, the terms relate to the perspective of the *code* as a "system of observation".

But what happened to the companies that seemingly disappeared from 1996 to 2002, that is the 84 in the first interim period and the 97 in the second period in "Eq. 2" above? And how new are the "new" ones among the entrants to the code in 1999 and 2002, i.e. analogously the 190 and the 141 companies in "Eq. 2", respectively?

2.1.2.2 Actual entries to and exits from the code

To investigate the possible "*fates*" of the companies that exited from the code, the database MM Partner was used. Thus in autumn of 1999 and 2002, to some extent also in the meantime, all companies were looked up that were identifiable in that source, i.e. *limited companies* (AB) as stated before. Since this source builds upon data from e.g. the Patent and Registration Office and Statistics Sweden – "packaging" it into somewhat more accessible form for non-statisticians and accountants – it contains certain information on mergers and acquisitions, bankruptcies, voluntary withdrawals as reasons for companies not being economically active.

Further, in order to somewhat qualify the number of companies that *entered* into the code 33101 in 1999 and 2002 depending on relative newness when entering for the first time in 1999 and 2002, the parameter that SCB calls "*starting time*" was analysed. (This is given as "year+week" in the two first measurements; full date from 2002). It must be noted that this is not an absolute measure; in connection with official changes of different kinds the companies are "turned on" as active in a new time series by SCB depending on a number of administrative criteria. Some of

these apply to genuinely new as well as older companies. It is the activity-based criterion that is the basis for "starting time" rather than the date for registration[24] of a company as such. For example it can take some time between a company is founded (or re-founded) and the point of time in which the company really becomes economically active and thus "turned on" by SCB. Still, the author thought that by studying the "starting time" parameter, one could at least filter out a group of companies that were definitely "not genuinely new at the time of measurement" – namely those that had starting times *before* the previous measurement three years earlier. Often the size class, indicating employment, also gave a hint that some seemingly new companies were no start-ups. Having been acquainted with the field of medical devices for many years, further, the author also knew from experience that some companies had had a "life before".

In this way the following results were obtained from the analysis of companies exiting and entering the code 33101:

Table 2-4 Follow up of exits from the code SIC 33101

Exit reason	1996 - 1999	1999- 2002	Legal forms	Control source
bankruptcy or liquidation	16	16	AB's only	MM 99-2, 02-2
other documented exits	18	12	AB's only	MM 99-2, 02-2
"unidentifiable" 9HB/KB+12SP	21	43	HB/KB+SP	no follow-up done 16HB/KB+25SP+2Other
to other SIC codes	29	26	AB's only	MM 99-2, 02-2
Total exits from the code	**84**	**97**		

Sources: Basic data: Statistics Sweden, follow-up data on AB's: MM Partner; own calculations

The picture emerges that 34 companies from the measurement in 1996-1999 and 28 from the comparison of 1999 and 2002 are *genuine exits* from industry, not only the code SIC 33101. This corresponds to around 8 and 6 per cent of the number of companies overall in 1996 and 1999, and 12 and 8 per cent of the corresponding number of limited companies, respectively. The number of *identified bankruptcies or liquidations* was16 in both periods, that is, around 4 and 3 % of the total number in the first stock of 1996 and the second of 1999, respectively. The firms in the second "real" exit category of 18 and 12 represent a mix of voluntary *withdrawals, companies disappearing due to mergers and acquisitions, and other reasons for economic inactivity*. Further, via the MM Partner source – again remembering it only gives data for limited companies, AB – it was found that 29 and 26 companies, respectively, had *switched to*

[24] Date of registration, on the other hand, is what MM Partner gives as the most "visible" date, although the database also gives dates for earlier changes in name, etc

other SIC codes. Many of these were either other medical-related (mostly SIC 51460 but some also going to 73103) or more associated with other kinds of measuring instruments, metalworking, etc, and thus found in such codes.

This leaves us with 21 companies in 1999 that *cannot be identified* via the sources at hand. This figure had had doubled to 43 in 2002. These are partnerships (HB/KB) and sole proprietorships (enskild firma) only, which are not covered by the MM Databases. SCB offers data on all genuine exits on demand. Further details than the above are considered outside the scope of this study, however.

Table 2-5 A relative measure of age of entrants into the code SIC 33101

Entry source	1996 - 1999	1999- 2002
"new starts" #	130	83
older, from other codes	60	53
Total entrants to the code#	190	136

Source: Statistics Sweden, own calculations

Note: The 136 in Total for 1999-2002 above are the companies in the former sub-group "z", to which the odd five in sub-group "zx" should be added to make up the 141 "entrants" in "Eq. 2" above. As the latter five have reappeared from the first measurement (absent in the second), they do not show in the table

2.1.2.3 A proxy measure of age of the companies studied

Let us look at the age distribution to the extent that the "starting time" parameter permits us in view of its limitations, again remembering that firms with earlier presence under other names, legal forms, etc, should have been filtered out in the process already. Then it appears that 130 of the 190 companies entering as *new to the code* in 1999 have "starting time" *within* the period from the previous measurement in 1999, and that the corresponding figure is 83 of 136 in the second time interval up to 2002. If these figures are correct, then 68 percent of the entrants in 1999 and 61 per cent of those in 2002 were less than three years "old" from "starting time" as SCB registers it. Basing the share on the *total* number of companies in the code in 1999 and 2002 instead, this means that 130 of 509, and 83 out of 553 of the firms in 1999 and 2002, respectively, have been "started" *after* the previous measurement point, or *26 vs. only 15 per cent* in 1999 vs. 2002.

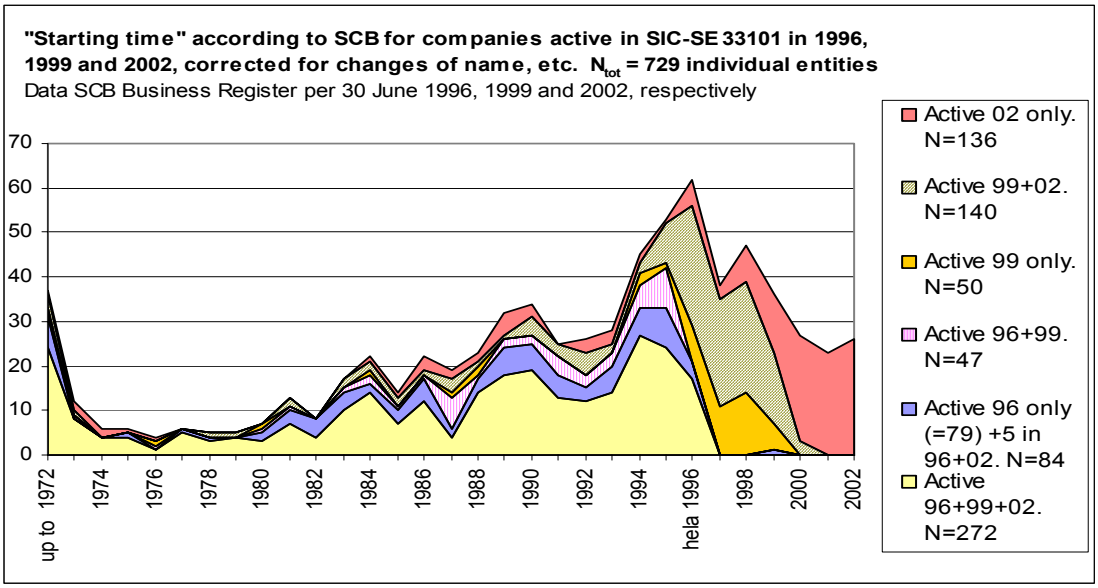
As a consequence, the remaining 60 and 53 that have "starting times" *before* the respective earlier measuring point must have *entered via other SIC codes*, having been reclassified due to changes in activity or production mix, etc, leading to them having a different SIC classification three years after. This final category then corresponds to 32 and 39 per cent of the new *entrants*

to the code in 1999 and 2002, and to 12 and 10 per cent of the *total number* of firms in the code 33101 in 1999 and 2002 respectively.

As no measurement has been made to reflect the situation in the Business Register for SIC 33101 *before 1996*, it is not possible to divide up the companies in that first group in the way we have done with the later cohorts. However, "starting time" has been analysed also for the companies in this category, indicating that 105 of the total of 403 in year 1996 had "starting times" that were more than three years old. This means that a share of 25 per cent must have started before mid-*1993*, which is comparable to the share for the "less-than-three-year-olds" in 1999. Thus it would appear that the share of young companies has fallen in the group of new entrants in the latest measurement point in 2002, which was 15 per cent according to the above, in relation to both the previous measurements of around 25 %. It has to be noted that mobility has been rather large in the overall picture, however.

To sum up this attempt to make an age analysis, the following figure records the starting dates for all the 729 individual companies appearing in between 1996 and 2002, distributed among all the sub-groups referred to above. It is not intended for detailed study, just to give a hint at the comparatively long-ranging "tail" of "ages" that the 272 firms being present at all three measurements reveal.

Figure 2-1 Analysis of "starting time" for the altogether 729 firms in the three runs of SIC 33101



Source: Statistics Sweden, own calculations

2.1.3 Geographical location of firms in SIC 33101 as primary branch

Table 2-6 below illustrates the regional distribution of firms in SIC 33101 as primary activity according to the Business Register the same years as above. The largest and the smallest of the size classes SCB apply have been merged with others so as to give a better overview. The distribution follows the official one, the counties M (Skåne län) and O (Göteborg area) having changed somewhat between 1999 and 2003.

Table 2-6 Regional distribution of firms with SIC 33101 as primary activity

SNI 33101 P1 Primary activity		No. of Companies 1996					No. of Companies 1999					No. of Companies 2002					New county
size class employment		tot	>50	20-49	10-19	<10	tot	>50	20-49	10-19	<10	tot	>50	20-49	10-19	<10	
ex-county																	
Stockholm	A(B)	96	6	4	6	80	97	6	6	6	79	99	6	7	8	78	A(B)
Uppsala	C	23					25	2	2	5	16	27	3	1	5	18	C
Södermanland	D	11					8				8	9				9	D
Östergötland	E	16	*Detailed distrib.*				23	1	1	3	18	21		1	1	19	E
Gotland	I	2	*not calculated*				2				2	2				2	I
Värmland	S	4					10			1	9	7			1	6	S
Örebro	T	2					4				4	3			2	1	T
Västmanland	U	11					11			1	10	12			1	11	U
Mid-Sweden		**165**	**7**	**8**	**14**	**124**	**180**	**9**	**9**	**16**	**146**	**180**	**9**	**9**	**18**	**144**	**Mid-**
share of co's in each class %		100	4	5	8	75	100	5	5	9	82	100	5	5	10	80	**Sw**
Jönköping	F	15					19	1	2	1	15	18	2	2	1	13	F
Kronoberg	G	10	*Detailed distrib.*				14		6		8	13		4	1	8	G
Kalmar	H	2	*not calculated*				6				6	9				9	H
Blekinge	K	2					8	1			7	7				7	K
Skåne (fd L+M) # §	fd L	7															new
	fd M	45	2	2	2	39	63	2	2	5	54	84	5	3	4	72	LM
Halland	N	15	*Det. distr. not calc.*				20	1	1	3	15	23	1	1	1	20	N
Västra Göt (fd OPR) # §	fd O	34	2	3	1	28	77	1	6	2	68	82	2	8	2	70	new
	fd P	19	*Detailed distrib.*														O
	fd R	3	*not calculated*														
South Sweden		**152**	**7**	**14**	**7**	**136**	**207**	**6**	**17**	**11**	**173**	**236**	**10**	**18**	**9**	**199**	**Sout**
share of co's in each class %		100	5	9	5	89	100	3	8	5	83	100	4	8	4	84	**h Sw**
Dalarna	W	8					14			1	13	10		1	1	8	W
Gävleborg	X	2					8				8	9			1	8	X
Västernorrland	Y	7	*Detailed distrib.*				13			1	12	13		1	1	11	Y
Jämtland	Z	8	*not calculated*				5			1	4	8				8	Z
Västerbotten	AC	8					14			1	13	13				13	AC
Norrbotten	BD	8					13		1	1	11	13	1		2	10	BD
North Sweden		**41**	**0**	**1**	**5**	**35**	**67**	**0**	**1**	**5**	**61**	**66**	**1**	**2**	**5**	**58**	**Nort**
share of co's in each class %		100	0	2	12	85	100	0	1	7	91	100	2	3	8	88	**h Sw**
Sweden Total, No of firms		**358**	**14**	**23**	**26**	**295**	**454**	**15**	**27**	**32**	**380**	**482**	**20**	**29**	**32**	**401**	**Total**
§ of which in A, LM+O(PR) area		*175*	*10*	*9*	*9*	*147*	*237*	*9*	*14*	*13*	*201*	*265*	*13*	*18*	*14*	*220*	*ALM*
ditto, ALMO share ot Total, %		49	71	39	35	50	52	60	52	41	53	55	65	62	44	55	Share
Regional distrib., share, %				**year 1996**					**year 1999**					**year 2002**			
Mid-Sweden				46					40					37			
South Sweden				42					46					49			
North Sweden				11					15					14			
				100					100					100			

Source: Statistics Sweden and own calculations

Again noting that these are firms with their main activity in SIC 33101, the overall distribution on major regions of the country is seen at the bottom. Thus from the runs of the Business Register in mid-1996, 1999 and 2002 it appears that South Sweden, and North Sweden have increased their number of companies with 55 and 61 per cent over the six-year period, respectively, as compared to Mid-Sweden increasing the number only with some 10 per cent. Thereby the overall shares of the industry with main activities in SIC 33101 in the large regions have shifted so that Mid-Sweden now has a share of 37 per cent (down from 46 in 1996 and 40 in 1999), the South region 49 per cent (42 and 46) and the North region presently 14 per cent (up from 11).

As was noted earlier, a massive proportion of the companies are in size classes with no or very few employees – a fact to which we will revert later when looking at the so-called CFAR register combining data of number of companies and number of employees. Conversely, there are very few large companies' with an even smaller number being very large for this kind of industry, that is, with more than 500 employees.

2.1.4 Companies in SIC 33101 with > 50 employees

Table 2-7 Companies with ≥50 employees in any of the years 1996, 1999 or 2002

Company Name 1996	Size 96	Company Name 1999	Size 99	Company Name 2002	Size 02
1996 not in 33101		Amersham Pharmacia Biotech AB (P2)	10	Amersham Biosciences AB (P2) --NCh	10
Siemens-Elema AB	10	Siemens-Elema AB	10	Siemens-Elema AB	10
Astra Tech AB	08	Astra Tech AB	08	Astra Tech AB	09
Forsheda AB (P3)	09	Forsheda AB (P3)	09	Forsheda AB (P3)	09
Gambro AB (former)	09	Gambro Lundia AB --NCh	09	Gambro Lundia AB	09
Pacesetter AB	08	Pacesetter AB	08	St. Jude Medical AB --NCh	09
BOC Ohmeda AB	09	Becton Dickinson Infusion Therapy AB --NCh	08	Becton Dickinson Infusion Therapy AB	08
Getinge AB	08	Getinge AB	08	Getinge Sterilization AB --NCh	08
Motala Verkstad, AB (P2)	08	*in 28520*		*2002 in 28520*	
Datex-Engström AB	07	Datex-Ohmeda AB --NCh, MA-	08	Instrumentarium AB MA+ (Merged.Datex-Ohmeda)	08
Nobel Biocare AB	07	*"emigrated" to 27450*		*"emigrated" to 33102*	
Nobel Biocare Produktion AB	07	*(inactive commissionary)*		*withdrawn*	
1996 not in 33101		*1999 not in 33101*		Arjo Hospital Equipment AB	07
1996 not in 33101		*1999 not in 33101*		GEMS Pet Systems AB	07
1996 not in 33101		Otto Bock Scandinavia AB	06	Otto Bock Scandinavia AB (P2)	07
in 33101, size class 05	(05)	Radi Medical Systems AB	07	Radi Medical Systems AB	07
1996 not in 33101		*1999 in 51460*		Atos Medical AB	06
in 33101, size class 03	(03)	in 33101, size class 05	(05)	Breas Medical AB	06
in 33101, size class 05	(05)	in 33101, size class 05	(05)	CMA Microdialysis AB	06
1996 not in 33101		Althin Medical AB	07	*restruct size class 01*	(01)
1996 not in 33101		Interspiro AB	07	Interspiro AB (reconstr)	06
1996 not in 33101		Reiners Industri AB (P2)	07	*merged and withdrawn*	
1996 not in 33101		Trienta Elektronik AB (P3)	07	*2002 in 70202*	
Dentatus AB	06	Dentatus AB	06	in 33101, size class 05	(05)
1996 not in 33101		CCS, Clean Chemical Sw eden A	06	*2002 in 24520*	
in 33101, size class 05	(05)	in 33101, size class 05	(05)	Liko AB	06
Olmed Ortopediska AB	06	Olmed Ortopediska AB	06	Olmed Ortopediska AB	06
1996 not in 33101		in 33101, size class 05	(05)	Orifice Medical AB	06
1996 not in 33101		in 33101, size class 05	(05)	Scanditronix Medical AB (P2)	06
Stille Surgical AB	06	Stille Surgical AB	06	Stille Surgical AB	06
Team Ortopedteknik Scandinavi	06	Team Ortopedteknik Scandinavi	06	Team Ortopedteknik Scandinavi	06
Tranås Rostfria, AB	06	in 33101, size class 05	(05)	Tranås Rostfria, AB	06
Västbo Plåt AB	06	*1999 not in 33101*		Västbo Plåt AB (P2)	06
Eneryda Vårdprodukter i Eneryda AB	06	in 33101, size class 05	(05)	in 33101, size class 05 as Proton Caretec AB --NCh	(05)
Hans Fält Elektronik AB (P2)	06	*1999 not in 33101*			
Louis Gibeck AB MA-	06	*1999 acquired; to 51460+NCh*		*51460 now as Hudson RCI AB MA+*	
Scandinavian Mobility AB	06	Scandinavian Mobility AB (P2)	06	*51460 now as Invacare AB*	
Willo Maskinaktiebolag	06	Willo Maskinaktiebolag (P2)	06	*2002 in 29120*	
Turon AB	06	*merged*		*withdrawn*	

Source: Name changes, codes outside 33101, other formal changes: MM 1999-2/3 and 2002-2.
All other data: Statistics Sweden, Business Register per 30 June each time, and own calculations

Notes: Size class 05=20-49 employees, 06=50-99, 07=200-499, 08=200-499, 09=500-999, 10=1000-1499
P2/ P3 = 33101 is secondary or tertiary SIC code
NCh = Company name changed compared to previous measurement
MA = Mergers & Acquisitions, MA+ the new company, MA- the merged one

2.1.4.1 Companies with secondary activities in SIC 33101

Table 2-7 includes the larger companies, defined as ≥50 employees, among those with SIC 33101 as primary activity as well as the ones for which it is a secondary or tertiary activity. The latter are marked in light brown and with P2/P3 after their names for further clarity. Of those, only Amersham Biosciences AB and Forsheda AB will be mentioned. At the company level these are both classified in SIC codes external to the topic of this thesis, but each has a *local unit* that is classified in SIC 33101, Amersham in Umeå for the production of some laboratory equipment intended for bioscience *research* purposes and Forsheda one in Småland, that among other things manufactures specialized components in rubber. From personal communication with representatives of the management of these two companies in 1999 and 2000, respectively, it is clear that none of the two consider(ed) their companies involved with medical devices or medical technology as implied here. The then Forsheda CTO, knowing his company's customers, also stated this in an earlier survey, separate from this study. This thus holds whether looked at from a general product segment or sub-supplier point of view or from the general aims of this study, even though there are admittedly grey areas in between biotechnology laboratory equipment and clinical medical technology.

However, the reason why it is important to keep track of which companies are present in a given SIC code with any *secondary* activities is *not academic but economic* – in particular when there are otherwise very few large actors with *primary* activity within the code as is the case in SIC 33101. The interpretation of the Business Structural Statistics (see section below) might well be confused if one does not realise this fact. Thus the presence of P2-3 companies directly affect the interpretation of aggregate income, costs, value added, etc, when one compares the official statistics at *company* level with the ones at *activity* level.

2.1.5 Companies ≥ 50 entering or exiting the code; structural changes inside

The following account takes some of the changes identified in the table 2-7 for the "50+ companies" above as a point of departure to give some glimpses from developments in the Swedish medical device industry between 1996 and 1999. Interspersed with this, some comments of interest for the interpretation of this (or other) statistics are made, based mainly on the author's general experience of the field after several years of monitoring.

2.1.5.1 Companies in mature segments of the device industry

The four companies marked in grey are no longer active and with one exception were never among the "core" companies in the manufacturing of medical devices. The exception is *Althin Medical AB*, which entered SIC 33101 between 1996 and 1999 following its investment in a major new production plant (the first in many years in the Swedish device industry) to manufacture dialysis equipment supplies in Ronneby in southern Sweden from 1995. Having been listed on the Stockholm stock exchange since the mid-nineties, Althin Medical AB was acquired by the main US actor in the renal systems segment *Baxter Medical* in spring 2000. Althin then left the stock exchange. In autumn 2001 Baxter closed the Ronneby facility that at most had employed some 200 persons.[25]

The fact that *Nobel Biocare AB* has withdrawn its former *commissionaire* company (for internal deliveries) Nobel Biocare Production AB is thought to be mostly of an administrative nature, not directly affecting the larger (economic) picture of SIC 33101. Being founded upon the Brånemark system for osseointegration of titanium implants, this company is one of the pioneers in Swedish medical device technology of later years; see e.g. Rickne (2000), Fridh (2002). But the reclassification of the main manufacturing company Nobel Biocare AB from SIC 33101 to the code 27450 – "manufacturing of titanium" – between 1996 and 1999 was a somewhat surprising "emigration".[26] It can be said to illustrate a classical problem in economic/industrial statistics – namely, how to balance between the nature of the manufacturing activity as a kind of *process*, and the "destination" industry for its products. This, of course, depends on who is going to use the data – for example, the metalworking industry community, or someone who, like this author, tries to elucidate the structure and economic volume of the medical device industry. It also depends on who determines the code; an SCB official informally hinted that the reasons might have to do with tax considerations.

Be that as it may, then in the next period between 1999 and 2002, Nobel Biocare AB came at least halfway back to the industry for medical equipment and instruments, since it was again reclassified. Thus it is now classified in SIC 33102 which is more logical than 27450 as the former specifically deals with the manufacture of dental prostheses. It also means that at the next aggregate level, Nobel Biocare will be included in SIC 331 that adds up the two daughter codes for more overall figures of the medical equipment and devices industry. Whether it is an optimal choice could be discussed, since many other dental companies coded in SIC 33101 (i.e.

[25] http://www.techservice-ecemea.com/news/indexronneby.htm (May 2002). Baxter Medical AB is one of the top ten companies in SE-SIC code 51460, Wholesale of medical equipment and pharmaceutical goods.

[26] In fact, there is no *manufacturing* of titanium in Sweden at all (also stated in the daily Dagens Nyheter in April 2002), although there are some entities that *process* titanium, manufacturing more or less finished goods out of it

not in 33102) have a lot less advanced *systems* technology than Nobel Biocare AB. At the same time there are no "equals" to this company in the 33102 code but mostly small dental laboratories fighting hard to keep their numbers, which in this author's opinion would merit a reclassification to 33101. However, as to structural changes it deserves noting that Nobel Biocare during the six-year period studied has decided to specialize in the *dental* segment only, spinning off a part of the former company that dealt with titanium implants for other medical needs to a separate company (Entific AB, also in the SIC 33101 code). Further it has invested heavily in another dental segment, which perhaps might help explain the "titanium fix" in the former coding, namely the Procera line of individualised single-tooth crowns (i.e. "caps", not implants) made from titanium.

Going back to the list of ≥50 companies that are still in the SIC 33101 code in 2002 as well as earlier years, a number of further changes may be detected. Some other ones are in the works although not yet visible. The latter might be disqualifying to bring up in the midst of a study of statistics, but it deserves noting as it might help identify explanatory factors for a follow-up of the statistics in not too long. With its historical ties to Swedish innovation through several groundbreaking products in, e.g. cardiac pacing, electrocardiography, ventilation, cardiac angiography equipment, etc, thus the top company on the list of ≥50 employees, *Siemens-Elema AB*, has recently initiated *divestment* of former core activities. This comes as a consequence of the competitive situation of the German mother company's division Siemens Medical Solutions, leading to a reduction of the number of production units and restructuring of the remaining ones between sites in other countries. The plan according to news in late 2002[27] is for the Swedish activity to concentrate *on medical information technology* systems. Already before that, in the summer of 2002, it was decided to start a major restructuring of, i.a. life support systems, involving a planned partner in Germany, a process that is now subject to deliberation at the EU level due to competition aspects.

Crossing over from size class 8 to 9, that is having now more than 500 employees in Sweden, *Astra Tech AB* is a separate company, manufacturing advanced healthcare devices and medical implants for needs in urology, odontology, surgery and radiology. As it belongs to the AstraZeneca group without dealing with pharmaceuticals, it is on both accounts rather unknown to a wider public and difficult to find facts about. However, having partial roots in the Brånemark tradition, also this company is an important node in the biomaterials research & industry cluster in Western Sweden.

[27] Siemens Press Release Stockholm 11 November 2002

During the 1996-2002 period studied in the Business Register of SCB, the Swedish manufacturing company of the Gambro group for several years has had 750-800 employees in Sweden (for formal reasons it was renamed *Gambro Lundia AB in* the period that table 2-7 covers). Within the *total* period studied in this thesis, however, i.e. from 1985 onwards, Gambro as a group has expanded very much by acquisitions. This also includes the manufacturing side, internationally, but the main change is that the company has become a *provider of care services* making the manufacturing of products small in comparison. Thus it has now very large global operations in renal care - services and products - and blood component technology, worldwide employment today counting some 21000 employees. Reverting to the Swedish manufacturing company, some restructuring of existing activities within the group have taken place after 2000 and since led to Gambro Lundia AB considerably increasing its turnover, however without any large accompanying change in employment.

After the acquisition of the pacemaker division from Siemens-Elema AB in late 1994, the US cardiovascular device company St Jude Medical Inc. has expanded its Swedish operation over the period studied making it a new addition in the 500+ size class. Originally called Pacesetter AB, it now has changed to the name of its mother company that presently is No. 19 of the top-20 list of publicly traded medical technology companies in the United States. In the section on actual production of medical devices in this thesis, it is noted that pacemakers are missing from the Swedish production statistics in 1995. This probably was a direct consequence of a completely new actor entering on the industrial scene in Sweden.

Two other changes of name in the 1999 and 2002 columns of Table 2-7 above reveal international actors in a large shuffle impacting on two early medical device companies in Sweden. Thus in spring 1998 the British gas company BOC divested the different parts of its medical device activity BOC-Ohmeda, to several large actors. The earlier BOC Ohmeda AB in Helsingborg (originally Viggo AB), a Swedish manufacturer of supplies for infusion systems, then was acquired by the US company Becton, Dickinson Inc and given the name *Becton Dickinson Infusion Therapy AB*.

In another end of the same overarching BOC deal, the large, publicly traded Finnish medical device company *Instrumentarium* OY acquired British BOC-Ohmeda's operation in ventilation and intensive care, etc, centred in Ohio, US. In this connection Instrumentarium changed the name of its Swedish subsidiary *Datex-Engström* (acquired in 1994 from then Gambro AB) to Datex-Ohmeda AB. In that process, the name Engström – a well-known innovator in ventilation and respiration who originally started the company – disappeared from the Swedish medical device industry altogether. After this move, Instrumentarium made an internal merger and restructuring after which the Swedish Datex-Ohmeda in the 1999 column was completely

absorbed and restructured by 2002. Now the Swedish company thus bears the name of the mother company. In December 2002 General Electric (US) and Instrumentarium announced plans for an acquisition by GE. Also this is a process subject to approval by competition authorities within the EU.

It would carry too far to go through every company on the ≥50 employees list. However, the examples given and the "50+table" (Table 2-7= itself have demonstrated that there is a considerable mobility in the SIC code 33101, both within itself and between this and other codes. Other information confirms that that the industry is highly involved in an international restructuring trend.

2.1.5.2 Newer technology-based companies on the ≥50 list

Before leaving this section, however, it is interesting to note that in the column for 2002, Table 2-7 includes five of the 33 research- and technology-based companies that Laage-Hellman analysed in (NUTEK 1993), and one of the four included in his study (NUTEK 1998).

Apart from *Radi Medical Systems AB* in Uppsala, a quickly growing actor in cardiovascular devices that had reached the ≥50 level already in the 1999 investigation, it is for the first time that the other five appear in this list:

- *GEMS PET Systems AB*, also Uppsala, supplies for positron emission tomography
- *Atos Medical AB* in Skåne, making implants for urology, artificial joints, etc,
- *Breas Medical AB* in ventilation devices, with a real rapid growth so far,
- *CMA Microdialysis AB*, in advanced analytic instrumentation for clinical neuroapplications, and finally
- *Scanditronix Medical AB* in radiation equipment.

At least four of these six companies have changed structure, ownership, etc, in various ways during the time period covered by this study. Atos for example now is part of the Perbio Science AB group (otherwise engaged in biotechnology), and Scanditronix Medical (one of several Scanditronix-related companies) is owned by Belgian actor Ion Beam Applications.

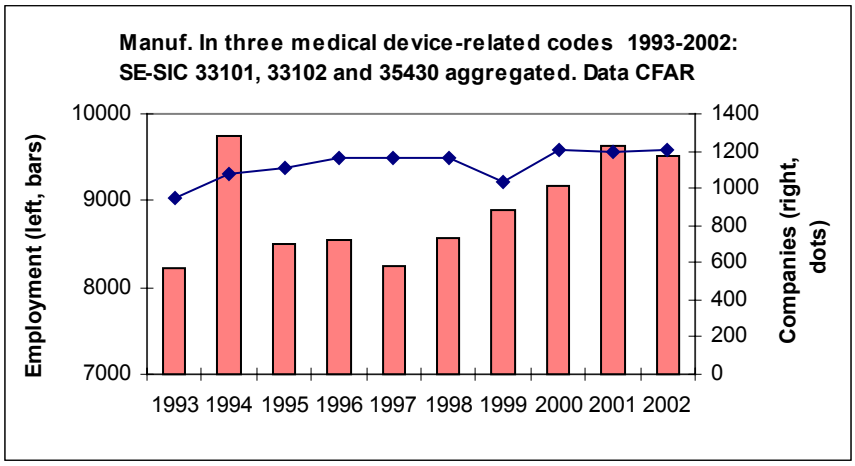
Actually another of Laage-Hellman's cases is indirectly implied by the ≥50 list as well, namely the earlier ICOR AB (NUTEK 1993). This company was acquired by *Louis Gibeck AB,* close to Stockholm, who in turn is on the list for 1996 above, at that time manufacturing supplies for intensive care, etc. The latter for a short time went public on the Stockholm stock exchange and subsequently was acquired by US actor in the same segment Hudson RCI. Upon moving the production out of Sweden, the company left the manufacturing code SIC 33101 for the wholesale code 51460.

2.2 A wider perspective: SIC 33102 and 35430, Dental products and Invalid carriages

2.2.1 Size classes and number of companies

Using the Central Business and Local unit Register of Statistics Sweden (CFAR), the number of companies and employment have been studied also for the two other manufacturing SIC codes of interest to this thesis. Figure 2-2 shows the overall picture from 1993, which is the first year for which these data are available according to the SE-SIC 92 industrial classification system. CFAR counts employment all the way from 0 and upwards.

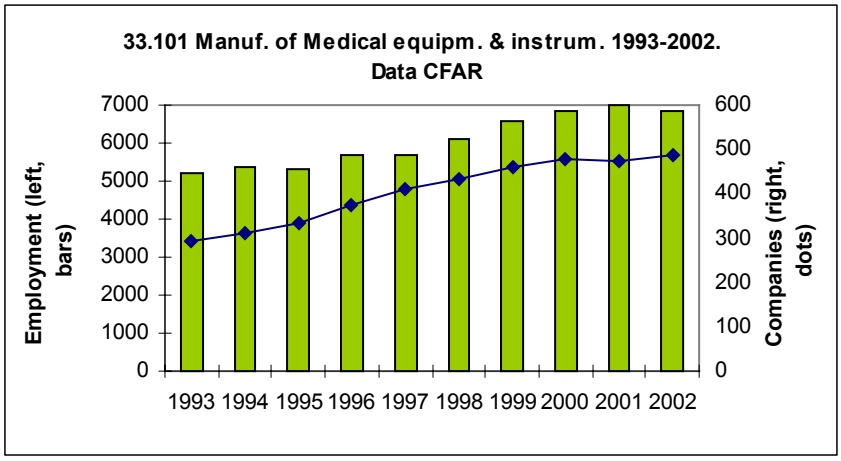
Figure 2-2 Employment and No. of companies in three manufacturing codes



Source: Statistics Sweden and own calculations

As with all aggregate figures, the picture looks different when one studies one branch at a time. Thus the SIC 33101 as well as SIC 35430 show growth over the entire period in both number of companies and number of employees, almost all size classes growing. The dental code has declined during 1995-2000, however. The following diagrams will show trends over the last decade in the three different industries:

Figure 2-3 Employment and No. of companies in SIC 33101

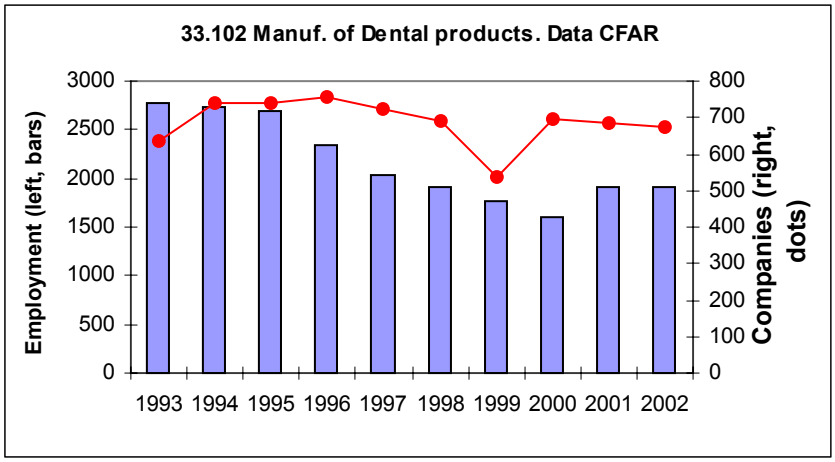


Source: Statistics Sweden and own calculations

Looking at size classes in the medical equipment and instruments industry (not shown here but available in the basic tables), the 50-99 and 100-199 brackets show the highest growth in number of companies as well as employment. Thus over the 10-year period studied, the "amplification factor" N_{02}/N_{93} is 3,24 for jobs in the 50-99 bracket and 2,65 in the 100-199 size class, these figures being larger than the corresponding growth of the number of companies in the code – 3,0 and 2,0 respectively.

Since some companies are at the border between two size classes, one step "across" changes the picture in both the size classes concerned. Thus in SIC 33101, one has to watch *two* size classes at a time. Otherwise there might arise confusion at sudden "losses" of some 1000 persons employed in companies in the bracket ≥500, which mostly are "retrieved" in the next lower class of 200-499 or the other way around. Thus the two largest size classes in medical equipment etc should probably be *viewed together*, as there is a tendency for the sum of these to stagnate in later years, in fact it has decreased somewhat from a high in year 2000. This is also reflected in the tapering-off in the most recent years 2000-2002 in the figure for 33101 above.

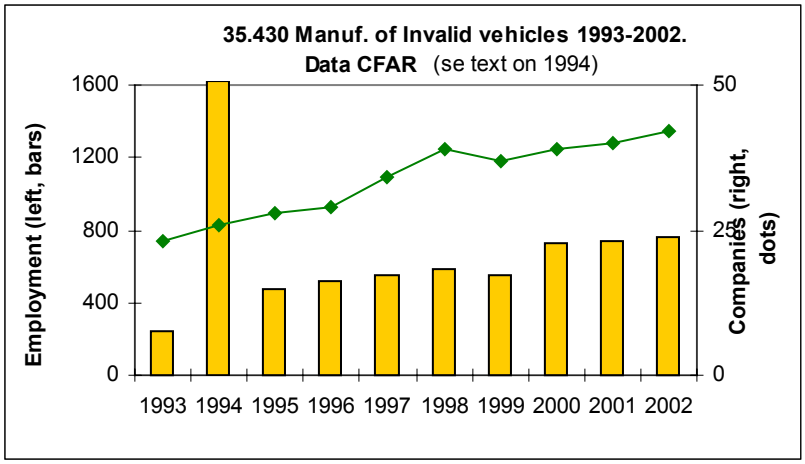
Figure 2-4 Employment and No. of companies in SIC 33102



Source: Statistics Sweden and own calculations

The *dental companies* include a very large share of companies/laboratories with less than 20 employees; further they have no representative larger than the 200-499-size class. The "dip" for 1999 in the *number* of dental companies, concerns companies with no employees (that is, sole proprietorships) and has not been explained. The upturn of the number of *employees* in the dental industry from 2000 to 2002, however, is explained by the reclassification of one of Nobel Biocare AB's local units; without its entry the employment in 2001 would have continued to decrease. This firm was placed in other codes before entering 33102, as has been related in the previous section on structural changes in the 33101 industry between 1996 and 2002. In fact, the seeming "stand-still" in the 33101 bars for 1996 and 1997 in the corresponding diagram for 33101 is likely to have the corresponding reason, that is the "exit" of Nobel Biocare from 33101 at that point of time.

Figure 2-5 Employment and No. of companies in SIC 35430



Source: Statistics Sweden and own calculations

In *the invalid vehicle industry* (or "…carriage" as the official name says) the few companies are well spread out among different size classes, the two largest ones being in the 100-199 bracket for all years since 1995. Of the three industries presently discussed, this industry demonstrates the highest growth, the number of jobs multiplying by a factor of ≥6 in the 20-49-size class and just over 3 in the 10-19 bracket. The number of firms ranges from 23 in 1993 to 42 in 2002. This helps explain why their number in the size class 20-49 has grown by a factor of 7 and that in the 10-19 class with a factor of 2,5.

The "monolith" bar for employment 1994 in the figure showing *manufacturers of invalid vehicles* is very likely an artefact that also explains the level for 1994 in the first, overall diagram. The probable origin was detected already in 1996, when a so-called branch report for "healthcare products" was commissioned from MM Publikationer AB (MMP 1996a,b)[28] for the present study. The company in question, a unit in Northern Sweden with a *highly diversified* production of a semi-protected kind, had more than 1000 employees. Directly contacting the company, the author learned that the number of employees who actually worked in the production of invalid vehicles was around 120 only. The case is now interpreted as a mistake in the *classification*, because at that period of time, companies or workshops of that kind were not to be classified as if they were operating under ordinary market conditions.

Provided the interpretation is correct, the situation also demonstrates the sensitivity of the classification when dealing with highly diversified entities. Thus even if had been correct to assign the company an SE-SIC classification, there would still remain the "problem" that by definition, the classification would be determined by the largest economic activity of the unit in question. This does not mean that the share of the dominant activity has to exceed 50 %; in principle it might be small as long as it exceeds that of other activities of the same kind (i.e., here manufacturing). Actually, the share of the economic value in this particular case is not known, but obviously the case illustrates the inherent risk of overstating figures of employment. See the chapter on Methodology for further details.

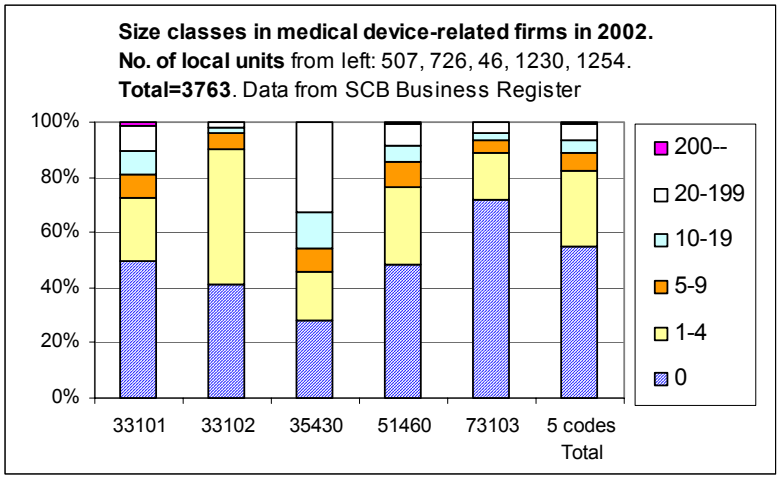
2.2.2 Manufacturing vs. other device-related codes, a brief look

To conclude these somewhat wider indications of the structure in medical device-related industries, two diagrams are given below where data for the three manufacturing industries are combined with the wholesale code 51460 and the R&D code 73103. The first shows the share of

[28] MM Publikationer AB, Uppsala was the predecessor of the present database company MM Partner

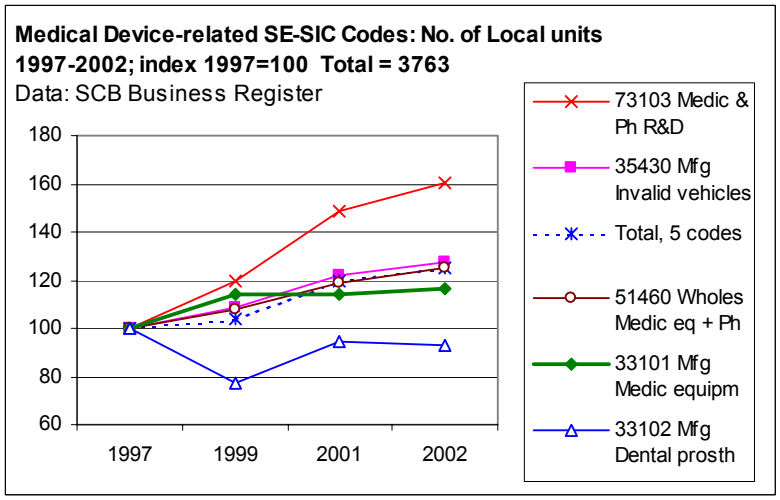
different size classes in each of the five codes as of 2002, demonstrating inter-industry differences in the shares of the largest and the smallest size classes. As the numbers of companies are very different across the five industries, we also show an index of the changes in number of companies (or, rather, local units – see chapter on Methodology) in the most recent years. Hereby, it should be remembered that SIC 51460 as well as 73103 have a substantial proportion of *pharmaceutical*-related activities, that is, medical devices and equipment represent only part of those codes.

Figure 2-6 Size classes in three SE-SIC codes related to medical devices



Source: Statistics Sweden, own calculations

Figure 2-7 Number of local units in five SE-SIC codes related to medical devices



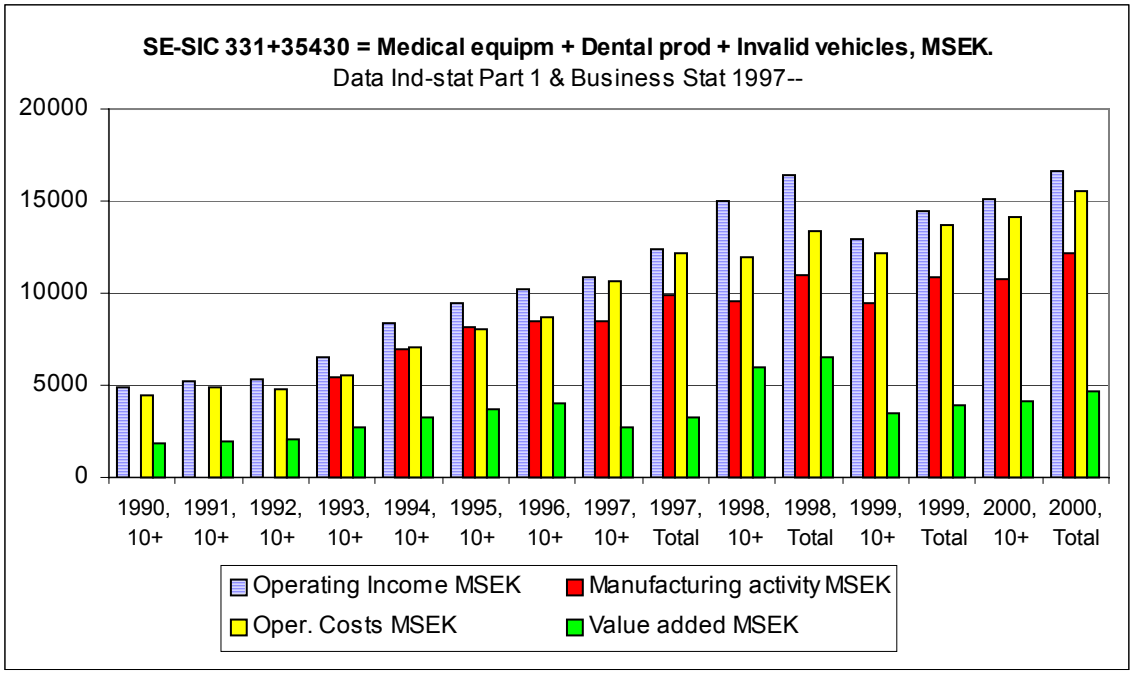
Source: Statistics Sweden, own calculations

2.3 Key economic indicators for SIC 331 and 35430

Based on data from the former Industrial Statistics Part 1 (up to 1996) and its successor Business Statistics (from 1997 onwards), we present an aggregate picture of key economic data for the codes SIC 331 and 35430 combined below. The SIC 331 is the 3-digit, semi-aggregate industry level for which data was publicly available until and including 1995. From 1997 and on, a new form of statistics was introduced, the Business Statistics (*Företagsstatistik*; see chapter on Methodology for a detailed description with definitions, etc). From that year onwards, figures are available not only for companies with at least 10 employees, as it was before, but now also for those who have less than 10 employees. The two categories of data are published separately so as to enable a long time series for those who wish to compare with the situation from 1988 and onwards, when the former *Industristatistik* Part 1 was introduced.

Representing the sums of SIC 33101 and 33102 as presented above, the figures for SIC 331 have here been added to those of 35430, Invalid vehicles. It deserves noting, that *Företags-statistik* as a statistical source gives an " annual corporate account" for "Sweden Ltd", as it is based on the corresponding basic data from Swedish manufacturing and service companies, etc, depending on what branches of activity one studies.

Figure 2-8 Key aggregate economic data for SE-SIC 33101+33102+35430



Source: Statistics Sweden, own calculations

The diagram here is *constructed* bottom-up from data for the three branches, but only the aggregate picture is shown for reasons of space. In line with the above there are *two* sets of bars for each year from 1997 on, the first of which gives Totals, i.e. covering companies of *all sizes* in the codes. The second set of the bars for 1997-2000 is only for companies with *less than 10 employees*. The "totals" in general exceed the sum of the "10+ only"-figures with around 10 per cent. In each set, the second bar from the left (from 1993 on) shows the volume of industrial *manufacturing activity*, which makes up the lion share of operating income. This figure is to be compatible with the corresponding product-based industrial statistics that are analysed in the next chapter on production and foreign trade with medical devices in Sweden. Operating income in both sets of bars for 1998 are "inflated" due to one of the large companies with SIC 33101 as *secondary* classification having had extraordinary income that year. As has been stated in the main investigation of the 33101 code and in the chapter on Methodology, this kind of (relative) *over-coverage* may occur when statistics are based on data from local units. Conversely, *under-coverage* may occur if one looks at company level only.

As to the proportions of the three industries in the total mix, the Invalid vehicles code (35430) contributes with 8 per cent of operational income and value added and 7 % of costs. The Dental code (33102) in year 2000 has almost doubled its share of the grand totals from 1999 to 2000 because of the reclassification of Nobel Biocare AB already mentioned. Thus this code contributed 14 percent of the income, 13 per cent of the costs and 19 per cent of value added in the grand totals (in 1999 the corresponding shares for 33102 was 7, 8 and 10 per cent respectively). This then means that 33101, our Medical instruments code, represented the lion share with some 70-80 per cent of operating income and cost and value added, respectively.

To quantify the aggregate development in the three industries considered – medical instruments, dental products and invalid vehicles – the compound annual growth rate (CAGR) has been calculated for the two five-year periods 1990-1995 and 1995-2000, as well as for the entire 10-year period. Although the periodisation may be considered somewhat arbitrary, it is obvious that the later five years were less successful than the first on most accounts. Looking at 331 only (i.e. two of the three branches), its values for operating income and value added are somewhat lower than the aggregate growth figures indicate in the right-hand columns above. Thus the "little sister", the invalid carriages industry, contributes to lifting the totals, growing with close to 18 per cent per year in income and close to 16 per cent in value added over the entire ten-year period.

Table 2-8 Economic indicators for three aggregated codes, 331+35430

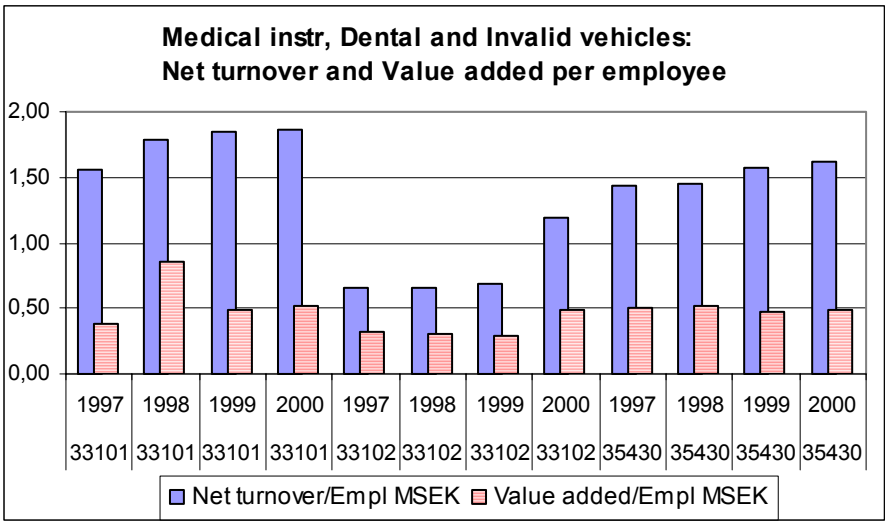
	2000, 10+	2000, Total	33101 % of 2000, Total	33102 % of 2000, Total	35430 % of 2000, Total	CAGR 1990-1995 %	CAGR 1995-2000 %	CAGR 1990-2000 %
Oper. Income MSEK	15082	16659	78	14	8	14,3	9,7	12,0
of w hich Manuf. MSEK	10780	12165	73	18	9	not appl.	5,6	not appl.
Oper. Costs MSEK	14131	15593	80	13	7	12,6	11,9	12,3
Employees	7798	9304	72	20	8	4,6	1,6	3,1
Value Added MSEK	4130	4707	73	19	8	14,7	2,3	8,3
No. Local units	151	1270	41	55	3	16,0	3,0	9,3
Income/empl MSEK	1,934	1,791						
Value added/empl MSEK	0,530	0,506						

Source: Statistics Sweden Business Structural Statistics/Basfakta, own calculations

The second row after "Operating income" in the table refers to the value of the *actual manufacturing* activity in the local units in question, the operating income also including e.g. income from *trade activities* (e.g. single-use supplies that without processing are added to shipments of instrumentation for the convenience of the user, etc) and also other income items that may or may not be related to actual production. The values of income from manufacturing are to correspond roughly with the figures extracted from the survey on industrial production of goods and services (*Industrins varuproduktion*, IVP) which is also the case here (see section 3.2). The manufacturing part of operating income is known only *from 1993* and onwards, which is why we have computed CAGR for that item for the period 1990-1995 only.

Value added (see chapter on Methodology) may be thought of as industry's contribution to a country's GDP. Likewise, at company (or local unit) level, value added is the contribution of that particular entity to the aggregate of companies (or local units) in a specific SIC code.
A calculation of operating income and *value added per employee* for each of the three branches reveals the following picture, finally. The latter relation, often called *labour productivity*, over the time studied here is around SEK 0,5 million per employee in 33101 and 35430 while it is around SEK 0,3 million in the dental code 33102. Turnover per employee increases from SEK 1,6 to SEK 1,8 million in medical instruments, 0,67 million in the dental code and grows from 1,4 to 1,6 million in the industry manufacturing invalid vehicles over the years 1997-2000.

Figure 2-9 Income and value added per employee in SIC 33101, 33102 and 35430



Source: Statistics Sweden Business Structural Statistics/Basfakta, own calculations

The diagram is based on Totals, i.e. companies both smaller and larger than 10 employees are included. The values are measured at *activity* level, not company level (see chapter on Methodology). Net turnover here is not identical with operating income in the Table 8, but the calculated relations are very similar. Again the "irregularity" in SIC 33101 the year 1998 is visible; mainly in the indicator value added per employee but not so much in turnover per employee. Further, the "Nobel Biocare effect" in the dental code raises both indicators radically from 1999 to 2000.

2.4 Research and development – a glimpse

As a complement to this chapter, a table with basic data on some 20 companies conducting R&D has been compiled using the MM Partner database for the years 1997-2001. See Appendix 6 for information on net turnover, employment and R&D expenditure of those companies.

3 Production and foreign trade in medical devices

3.1 Method applied

Before, or in parallel with, taking part of this chapter, the reader is recommended to have a look at Chapter 4 on Methodology, to begin with section 4.3. The international product classification system as well as the basics for identifying product groups for this investigation will there be described more in detail. Table 3-1 on product groups below thus is a simplified version of the full one in 4.3.2 and intended as an introduction to the following account on production, exports and imports etc of medical devices in Sweden. Also, sections 4.6.2 and 4.6.3 on principles for collecting production and foreign trade statistics would be useful to refer to. Further, Master tables for the *aggregate* production, exports and imports figures and some diagrams showing the same time series distributed by product group, are presented in Appendix 2.

Starting from the most disaggregate level possible, the following product groups are included in the analysis of commodities produced in Sweden and traded with other countries:

Table 3-1 Simplified scheme of product groups covered

HS/CN 4-digit level	Product group
Main group	***Aids and implants***
8713	Invalid carriages (incl. spare parts) *(8-digit level is covered + 871420)*
9021	Orthopaedic appliances, implants,… *(All 8-digit items included)*
Main group	***Medical equipment and instruments***
9018	Instruments and appliances used in medical, surgical, dental or veterinary sciences…*(All 8-digit items included)*
9019	… Therapeutic respiration apparatus; parts and accessories… *(Only 901920)*
9022	X-ray etc. apparatus, including radiography or radiotherapy apparatus, etc…*(All 8-digit items except 1900+2900= for non-medical purposes)*
8419	Sterilisation apparatus (841920)
9402	Medical, surgical, dental or veterinary furniture *(8-digit level covered)*
Main group	***Miscellaneous***
3005	Bandages and similar articles,… (see section 4.3.2 for coverage)
3006	Pharmaceutical goods for medical device needs (see section 4.3.2 for coverage)
9001	Optical lenses & glass for corrective use…(see section 4.3.2 for coverage)
9004	Spectacles… for corrective use… (see section 4.3.2 for coverage)
3701	Photographic plates and film … (= 37011010)

Source: Statistics Sweden, own compilation

Production, exports and imports values have been collected from 1985 up to the present for each of a number of product groups concealed under the summary numbers above, in all close to 100 groups. For the aggregated production, exports and imports figures, the totals for the three main

groups indicated (again, see 4.3.2) have been calculated in current as well as constant prices; see 4.3.2 for the procedure on constant prices.

The deflator to calculate constant prices has been constructed in this way: *First* we combined the respective price index series for the 3-digit level SIC 385 in the earlier SE-SIC 69 scheme for the years 1985-1995 and the 2-digit level SIC 33 in the newer SE-SIC 92 from 1995 and forward into one "uninterrupted" series[29]. This was done in a way that follows advice from Statistics Sweden of the effect that *1995* was taken as the year from which to introduce the new index series. *Second*, after calculating the new indices and multiplying with the relevant economic values for year X, we have divided them all by their respective 1985 value, the resulting series thus expressing all values in constant 1985 currency (MSEK).

Following this procedure, raw data have been turned into aggregate values for each of the three variables *Production, Exports, Imports*, presenting in current and constant prices

a) Grand totals for *all* product groups = all three Main groups aggregated as well as
b) Totals for Main group "Technical aids and implants" and
c) Totals for Main group "Equipment and instruments" according to the Table 3-1 above.

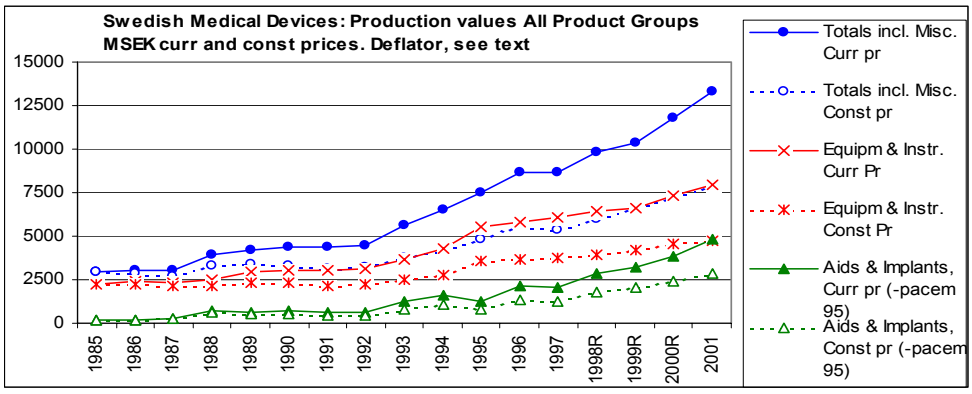
As to the Main group "Miscellaneous", however, it is comparatively small in volume and looking rather "erratic" on the production side (see Appendix 2 with Master tables for the relevant HS/CN codes). Therefore, no separate curve was made for the "Miscellaneous" main group, but its values are included in the curves for Grand totals, of course. Three sets of diagrams intended to be as symmetrical as possible are presented below. First comes the development over the period 1985-2001 for Production and 1985-2002 for Exports and Imports, respectively. Second, we present for each a bar diagram showing the compound annual growth rate (in current prices) for the two large "Main groups" and for Totals (incl. Miscellaneous). The third diagram in each series (a pie chart) shows the Totals distributed by product groups.

Some results are discussed directly after the separate production – exports – imports diagrams. The main discussion, on integration of production and trade data and calculations of the apparent domestic market, will take place after the presentation of all three sets of diagrams below. After that in turn, we will present some data on the geographic distribution of exports, identifying the main receiving countries for Swedish medical device products.

[29] Although it might sound asymmetric with one 2- and one 3-digit level, this is not the case. Since there was no "medical device" industrial code in the old SE-SIC 69 system in contrast to the then new SE-SIC 92 nomenclature, we chose the next higher level in both systems for the deflator, i.e. SIC 385 in the old and SIC 33 in the new SE-SIC nomenclature, both signifying precision and scientific instruments, etc.

3.2 Production 1985-2001

Figure 3-1 Production 1985-2001, SEK million, in current and constant 1985 prices



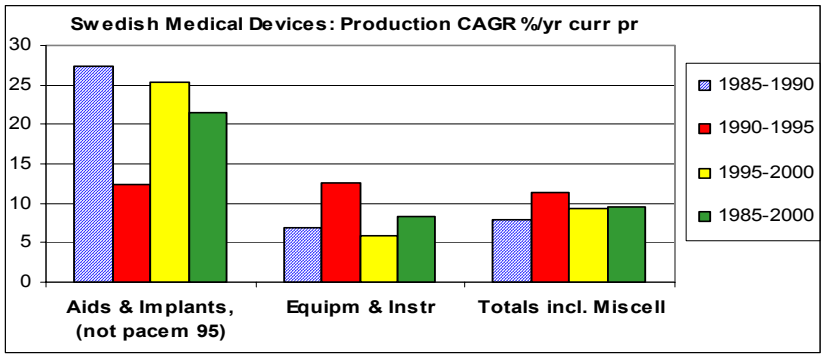
Source: Statistics Sweden, own calculations
Deflator for Production in constant values: PPI SE-SIC 69:385/SE-SIC 92:33, converted to 1985=100
All Price Indices (PPI, ExPI & ImPI) measured as at December the respective year

Production roughly doubled in the eight-year period 1985 to 1993, then another time in the six years to 1999. A phenomenon worth noting is the flat level between 1996 and 1997 in the curves for all three product groups. Although "flat" periods may be seen also in 1990-1992, the latter one might rather illustrate the general difficulties in the economy during that period. The one in 1996-1997 might instead be attributable to a *change in statistics collection principles* that took effect from the reference year 1997. Thus the industrial production statistics from that year only takes into account the production in local units (see chapter 4 on Methodology) belonging to companies with *at least 20* employees, whereas before 1997 the limit was *10 employed* persons only. As we have shown in Chapter 3 that a large proportion of medical device companies are quite small, it is likely that production statistics in this way "misses" real values. The same factor was noted already in (IVA 1988), at that time referring to companies *even smaller* than 10 employed persons actively participating in production as well as exports. Somewhat speculatively speaking, one is tempted to imagine the part of the curve for the years 1992 to 1996 to "continue" roughly in parallel to the present 1997 to 2001 part of the curve.

The reader might observe a temporary dip in the curve for "Aids and implants" in 1995. This is an effect of *pacemakers* missing in the raw data from Statistics Sweden (SCB) that year, a likely figure being at least SEK 600 million. Especially in view of exports and imports of pacemakers showing a "normal" development for the reference year 1995, the reason is believed to be that the statistics did not manage to keep pace when Siemens-Elema AB in late 1994 divested their pacemaker division to the American company St Jude Medical, Inc. This process resulted in a

new industrial actor entering the scene and taking over responsibility: Pacesetter AB, which is now renamed after its mother company to St Jude Medical AB.

Figure 3-2 Production growth CAGR in five-year periods 1985-2000



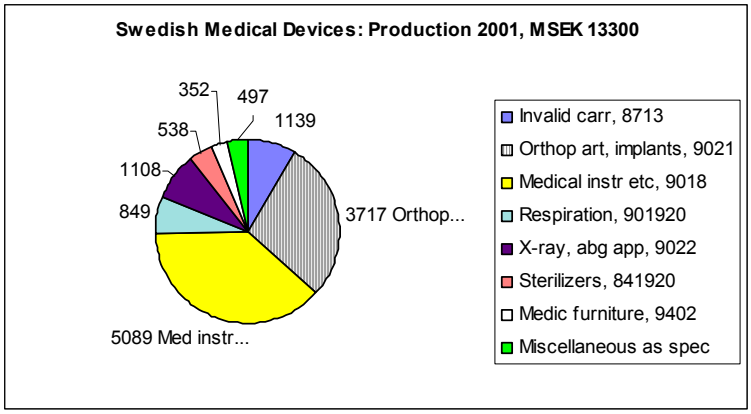
Source: Statistics Sweden, own calculations

As the 5-year intervals chosen have proven somewhat impractical in view of what has been said about pacemakers missing in the raw data for 1995, the compound annual growth rates (CAGR) for "Aids and implants" are adversely affected in two of the three five-year periods indicated. Thus growth appears lower than it should be in the period 1990-1995 and, conversely, higher than it ought to be in the period 1995-2000[30]. From the relations between the other bars it is likely that CAGR in the "*Totals* incl. Miscellaneous" bars would be higher for 1990-1995 as well as for 1995-2000, especially the former.

The Swedish overall growth figures for production may be compared to the overall growth of the international medical devices market of 5-6-7 per cent annually in the last few years. Although the period 1990-1995 was still better (despite the pacemakers missing that last year), growth over the entire period for grand totals, i.e. all product groups aggregated, thus have been around 10 per cent per year in current prices.

[30] If one looks at the "*Aids and Implants*" only, CAGR of production values for a periodisation *one year ahead* of the periods chosen above, the figures look like the following (all in per cent per annum):
1986-1991 = 28,6 %, 1991-1996 = 26,5 %, 1996-2001 = 17,5 % and 1986-2001 = 24,1 %, vs. the diagram figures:
1985-1990 = 27,5 %, 1990-1995 = 12,3 %, 1995-2000 = 25,4 %, and 1985-2000 = 21,5

Figure 3-3 Production 2001, SEK million, distributed by product group[31]



Source: Statistics Sweden, own calculations

It is seen that the product group "Medical instruments and appliances" (HS/CN 9018) is a dominating group with close to 40 % of total production, slightly larger than the groups "Orthopaedic articles & implants" (28 %) and "Invalid carriages" (9 %) taken together. Apparatus for X-ray and radiation treatment (Sweden working mostly in the X-ray part) and Respiration products make up around 8-10 % each.

3.3 Foreign trade, general aspects

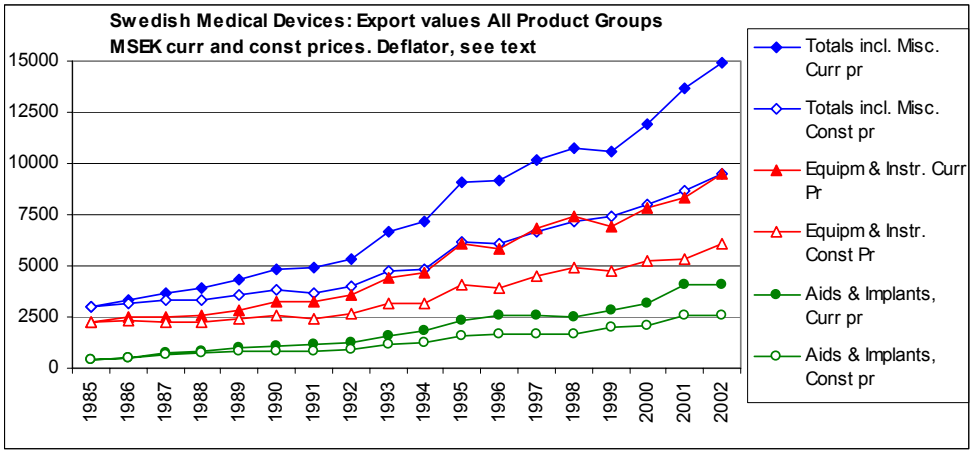
Note that exports figures in the diagram stretch until 2002 in contrast to those for production. As explained in the chapter on methodology, foreign trade figures are "easier" to collect than production figures, provided the exports values exceed a certain "floor"; otherwise exporters do not have to have their merchandise registered according to the EU regulations. As is noted in the methodology chapter, the principles for accounting for foreign trade have changed due to Sweden's membership in the EU. Before membership, all goods were registered also according to country of origin and country of final destination. Within the EU, however, trade *between two member* countries is *not* recognised as "exports" or "imports". Therefore, imports can be traced only to "dispatching country", whether or not that is the country of origin or just a transit point. If trade takes place with *non-EU members*, however, then like before, the data are relevant for country of destination and country of origin, respectively. As a consequence of this asymmetry, it is no longer relevant to calculate net trade on a *geographical* basis, as one will never know from where they really originate. Taking certain other conditions for comparison into account, one may still calculate net trade on an overall basis, however. Thus overall net trade is also presented further below.

[31] In all three pie charts on production, exports and imports values distributed by product groups, the latter start with *Invalid carriages* "at 12 o'clock" and then go clockwise via the striped section that denotes *Orthopaedic appliances*, etc

3.4 Exports 1985-2002

In the following exports and imports diagrams, the time period as explained is one year longer than for production.

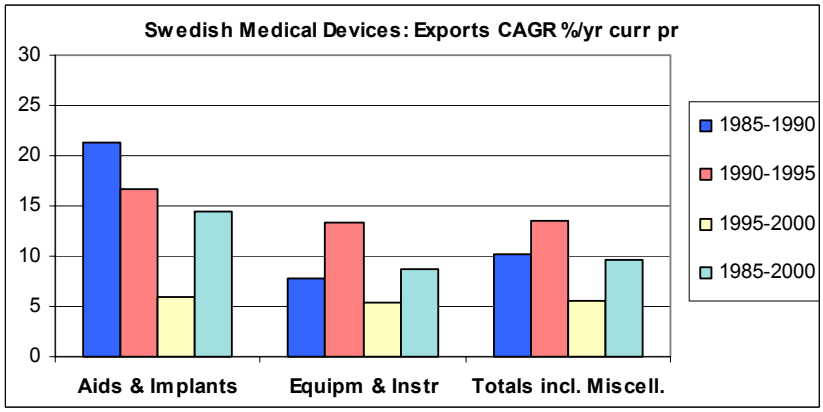
Figure 3-4 Exports 1985-2001, SEK million, in current and constant 1985 prices



Source: Statistics Sweden, own calculations
Deflator for Exports in constant values: ExPI SE-SIC 69:385/SE-SIC 92:33, converted to 1985=100
All Price Indices (PPI, ExPI & ImPI) measured as at December the respective year

As may be seen from the curve, total exports almost doubled in five years from 1985 to 1990, after which it took seven years to double again, to 1997. During the most recent five years exports values increased by another 50 % reaching the present level of some SEK 15000 million, everything in current prices. The good growth in the period 1999-2002 is not fully being captured in the following CAGR values calculated here, as those presently "end" in 2000.

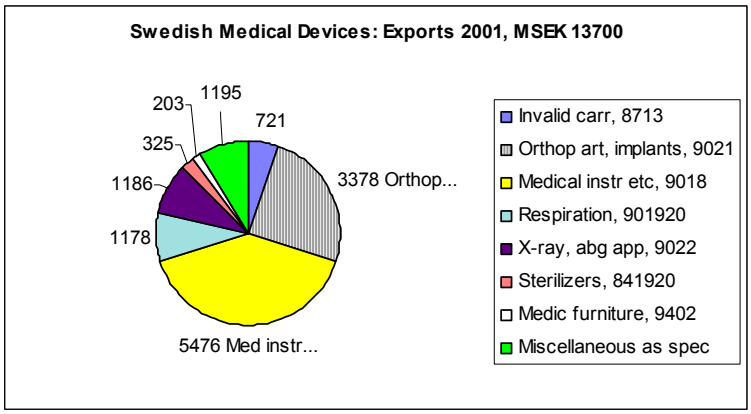
Figure 3-5 Exports growth CAGR in five-year periods 1985-2000



Source: Statistics Sweden, own calculations

The CAGR profile for the periods indicated follows – not unexpectedly – a pattern similar to that of production, exports growing somewhat less than production in the "Aids & Implants" main group and somewhat more in the Totals, the latter also including the "Miscellaneous" main group. The last five-year period, i.e. 1990-1995, clearly shows lower annual growth with some 5 or 6 percentage points; however overall export growth in current prices is close to 10 per cent per annum over the entire 15-year period.

Figure 3-6 Exports 2001, SEK million, distributed by product group

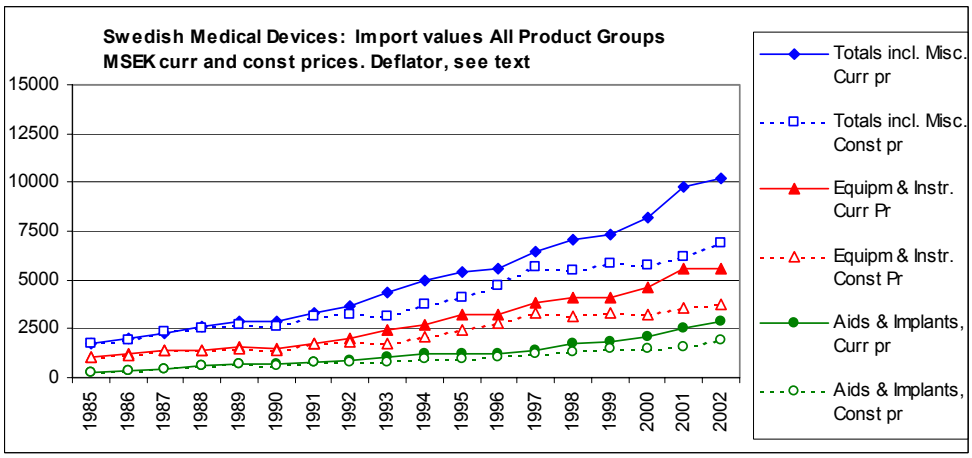


Source: Statistics Sweden, own calculations

The distribution of exports by product area is rather similar to that of production. Thus in both, two thirds of the total values are represented by the two large product groups "Orthopaedic articles and implants" plus "Medical instruments, etc".

3.5 Imports 1985-2002

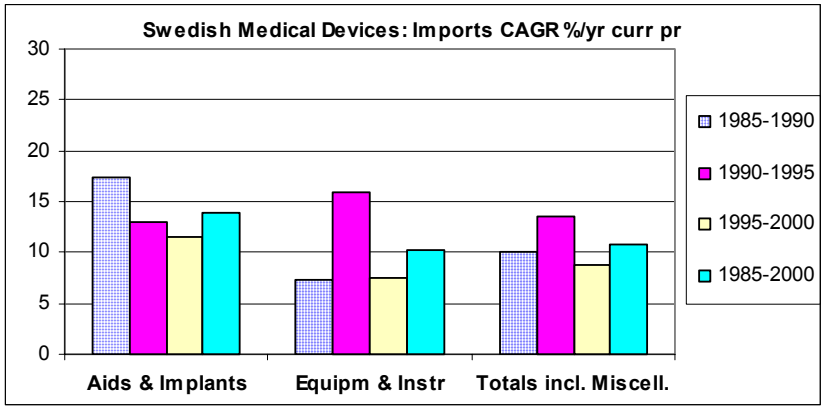
Figure 3-7 Imports 1985-2001, SEK million, in current and constant 1985 prices



Source: Statistics Sweden, own calculations
Deflator for Imports in constant values: ImPI SE-SIC 69:385/SE-SIC 92:33, converted to 1985=100
All Price Indices (PPI, ExPI & ImPI) measured as at December the respective year

Shown in the same scale as production and exports, imports are seen to be significantly smaller. It took 15 years, i.e. 1985 to 2000, for imports to increase with a factor of 4 as compared to 14 years for production and 12 years for exports, counted from 1985. Imports have not been studied in detail in this thesis; these data are intended for calculations of net trade and for preliminary estimations of the supply to the domestic market mainly.

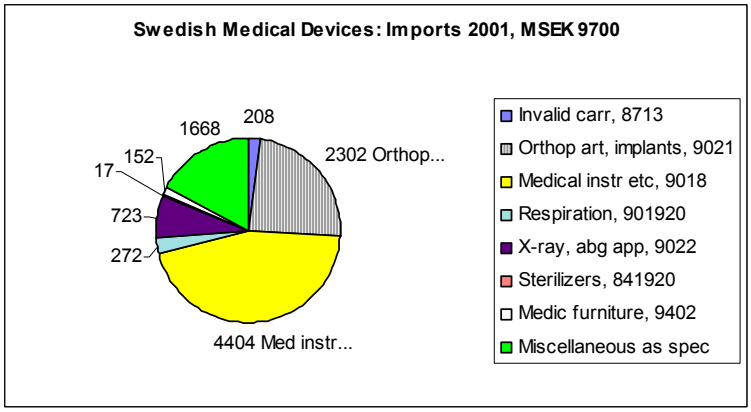
Figure 3-8 Imports growth CAGR in five-year periods 1985-2000



Source: Statistics Sweden, own calculations

Imports CGAR are similar to the results for exports. Imports growth was lower in the main group "Aids & Implants" in the decade 1985-1995 and somewhat higher in the "Equipment & Instruments" main group during the later periods, otherwise there are no big differences.

Figure 3-9 Imports 2001, SEK million, distributed by product group



Source: Statistics Sweden, own calculations

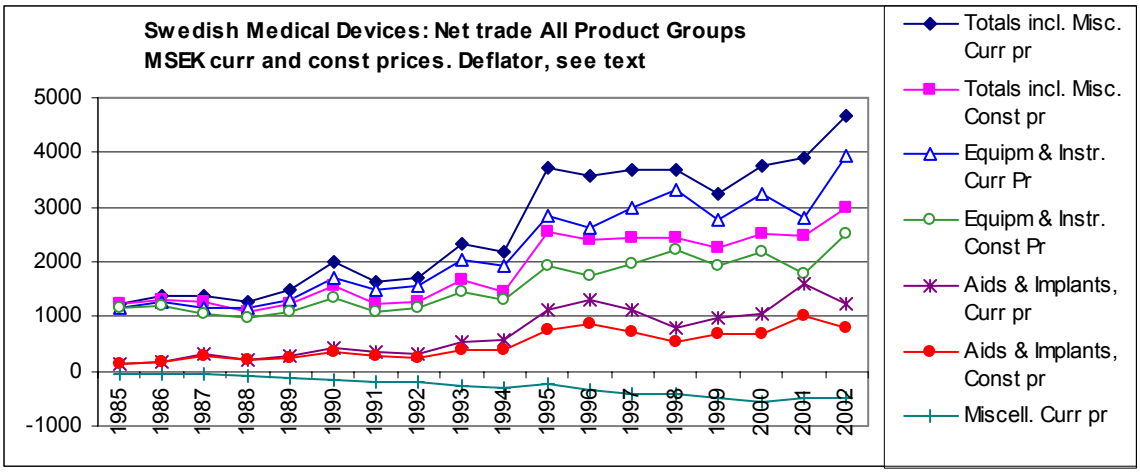
In comparing the pie charts for production, exports and imports, the main differences in imports distributed by product group reflects Sweden's relative strengths and weaknesses and (broadly

speaking) degree of self-sufficiency. Thus the product group "Invalid carriages" is an obvious strength, representing only 2 % of total imports value but 5 % of exports and 9 % of production. Conversely, a relative *lack of* strength is found in domestic production of the several types of products hidden under the "Miscellaneous" heading (for its coverage, see Section 4.6.2). Out of total imports, the "Miscellaneous" main group represents a full 17 %, and although it makes up 9 % of exports, its share of production is only 4 %.

3.6 Net trade

The balance of trade, i.e. the difference between exports and imports of goods, is usually calculated on a national basis. The corresponding number on the industry level is often called Net trade. Since the figures in the diagram below by and large are decidedly >0, i.e. Net trade is Net *exports*, the deflator calculated uses the Export Price Index only, applied to the difference between exports and imports for a given product group. The overall picture of Net trade in the product groups studied *appears* very positive, arithmetically indicating a trade surplus of an order of size corresponding to 40 per cent of the Swedish production in 2002 in current as well as constant prices. This is not the complete picture, however, as will be understood from the next section on comparisons of data and data integration from production and foreign trade.

Figure 3-10 Net trade 1985-2002, SEK million in constant and current prices



Source: Statistics Sweden, own calculations
Net Exports in Constant prices calculated as $(Exp\text{-}Imp)_{curr}$ deflated with ExPI SE-SIC 69:385/ /SE-SIC 92:33 and converted to 1985=100 All Price Indices measured as at December the respective year

The somewhat odd curve below zero in the figure is just to indicate that the third main product group, "Miscellaneous", follows a different pattern from that of the two other groups; thus it demonstrates an almost constant deficit over the 17-year period. Using the same price index for

all three main groups might be questioned; the "Miscellaneous" group being rather different from the other two. Additionally, there are differences among the main groups "Equipment & instruments" and "Aids & Implants" as well. On the other hand, it would be very difficult to define what other indices to use in order to keep a reasonable symmetry. Since the "Equipment & instruments" main group dominates in all instances (60 per cent of total production value in 2001), and as the main group "Aids & Implants also includes certain products relating to the kind of precision instruments goods (pacemakers, hearing aids etc) that the price index codes are intended to capture, we feel it is reasonable to try the same indices for all product groups.

3.7 Data integration - Comparing production and foreign trade

The observant reader may already have noted that exports seem larger than production for most of the time period studied. This is indeed the case. Let us see what the curves presented above for production, exports and imports look like if we put them together.

For reasons of space, figures in Table 3-2 below are given in five-year intervals up to 2000. Also year 2001 is included, the most recent year for which *production* values are available at the time of printing (in May 2003). Preliminary trade data for 2002 are at hand, however. Overall compound annual growth rates in current prices for the period 1985-2000 are given as well.

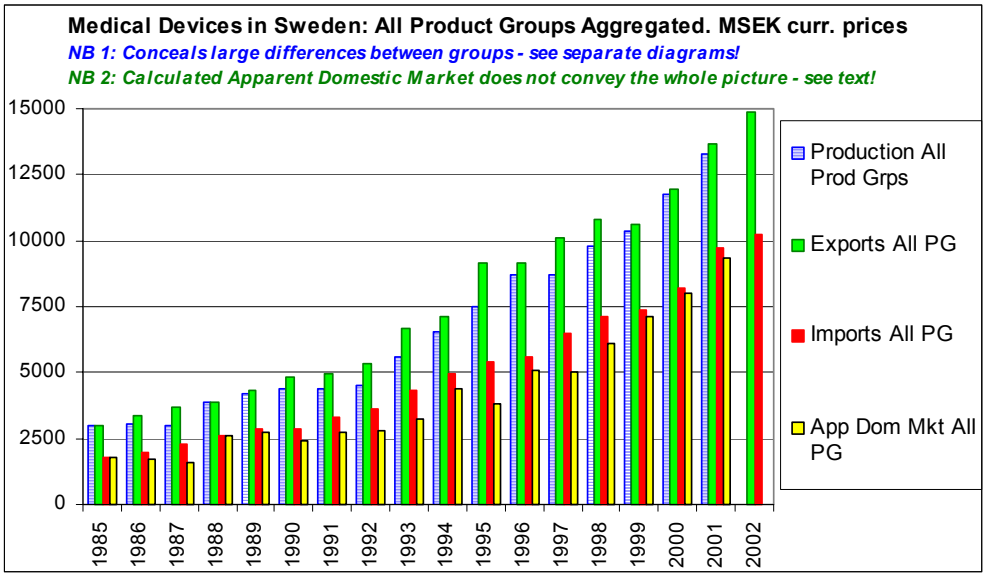
Table 3-2 Summary of product-based economic values in five-year periods and overall CAGR

Totals, MSEK, based on product groups acc. to section 3.1 above	1985	1990	1995	2000	2001	2002	CAGR 1985-2000 % p.a.curr
Production	2987	4381	7510	11766	13289	n.a.yet	9,6
Exports	2991	4850	9124	11946	13662	14891	9,7
Imports	1769	2855	5397	8200	9746	10202	10,8
Net trade (Exports-Imports)	*1222*	*1995*	*3727*	*3746*	*3916*	*4689*	
Apparent Domestic Market	1690	2386	3783	8020	9373		

Source: SCB, own calculations

The full time series for the table above is presented in the Master table (see Appendix 2), on which also the following diagram is based:

Figure 3-11 Production, Export, Imports and Apparent Domestic Market, SEK million



Source: Statistics Sweden, own calculations

3.7.1 Calculation of Apparent Domestic Market

Production is represented through the first bar from the left, followed by Exports and Imports, respectively. The fourth bar is the so-called Apparent Domestic Market, which is calculated according to an idealised "materials balance":

In + Prod = Out + Acc ("Acc" = accumulated)

as a chemical engineer would write it (e.g. the author), or

Imports + Production = Exports + Domestic consumption

as a simplified text in general economics could express it, looking from the perspective of production of (physical) goods, or

Apparent domestic market = Manufacturing shipments + Total imports - Total exports

as a paper on definitions in trade statistics formulates it (IndCan 2000), where

⊗ "Total exports" include domestically manufactured goods, including imports that have been *substantially enhanced* in value, but also *Re-exports*. The latter term refers to imported goods that leave the exporting country unchanged (or minimally processed, *not* substantially enhanced in value)

⊗ "Total imports" include genuine imports as well as *re-imports*. The latter are former exports that return from a "visit" abroad *without* being materially altered or substantially enhanced in value

The term (manufacturing) "*shipments*" is not identical to production values, but as explained in section 4.6.2, a sales-based market value is used as a *proxy* by Statistics Sweden, similar to an official US definition of "shipments" that is also given in the same section. Thus we will use the

latter, outside the EU more common, term somewhat interchangeably with "production" for the remainder of the present discussion.

3.7.2 The "Exports greater than Shipments" problem

Since export values are greater than production values for the entire period, a phenomenon that was also noted in the Academy study (IVA 1988), there is a clear indication that the production values identified in this study do not capture the real production values. Although it might appear illogical that Exports > Imports, it is not necessarily because of errors in recording. Thus there are several possible reasons for the situation at hand, some of which have been listed in section 4.7 of the methodology chapter:

A major *principal* problem of a *general* nature affecting the compatibility of production and foreign trade data is that the collection methods differ. Thus data on *shipments* of goods are based on annual *surveys* to local units in the manufacturing industries, in Sweden through "*Industrins varuproduktion"* (Production of commodities; see section 4.6.2). *Foreign trade* values, on the other hand, in Sweden's case are based on *a mix of* a) for intra-EU trade, actual trade data reported by companies each month, provided exports or imports are at least SEK 1,5 million on an annual basis, and b) for non-EU trade, *administrative data* in the form of customs documents are used. The different data sources differ conceptually on a number of points, including coverage (e.g. cut-off number of employees of the local units to be included in production figures, cut-off values for reporting of exports/imports data to be compulsory, etc), valuation (production figures reflecting value at the factory door while exports values are quoted f.o.b. and imports c.i.f., etc), classification (of companies *and* goods), period of reporting (due to companies having different financial year), and level of estimation (modelling of missing data, etc).

Reasoning about these factors is rather brief in the one source (co-)produced by Statistics Sweden that the author has managed to identify (NUTEK 1999 & 2000, also referred to in the chapter on methodology). In fact it only *cautions* about comparing manufacturing and foreign trade data, indicating *some* of the potential problems identified here. However, it does not give any advise as to possible ways of *handling* situations as the one present here, and no references for further study are given. This is despite the fact that the tables in those reports include medical electronics, partially with figures identical to those of the present report.[32]

[32] It should be noted that the topic of the NUTEK reports referred to is the *entire Swedish electronics industry* (and a large part of the IT industry); where production at an aggregate level generally is greater than exports.

However, in a methodology paper published by Statistics Canada a thorough analysis is presented of the problems involved in integration of international trade and manufacturing shipments commodity data (StatCan Rupnik 2000). A further aspect making this paper highly relevant for the present work is that it identifies three dominating manufacturing branches of its industry where the Exports > Shipments problem is *persistent*. Two of these relate to *instruments*, one of them being the (earlier[33]) Canadian SIC code "Other Instruments, Related Products". The source here explicitly refers to the *HS/CN chapter 90* with its contents of, e.g. medical/surgical goods that make up major portions of the product groups under study in this thesis. Although not all Exports > Shipment cases may be relevant to other countries (the third major Canadian problem being indigenous *fish* products, for example), there is reason to believe that instruments in fact *do* represent a very difficult area at large, as is pointed out by the British study referred to earlier (DOH-ABHI 1997).

3.7.3 Ways to tackle the problem – in principle

The Canadian analysis (StatCan Rupnik 2000) points out that actual calculation of corrections for the various "inconsistencies" referred to must be seen as a responsibility of the real *stakeholders* – industry, policymakers, etc - rather than an official statistics agency. This is all the more so as the task is computationally very demanding. But an obvious Exports > Shipments case as such, it says, could be an *indicator for statistics people to co-operate with manufacturers* to more closely check that the coverage of Shipments is reasonably symmetrical to that of Exports. As an assistance, the paper identifies a number of generic items that should be taken into account in such a further analysis.

Table 3-3 Shipments/Exports Reconciliation (within a 4-digit HS) according to a Canadian analysis

Shipments	Exports
Data adjustments in annual manufacturing survey	**Adjustments of foreign trade data**
Starting point: Value of a good produced by a manufacturer, from annual survey of manufacturers (*or corresp.*)	Starting point: Value of an exported good
+ undercoverage adjustment (*for small establishments*)	+ undercoverage adjustment (*for small*)
+ allocated shipments coded to *miscellaneous* (*i.e. in lieu of specific HS/CN items*)	– re-export value
+ time period adjustment (calendarisation of shipments *due to firms having split financial year*)	– freight costs
– double processing of primary goods (e.g. by metal fabricators)	– re-import
+/- known classification errors	+/- known classification errors

[33] Canada in the meantime has switched to the new North American industry classification system NAICS mentioned in the methodology chapter

Shipments, cont'd	Exports, cont'd
+/- known transfer price differences	+/- known transfer price differences
+ other known adjustments	+ other known adjustments
= adjusted manufacturing shipments	
Plus: Non-manufacturing data adjustments:	
+ goods produced by wholesaling establishments	
= Adjusted value of shipments by manufacturers	***= Adjusted value of exports***

Source: StatCan Rupnik 2000 p. 15, slightly generalised by the author

Relating to the factors included in Table 3-3, the major practical problems *specific* to the field of medical devices is thought to be undercoverage for *small establishments* on the one hand and corrections for *goods produced outside the manufacturing sector* as defined in official statistics on the other. As to the first factor, the contribution to real production values from manufacturing in smaller establishments could be considerable, given the large share of companies in SE-SIC 33101, 33102 and 35430 that are smaller than the cut-off level of 20 employees in a firm for its local units to be included in the Swedish annual survey of industrial production (IVP). The contributions of firms in the *10-19 employees bracket* are only "modelled" in the total statistics, not surveyed, which means that distribution by detailed product items, etc, may not always be carried out correctly. In combination with the unknown production by highly specialised manufacturers with *less than 10* employees, it is thus extremely difficult to correctly quantify the contribution from companies in the "less than 20" category.

Before we leave the manufacturing sector, the item "*known classification errors*" under Shipments in the Canadian Table 3-3 above should be noted. Although "known" may be too strong a word, this item *does* include medical devices produced by companies in manufacturing codes *other* than those mainly identified in this study, i.e. SE-SIC 33101, 33102 and 35430. Examples would include products from, e.g. companies *processing materials* (metals, polymers, fibres, etc) or in manufacturing of *machinery or electronic products* in *other* SIC 33 codes than the 3310X in this thesis. Such production is not necessarily recorded under the HS/CN items defined under section 3.1 above and thus would be "concealed". Some concrete instances of (so far) missing data are mentioned under section 4.3.3 in the methodology chapter.

Let us cross over to the other problem specific to (i.a.) medical devices among to the generic ones presented above. Thus goods are also produced *outside* the manufacturing sector, *de facto* manufacturing taking place in companies coded in SE-SIC 51460, *Wholesale* in medical equipment and pharmaceutical goods. Although not mentioned in the generic Canadian reference, very likely some manufacturing also takes place in firms classified in other service

industries than wholesale, such as codes related to consulting and other *knowledge-intensive services*. These include, e.g. the SE-SIC codes starting with 72, i.e. electronics- and IT- related *consulting*, SIC 74202, Construction and other *engineering activities*, and codes for *research and development*, notably SIC 73103, R&D on medical sciences. A further reason for adjustments that logically enough does not appear in (StatCan 2000 Rupnik), is the potential contribution to foreign trade by Swedish firms whose intra-EU exports or imports values are less than the cult-off limit SEK 1,5 million.

Most of what has been said hitherto has the effect of raising the production or shipment values in relation to export values, thus bringing down the Export/Shipments ration from >1 to something that is probably in the order of size 0,80 at the aggregate level. However, although some *general* figures to model corrections are given in the source, a study like the present one cannot evaluate whether they would correctly reflect the situation in medical devices, and for Sweden. But it might be mentioned that looking at shipment corrections only, *adjustments of +20-25 per cent of starting values* might be undertaken, based on contribution from small establishments <10 employees (7 % in source, 10 % in section 2.3 of this thesis), *calendarisation* (i.e. aligning all companies to the *same* actual 12-month calendar year, 9 % according to source), and corrections for establishments outside the manufacturing sector (4 % in source, perhaps more for medical devices in Sweden). According to the source, (StatCan Rupnik 2000) overall *re-exports* represented some 6 % in 1996 and overall re-imports 1-2 %.

3.7.4 Data integration on product group level – a "message"

In Appendix 2, we present diagrams showing Production, Exports and Imports values as *identified* in the relevant sources from Statistics Sweden, and *calculated* values for Apparent domestic market for *each of the 12 product groups* that are included in the Master tables (same Appendix). Broadly speaking the groups self-assemble in three categories as to the ratio between Production and Exports values. Quite expectedly in view of the cautions expressed earlier, some of these diagrams show strange pictures of the *apparent domestic market*. Partly, however, this is also because the in-data for Swedish *productio*n seem oddly variable where it would *not* be expected, namely in the main group of products we have called "Miscellaneous".

The most important problem product category below, however, is that showing individual product groups where *Exports > Production*. The look of the associated diagrams (Appendix 2) *clearly signals a need* for representatives of the manufacturers, jointly with Statistics Sweden, to take a closer look at the situation for reporting production in those product groups, in line with the source referred to earlier (StatCan Rupnik 2000).

Category 1: Production greater than Exports (i.e. the "normal" case)

⊗ Invalid carriages (HS/CN 8713/871420)
⊗ Sterilizers (HS/CN 841920)
⊗ Medical furniture (HS/CN 9402)

Category 2: Exports greater than Production ("important problem cases")

⊗ Orthopaedic articles, implants, etc (HS/CN 9021)
⊗ Instruments and appliances, etc (HS/CN 9018)
⊗ Therapeutic respiration apparatus (HS/CN 901920)
⊗ Medical X-ray and radiation apparatus (HS/CN 9022)

Category 3: Ratio Exports/Production mixed (and/or Production in-data erratic)

⊗ Bandages etc (HS/CN 3005)
⊗ Pharmaceutical goods for medical devices (parts of HS/CN 3006)
⊗ Optics for corrective lenses, etc (parts of HS/CN 9001)
⊗ Corrective eyeglasses, etc (parts of HS/CN 9004)
⊗ Medical X-ray film (HS/CN 37011010)

The overall picture is that the statistics are *better* at capturing production values in "medium-technology" products of Category 1, whereas it is much more difficult in the highly advanced, often complicated systems technologies that characterise several product segments in Category 2[34]. The latter category is by far the most economically important one, representing 90 per cent of Swedish production in 2001. As it includes the products of most of the larger companies, including also, numerous outsourcing relations, etc. Category 2 probably represents a major source of as yet *unidentified* Swedish production/shipments. This would be an important point of departure for a possible further exploration of the field.

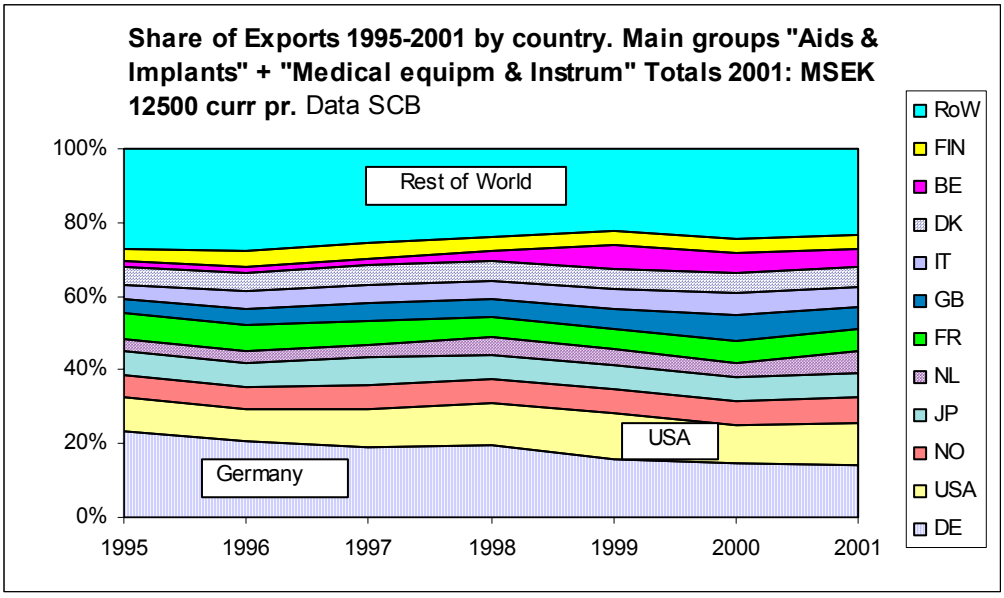
As to Category 3, it in fact proves to include all product groups identified in our main group "Miscellaneous" as recorded in section 3.1 above (and fuller in 4.3.2 below). None of the Category 3 product groups represent more than SEK 500 million in any of the three input parameters Production, Exports or Exports over the 16-year period studied. In fact production has been in the order of some SEK 100 million except for "Bandages etc" and "Pharmaceutical goods" which at times have reached some SEK 300 million. Nevertheless, the products in Category 3 should be accounted for if one looks at medical devices at large. However, there are also *additional* products to be accounted for but where the time series as yet is incomplete.

[34] This is *not* to say that there are no products in Category 1 that contain advanced systems or that there are no "low/medium-tech" segments in Category 2

3.8 Exports by receiving country and product groups

Let us finish this chapter by looking at the overall distribution of Swedish exports, as identified in this study, by country and by product groups, respectively. The following will be based on data for the period 1995 to 2001 from Sweden's Statistical Databases, again starting from 8-digit level in the HS/CN system. Here, however, we will only look at the *two major* main groups and their respective product groups as defined in Section 3.1 above, leaving aside the third main group "Miscellaneous". For computational reasons, the geographical data as a basis for diagrams has been chosen to include 12 entries, consisting of 11 individual countries – USA, Japan and nine European countries – the 12th being "Rest of World (RoW). For reasons of space, not all individual countries may be shown in a given diagram, however.

Figure 3-12 Export countries – relative percentage shares of exports 1995-2001

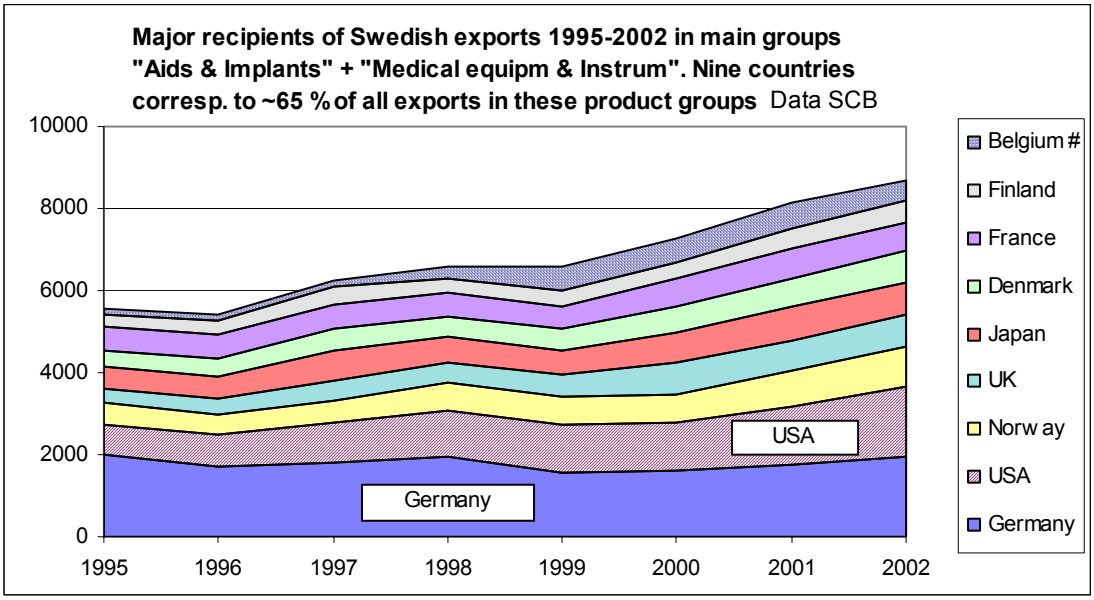


Source: Statistics Sweden, own calculations

It has to be noted that the diagram shows *relative shares* of the different countries. In absolute economic terms, the diagram spans from a total identified exports value from SEK 8500 million in 1995 to SEK 12500 million in 2001. Germany is seen to have been the dominating export country over the period covered (14 % share in 2001), with the United States as second of the individual countries (11 % share in 2001). The share of Germany is decreasing, while that of the US is increasing. Norway and Japan come as No 3 and 4 in 2001 with a share of 7 % each. The eleven countries taken together have increased their share somewhat in comparison to "Rest of World". Most of the remaining nine countries keep their shares, *Belgium* being an exception in that its share has increased over the last three-year period. A very likely explanation is that a

major exporting company, St Jude Medical AB, during the period has started using Belgium as a hub for further exports of pacemakers manufactured in Sweden. As this pacemaker activity was acquired from Siemens-Elema AB with 1995 as the first full financial year, one could also think in terms of the increasing "Belgian" share compensating for (part of) pacemakers that Siemens-Elema would otherwise have exported to Germany.

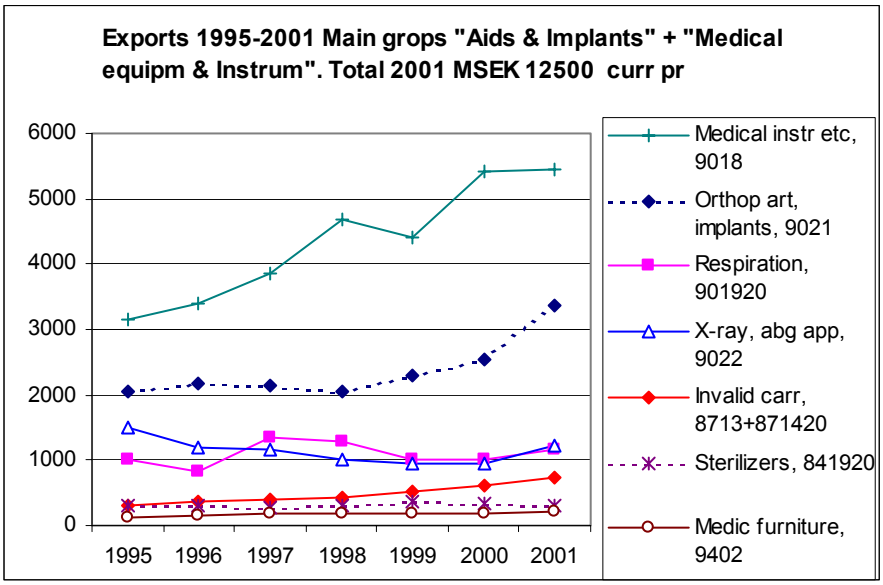
Figure 3-13 Export values, nine most important countries, SEK million current prices



Source: Statistics Sweden, own calculations

The diagram above shows the development of exports over time in economic terms. For computational reasons the diagram only covers the nine most important countries overall. These nine together represent about two-thirds of the total exports over the entire period in the two main groups indicated, i.e. "Aids & Implants" and "Medical equipment & Instruments", spanning from SEK 8400 million in 1995 to SEK 13750 million in 2002 according to the very latest figures available.

Figure 3-14 Exports in the two major groups distributed by product groups 1995-2001



Source: Statistics Sweden, own calculations

Among the product groups concerned, the two major ones naturally are the same as those that dominate Swedish production. Thus the growth previously implied for product groups "Medical instruments" (HS/CN 9018 family) and "Orthopaedic articles and implants" (HS/CN 9021 family) also is visibly demonstrated here. As it would be very difficult to illustrate exports in geographical *and* product terms at the same time, we below summarise the situation in 2001. Diagrams for the seven individual product groups are found in Appendix 2.

Table 3-4 Major export countries by product group 2001

Product group (HS/CN)	No. 1	No. 2	No. 3	No. 4	No. 5
Invalid carriages 8713/871420	Norway	Germany	USA	Netherlands	France
Orthop. art & Implants 9021	"All others"	Japan	Germany	France	UK
Medical instruments 9018	"All others"	Germany	USA	Norway	Denmark
Therapeutic respiration 901920	Spain	USA	"All others"	Germany	Japan
Medic X-ray + radiation 9022	Germany	USA	Other	Japan	UK
Sterilizers 841920	"All others"	USA	Japan	Italy	several indiv.
Medical furniture 9402	Norway	"All others"	USA	Denmark	Japan
All product groups above	*"All others"*	*Germany*	*USA*	*Norway*	*Japan*

Source: Statistics Sweden, own calculations

Entries in Table 3-4 above symbolise *absolute export values* in SEK million 2001. As "Rest of World" here is not the same as in the overall diagram above, the term "*All others*" here refers to "Rest of World" *plus* those of the eleven individual countries that are not named in positions 1-5 above.

4 Methodological aspects and problems

The information put forward in this thesis to a high degree is based on official statistics originating from several sources within the Statistics Sweden (SCB) sphere. As a source to additional economic information, a commercially available company database has been used, nowadays called MM Partner. Originally recommended to the author by SCB, this database has been used in several editions (in particular 1999-2 and 3, and from 2002-2 to 2003-1). These sources describe the area investigated in several ways. Each source has its own peculiarities, and comparison between different sources – as always – may entail complications. As to the SCB sources, the following account draws frequently from (NUTEK 2000:4) but also on a series of so-called Statistics Descriptions and other guiding material from SCB, available on the Internet from SCB's homepage www.scb.se.

References of particular relevance for the interpretation of data presented in this thesis have been highlighted with "➔". However, most of the information given may be seen as basic for anyone who wants to understand how the official statistics system works in matters related to production and foreign trade with manufactured goods.

4.1 Scope and limitations

The thesis describes the production of medical devices and related products in Sweden at the aggregate industry level in three manufacturing branches with SE-SIC codes (33101, 33102 and 35430) and the production and foreign trade at commodity level of products manufactured by companies and local units[35] in these branches. To some extent it also takes into account two service branches related to the field of medical devices, the wholesale code 51460 and the research and development code 73103, also identifying at the company level some major actors in medical devices in economic terms. The latter two codes represent considerable, but difficult-to-measure contributions to the production of medical devices, while also making up important sectors of the wider medical-healthcare industrial framework – and network – in Sweden. Where *economic data on the individual company level* are given, unless otherwise stated the source is MM Partner (MM for short). In such cases, only limited companies (*aktiebolag*, AB) will be the objects. This is because MM, for the purposes of this thesis, has proved unsuitable for analysing companies in other legal forms. At times, further, a few complementary data have been obtained in personal communications with representatives of some companies.

[35] In the international economic literature, the Swedish word "arbetsställe" is often translated as "establishment" although SCB in accordance with the EU nomenclature uses the term "local unit".

For clarity, an overview of the statistics and data studied is given below

Table 4-1 Statistical sources used for the respective SE-SIC codes

	SE-SIC codes investigated				
Statistical source	**33101**	**33102**	**35430**	**51460**	**73103**
SCB Business Register	X				
SCB Central Firm and Local unit Reg (CFAR)	X	X	X	some	some
SCB Structural Business Statistics	X	X	X	some	
SCB Industrial Production Statistics (IVP)	in principle, all goods covered			(might be partially included; not sought)	
SCB Foreign Trade	in principle, all goods covered				
MM Partner Data on "fate" of indiv. firms (AB's)	X				
MM Partner Data on turnover (AB's)	some	some		some	some
MM Partner Data on indiv. firms' R&D (AB's)	some	some		some	some

4.2 Units observed in official Swedish statistics

Statistics Sweden collects information so as to describe activities at different levels:

- the production value of a certain *good or service*
- all activities at a certain *local unit* (normally comprising several products or services)
- all activities within a certain *company* (often the same thing as a local unit, but a company can comprise several local units)
- all activities within a certain *group,* normally comprising several companies. However, most companies do not belong to a group at all. ⇔ In this thesis, company *groups are not identified or studied*

The smallest administrative unit about which data is collected is called the local unit. The principal orientation of activities conducted at the local unit leads to a branch classification of the *unit* following SE-SIC 92. The latter means Swedish Standard Industrial Classification (*Svensk Näringsgrensindelning, SNI* in Swedish). This is a classification of different industrial and commercial activities primarily for statistical purposes that was established in 1992 and officially applied from 1994, in practice starting from 1993.

4.2.1 Distinctions between "company" and "local unit" level

A company may comprise one or more local units. Companies as well as local units are classified according to SE-SIC 92. However, a company's various local units can receive different classifications, since the activities of an individual local unit may have a different orientation than the company as a whole. ➔ The branches to which both companies and local units belong are determined by the *dominant activity* of the company. This means that the company is classified according to the activity that represents the largest share of the value of the company's sales. The sales of this particular activity, however, *may be less than half* of the total sales value in a company with a diversified range of activities.

➔ The *company* most often is the natural unit of study for most economic information, since financial accounts are often reported at company level, for example in annual reports. This

renders the costs and revenues for individual local units invisible; moreover, these may be internal to the company. Nevertheless, in some sense the *local unit* level constitutes the basis for financial data, since it can be more uniform in nature than an entire company comprising a number of local units. Further, the unit can be identified with a definite geographical location in contrast to a company, which may have local units in geographically diverse locations. However, most companies consist of a single local unit. As an example, SE-SIC 33101 per 30 June 2002 according to the SCB Business Register includes 553 companies (all legal forms) and 592 local units.

In order to make functional and regional reporting manageable, certain companies have to be divided up into sub-units. (not necessarily, but sometimes coinciding with the physical local units discussed above) Companies with activities in different branches submit data for each activity separately, reported by so-called activity units. The number of the latter tends to be overestimated if reporting occurs under the heading “company”. However, most companies have a single local unit and therefore most local units also have the same branch assignment as the companies to which they belong.

For the *manufacturing* industries, considerably more information is available at the local unit level than at the level of product groups. In the service sector, no information exists for categories of services; only company level data is available. One exception is data on employment, which exists at the local unit level as well as company level for firms producing services as well as forms manufacturing goods.

➔ Sources of uncertainty in the calculations should be noted. The information given at industrial branch level from the Structural Business Statistics (*Företagsstatistik*; and in this thesis also from one of its predecessors, the former *Industrial Statistics, Part* 1 – see below) is based on companies and local units being registered in a certain primary SE-SIC code. However, also other companies may produce medical devices in a branch different from those investigated. Data from such companies' *secondary* (all non-primary) activities cannot be taken into account in recording information on the branch as such; this is known as *under-coverage*. On the other hand, so-called *over-coverage* arises when data reported for the branch under study include companies *within* the code(s) in question who manufacture *products that fall outside* the area under study.

In the newer statistics "Basic Facts" (*Basfakta*) from the Structural Business Statistics available via the Internet at Sweden's Statistical Databases website, it is now possible to look up a certain (manufacturing) branch code *either* at *company* level or at *activity* level. This makes it possible

to somewhat differentiate between the two types of statistics, i.e. one that is institutionally and one that is functionally orientated.

4.3 Product groups in the statistics covered in this thesis

➔ Before we go further, the reader may recall that the Introduction of this study mentioned a new European standard, the Global Medical Device Nomenclature for classifying medical devices (GMDN, Appendix 3). However, the new standard has not (yet) been recognised for the purposes of international industrial or trade statistics. In the extensive mapping of the British medical devices industry (DOH-ABHI 1997), the ambition in fact was to "pioneer" a breakdown of foreign trade by product sector according to ECRI, the predecessor healthcare product classification underlying GMDN before the latter was accepted in 2000. However that proved impossible, leading to a complicated cross-tabulation procedure, weighing of production data and other adaptations.

To revert to official statistics, the classification of products follows internationally agreed nomenclatures for economic statistics. Detailed classifications of product groups exist for both production and foreign trade in the manufacturing sector with various ways devised to cross between them if necessary (including UN, EU and also NAICS, the new North American Industrial Classification System).

4.3.1 International nomenclatures for production and foreign trade

For the manufacturing industries, the information is based on two nomenclatures. *Production data* is reported according to the HS nomenclature for goods, the *Harmonised Commodity Description and Coding System*. Nearly all other statistics on goods are also recorded using HS codes. This is a seven-digit numerical code comprising approximately 5000 product groups. It has been used by Statistics Sweden since 1988, but does not cover any categories of services[36]. A new, somewhat revised version of the HS, SE-SIC 2002, has been introduced from 2003.

When Sweden joined the European Union in 1995, it was required to report foreign trade according to a somewhat different nomenclature, called CN for *Combined Nomenclature*. This nomenclature, adopted within the EU already in 1988, in principle at the 6-digit level directly

[36] Apart from the sections that include information on SE-SIC 51460 and 73013, *services* are not addressed at all in this thesis. It may be noted that especially in advanced medical equipment, with high demands on user education, safety, reliability, etc, the sale of physical products often entails considerable amounts of services. This is not identifiable in the production statistics, however.

corresponds to the Harmonised System (HS) used by the vast majority of trading nations throughout the world. The CN nomenclature comprises approximately 10000 product groups and like HS, CN does not cover any categories of services. Both HS and CN and related nomenclatures are accessible from the Internet[37].

It should be noted that SCB cautions that the agreement between the two nomenclatures is not complete. This leads to some uncertainty when dealing with many different product groups from different branches at the same time. For certain product groups, the six-digit levels in HS and CN are not in agreement. This problem arises every time a nomenclature is revised or replaced by a new nomenclature.

➔ On the other hand, problems of this kind generally have been negligible in the present study. However, changes have occurred *within* the HS classification system at least twice from the first year of the commodity statistics here, i.e. 1985, in the period to 1995 (and also 1996) when the CN system was introduced in Sweden. Also in this case, accommodating to somewhat different "last" digits in the commodity codes (No. 7 in the HS code and Nos. 7 and 8 in the CN codes) has been manageable. But there remains a *lack of figures* for a few of the commodity groups in the earliest years (1985-1987) of the period covered in this study. On the practical side, a problem is that due to a broken-up hierarchy in the naming of product groups, the names of some new CN codes on 6- and 8-level have become very bulky. This makes them difficult to communicate in a few words on the 8-digit level in tables such as those found in this study.

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With the HS/CN codes as a point of departure, the statistics on medical device products in the thesis have been organised into 12 basic commodity groups, summarised in three larger groups as shown in Table 4-2. Originally a combination into main groups was made in order to facilitate the drawing of diagrams for the main presentations of Swedish production, exports and imports of medical devices. The grouping was chosen so as to resemble the corresponding broad groups in which the Swedish Association of Suppliers of Medical Devices (SLF) categorised their members' product areas. Whether this grouping today is the most optimal one may be discussed. As all basic data are taken from the most detailed level there exists, however, they are reproducible and may be recombined for other purposes as desired.

[37] See e.g. http://unstats.un.org/unsd/cr/registry/regdnld.asp?Lg=1, and http://europa.eu.int/comm/eurostat/ramon/geninfo/geninfo_en.html, which are the addresses to the classification servers of the United Nations and the European Union, respectively.

4.3.2 Codes for the product groups covered

Table 4-2 HS/CN codes and medical device product groups used in basic tables and figures

HS/CN 4-digit level	Product group: Swedish name used in basic tables and further information to identify the most detailed product level covered	Product group in English (Official US translation) and further information to identify the most detailed level covered in the thesis
Main group	***Hjälpmedel och implantat***	***Aids and implants***
8713	Invalidfordon inkl 8714.20, reservdelar till invalidfordon *(8-digit level covered)*	Invalid carriages, whether or not motorized or otherwise mechanically propelled including parts to these *(8-digit level is covered, also Spare parts to Invalid carr in 871420)*
9021	Ortoped artiklar, implantat etc. *(all 8-digit items included)*	Orthopaedic appliances; splints etc.; artificial parts of the body; hearing aids and other appliances to compensate for a defect etc.; parts etc. *(All 8-digit items included)*
Main group	***Apparater & instrument***	***Equipment and instruments***
9018	Instr med kir dent bruk *(All 8-digit items included)*	Instruments and appliances used in medical, surgical, dental or veterinary sciences (including electro-medical and sight-testing); parts etc. thereof *(All 8-digit items included)*
9019	App för andn-terapi mm *(Only 901920 = for therapeutic use included)*	Mechano-therapy, massage, psychological aptitude-testing appliances and apparatus; ozone etc. Therapy and respiration apparatus; parts and accessories. *(Only 901920 = for therapeutic use included)*
9022	App för X- och αβγ-stråln m m *(All 8-digit items counted except 1900+2900 that are for non-medical purposes)*	X-ray etc. apparatus, including radiography or radiotherapy apparatus, x-ray tubes and generators, high tension generators etc.; parts and accessories *(All 8-digit items counted except 1900+2900 that are for non-medical purposes)*
8419	841920 Steriliseringsapp *(only relevant item in 8419)*	Sterilisation apparatus 841920 *(only relevant item in 8419)*
9402	Möbler för med, kir...bruk *(8-digit level covered)*	Medical, surgical, dental or veterinary furniture; barbers' and similar chairs having rotating, reclining and elevating movements; parts thereof *(8-digit level covered)*
Main group	***Blandat***	***Miscellaneous***
3005	Vadd, förband, medic & kirurg bruk *(3005~1000+90XX included)*	Bandages and similar articles, impregnated or coated with pharmaceuticals or put up for retail sale for medical, surgical, dental or veterinary uses *(3005~1000+90XX included)*
3006	Farmaceut prod för medicintekn behov (3006~*10XX+2000+3000+4000+5000 incl.)*	Pharmaceutical goods specified in note 4 to chapter 30 (3006~*10XX+2000+3000+4000+5000 included)*
9001	Optik *(only 9001~30XX+40XX+50XX incl. = corrective contact and spectacle lenses)*	Optical fibers and optical fiber bundles; optical fiber cables nesi; sheets and plates of polarizing material; optical elements, unmounted *(only corrective 9001~30XX+40XX+50XX incl.)*
9004	Glasögon o dyl *(only corrective uses = 9001~30XX+40XX+50XX included)*	Spectacles, goggles and the like, corrective, protective or other *(only corrective uses = 9001~30XX+40XX+50XX included)*
3701	Fotograf plåt, bladfilm… medic bruk *(only 37011010 for medical purposes incl.)*	Photographic plates and film, flat, sensitized, unexposed, not of paper, paperboard or textiles; instant print film, flat, sensitized, unexposed *(only 37011010 for medical purposes incl.)*

Sources and Note: Swedish names from Statistics Sweden, here abridged for reasons of space in the basic tables. English names from US International Trade Commission[38]. In italicised parenthesis author's comments on the commodity levels or groups actually covered in the basic tables

[38] http://reportweb.usitc.gov/commodities/naicsicsitc.html 9 March 2002

The items under 8713 (including 871420) mainly are manufactured by companies in SE-SIC 35430, "Industry for invalid carriages". The product groups representing dental products under item 9021 (902121 and 902129) are manufactured by companies in SIC 33102, "Dental laboratories" as well as by companies in SIC 33101, "Medical and surgical equipment and orthopaedic appliances". Other items under 9021 and *all items* in them main group called "Equipment and instruments" in the table are mainly manufactured by companies in SE-SIC 33101. It may be noted, that the author has *not included* two sub-groups under item 9022 that explicitly are intended for *non-medical use*.[39]

Except for some items under "Miscellaneous" above, the 4-6 digit-level statistical categories included in the table originally emanate from so-called *keys* between industrial classifications and product classifications according to Statistics Sweden[40] (although the number of items has expanded over the time period studied). The "Miscellaneous" group codes mainly have been sought out by the author in the pursuit of identifying further product groups that (according to international habits) either come together with medical devices or are to be counted as such products themselves, regardless of who manufactures them. Examples of the first category are the supplies items under HS/CN 3005, 3006 and 3701 above. The optical items under 9001 and 9004 are examples of the second type, chosen so as here only to include ophthalmology products such as lenses, glasses etc for *corrective* use only. Optical microscopes are not counted, however, as they cannot be separated into medical- and non-medical use.

4.3.3 Examples of missing data

➔ One economically important product category is still missing in the underlying basic data, however, that of *In-vitro diagnostic reagents* (HS 3822/CN3822000) where Sweden has one major international industrial actor and some smaller ones. Such reagents in Sweden are manufactured outside the medical device industry proper (whereas the associated diagnostic instruments are *de facto* medical devices and thus *should* be included under relevant other categories above). Complementary information on this item is being sought; the times series available via Sweden's Statistical Databases being for later years only and even so somewhat incomplete. In analogy with the case when pacemakers in 1995 were missing from Swedish production statistics, also the "gaps" in the in vitro-device code may be due to industrial

[39] It may be noted that figures for X-ray equipment as well as apparatus for non-ionising radiation equipment sometimes have led to exaggerated interpretations of the demand for medical equipment. A Swedish report from the mid-eighties unknowingly included equipment for artificial sun-tanning, which at the time was very popular – before its medical side-effects were known. Likewise an EU-commissioned report on medical devices from the mid-nineties included some odd figures for imaging equipment, probably caused by counting x-ray crystallography and similar as medical equipment

[40] Meddelanden i samordningsfrågor, MIS 1992:6

restructuring in the company group to which the dominating manufacturer belongs. In terms of the sales value of Swedish production, the planned addition represents a factor of 2 or 3 times the present totals of "Miscellaneous". Therefore, the latter main product group so far is included *only in the grand totals* in the tables and diagrams for Swedish production, exports and imports, – i.e. together with the main groups "Equipment and instruments" and "Aids and implants" – but not represented in them as an entity of its own.

➔ A more thorough search for products in the entire Combined Nomenclature for combinations of "surgical", "medical", "dental", etc, reveals one further item, CN 48189010x, dedicated high-quality cellulose-based hospital supplies such as surgical clothing, etc. Also this item is attributable to one major Swedish manufacturer and will be added. In 2001 it represented some 60 % of the present total of "Miscellaneous" (before including 3822 in line with the above).

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A generic source of uncertainty not yet mentioned is *confidentiality* in connection with product groups where there is only one single manufacturer in Sweden. Such cases do occur sometimes in the type of commodity statistics used here. This seldom has caused any problems in the present study, as totals on the next higher level will compensate.

4.4 Classification of industrial branches

As mentioned under "Units used in official Swedish statistics" above, the economic activities pursued at local units, companies and groups are classified by Statistics Sweden using a branch nomenclature, SE-SIC 92 introduced from 1993 onwards. The statistics are internationally comparable, since the nomenclature is an elaboration of the European Community standard for economic activities, NACE rev. 1 (Nomenclature Géneral des Activités Economiques dans les Communautés Européennes)[41]. This nomenclature in turn is co-ordinated with the United Nation's classification of industrial activities, ISIC rev. 3 (International Standard Industrial Classification of All Economic Activities). A somewhat modified industrial classification has just been introduced, SIC 2002[42], and preparations have been initiated for a major revision to take place in 2007.

➔ The SE-SIC 92 for the first time meant that a code particularly aimed at (companies and units) manufacturing of medical instruments and equipment, etc, was introduced – i.e. SE-SIC

[41] See for example http://europa.eu.int/comm/eurostat/ramon/intro_nace_rev1/en.html

[42] The name of one of the codes of interest in this thesis, SE-SIC 73103 has been modified in the 2002 version from "Research and development on medical sciences" to "… medical *and pharmaceutical* sciences". This latter change further underscores the reality that many more of the 73103 companies are oriented towards *biopharma* rather than in R&D leaning more towards *(bio)medical engineering*.

33101, "Industry for medical equipment and instruments", and its little sister branch 33102, "Dental laboratories"; the two together making up the more aggregate code 331, "Industry for medical, surgical and orthopaedic equipment". Before Sweden's Statistical Databases started to become publicly accessible on the Internet, successively from around year 2000, the latter 3-digit code (and 4-digit codes in other cases, but not 5-digit ones), 331 was the most detailed industry/activity level available via printed publications from SCB.

➔ It deserves noting that SCB uses somewhat different names for the same manufacturing code under certain conditions. Depending on whether *institutional* or *functional* aspects are to be emphasised, the former have the *company* (or, at aggregate level, a branch of industry) as its basis, and the latter the *activity* being pursued at a particular local unit (or in the industry in question). Therefore the names of SE-SIC 33101, 33102 and 35430 can differ somewhat depending on whether the industry or the activity is in focus (i.e. "Industry for XXX" vs. "Manufacture of XXX" in generic terms or, e.g., "Dental laboratories" vs. "Manufacture of dental prostheses").

4.4.1 Combining sets of data from SE-SIC 69 and SE-SIC 92

➔ For the purposes of this thesis, it should be noted that some of the production and foreign trade data originate from before the introduction of SE-SIC 92, the predecessor of which was called SE-SIC 69. In that nomenclature, medical instruments and the like made up a part mainly of the code SE-SIC 69 385, "Manufacture of professional and scientific, and measuring and controlling equipment not elsewhere classified, and of photographic and optical goods". This title is in effect not too different from that of the 2-digit SE-SIC 92 code 33 "Manufacture of precision instruments, medical and optical instruments, and clocks".

➔ Despite the nomenclatures being quite different in other ways, the change from SE-SIC 69 to SE-SIC 92 generally did not affect the *collection* of data here much, since "keys" were available when the collection started. By way of these keys one could translate between the older and the newer SNI nomenclature on the one hand, and between the two SNI systems and the categories of goods manufactured by companies and company units in a certain code on the other. For the branches and products relevant to this study, this posed no particular – i.e. *identified* – problems although it may certainly have been more difficult in other cases. However, see comments under the heading dealing with calculation of constant prices below.

4.5 Definitions of economic measures; calculation of prices

Production value is the measure that is used in statistics describing production. This measure gives the total value of the goods produced, sold or unsold. What is called "*market value"* in the translation of (NUTEK 1999) indicates the value of the products sold only. *Turnover* includes not only the value of sales but also other revenues, e.g. from trade. *Value added* consists of the difference between revenues and the costs excluding capital income, wages and payroll taxes that are required in order to generate the revenues. This measure is often thought of as (a specific or the entire) industry's contribution to GNP. *Value added per employee*, which is calculated by this author, is often used as a measure of labour productivity. Below will be found the full definitions[43] used by the European Union in the Structural Business Statistics:

> **The production value** measures the amount actually produced by the unit, based on sales, including changes in stocks and the resale of goods and services. The production value is defined as turnover, plus or minus the changes in stocks of finished products, work in progress and goods and services purchased for resale, minus the purchases of goods and services for resale, plus capitalised production, plus other operating income (excluding subsidies). Income and expenditure classified as financial or extraordinary in company accounts is excluded from production value. Included in purchases of goods and services for resale are the services purchased in order to be rendered to third parties in the same condition.
>
> **Turnover** comprises the totals invoiced by the observation unit during the reference period, and this corresponds to market sales of goods or services supplied to third parties. Turnover includes all duties and taxes on the goods or services invoiced by the unit with the exception of the VAT invoiced by the unit *vis-à-vis* its customer and other similar deductible taxes directly linked to turnover. It also includes all other charges (transport, packaging, etc.) passed on to the customer, even if these charges are listed separately in the invoice. Reduction in prices, rebates and discounts as well as the value of returned packing must be deducted. Income classified as other operating income, financial income and extraordinary income in company accounts is excluded from turnover. Operating subsidies received from public authorities or the institutions of the European Union are also excluded.
>
> **Value-added at basic prices** is calculated from the production value plus subsidies on products less the purchases of goods and services (other than those purchased for resale in the same condition) plus or minus the change in stocks of raw materials and consumables less other taxes on products which are linked to turnover but not deductible. It represents the value added by the various factor inputs in the operating activities of the unit concerned. Income and expenditure classified as financial or extraordinary in company accounts is excluded from valued-added. Value-added at basic prices is calculated 'gross' because value adjustments (such as depreciation) are not subtracted.

The value of a good or service can be expressed in current or constant prices. *Current prices* state the price on a particular date. *Constant prices* mean that the price at any particular date is converted to the price level at a specified point in time. By converting all values from a certain period of time to a single price level, real changes can be observed. However, it should be noted that the content of the product or service changes, so that comparisons over time can be misleading. This is particularly relevant when studying technology-intensive sectors of industry and thus should be the case also in considerable parts of the product segments studied here.

[43] The following definitions originate from the EN Official Journal of the European Communities L 344/53 18.12.98

➔ Price indices are used in this study for the purpose of illustrating not only the nominal changes in current prices but also the real changes in Swedish production, exports and imports of goods over the period 1985 – present. The indices, called PPI, ExPI and ImPI – were chosen in consultation with relevant expertise at SCB in 1996-1997. Since the time series starts in 1985, when the SE-SIC 69 nomenclature was still in use, the indices from the old system must be combined with as closely as possible related indices from the new system SE-SIC 92. This is in order to enable an unbroken time series, or at least one that reduces the *hazards of merging* statistics emanating from two different industrial classification systems. The solution chosen was based on the *older* indices from SIC 69 385 (cf. above), extrapolating them *forward* with the aid of the new index series started when the new SE-SIC 92 system came into force. In analogy with major products sorting under code 385 in the former system, the closest "relative" in SIC 92 code was 33 (rather than 331). Thus by choosing SIC 92-33 and SIC 69-385, "symmetry" is kept in that both codes are one level above the first level where medical device contents are identified. Whether this particular choice was optimal may be discussed, but it was preferred to a solution where only one of the indices would be medical-related.

According to (NUTEK R 1999:15) and its succeeding updates, the price index that is used in calculating fixed prices in these reports "take into account the changes in function that have occurred in the products". It proved very difficult, however, to obtain an explanation of *how* this was brought about. Thus when consulted about this after the first widely disseminated report was published in 1999, neither NUTEK nor SCB could clarify how this kind of "intelligent" index was calculated.

4.6 Statistical sources

The overviews put forward in this thesis are based on data from several different statistical sources. It deserves noting that different sources can define the same variable in different ways. The ambition is to show that they supplement one another and contribute to a better overall picture of the field studied.

4.6.1 Structural Business Statistics and its predecessor

Before 1996, statistics on production at branch and commodity levels were collected in the so-called Industrial Statistics. Up to and including the reference year 1995 the aggregate branch statistics were published in detailed printed reports as *Industristatistik Part 1* and the data on production of goods as *Industristatistik Part 2*. From 1997 onwards, the surveys Industrial

Statistics and also Financial Statistics have been merged, the "fusion" named Structural Business Statistics (*Företagsstatistik*). Based on corporate annual accounts, the Structural Business statistics cover the manufacturing sector as well as the service sector. In a way one could see this as an "*Annual Report" for "Sweden, Inc*.".

For companies with at least 50 employees, figures are collected directly from the companies. The collection of data for the remaining group mainly builds on the administrative register of Standardised Accounting Statements (SRU).
➔ A change of importance to branches with a high proportion of very small companies is that from 1997, the population includes companies both smaller and larger than 10 employees. This was not the case before 1997, when the economic data of the smaller ones were included only at the 2-digit branch level (e.g. for SE-SIC 33 as mentioned above). Thus from 1997, also companies with less than ten employees are counted at detailed levels. Aggregate data on revenues, costs, value added, etc, are presented for populations of companies in the size brackets less than ten and at least ten employees, respectively. This is possible all the way down to the most detailed 5-digit branch level. The latter from SCB at a cost, though, while the 3- and 4-digit levels are freely accessible on the Internet.

Depending on the degree of (dis)aggregation, the Structural Business Statistics for reference year X are made successively available between August and October in the year X+2, i.e. some 20 months after. Apart from aggregate production data, the information covered includes the number of persons employed, wages and investments made per local unit, etc.

➔ From 1990 onwards branch data exist according to the new classification of economic activities, SE-SIC 92, data for the first three years 1990-1992 having been converted by SCB from SIC 69 to match the SIC 92 framework. In the present study Business Structural Statistics are used for the reference period 1990 – *2000*, the most recent data available as of spring 2003. For generic purposes it may be noted, however, that branch data has been produced since 1988, i.e. initially under the then applied SE-SIC 69 industrial nomenclature. This in principle means there is a break in the statistics between 1989 and 1990. For 1990, SCB reported information according to the old as well as the new classification of economic activities. This makes it possible to at least partially compare information for the years up until 1988- 1989 with younger data according to the new classification of branches.

The information given in the published version of Structural Business Statistics is based on calendar year data. On this topic SCB says in (NUTEK 1999:13), and also in its Statistics Description for *Företagsstatistik*, that it "is liable to some uncertainty because *15-20 per cent* of

the local units use a different accounting year…". However, according to the Manual of the MM Partner company database used in this study (most recent edition 2003-1 as of February, 2003), the proportion of companies not having the calendar year as its fiscal year is as high as *50 per cent*. Were this latter figure to be correct, it would mean that substantial – if unavoidable – miscalculations might occur for any given year[44], since limited companies (AB's, which is what MM covers) by far represent the lion share of the *economic* value in the production statistics.

As to data for the manufacturing sector, such as SE-SIC 33101, 33102 and 35430, Statistics Sweden collects this at the local unit level. The data collection for the service sector – including e.g. SE-SIC 51460 and 73103 – is at the company level.

➔ Before the stepwise introduction of the publicly available parts of Sweden's Statistical Databases (SSD) on the Internet from year 2000, the data from *Industristatistik* Part 1 and *Företagsstatistik* were available only at the 3- and 4-digit SIC level, whereby 331 (=33101 + 33102) and 3543 (= 35430) represented the units of investigation used for this study. *Industristatistik* Part 1 for the reference year 1995 was the last to be published, in 1997, in printed form *down to the 3/4-digit level*[45]. Although the Internet version of SSD from 2001 is now more fully developed, data from the Business Structural Statistics for this study have been commissioned directly from SCB annually from actual year 1998 (reference year 1996) so as to ensure the closest possible

The *Företagsstatistik* covers limited companies, cooperative economic associations (*ekonomiska föreningar*), partnerships (*handels- och kommanditbolag*) and some non-profit foundations. From the survey year 1997 onwards, sole proprietorships (*enskild firma*), finance companies, real estate companies and property management companies are also included.

4.6.2 Production of commodities and industrial services

In terms of organisation, this survey, called IVP for short, belongs with the Structural Business Statistics (*Företagsstatistik)*. It collects and processes information on the production of manufactured goods. Data are collected at the local unit level and include quantities produced and the value of this output in market terms, distributed by goods category according to the CN system described above. From the reference year 1996 commodities data are included in an EU-

[44] see further (StatCan Rupnik 2000).

[45] The *Statistiska Meddelanden* from the Structural Business Statistics published annually presenting the data in popular form (on paper and as downloadable files in pdf format), are at the 2-digit SIC level, sometimes several ones taken together. The Internet version of the statistical data as such, Basic Facts (*Basfakta*) may be selected down to the detailed 5-digit level also used here in this thesis

wide co-ordinated survey called PRODCOM. Due to companies' lacking ability[46] in reporting true production values (see 4.5 "Definitions of economic measures" above), the values entered *de facto* measures products *sold during the year*, i.e. also including goods that may have been manufactured before the reference year[47].

➔ For the purposes of this thesis, it must again be remembered that the SE-SIC regime has been changed during the period over which Swedish production and foreign trade with goods have been studied, i.e. 1985 to present. For *goods* related to the manufacturing codes relevant here, this has not resulted in any major changes. Thus in general no difficult problems have arisen to follow the production data through to the new SIC system. It has already been noted that price indices had to be extrapolated to the new system, however, including the Production Price Index, PPI. This was recorded for December in the reference year.

➔ Up until 1996, IVP included local units that belonged to companies with *at least ten* employees. From 1997 onwards, the corresponding limit is set at local units that belong to companies with *at least 20* employees, the data for companies with between ten and 20 employees being based on administrative sources. All analyses based on data from before as well as after 1997 – such as this study – must note this change in collection principles. This is visibly reflected in that actual figures for the sales value of production for 1997 may *seem lower* than they should have been, had the old principles counting from 10 employees and upwards still been applied.

4.6.3 Foreign Trade Statistics

Exports and imports of products are reported at the product group (goods category) level in the Foreign Trade Statistics according to the HS/CN systems described above. When Sweden became a member of the EU in 1995, the collection and reporting of data for the Foreign Trade Statistics had to be changed. Up until 1994, records of exports and imports included a distribution by each individual country according to the principle of country of origin. This is no

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[46] Statistical description, *Industrins varuproduktion* (IVP) 2001 NV0207

[47] In North American statistics, the term (value of) *shipments* is often used instead of production (value), e.g. when referring to comparisons with foreign trade, etc. Thus "*Value of shipments* covers the received or receivable net selling values, f.o.b. plant (exclusive of freight and taxes), of all products shipped, both primary and secondary, as well as all miscellaneous receipts, such as receipts for contract work performed for others, installation and repair, sales of scrap, and sales of products bought and resold without further processing. Included are all items made by or for the establishments from materials owned by it, whether sold, transferred to other plants of the same company, or shipped on consignment. The net selling value of products made in one plant on a contract basis from materials owned by another was reported by the plant providing the material." http://www.fedstats.gov/cgi-bin/A2Z.cgi

longer possible. Trade in goods within the EU is not classified as imports and exports and thus may not be reported according to country of origin.

This means, for example, that a tomography apparatus entering Sweden from the United States via an EU country is no longer classified as imported from the US but instead counts as trade within the EU. It is still counted as imports if the equipment reaches Sweden directly from the US, and before Sweden joined the EU, it was an import in both cases and thus recorded by country of origin. The change from reporting by country of origin to reporting by country of dispatch has caused major changes in the statistics and it is therefore very difficult to compare information from before and after the end of 1994 – beginning of 1995. In addition, it is no longer meaningful to calculate net trade by country. ⇔ Accordingly, this thesis does not give any figures for imports in a geographical sense, despite some figures having been calculated on dispatch country basis.

➔ As to this study, since the SIC regime changed during the period under study 1985 – present, *price indices* had to be extrapolated to the new system. These included the Export Price Index, ExPI, and Import Prize Index, ImPI. Both were recorded for December in the reference year.

➔ For the purpose of this study, a further change should be noted: there is *less basic data* at hand nowadays. Before Sweden's joining the EU, in principle the Customs Service registered every good crossing the Swedish border. Also it should be noted that this took place regardless of size of the company concerned, in terms of either the number of employees (in contrast to the case with production statistics, see above) or economic volume.

Becoming an EU member, however, Sweden was no longer allowed to collect information from companies that brought in goods or services from other EU countries worth less than SEK 900 000 per year, a "floor" level that has subsequently been raised to SEK 1,5 million. An estimate of the trade of these companies is made based on their VAT returns. Likewise, companies that had foreign trade exceeding SEK 900 000, now raised to SEK 1,5 million, are subject to special survey by the Customs Service in its Intrastat work. For companies trading with non-EU countries data are used as before based on export and import declarations submitted to the Customs Service.

➔ Furthermore, it should be noted that *Exports* also take place in goods that have been produced in companies classified in branches *outside the manufacturing* sector (SE-SIC sectors 15 – 37). Although this was a fact also before the EU membership, it is very more important to observe because it is *in contrast to the production statistics* presented above. The importance is

further underlined by the fact that the *cut-off for inclusion* in the production statistics has been raised in the period studied. Thus at the beginning of our time series here (i.e. 1985), production data were collected from (local units in) companies with at least *10 employed* persons, whereas from 1997 onwards the limit was *20 employees*. The combined effects of these facts need to be considered when comparing exports and production data, both as a phenomenon in itself and with particular regard to (possibly negative) changes in production between 1996 and 1997; see specific heading on this topic further below.

4.6.4 The Central Register of Companies and Local Units; the Business Register

CFAR is a major building-stone in the overall economic statistics in Sweden, listing all companies, government agencies, and organisations and their local units. It is used in all statistics areas and has an important role as selection frame for surveys and basic data. It contains a large number of data for each object such as name, address, organisation number, legal form, SE-SIC code(s) for primary and any secondary activities, starting time etc, further the number of employees (company and unit levels), and for companies also number of local units, financial reporting year, stock capital, etc. Data in CFAR is based mainly on administrative information from the Patent and Registration Office (PRV), the National Tax Board (RSV) and Svensk Adressändring, a company that keeps track of changes of addresses. The register is updated every two weeks. Under-coverage may occur e.g. because an entity is not liable to paying value-added tax. Over-coverage may likewise happen, i.a. due to discontinued activities not being deleted in the VAT register.

➔ CFAR is of importance to the present work in three ways, two of which are associated with Statistics Sweden:

⊗ It makes up the basis for the Business Register (*Företagsregistret*) that SCB at a cost makes available to interested customers according to wishes for SE-SIC codes, etc. Thus three runs of SE-SIC 33101 have been utilised for this thesis, giving data for companies with primary activity in 33101 as well as companies with primary activity in other codes but with local units classified in 33101

⊗ CFAR data on number of companies (not units) and number of employees in companies in total and distributed among different size classes is easily accessible via the Internet. This has been downloaded from SCB's website to illustrate various developments in SE-SIC 33101, 33102, 35430, 51460 and 73103.

4.6.5 SCB R&D Statistics (tested but not covered in the study)

The R&D statistics are presented every second year and comprise information on research and development projects in companies that have at least 50 employees. "Both manufacturing and service branches are involved, even if in practice only some service companies are counted. The concept research and development is not easily applicable to *service companies*, and many of them therefore consider that they do not carry out any research and development", it is stated in (NUTEK 1999:13) by SCB as one of the producers of that series of reports. This probably would be true also for some companies who *de facto* produce medical devices of the kinds under study in this thesis, although the firms in question are classified outside the manufacturing codes identified in the table above.

After making a test run of SCB's R&D statistics for SE-SIC 33101 for the reference year 1995 – available in 1997 – no more run has been made as yet. The reason is two-, or perhaps three-fold: *First*, share of companies with at least 50 employees is very low – 15-20 companies out of 400 to 500 according to the runs of the Business Register made in 1996, 1999 and 2002. *Second*, apart from a handful of "core" companies (some very large and some mid-sized in terms of the medical devices industry), the "*mobility*" among with more than 50 employees in any of the three years has been considerable between the runs of the Business Register. This holds not only *within* the code 33101 (i.e. companies may cross the cut-off border between 50 and 49 employees between measurement points), but companies also have been "emigrating" from it, the more interesting ones mostly into other medical codes like 51460 or 73103.

Besides, when commissioning industrial R&D statistics at the 5-digit SE-SIC level – which are *not* available on the Internet – it is not disclosed *which* companies are included. Although a researcher may apply for permission to take part of specific micro-data, it would yet have to be confidentially treated. And still, it would be possible via SCB only to know that a *very* small population of companies are included over time. If one were to look at SIC 33101 only, this would not enable the use of a closed panel with more than perhaps 6 or 7 companies over the six years, to judge from the Table 2-7 of "constant" 50+ companies with primary activity in Section 2.1.4 above. Thus for the present purposes, we have chosen give only a short glimpse of R&D figures for some important companies as available (mostly) from the MM Partner. The thought is to revert to the issue of monitoring the development of R&D activity and expenditure in a panel of companies over time in a future study that is independent of SE-SIC classification.

4.7 Problems in comparing production and foreign trade

Since production data is reported according to one nomenclature, HS, while foreign trade data is reported using another, CN, comparisons between the two are not entirely reliable as has been explained above. Caution should therefore be exercised when making comparisons, but in the main, HS and CN are equivalent at the six-digit numerical code level in the areas under study here.

➔ In (NUTEK 2000:4), SCB cautions that some calculations can yield strange outcomes. One main factor they pinpoint is that in a real world, it is misleading to calculate the value of the (supply to) domestic market as that it would represent under perfect textbook conditions, namely production plus imports minus exports. For example they say,

> "it is difficult to estimate how large a portion of exports are (*sic*) produced in the country and how large a portion are onward export of imports. Similarly, it is difficult to judge how much of the domestic production stays on the domestic market. There are reasons for this beyond differences in nomenclatures, including:
>
> - values entered differ in that production is quoted *ex w*orks while exports are quoted *f.o.b*. (free on board), which also includes costs for transportation and insurance to the Swedish border plus trade margins. Similarly, import values include transportation and insurance costs to the Swedish border, i.e. what is known as *c.i.f.* (cost insurance freight).
> - the statistics do not take into account any changes in inventories
> - the production statistics do not cover the smallest production units
> - goods can be misclassified
> - some double accounting can occur in that, for example, values of components may later be included in calculations of the values of complete machines
> - Sweden may have been a country of transit
> - purchases of services in other countries may be classified as trade in goods. For example, repairs to aeroplane engines are carried out abroad. When the damaged engine is carried out of the country this is counted as a goods export and similarly when the repaired engine is brought into Sweden this is counted as an import of goods." (NUTEK 2000:4)

4.8 MM Partner

As it builds on the formal financial accounts that all Swedish registered firms have to submit to the Patent and Registration Office (PRV) and that is bought from PRV, the main contents of the

MM Partner[48] database contents should be of the same quality as that of the source. As stated before, the main role of MM for this study has been as a source of selected micro-data for limited companies (AB), the small share of other legal forms it covers not being relevant here. By definition MM does not include any data on trade whatsoever, also on this account making it unsuitable for any aggregate comparisons with production/trade data from Statistics Sweden.

A potential asset of this database is that it works with a breakdown by industrial activity *of its own* that aims to capture changes in dynamic industries more rapidly than the official SE-SIC nomenclature does. The ways in which this is done (and by what kinds of expertise), however, is largely not explained. This means that a comparison between MM and SE-SIC for names of branches that seem similar sometimes yield surprising results.

Used in the study from 1999 onwards, several features in the MM Partner database have improved considerably over time. However there have been, and are still, some difficulties in using this kind of commercial database as an instrument for research purposes. A *principal* problem is that reproducibility is hampered by a "time-lock" that in editions from 2001 onwards, renders the CDs impossible to reinstall and use after a certain – not disclosed – "best-before date"[49]. Editions older than that may sometimes be opened, but not always usable. Since this problem could not be foreseen, every re-run (or attempt to do one) requires the user to uninstall and reinstall in a never-ending procedure as the objective of the company producing the records is to sell up-to-date versions only.

A *financial* problem is that on top of the cost for subscribing to the database as such, additional costs are incurred if the user wants to export the data from the CD to processable files (in Excel) of one's own. These costs could be considerable depending on the number of companies or parameters studied. Thus such databases are not suitable for "data-mining" exercises of the kind that this study tentatively has tested (not cited here[50]), with more than 2000 companies potentially involved in medical device-related activities in the codes referred to above. In those trials, work has had to be done manually from printouts of database information rather than via exports to a computer, sometimes followed by scanning.

---

[48] When the first contacts were made, it was an independent company, MM Publikationer AB, which was subsequently acquired by Bonnier Data AB

[49] This was confirmed by the company in summer 2002 and due to market considerations, but they were not able to explain exactly *when* a certain edition would become invalid

[50] Even though perhaps 1000 might be a more realistic upper limit, to judge from the detailed data, another two hundred or so companies have been identified as "somehow" involved, e.g. via lists from other sources and from companies advertising for new staff in newspapers during three years. With the tentative aim to start a long time-series of basic data on a relevant set of individual companies among these, basic data mainly including employment, net turnover, R&D expenditure, registration year have been collected for some 1500 companies, for practical reasons however up to 20001 only as yet.

Although much is intuitive once a CD is installed, a person who is not familiar with the fine print in financial reports needs to take part of the explanations to how some of the economic data are presented. The following is a case in question: In the edition 2003-1 (February 2003) the database lists 642 limited companies classified in SE-SIC 73103, i.e. now "Medical and pharmaceutical R&D". Out of these, MM gives R&D figures for 19 companies and says the figure is zero for another 12, indicating a "-" for the remaining 610. This does not mean they have no R&D (hopefully - considering the name of the code), however. What it does mean is that the companies concerned have not given any information or that they do not have annual statements of accounts broken down by *function* ("*funktionsindelad resultaträkning*") but rather the traditional one based on type of costs ("*kostnadsslagsindelad* "). However, the Association of Authorised Auditors (FAR, *Föreningen Auktoriserade Revisorer*) recommends that companies with large R&D activity do use this kind of accounting rather than the traditional one based on type of costs.

5 Appendices

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Appendix 2A – Corresponding to text in Chapter 3

Master table for Production, Exports, Imports and Apparent Domestic Market (calc.) by product group and aggregated. All figures are in SEK million.

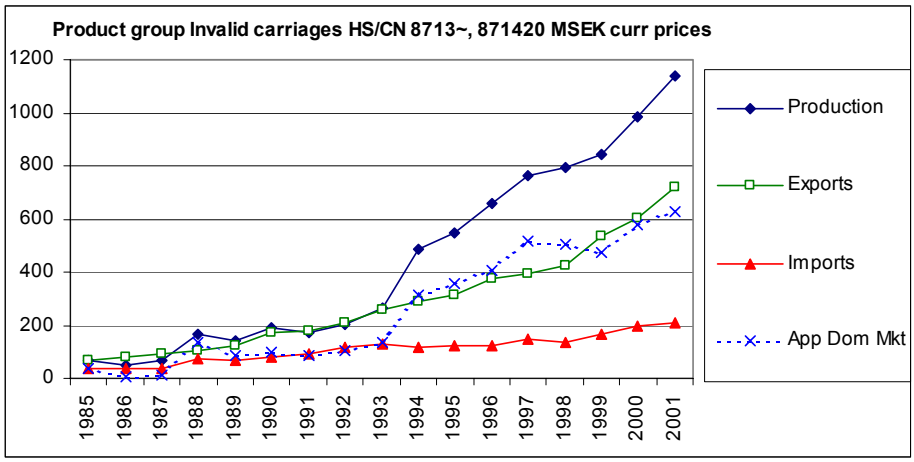
Source: Statistics Sweden, own calculations

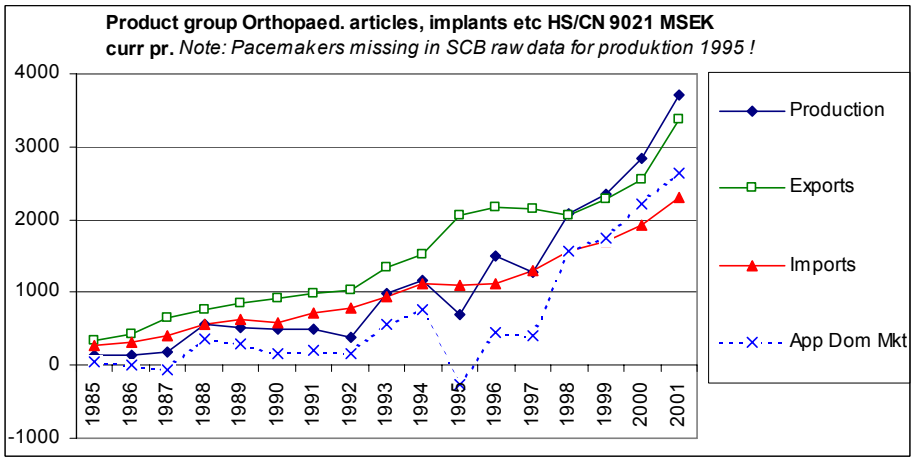
HS/CN	NB: Great caution should be taken with figures for "Apparent Domestic Market" as they have several inherent sources of error																		
4-digit or as spec.																			
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
8713	Production	70	49	65	168	140	191	173	202	263	484	550	661	764	796	844	983	1139	
inkl 8714.20	Exports	70	78	91	103	124	175	178	211	258	290	315	375	393	425	535	601	721	713
	Imports	36	35	37	71	70	81	94	116	130	117	123	123	147	136	167	196	208	236
	App Dom Mkt	36	6	11	136	86	97	89	107	135	312	358	409	518	507	476	578	626	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
9021 #	Production #	136	141	192	557	523	502	495	395	990	1166	687	1505	1280	2071	2340	2846	3717	
	Exports	348	436	648	755	858	920	995	1024	1351	1522	2047	2178	2153	2063	2287	2555	3378	3357
	Imports	264	309	402	566	630	587	710	789	931	1130	1108	1129	1288	1569	1693	1924	2302	2614
#	App Dom Mkt#	52	14	-54	368	295	169	210	160	571	774	-252	456	415	1577	1746	2215	2641	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
9018	Production	1369	1464	1501	1282	1326	1395	1523	1674	2056	2329	3144	3470	3681	3622	3852	4531	5089	
	Exports	1312	1458	1413	1430	1642	1844	1885	2102	2786	2932	3153	3410	3866	4669	4420	5425	5476	5606
	Imports	793	870	974	1136	1246	1228	1373	1583	1946	2168	2408	2339	2993	3224	3247	3652	4404	4369
	App Dom Mkt	850	876	1062	988	930	779	1011	1155	1217	1564	2399	2399	2808	2177	2679	2758	4017	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
9019.2000	Production	112	96	91	476	588	616	523	556	581	560	704	785	619	868	807	729	849	
	Exports	253	311	466	528	517	570	492	627	621	611	1010	823	1340	1275	1013	1010	1178	1543
	Imports	31	44	39	44	51	57	97	73	89	65	106	156	147	207	170	210	272	250
	App Dom Mkt	-110	-171	-336	-8	122	103	128	2	49	13	-200	118	-574	-200	-36	-71	-57	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
9022	Production	534	643	581	584	557	629	507	509	543	726	954	851	639	756	786	963	1108	
	Exports	538	574	512	392	478	572	584	550	692	647	1451	1168	1144	991	895	863	1186	1722
	Imports	209	228	288	198	196	170	200	273	262	340	516	611	522	516	543	566	723	778
	App Dom Mkt	205	297	357	390	275	227	123	232	113	419	19	294	17	281	434	666	645	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
8419.2000	Production				2	253	233	270	276	343	454	456	462	592	665	620	654	538	
	Exports				133	134	147	187	186	248	319	292	299	282	302	356	378	325	457
	Imports				10	8	14	15	18	25	19	15	40	48	37	28	30	17	41
	App Dom Mkt				-121	127	100	98	108	120	154	179	203	358	400	292	306	230	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
9402	Production	179	186	185	170	218	199	189	139	176	187	289	231	574	511	516	472	352	
	Exports	128	121	122	98	94	107	97	105	111	156	136	164	175	187	193	180	203	205
	Imports	39	52	60	46	57	56	75	69	101	150	153	102	122	107	124	143	152	145
	App Dom Mkt	90	117	123	118	181	148	167	103	166	180	306	169	521	431	447	435	301	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
3005 (partial)	Production	300	195	59	179	191	190	302	296	177	223	250	336	266	212	300	306	159	
	Exports	134	140	161	177	209	209	225	239	242	250	290	315	320	254	378	352	437	383
	Imports	158	172	190	203	211	229	231	224	242	253	300	301	347	326	347	409	471	538
	App Dom Mkt	324	227	88	205	193	210	308	281	176	226	260	322	293	284	269	363	193	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
3006 (partial)	Production	58	60	68	229	221	161	229	281	269	260	143	46	85	61	66	39	40	
	Exports	59	74	80	145	143	155	159	143	181	195	176	186	203	215	213	252	316	430
	Imports	58	63	64	127	139	162	201	208	273	323	301	350	330	361	420	364	433	446
	App Dom Mkt	57	49	52	211	217	168	271	346	361	387	268	210	212	207	273	151	157	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
9001 (partial)	Production	78	87	94	95	85	70	75	67	63	61	71	130	99	139	148	147	164	
	Exports	15	13	15	14	22	17	17	20	24	30	32	35	72	213	109	112	154	156
	Imports	78	96	111	128	157	155	165	162	194	232	196	225	268	292	327	393	455	472
	App Dom Mkt	141	170	190	209	220	208	223	209	234	263	235	320	295	218	366	428	465	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
9004 (partial)	Production	8	4	5	16	15	74	0	0	3	0	125	69	79	79	90	96	134	
	Exports	12	8	6	8	10	9	8	15	2	1	28	32	32	35	68	35	28	43
	Imports	22	24	25	28	31	38	43	52	34	52	51	55	73	88	82	57	61	76
	App Dom Mkt	18	20	24	36	36	103	35	37	36	51	148	92	120	132	104	118	167	
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
3701.1010	Production	143	150	163	129	100	121	94	95	116	111	138	150	0	0	0	0	0	
	Exports	122	138	156	120	115	125	109	115	143	175	194	170	156	146	145	183	260	276
	Imports	81	73	84	72	80	78	81	80	100	112	120	138	174	224	212	256	248	237
	App Dom Mkt	102	85	91	81	65	74	66	60	73	48	64	118	18	78	67	73	-12	
	#) 1995 excl. Pacemakers (CN 90215000) which for reference year 1995 were missing in raw data from SCB. Impacts on Main group "Aid & Implants", Total production and Apparent Domestic Market for that year																		
		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Production All Product Grps		2987	3075	3004	3887	4217	4381	4380	4490	5581	6560	7510	8696	8678	9780	10369	11766	13289	n.a.yet
Exports All PG		2991	3351	3670	3903	4346	4850	4936	5337	6660	7128	9124	9155	10136	10775	10612	11946	13662	14891
Imports All PG		1769	1966	2274	2629	2876	2855	3285	3647	4327	4960	5397	5569	6459	7087	7360	8200	9746	10202
Apparent Domestic Market All PG		1765	1690	1608	2613	2747	2386	2729	2800	3249	4392	3783	5110	5001	6092	7117	8020	9373	
030411 Latest updates for 1996-2002 from SSD (Prod, Exp, Imp data)																			

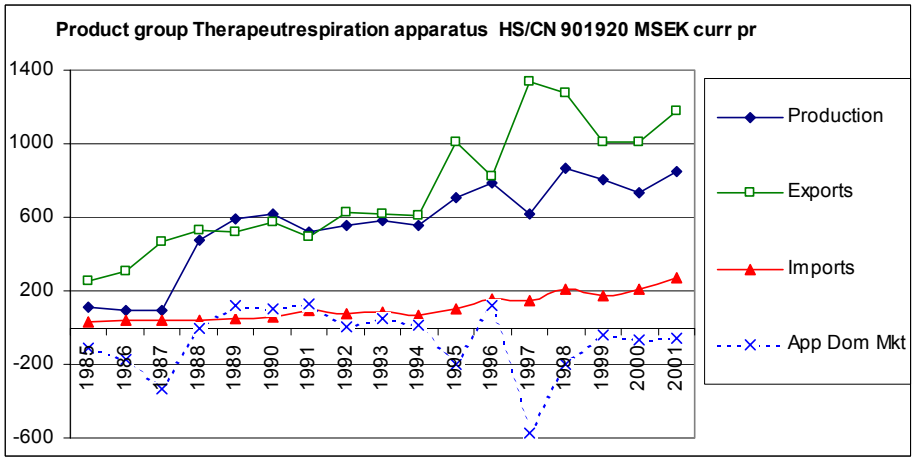
Appendix 2B – Corresponding to text in Chapter 3

Diagrams showing Production, Exports, Imports and (calculated) Apparent Domestic Market for all product groups within the three main groups "Aids & Implants", "Medical Equipment and Instruments" and "Miscellaneous"

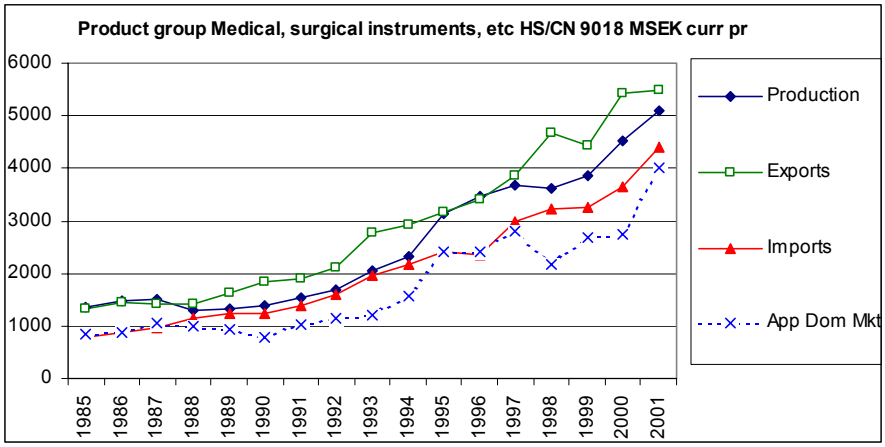
All the following twelve diagrams are in SEK million and are based on data from Statistics Sweden and the author's calculations

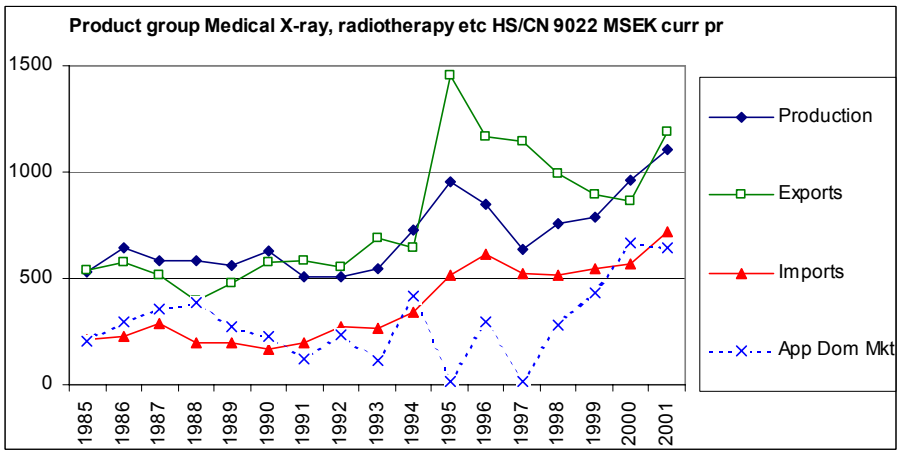


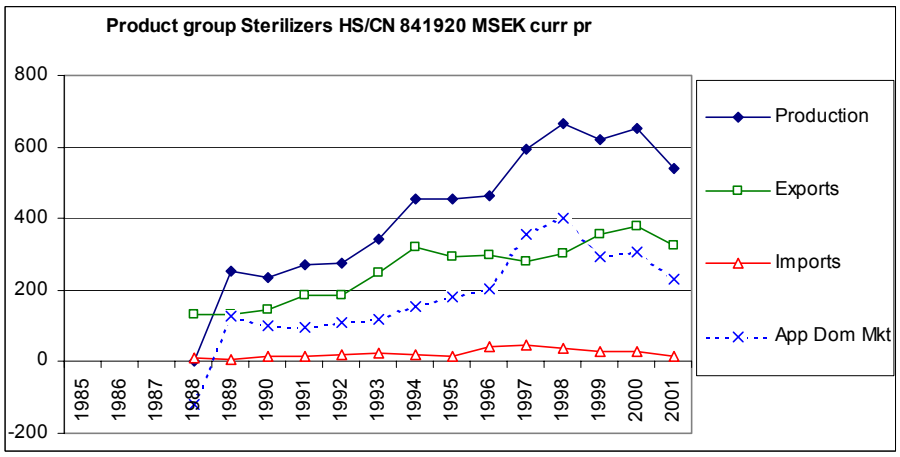




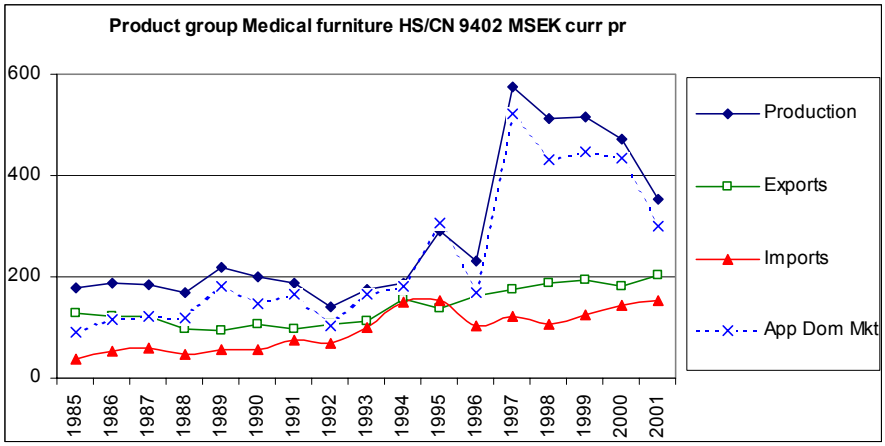
Appendix 2B, continued

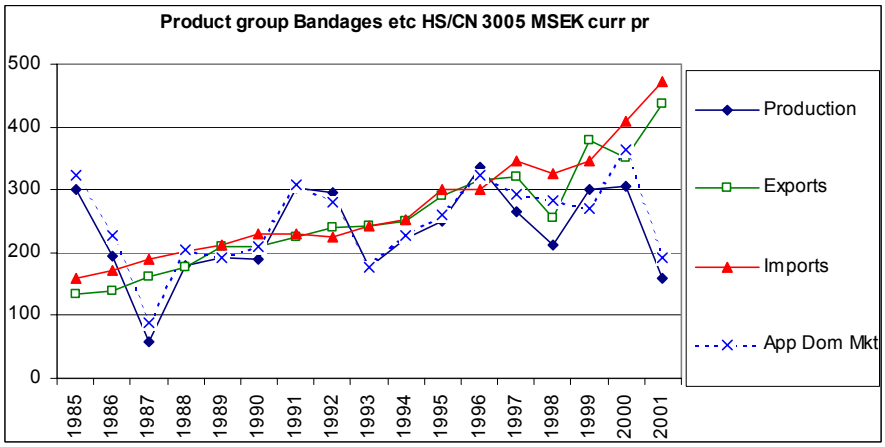


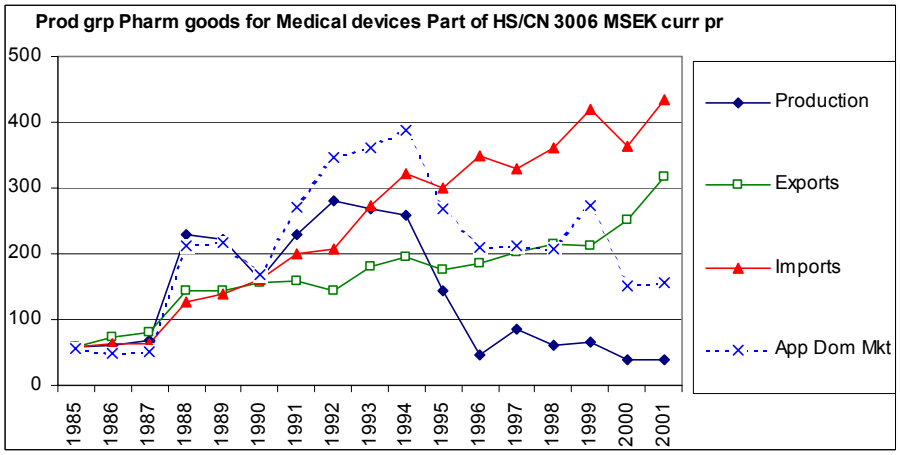




Appendix 2B, continued







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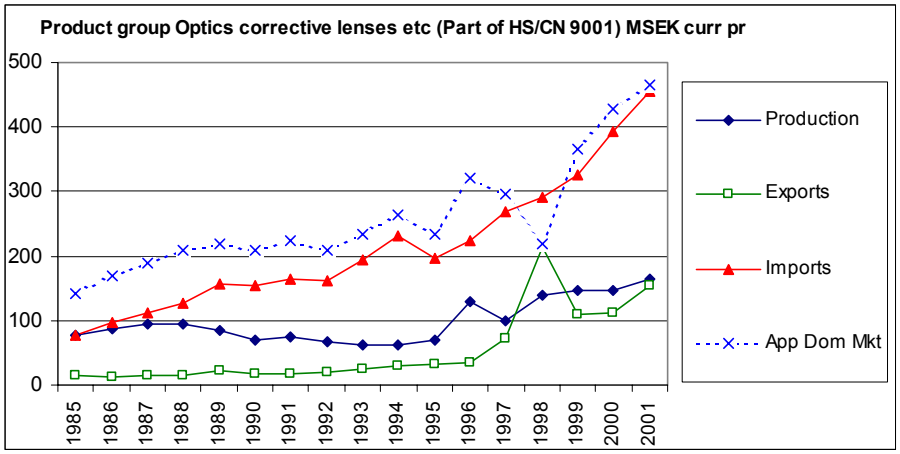
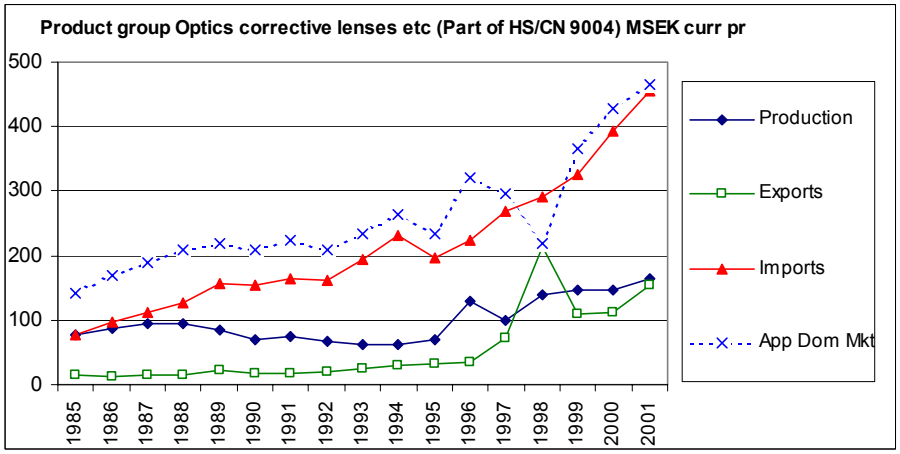
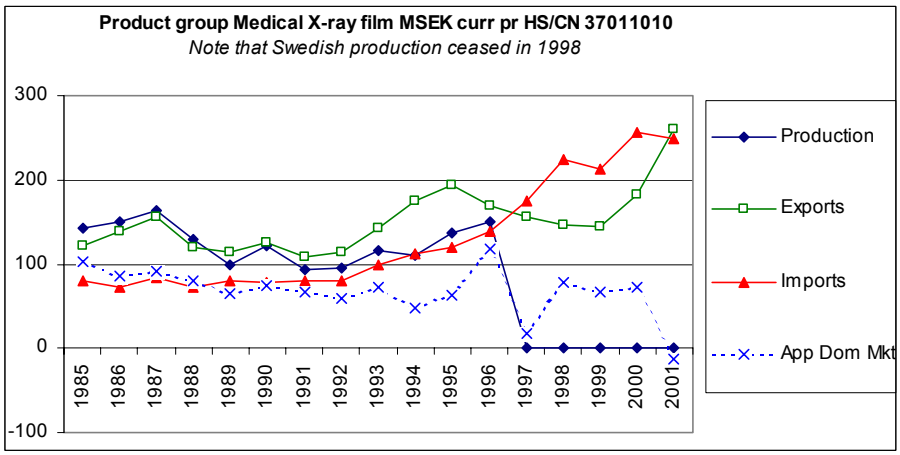


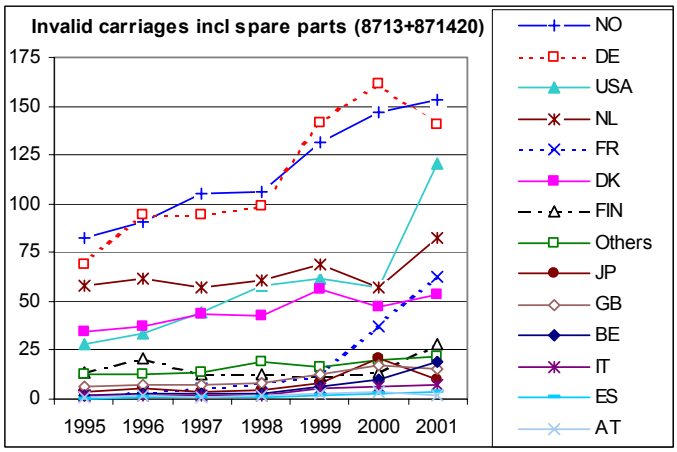


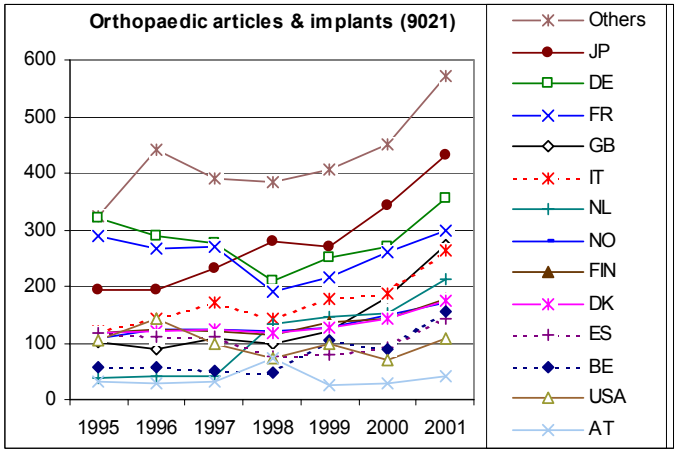


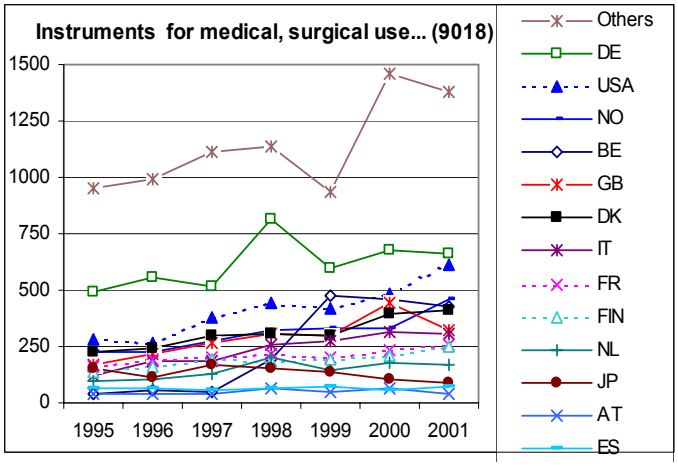
Appendix 2C – Corresponding to text in Chapter 3

Diagrams showing Export country vs. Product Groups in main groups "Aids & Implants" and "Medical Equipment and Instruments

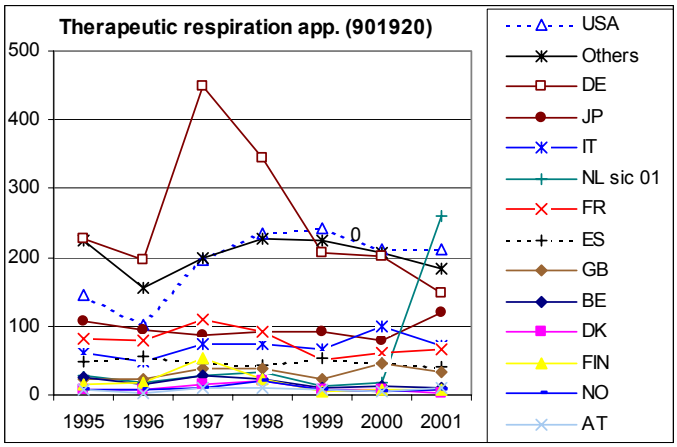
All the following seven diagrams are in SEK million and are based on data from Statistics Sweden and the author's calculations. ***Note: "Others" = Rest of World***

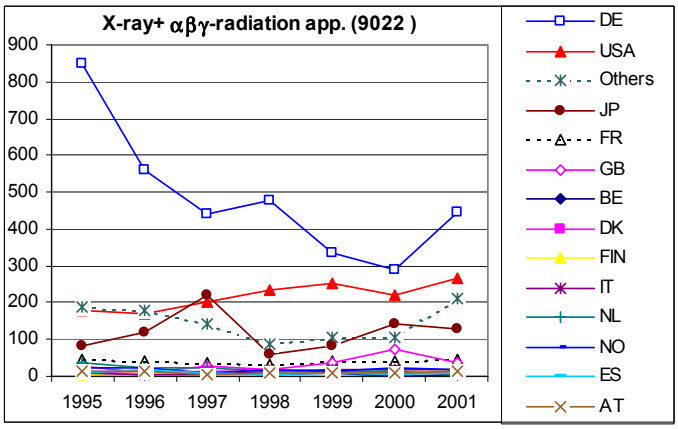


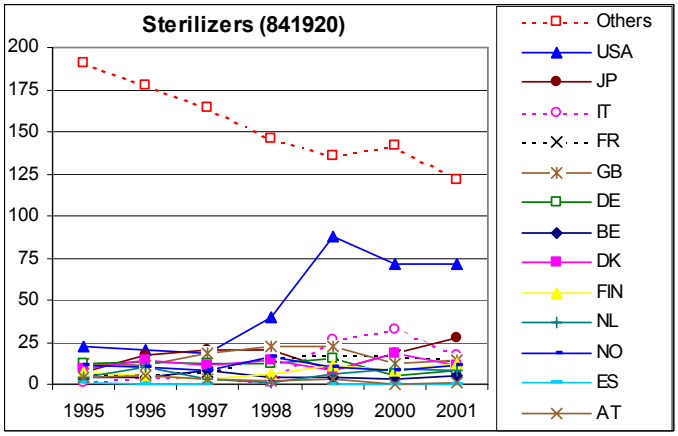


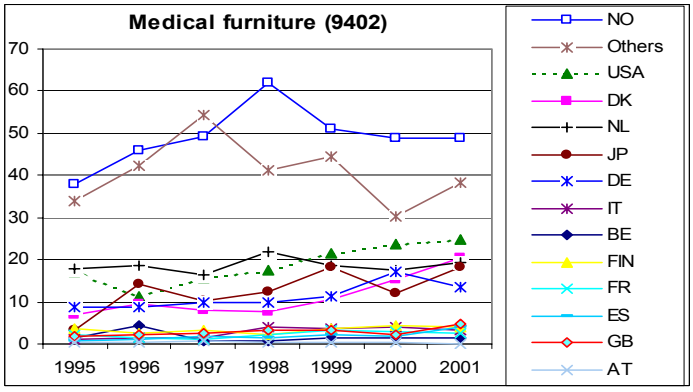


Appendix 2C, continued









The GMDN Device Categories as defined in EN ISO 15225 (2000)

Svensk Standard SS-EN ISO 15225

Code 01 Term: Active Implantable Devices

This category includes devices relying on a source of power other than that directly generated by the human body or by gravity and intended to be totally or partially introduced, surgically or medically into the human body, or by medical intervention into a natural orifice, and which is intended to remain there after the procedure.
Note: Examples of devices in this category are pacemakers, implantable infusion pumps, cochlear implants and their accessories.
Note: See Active implantable medical device directive.

Code 02 Term: Anaesthetic and Respiratory Devices

This category includes devices and accessories for supplying, conditioning, monitoring, dispensing and delivering respiratory, medical and anaesthetic gases and vapours for providing and/or controlling respiration and/or anaesthesia.
Note: Examples of devices in this category are anaesthetic work stations, respiratory circuits, ventilators and their accessories.

Code 03 Term: Dental Devices

This category includes devices for use in diagnosis, prevention, monitoring, treatment or alleviation of oral, maxillofacial and dental disease.
Note: Examples of devices in this category are dental hand instruments, impression materials, dental amalgam, dental tools and their accessories.

Code 04 Term: Electro mechanical medical devices

This category includes devices where the operation depends upon a source of electrical energy (electromedical) or source of energy other than that directly generated by the patient's body or gravity and which uses this energy to produce its effect or action (mechanical).
Note: Examples of devices in this category are EEG, infusion pumps, monitors for haemodialysis, monitors for ECG, spring driven and elastomeric pumps.

Code 05 Term: Hospital hardware

This category includes devices which are not directly used in diagnosis or examination, nor have direct influence on the clinical evaluation of the patient's condition, test results or further treatment.
Note: Examples of devices in this category are sterilizers, patient transfer equipment, as well as disinfectants.

Code 06 Term: In vitro diagnostic devices

This category includes devices which are used for in vitro examination of samples from the human body for the purpose of determining physiological or pathological conditions.
Note: Examples of devices in this category are blood glucose monitors, bilirubinometers, microbial sensitivity systems and their accessories.

Code 07 Term: Non-active implantable devices

This category includes devices other than active implant-
able devices, which are implanted for longer than thirty days.
Note: Examples of devices in this category are interuterine devices, heart valves, bone prosthesis and their accessories. 78 GMDN User Guide: version 2002

Code 08 Term: Opthalmic and optical devices

This category includes devices for use in diagnosis, prevention, monitoring, treatment, correction or alleviation of eye diseases and optical malfunctions.
Note: Examples of devices in this category are tonometers, intraocular lenses, slit lamps and their accessories.

Appendix 3, GMDN Nomenclature, continued

Code 09 Term: Reusable instruments

This category includes devices which are used in surgery or elsewhere and are intended to be cleaned and sterilized for reuse.

Note: Examples of devices in this category are retractors, haemostats, drills, saws and their accessories.

Code 10 Term: Single use devices

This category includes devices which are intended to be used only once.

Note: Examples of devices in this category are intravenous infusion sets, condoms and laparotomy sponges.

Code 11 Term: Technical aids for disabled persons

This category includes devices specially produced or generally available which compensate for, relieve, prevent or neutralize an impairment, disability or handicap.

Note: Examples of devices in this category are crutches, artificial limbs, hearing aids, wheelchairs and their accessories.

Code 12 Term: Diagnostic and therapeutic radiation devices

This category includes devices which are diagnostic and/or therapeutic and use such modalities as x-rays, **magnetic resonance imaging, ultrasound imaging, computed tomography scanners and their accessories.**

Note: Examples of devices in this category are x-ray equipment, computed tomography scanners and their accessories.

Excerpt from
"*Den medicintekniska industrin, sjukvården och samhället*
En ansats till analys av samspelet mellan näringsliv och samhälle
inom området medicintekniska produkter"

Ingenjörsvetenskapsakademien PM 9:1987, 231 pp
Lena-Kajsa Sidén et al 1988-03-30

DEFINITIONER

*Nedan återges ett antal definitioner som antingen utnyttjats direkt i rapportens textavsnitt **eller** som medtagits för att visa vilken spännvidd som kan råda mellan term och innehåll.*

*Om intet annat framgår av rapporttextens sammanhang, avser IVAs användning av uttrycket "medicinsk teknik" i flertalet fall sådan teknik som förknippas med termen "medical devices" i OTAs definition och "medicintekniska produkter" i säkerhetsutredningens. Den motsvarar därvid i huvudsak STUs definition av "biomedicinsk teknik" **exklusive** läkemedel och **administrativa** hjälpmedel (t ex datasystem).*

"The basic definition of **biomedical research** comprises:

- the study of specific diseases and conditions (mental or physical), including detection, cause, prophylaxis, treatment and rehabilitation of persons;
- the design of methods, drugs and devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions;
- the scientific investigation required to understand the underlying life processes which affect disease and human well-being, including such areas as cellular and molecular bases of diseases, genetics, immunology."

B 15, p 26 (OECD 1985)

"Industriellt representerar **biomedicinsk teknik** den FoU som inriktas mot hälso- och sjukvårdssektorns behov. Den innefattar medicinsk teknik, läkemedelsteknik, handikappteknik samt sjukhus- och vård-teknik.
" - **Medicinsk teknik**, dvs utrustningar för diagnos och terapi m m
- **Läkemedelsteknik**, dvs läkemedel, diagnostika m m
- **Handikappteknik**, dvs hjälpmedel för handikappade - **Sjukhus- och vårdteknik**, dvs vårdhjälpmedel, utrustningar för drift och administration."

A 6, p 1 resp 5 (STU 1986)

"**Health care technologies** comprise all diagnostic and therapeutic procedures, incl. equipment and devices and other technologies that support these procedures."

B 16, p 116, not 11 (FN 1987)

"**Health care technology**: The drugs, devices and medical and surgical procedures used in medical care and the organizational and support systems in which such care is provided."

B 8, p 380 (STG-WHO 1986)

"The term **medical device** refers to any instrument, apparatus or similar or related article that is intended to prevent, diagnose, mitigate or treat disease or to affect the structure or function of the body."

"OTA has defined **medical technology** to include drugs, devices, medical and surgical procedures, and the organizational and supportive systems within which medical care is provided."
B 4, p 4 (OTA 1984)

"**Medical technology** Specialized technology applicable to the practice of medical care, including techniques, drugs, procedures, products, or systems combining these elements"

-"**Ancillary technology** Medical technology used directly to support clinical services, including diagnostic radiology, radiation therapy, clinical laboratory, and other special services.

-**Clinical technology** Medical technology used in the provision of direct patient care, including medical and surgical services.

-**Coordinative technology** Technology used to facilitate and support the provision of health care services but not directly associated with patient care, including administration, transportation, and communication both within and among health care facilities."
B 17, p 85 (NAS 1979)

"**Medicinska teknologier**: alla medicinska åtgärder för prevention, diagnostik, behandling och rehabilitering samt för organisation och administration". (Denna /internationellt accepterade definition/ innebär att medicinsk teknologi kan avse allt från utnyttjande av avancerad medicinsk utrustning till enkla medicinska åtgärder".)
A 3, p 1 (MFR/FRN/STU/SoS 1984)

"...**medicin-teknisk FoU** avser 'det materiella inslaget och de diagnostiska, terapeutiska och rehabilitiva medicinska hjälpmedel som fysiskt är förkroppsligade i utrustning eller relaterade tekniker'"

"**Sjukvårdsmiljöteknisk FoU** ... används av RRV som term för utvecklingsarbete rörande frågor av 'teknisk/praktisk karaktär, typ utrustning för sjukhusvården i allmänhet (sängutrustning, lyftanordningar och annan generell sjukhusutrustning) "

"**Hälso- och sjukvårdsteknisk FoU** ... användas som ett sammanfattande begrepp för medicinteknisk FoU och sjukvårdsmiljöteknisk FoU".
A 2, p 15-16 (RRV 1983)

"Med **medicintekniska produkter** avses apparater, instrument, implantat, sterila engångsartiklar och andra produkter, som är avsedda att i hälso- och sjukvård eller tandvård nyttjas för undersökning, vård eller behandling av patienter eller för undersökning av prov från patienter och som inte är läkemedel eller naturmedel."
A 4, p 23 (stencilerad version; Utredningen om medicinteknisk verksamhet 1987)

(…)
"**Utvärdering av medicinsk metodik** avser en på vetenskaplig grund samlad bedömning av medicinska metoders nytta, risker och kostnader. Bedömningen ska utöver de medicinska effekterna även innefatta andra för patienten och samhället relevanta aspekter som de sociala, psykologiska, etiska och ekonomiska konsekvenserna."
A 23, p 1 (MFR 1987)

Somewhat later addition:

“Health technology is defined as the drugs, devices, and medical and surgical procedures used in the prevention, diagnosis, treatment, and rehabilitation of disease. “Management of health technologies: an international view. British Medical Journal 1999;319:1293. Jonsson, E. & Banta, D.

Appendix 5 Introduction from the Academy study (IVA 1988)

THE MEDICAL EQUIPMENT INDUSTRY, HEALTH CARE AND SOCIETY IN SWEDEN

An analysis of the interaction between industry and society in the field of medical devices
Royal Swedish Academy of Engineering Sciences (IVA, 1988)

1. Background

This study is one of four on the common theme, "Interaction between industry and society", conducted by the Royal Swedish Academy of Engineering Sciences, IVA, in 1986-87 upon request by the Swedish Ministry of Industry. In effect, IVA was requested "to analyze the connections between different societal infrastructure and public service programs, and conditions for long-term industrial growth and renewal". The Ministry in its terms of reference noted three items for IVA to consider:

(a) To give an overview of important segments in Swedish industry that have mainly been based upon infrastructural programs or originated through close cooperation between society and industry.

(b) To attempt, on the basis of this overview, to identify critical conditions for successful interaction between industry and society in different types of infrastructural/public service programs, and in different stages of development-oriented cooperation.

(c) To identify, through IVA's own analysis, concrete opportunities for society (government) to promote industrial development in the longer term. IVA should hereby include societal efforts in the sectors of health care, education, and environmental protection. The role of innovative (technology) procurement should be considered.

The commission should, according to the brief, "result in proposals for concrete actions to be taken by industry and society".

The background thus is that in Sweden, very considerable resources are directed towards development of the societal infrastructure in a wide sense. The Ministry of Industry therefore is interested in trying to assess, to what extent these investments can contribute - or directly result in - a corresponding expansion of the Swedish industrial base.

What, then, is meant by the term *"infrastructure"* -together with *"interaction"* one of the key words in this commission? As a military term it means the permanent, rear installations and structure in a defense system. In a civilian context, it refers to a country's supply system - or the sum of its installations - for transportation, energy distribution, telecommunications, etc. These are often collectively called the *physical* infrastructure, which could also include, for example, environmental protection. In a wider sense, the term may also be interpreted to include the *"intellectual"* infrastructure - that is, the educational system, etc, and other public services at large. It is mainly in this latter context, public services, that a country's health care system comes in.

The Ministry's brief gave no instruction as to *how* IVA should tackle the items (a) - (c) above. After thorough discussion in the Academy's Executive Committee, it was decided to divide the task into four independent studies. One of these was directed towards creating a general ”political science” background to the concept of interaction between "society" (government and other public bodies including for example universities) and "industry" (including commerce, finance etc), with three accompanying but rather loosely connected cases (telecommunications, ground transport, and government-owned enterprises; these three analyzed from a Swedish point of view). This study roughly was to cover item (a) in the brief as above.

At the same time, three other studies were started, directed towards each of the three sectors mentioned in item (c) above. These were given the working titles, "Interaction between industry and universities" (Samverkan näringsliv -högskola), "Environmental protection policy and industrial development" (Miljövårdspolitik och näringslivsutveckling), and "The role of health care in industrial development".

The two first-mentioned titles have been maintained in the respective final reports to the Ministry of Industry, whereas the title of the present report subsequently has been more accurately defined.

In the fall of 1986, the Academy appointed a Program Committee for the "health care study". One of its two main tasks was to sketch realistic contents for the study, which not least meant to set up limitations. The second was to design the program of several discussion meetings, etc, that were to become central components in the work, according to preparatory contacts between IVA and the Ministry. The members of the Program Committee, whose contribution IVA gratefully acknowledges, were:

- Dr Sven Kvarnström (MD), Chief Corporate Medical Officer, ASEA AB, Västerås. Chairman of the Committee
- Mr. Sven-Eric Bergman (M.Pol.Sc.), Chief Administrative Officer, Board of Health and Medical Care, Stockholm County Council
- Professor Gunnar Birke (MD), Clinic of Internal Medicine, and former Chief Medical Officer, Huddinge University Hospital
- Dr Lars Magnus Bjursten (MD), Researcher at the Institute for Applied Biotechnology, Gothenburg (private foundation specializing in titanium-based biomaterials)
- Dr Andras Gedeon (Dr.Eng; Physics), Deputy Executive Officer and Development Manager, ICOR AB (small technology-based company specialized in intensive care and operating room equipment)
- Dr Bengt Jönsson (PhD, Economics), Professor of Health Care Economics, University of Linköping
- Ms Lena-Kajsa Sidén (M.Sc., Chem Eng), IVA, Secretary of the Committee and Project Manager for the study.

In order to reasonably limit its scope of work, the Program Committee at its first meeting in the fall of 1986 looked for guidance in the "spirit" of the terms of reference as above. This initially resulted in the exclusion of such supplies and services to the health care sector that were "non-development-intensive" or not directly related to actual medical or other care activities. Thus products such as food, fuel, and furniture and other equipment for administrative purposes were left out. Neither were building and installation technology included, despite their representing several product areas of considerable economic value. It deserves to be mentioned, that health/medical care services were subsequently left out by and large, too. This was not the result of a decision; the Program Committee did consider this field important. In reality, the field proved so little researched in Sweden, however, that the Swedish Trade Council and the Swecare Foundation had only recently started an investigation of their own on this topic.

Thus there remained, principally, two central fields of products to consider: *pharmaceuticals* and *medical equipment/devices*. (The latter terms are used interchangeably; no obvious distinctions can be made for the purpose of this study - but please see below regarding definitions.) The Program Committee here chose to leave also pharmaceuticals aside; one reason being that drugs and the Swedish drug industry had been subject of several other investigations, one of which very recently. These studies have focused on different aspects such as research and development, industrial structure, regulatory mechanisms, industry-university interaction, etc. The pharmaceuticals field, further, is very different - not least from a structural point of view - from the second remaining field, that is, medical equipment.

A "gray zone" that the Committee initially found of interest to include in the study, due to its rapid expansion scientifically and technologically, was *diagnostics* (substances and kits, etc). Subsequently also this product field was left out, however. Commercially, it is more often referred to in discussions about the pharmaceutical industry's structure and development (roughly, the turnover of diagnostics is estimated to correspond to 3-5 % of the world market for drugs). Certain qualitative conditions, though, are common to (companies and development in) drugs, diagnostics, and medical devices. Thus the limitation is motivated primarily from a practical point of view. In the many discussions held throughout the course of the study, several parallels and contrasts with the pharmaceuticals field have been demonstrated, naturally.

Against this background, IVA decided to primarily consider the broad spectrum of products that when the study started were most accurately defined as "*medical devices*", according to the U.S. Office of Technology Assessment (1984): *"The term medical device refers to any instrument, apparatus or similar or related article that is intended to prevent, diagnose, mitigate or treat disease or to affect the structure or function of the body". (ref B4)*

Somewhat later, however, the Swedish Public Commission investigating Medical Equipment Safety (Den offentliga utredningen om medicinteknisk säkerhet) in 1987 gave a definition in Swedish that IVA, for practical reasons, found simpler to use despite its being not wholly symmetric with that of OTA.

The Swedish term "*medicintekniska produkter*" that was put forward by the Commission, thus was defined to include

⊗ *"equipment, instruments, implants, sterile single use articles, and other products intended for use in health, medical or dental care for diagnosis, therapy and care, or for processing of samples from patients, and which are not pharmaceuticals or biologicals" (ref A4; IVA's translation)*

As to the contents and disposition of the study, the Program Committee early on formulated three issues/themes that were of central importance and well designed to bring up in informal discussion meetings with different groups of actors:

- Procurement, budget and financing mechanisms in the (Swedish) health care sector
- The process from idea to product and market in medical devices
- Development trends in health care and their impact on industry and commerce.

In addition, the responsible IVA staff and the Program Committee jointly identified a number of themes for other parts of the study and its report. These are descriptive and/or give data about the health and medical care sector in Sweden, the medical devices industry in Sweden and internationally, R&D aspects, etc. This background work -including interviews, a questionnaire survey, statistical analyses and other elements of investigation - and the presentation hereof in the report, has been carried out independently by IVA staff with advise and support from the members of the Program Committee and other specialists.

Based upon those trends and results that have emerged from the discussion meetings mentioned above, from its own considerations and from parts of the background material produced, the Program Committee formulated a number of proposals for action to be taken by several parties. Certain complementary additions have been made by IVA's project management group for the entire commission from the Ministry. Taken together, these constitute the Academy's proposals to the Ministry of Industry with the aim to contribute (1) to a more substantial interaction between the health care sector and industry in Sweden, and (2) to a continued positive development at large for the industry concerned.

The report is written by IVA's project manager for the study, Ms Lena-Kajsa Sidén, who has also been responsible for the interviews, the literature survey, the questionnaire survey, and other staff work. The underlying statistical analysis and related background work, published in Appendix II and summarized in the text's Chapter 6, Section 1, has been carried out by Mr. Göran Reitberger, who has also contributed valuable advise on the layout of the work and the report as a whole.

2. A guide to the reader

This report mirrors the fact that the investigation is made up by several parts of rather different character. To facilitate the reader's orientation and to explain what type of background material various parts are based upon, a "declaration of ingredients" is given below.

Chapter 3 gives a summary of the main results of the study, including the Academy's conclusions and recommendations, the latter being based upon the considerations of the Program Committee.

Chapter 4 gives an account of various aspects of the Swedish health and medical care system, which are of present or potential importance for purchasing, etc., of medical equipment today or in the medium term. This is primarily based on statements, opinions and comments put forward at two of the three discussion meetings that have been held, concerning procurement and financing, and development trends in health care, respectively. Additional material comes from discussions within the Program Committee itself, as well as from literature and interviews, etc, made in other stages of the project.

Chapter 5 considers the medical equipment industry in a general, mainly international perspective; the world market for medical devices, etc. To a great extent, this rests on literature sources, particularly those presented more closely in Appendix I (*cf.* below), but also from others, documented in Supplement 2 (Literature references). Parts of the material resulting from the meeting "From idea to product and market", interviews, etc., have also been utilized.

Chapter 6 looks at Sweden's medical devices industry. It summarizes the principal results of a special analysis that IVA has conducted regarding the Swedish production of and trade with medical devices (*cf.* Appendix II below). Further, it presents the results of a questionnaire survey sent to medical technology companies concerning their opinion of the future in the medium term. The chapter concludes with a section about the role of the domestic market and some other aspects that complement the picture given by the two first-mentioned surveys.

Chapter 7 attempts to give a structure for those parts of the Swedish publicly financed R&D system that are relevant to the development of knowledge, technology and products for the health care sector. A number of central bodies and their activities within the field are discussed. This is an informal account of a mixed reporting and reasoning character based upon printed material, discussion meetings, interviews, etc. A table of development-intensive medical technology areas, as seen in a number of countries, is given.

Chapter 8 discusses issues relating to the start-up and development of new firms; the process from idea to product and market in medical technology and the forces that influence the different stages in this process. This chapter primarily builds on the meeting with innovators, etc., arranged under the same title, but also on the meeting on purchasing, on interviews, and the opinions of the Program Committee. This chapter is of a decidedly "soft" character - partly including speculative elements, too. Some other parts relate to hard facts; the distinction should be easily seen.

Chapter 9 discusses some particular aspects of interaction and cooperation: intellectual interaction between industry, health care and academic research; customer-supplier interaction in a more general sense; interaction between large and small firms, and the like. This is mainly based on discussions in the Program Committee but also on the results of one of the simultaneous IVA studies ("Interaction between industry and universities", which primarily deals with diffusion of new technology and new technology-based companies).

Chapter 10 gives special consideration to "system differences" between health care and industry in Sweden. These, it is argued, call for a more well designed, cross-sectoral government policy for long-term promotion of medical technology R&D and industry in line with needs in health care and society at large.

Appendix I gives an extensive overview of six foreign studies and, more in summary, six Swedish reports/studies, which all relate to the main topics of the present study. The foreign studies are all strongly policy-related; four of them also treat medical technology development trends *per se*. A short, comparative summary of these twelve studies is given as well.

Appendix II presents an analysis of the development of the Swedish medical devices industry in the 1980s, based on, among other sources, official statistics on production and foreign trade. Figures for production, exports, imports and the calculated Swedish market are given for different product groups. Market patterns, value contents of imports and exports, etc., are analyzed. No previous analyses of a corresponding character have been undertaken in Sweden.

Appendix III describes the Swedish health care system, its policy, present and estimated future costs as well as some important bodies. The sources here are printed material only.

(Informal translation by the author 1988)

Appendix 6 Medical device companies with ≥50 employees in 2002 for which R&D figures have been identified

Company	SIC MMP 2003-1	SIC SCB 2002-06	NTO 2001	R&D 2001	Empl 2001	NTO 2000	R&D 2000	Empl 2000	NTO 1999	R&D 1999	Empl 1999	NTO 1998	R&D 1998	Empl 1998
Siemens-Elema AB	33101	33101	3638	471	1061	3249	452	1066	3192	441	1056	3130	429	1107
Gambro Lundia AB (2001 reorg)	33101	33101	5361	223	832	1837	201	789	1684	172	761	1620	198	744
St. Jude Medical AB (R&D pers. info)	33101	33101	1849	113	535	1441	104	432	1357	97	431	1597	109	452
Becton Dickinson Infusion Therapy AB	33101	33101	459	16	473	508	17	526	491	17	505	526	23	550
Astra Tech AB	33101	33101	860	61	460	683	49	384	# 666	# 47	# 376	# 648	# 45	368
Getinge Sterilization AB (2001 reorg)	33101	33101	503	26	328	582	19	360	551	14	379	560	23	359
Instrumentarium AB omstr	33101	33101	536	28	203	514	57	386	25	6	403	(restr to Datex-Ohmeda)		
Althin Medical AB	33101	33101	115	5	184	319	4	174	341	6	169	354	9	158
Arjo Hospital Equipment AB	33101	33101	421	13	152	376	14	150	358	18	150	347	19	154
Radi Medical Systems AB	33101	33101	232	44	125	160	34	101	132	15	90	107	11	89
Atos Medical AB	33101-P2	33101-P1	128	8	86	101	10	82	86	9	57	76	3	42
GEMS PET Systems AB (reorg 2001)	33101-P2	33101-P1	205	22	84	91	14	54	57	9	38	34	8	33
Stille Surgical AB	33101	33101	78	2	67	68	10	62	77	3	65	65	0	56
Vitrolife Sweden AB	24660	33101	61	13	54	28	8	21	1	4	3	0	2	1
Nobel Biocare AB ex-33101	33102		1269	80	351	965	72	372	882	60	346	689	68	352
Mölnlycke Health Care AB	51460		1343	65	206	570	65	292	734	58	422	160	0	126
Elekta Instrument AB	73103		681	57	118	601	43	95	431	52	91	404	54	87
Etac Supply Center AB	35430		217	4	115	198	6	125	168	10	119	162	6	121
Jomed i Helsingborg Int'l AB	51460		426	7	54	307	10	52	246	10	36	163	5	22
Ortivus AB	51460		85	42	53	66	44	54	76	30	59	42	26	49
Sum of the above			18466	1303	5541	12663	1233	5577	10890	1030	5180	10035	995	4870
Sum corr. for Gambro 2002 & Astra Tech 1998-1999			15042	1303	5541	12663	1233	5577	11556	1077	5556	10683	1040	4870
R&D/net turnover, %			8,7			9,7			9,3			9,7		
net turnover/empl, MSEK			2,715			2,271			2,080			2,194		
R&D/empl, MSEK			0,235			0,221			0,194			0,213		

Notes:

1) NTO = Net turnover in SEK million, R&D = Research and development expenditure in SEK million. With exceptions noted below, all figures are from the MMP database (versions 2003-1 and 2001-4)
2) Table includes a) all companies in SE-SIC 33101 according to Statistics Sweden (SCB; Business Register) per June 30, 2002, which have ≥50 employees AND for which R&D figures have been identified; b) PLUS the *six companies at the bottom* which are medical device companies with ≥50 employees in *other* relevant SE-SIC codes (see Table 1-1 in thesis for names of the codes in question)
3) Table does NOT include those 50+ companies with SE-SIC 33101 as main code (P1) from Table 2-7 in the thesis (page 51), for which R&D figures are either not disclosed or which are = 0 in the database MMP version 2003-1
4) Figures on R&D for *St Jude Medical AB* have kindly been supplied by Per Wasell (and thus do not appear in the MMP database)
5) As *Gambro Lundia AB* has made an internal rearrangement in 2001 with the effect of considerably changing its *net turnover* but which does not involve R&D, a correction has been made, "reusing" the net turnover/employee ratio for 2000 also for 2001
6) and #) As *Astra Tech AB* earlier has not been separately accounted for in the MMP database, but since employment figures were known and turnover has not changed considerably before 2000, the author has made estimates for 1999 and 1998 marked with a "#" above
7) Figures for *Instrumentarium AB* in *1999* seem incomplete compared to 2000, a likely reason being the restructuring that took place in the former Datex-Engström AB and later Datex-Ohmeda AB between 1996 and 1999
8) MMP 2003-1 gives other main ("P1") SE-SIC codes for three companies that as of June 30, 2002 were in 33101-P1 according to Statistics Sweden. This illustrates the problem of capturing all relevant R&D in ≥50 companies as the official R&D statistics are based on main code

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