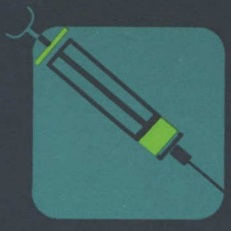
CANADIAN MEDICAL DEVICES SECTOR INITIATIVE

April 1991

Medical Devices Sector Initiative Performance Indicators



Industry, Science and Technology Canada
Industrie, Sciences et Technologie Canada

Canada

April 1991

Medical Devices Sector Initiative Performance Indicators

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Le rapport final est disponsible en français

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1. Introduction

The 1990 Canadian medical devices market can be estimated at approximately $2.4 billion.* About 85% of the products purchased by Canadian public hospitals and private institutions are imports.

Demographic changes will translate into an increase in the demand for health care products and services. If the present level of import is maintained, the trade deficit in this industrial sector will keep expanding.

In order to improve the situation, Industry, Science and Technology Canada (ISTC) signed a Memorandum of Understanding (MOU) with Medical Devices Canada (MEDEC) and is now in the process of launching a major medical devices sector initiative. The strategic importance of this sector has been recognized by the provinces and the municipalities as well. London, Edmonton, Toronto, Winnipeg, Montreal and Ottawa, have selected the medical devices area as a priority sector for near-term industrial development.

Industrial development means planning new ventures. And new ventures are associated with difficulties and uncertainties. Even a new hardware store should not be undertaken without a thorough analysis of the opportunity, an overview of the products and services to be offered, the market to be served and a forecast of revenue projections and cash flow. Information is a significant ingredient in each step of the planning process.

Ezra Vogel writes in his book, Japan as Number One, that one of the most revealing characteristics of Japanese society is the continuing quest for information and resulting high level of economic literacy. We in Canada should begin to think about emulating this aspect of Japanese society.

Information on medical devices market size and trends is crucial in planning industrial development projects. The same market information should be sought and widely used by established manufacturers and distributors for operational purposes.

Market research is probably the most difficult part of the planning exercise. While it may be easy to visualize a product and how it will be brought into production, its acceptance in the marketplace can be very difficult to gauge.

Neither in the planning nor in the operational phase should one underestimate the importance of market information.

ISTC and the provinces, throughout this campaign, should be major consumers of market statistics, not only in their planning of industrial development, but also in measuring the annual progress and the final result of the sector initiative.

This report on Performance Indicators attempts to identify different sources of medical devices market statistics in Canada and abroad, and to analyze their completeness, relevance and timeliness in order to ensure that ISTC is not going to miss this major building block as the campaign unfolds.

* Sources: ResCan database and consulting work

2. Executive Summary

Medical devices is one of the industrial sectors chosen by ISTC for development. The services of ResCan Consultants were retained to identify sources of market data for monitoring the medical devices sector, to attempt concordance of data from various sources and to suggest options to improve the quality of currently available data.

To meet the study objectives the Consultant approached 64 experts in different government departments and associations, and 154 industry managers of whom 48 provided an answer to the questionnaire.

Statistics Canada is the main source of information. Reports are issued on imports/ exports on a regular basis. The product classification used by Statscan is the internationally accepted HS system, which is different from the BRMD and ResCan classifications or from the way MEDEC defines market sectors. Statscan measures imports in FOB transfer prices. The data generated is not a true reflection of the size of the Canadian market. The big advantage however is that everything gets measured regardless of final destination. While ResCan monitors the hospital and the private lab markets, Statscan import data sheds some light on all potential markets should it be hospital, educational labs or other.

ISTC's Market Intelligence division is the second most important source of government generated data. Reports are issued free of charge on request with a level of detail superior to that of Statscan. The raw data used by ISTC, just like Statscan, is in FOB transfer price. The ISTC reports measure more than just the hospital market. The classification used is HS based.

Provincial governments do not seem to have detailed information on hospital purchases. Aggregate data was only available in a few provinces and was found to be very difficult to obtain.

The ResCan database measures the hospital and private lab markets (acute care, general hospitals of 50 beds and over). It is the only regular Canadian private source market audit providing data at the level of generic product groups and individual products. The ResCan database generates brand and company market share information. This kind of data cannot be obtained from either Statscan or ISTC's market intelligence department. Consultants' studies are irregular, ad hoc measures of global markets at a level of detail requested by the client.

Continuity in the supply of raw data (either hospital invoices used by ResCan, or company invoices used by Statscan and ISTC) is extremely important to ensure the availability of market statistics.

Free Trade may have a negative impact on the source used by Statscan and ISTC. If so, alternative sources will have to be considered if the government wants to maintain its position as a reliable provider of information. Free Trade has no impact on the data collection method of the ResCan database or custom surveys from Consultants.

Data on the medical devices market in the US, Europe, Japan and Israel was very difficult to obtain. Details needed by manufacturers cannot be found in government generated reports.

69% of the industry respondents to the market survey on performance indicators use statistical data to monitor their market position or when introducing new products. Most of them use a combination of different sources such as: internal sales force, US data divided by 10, Statscan, ISTC and/or Consultants' reports.

63% of the respondents felt that ISTC and/or the provincial governments should provide companies with regular domestic market data as a service to industry. Even though the majority have some knowledge of the BRMD, MEDEC, ResCan and HS classification system, there was no clear indication as to the preference of one of these classification models. It is clear, however, that a great deal of precision and detail is needed.

Data concordance among the different domestic and international sources are difficult to establish due to differences in markets measured, product nomenclature and classification. Furthermore, Statscan and ISTC measure imports in transfer price while ResCan and Consultants surveys measure the market in average selling prices.

In order to increase the access and awareness, especially of small and medium size companies, TIMEC and the trade associations should take a more active part in data dissemination and in user education of data manipulation.

3. Study Objectives

The following study objectives are based on the terms of references issued by ISTC on October 4, 1990, and the Consultant's proposal submitted 18 October, 1990.

3.1 Identify and Review Existing Sources of Statistical Data

3.1.1 Domestic market: Statistics Canada

- Statistics Canada: Data
  - import/export data (all medical devices suppliers)
  - annual survey of manufacturers (manufacturers only)
  - all other statistical data on the medical devices market and industry
- Statistics Canada: Classification
  - HS (Harmonized System) coding system and its relation to import/export codes
  - SIC (Standard Industrial Classification) coding system
- Statistics Canada: Services
  - standard reports
  - custom surveys
- Statistics Canada: Strength and Weaknesses of
  - data collection methodology
  - coding/classification of products
  - quality control of data entry
  - incompleteness of data due to confidentiality (less than 3 companies competing for a product market), role of custom brokers and industry definition
  - access and method of data dissemination
  - others

3.1.2 Prepare a listing of codes from the Standard Classification of Goods and their relationship to the commodity statistics currently used.

3.1.3 Domestic market: other public sector sources:

- ISTC; Market Intelligence Division, and Services to Business Branch, Interfirm comparisons, others
- NRC (CISTI and other database of projects)
- Federal/Provincial Ministries of Health (re hospital, private and provincial lab statistics)
- Provincial Ministries of Economic Development
- Western Economic Diversification
- Atlantic Canada Opportunities Agency

3.1.4 Impact of free trade on the continuity of public sector data sources.

3.1.5 Domestic Market: Private Sector Sources:

- ResCan (primary data base)
- Cantech (secondary data base)
- Stanorm (secondary data base)
- Business Dateline (tertiary data base) and
- Others that would be useful in monitoring the Canadian Medical Devices Sector and in assessing market size and trends worldwide.

3.1.6 Export market: Public sector sources:

- Government sources by region. Market data. Health care budget. Identify and review all import/export data and/or health care budget information as source of data on market size and trends.
  - US (US Department of Commerce, Bureau of Census: Census data plus publication entitled 1990 US industrial outlook, and other documents)
  - Europe
  - Pacific Rim
  - Review documents obtained directly from the local governments or their Canadian Consulates, as well as from Statistics Canada, ISTC, and External Affairs, (both federal and provincial).

- Agencies. Commodity Market data. Health care budget.
  - UN: Trade Statistics; International Trade Statistic Yearbook.
  - WHO
  - UNIDO

- Identify publications using government generated data that may be disseminated by the private sector.

3.1.7 Export Market: Private sector sources: By geographical region. (US - Europe - Pacific Rim)

3.2 Prepare a Users' Guide for all on-going domestic and foreign data sources.

3.2.1 Listing of all primary and secondary public/private sector sources of statistical data.

3.2.2 Discuss:

- content, level of detail
- frequency of collection and publication,
- sample size and methodology,
- timeliness of reporting,
- completeness and relevance of data,
- conditions of access,
- price
- contact information.

3.3 Discuss end users' attitude:

3.3.1 Level of knowledge of existing sources of statistics. What is being used by industry and governments.

3.3.2 Level of acceptance and satisfaction. Industry and government users.

3.3.3 How to improve user awareness and access.

3.4 Recommendations:

3.4.1 Discuss the need and possibility of linking the different classification/coding/nomenclature systems currently in use to create a working nomenclature cross-reference among the different systems.

3.4.2 Comment on the needs for revision and changes required in the:

- HS classification
- SIC coding system
- Annual Survey of Manufacturers (see document #6 under attachments)
- Statistic Canada data collection/processing/dissemination methodology.

3.4.3 Identify ways of improving usefulness of available statistical data for industrial development and performance monitoring.

3.4.4 Identify an appropriate catalytic role for ISTC in the development of on-going means of obtaining meaningful sector information to measure sector performance.

3.4.5 Comment on the method and practicality of ISTC accessing different public and private sector data sources, on an on-going basis to better service the medical devices sector.

3.5 Pilot study of statistics in selected areas:

3.5.1 Consult with ISTC and the associations (MEDEC, TIMEC, AQFIM) to select one or two sectors with growth potential.

3.5.2 Run a pilot study by using all public and private sector data available at no charge, to calculate market size of the selected sectors.

3.5.3 Document the extent of data concordance. Comment on obstacles due to coding/classification/nomenclature.

3.5.4 Recommend solutions to overcome obstacles encountered in the process.

3.6 Proposal for industry-wide market survey in years one and five of the sector initiative:

3.6.1 Identify a representative sample of 400 product categories. (Could be in a sub-sector according to MEDEC's classification or 400 out of the +/- 5,700 prefcodes of the BRMD and ResCan classification.)

3.6.2 Evaluate for each category:

- present situation (market and competitive climate)
- future outlook, regression analysis, market forecast
- replacement technology (source of technology, source of funding)
- impact of global "cost of health care" problems
- other factors influencing market trends

3.6.3 Quantitative analysis:

- market size in $ and units (SKU)
- production (domestic manufacturing and cost)
- shipments
- imports/exports
- company and product market shares (manufacturer vs distributor market shares)
- employment (manufacturing, R & D, others)
- R. & D. expenditure as % of sales
- financial performance indicators by manufacturer vs distributor
- other data as they may apply

3.7 Recommendations for on-going sector monitoring taking into consideration:

3.7.1 Continuity of data collection by public and private sector data suppliers

3.7.2 Survey methodology: source of raw data, sample size, raw data transmission, QC. If product is locally manufactured, import statistics will not measure it.

3.7.3 End user markets covered: hospitals, private labs, provincial labs, others.

3.7.4 Cost

3.7.5 Timeliness and frequency of publication

3.7.6 Product classification/coding/nomenclature used

3.7.7 Confidentiality or non-confidentiality of classification and statistical market information.

4. Methodology

The very broad scope of information required by ISTC necessitated the use of a large number of survey methodologies and data collection instruments.

4.1 Desk Research

ResCan Consultants has been in health care market research for over 16 years. The company's library contains a wealth of market statistics from different sources. The first step consisted of a review and analysis of material already at hand.

Further research to identify sources of publicly available provincial statistics was conducted with the help of ISTC's provincial health sector specialists.

International market data was collected through the cooperation of technology inflow program (TIP) officers of external affairs posted in embassies in Europe, Japan, USA, and Israel.

Data generated by federal government sources such as Statistics Canada (Statscan) and ISTC's market intelligence department were also collected and analyzed.

Trade Associations, such as MEDEC and AQFIM were approached as potential sources of statistical data.

In order to assess the different classification, coding and nomenclature systems, the Consultant had to study the HS, SIC, MEDEC, BRMD, ECRI, FDA, and ResCan classifications. Data was found in the ResCan library and data base, as well as at Statscan and in the ISTC library.

In order to complete the desk research, ResCan had to complement its data by contacting:

- 16 technology inflow program officers
- 2 officers at External Affairs, Ottawa
- 12 experts at Statistics Canada
- 11 ISTC health care specialists
- 3 presidents of associations
- 12 department heads at provincial governments
- 1 department head at BRMD
- 5 managers of provincial hospital associations.
- ISTC library and market intelligence division

A total of 64 experts had to be approached to collect background documentation needed to perform the study.

4.2 Primary Data Collection

Provincial and federal government personnel involved in industrial development projects were interviewed:

- To identify the type of market data readily available and currently used
- To assess future needs

154 questionnaires were mailed to Canadian companies with questions on domestic and international data sources used, as well as level of satisfaction and future needs. A total of 48 answers were received. The original mailing had to be followed-up twice with fax messages requesting cooperation.

The Consultant designed a computer program to support data tabulation to establish frequency distributions and cross tabulations of answers received. All questionnaire data was captured directly onto computer readable files.

4.3 Data Retrieval

The ResCan data base was used to establish a random sample of companies approached with the questionnaire.

The ResCan classification, which is built on the BRMD and FDA model, was cross-referenced with the MEDEC classification. Validation of the results was performed by MEDEC on the assistive devices and hospital equipment sector.

For the pilot study, ResCan attempted to establish a limited number of cross referencing with the HS system as well.

A pilot study on data concordance was performed by retrieving data from the ResCan data base, Statscan publications and other sources the Consultant managed to identify.

4.4 Workshop on Performance Indicators held July 26-27, 1990

The Consultant attended the meeting and carefully reviewed the minutes issued by ISTC. Material was used to complement information obtained through primary research

4.5 Data Analysis and Validation

All domestic and international statistics have been thoroughly reviewed and analyzed. Their relevance was established based on content, level of detail, timeliness and ease of availability.

During the validation process, inconsistencies were uncovered and resolved by conducting additional interviews.

5. Domestic Market Data

Among the most commonly used government generated, publicly available data sources are the Statscan publications, and the ISTC market intelligence reports.

5.1 Statistics Canada Market Data

5.1.1 Publications

The Statistics Canada Catalogue, document #10-2045E, is a listing of available publications.

For the purpose of this study, the following publications were analyzed:

- Canadian Export-Import Alphabetical Index; based on the harmonized system (HS). (12-579E)
- Exports by Commodity; HS based (65-004)
- Customs Tariff (RV55-2 from Supply and Services)
- Imports by commodity; HS based (65-007)
- Products shipped by Canadian Manufacturers (31-211)
- Standard Classification of Goods, 1988, based on the HS commodity description and coding system (12-580E)
- Standard Geographical Classification, 1986 (12-571 to 12-573) SGC
- Standard Industrial Classification, 1980 (12-501E)

5.1.2 Classification System Used

- Standard Industry Codes (SIC)

  The SIC codes are used to report statistics on activities rather than on commodities. The annual survey of manufacturers shows the contribution of the industry to the economy in terms of: employment, total shipments, goods purchased for re-sale, etc.

  The first standard SIC codes in Canada were created in 1948. In Canada, there is a revision every 10 years. In the US it's every 5 years. The most recent Canadian publication is dated 1980. The 1990 revision was unissued. It is only in 1997 that Canada will publish an updated version of the 1980 SIC, coincident with the revision of the US SIC.

  There are no specific codes in the Canadian SIC for the different medical devices industrial sectors. Manufacturers of medical and related instruments, apparatus and equipment, in the Canadian publication, are grouped under the code 3912, "Other Instruments and Related Products Industry". Suppliers of disposables, laboratory reagents or general labware are likewise included in industries covering other products as well.

  Manufacturers of ophthalmic goods are classified under 3914, Ophthalmic Goods Industry. Most distributors of medical devices would be under the code 5793.

The USA does not use the same industrial classification, or codes, as Canada. They have industries such as 8071 - Medical X-Ray Lab, or 8062 General Medical / Surgical Hospital, or 5086 Professional Equipment and Supply - Wholesale, etc. In the 1997 edition of these classifications, an attempt will be made to make the two standard industrial classifications compatible.

•Harmonized System (HS)

This is an international commodity classification used for Customs tariffs, import statistics and export statistics by most countries in the world. There are 21 sections divided into 96 chapters. It is structured primarily by component material. The HS was developed under the auspices of the Customs Cooperation Council, Rue de l'Industrie 26-38, B1040 Bruxelles, Belgium.

Chapter 90 in Section XVIII will serve to illustrate the structure of the classification.

Section XVIII	Optical, photographic, cinematographic measuring, checking, precision, medical or surgical instruments and apparatus; clocks and watches; musical instruments; parts and accessories thereof.
Chapter 90	Optical, photographic, cinematographic, measuring, checking, precision medical or surgical instruments and apparatus; parts and accessories thereof
Heading 90.18	Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments.

Subheadings

Syringes, needles, catheters, cannulae and the like

90.18.31	Syringes, with or without needles
90.18.32	Tubular metal needles and needles for sutures
90.18.39	Other

Statscan has extended the application of the Harmonized System to all commodity statistics, notably shipments by manufacturers to provide for the extra detail required in Canada, and to co-ordinate the application of the HS at this finer level of detail. Statscan created the Standard Classification of Goods (SCG) for this purpose. The extra level of detail in the SCG is illustrated below, following the HS examples given above:

90.18.32.10	Tubular metal needles
90.18.32.20	Needles for sutures

The Canadian Customs Tariff, however, which is used to collect import data requires a tariff code in the 7th and 8th digits and, therefore, cannot use the SCG code as is. The corresponding tariff codes are as follows:

90.18.32.00	Tubular metal needles and needles for sutures
90.18.32.00.10	Tubular metal needles
90.18.32.00.20	Needles for sutures

Medical devices are mostly grouped in chapter 90. Chapters 30, 40, 42, 48, 56, 68, 69, 70, 84, 87 and 94 seem however to contain information on medical devices as well.

5.1.3 Data Collection and Treatment

Medical devices import data is collected at Customs and Excise on a daily basis.

The HS classification codes are assigned to each product by either the importer or their customs broker, and appear on the B3 forms attached to the invoice.

Most medical devices are duty free; therefore, only high dollar transactions are subject to quality control which consists of random manual verification of HS code, corresponding product description on the invoice, and unit price. Right now a $10,000 transaction is considered a high $ value invoice. In the near future however, only $25,000 and more would qualify for this type of quality control.

Data on computer tape is channeled from Customs to Statscan on a weekly basis. After editing, the data is organized and published by Statscan monthly and annually in: "Imports by Commodity and Country".

Import and export statistics are available monthly within 3 months of the reference month. Data on shipments is published annually about 2 years after the reference year; the year being defined as the fiscal year ending the reference year; i,e. 1988 data will be published in 1991.

Rules of confidentiality are imposed by the Statistics Act to protect the identity of individual respondents. The rules are difficult to apply to import statistics because of the mass of detail available. In this case, data cells are suppressed only if an importer brings the problem to the attention of Statscan.

5.1.4 Impact of Free Trade on the Continuity of Public Sector Data Source

Due to free trade with the US some changes may be witnessed in import data before the year 2000. Among these, the most significant seem to be:

- companies will file only once a month or once a quarter
- documents will be forwarded on EDI (electronic data interchange) on which HS classification may be ignored
- commodity details may be lost

The Customs Act requires detailed documentation for duty collection. Where duty is not collected, the documentation might not be required. In that case, the data might be collected by other means. Without the threat however, that goods could be held up at the border, respondents may not be inclined to report in the same degree of detail and accuracy.

A Statscan committee is studying the impact of free trade on the continuity of data flow and will be preparing recommendations. If the movement of goods cannot be properly measured at the level of Customs, Statscan may have to sample companies.

The problem with such a sampling technique is that accurate projections cannot be established in the detail presently available. The sample may not be homogeneous, and therefore it would be unrepresentative. The quality of the information thus generated is expected to significantly deteriorate if this method is adopted.

5.1.5 Statscan Strengths and Weaknesses

Weighted rankings of respondents evaluation can be seen on Table 6, page 40. The major strength of Statscan is the cost of their published documents followed by ease of data interpretation. Every item crossing the border is recorded. The publications are therefore census based and as such should have a very high level of accuracy.

The fact that Statscan uses a universal system for coding and classification should be an advantage from the standpoint of concordance of international/domestic data.

There are however several problems decreasing the value of the information. Among the weaknesses let's mention:

- $ totals are obtained through the compilation of FOB transfer prices. Therefore, import statistics are not a true reflection of the size of the Canadian market for imports. It is impossible to determine from the information at hand what the corresponding market prices are. It is therefore safe to assume that using Statscan data, one would underestimate the Canadian market.

- Not all products used are imported. If we want to calculate the Canadian market, we have to add imports to locally manufactured products that have been sold on the domestic market. This is difficult to do as the publications required to perform the extrapolation are out of phase and information is suppressed because of confidentiality.

- Rough market estimates are established by adding imports to production (shipments) and by subtracting exports. The result is called "disappearance" by Statscan.
  Example:

  9019.10 Mechano therapy appliances; massage apparatus; psychological apptitude - testing apparatus

	$ in '000:	
shipments (1988):	6,197	plus
imports (1990):	13,912	
	20,109	minus
exports (1990):	6,109	equals
disappearance:	14,000	

- The above two points may represent the major reason why precision was given such a low ranking in Table 6.

- The HS system was implemented two years ago, therefore HS trends are not available.

- The Consultant identified 52 HS codes related to medical devices. The HS codes are further sub-divided into SCG codes. According to Statscan, there are 180SCG codes which give more detailed statistical data than the HS categories. Industry often needs information at the level of the product, to calculate market size, brand and company market shares as well as average selling price. None of these can be provided by Statscan.

- Timeliness of publications seems to be another weakness reported by industry respondents. The most recent publication on Products Shipped by Canadian Manufacturers (which is needed to calculate market size) seems to be 1986. The most recent Annual Hospital Statistics report giving a consumption total for supplies (not for equipment, as hospitals do not have to report to Statscan on equipment purchases) is dated 1986/87. Import and export statistics are fairly current.

Statscan does not seem to make any major effort to promote their publications.

A new system called TIERS (trade information enquiry retrieval system) which is presently being introduced, may represent an improvement in data access over the publications presently available. It is a new software package which accesses data including medical devices at the most detailed level; i,e. 15,000 classes for imports and 5,500 classes for exports for approximately 200 countries.

5.2 Statistics Canada - Hospital Data

5.2.1 Publications

For the purpose of this study, the following publications were analysed:

- Annual return of hospitals, hospital indicators (83-233)
- Canadian classification of diagnostic, therapeutic and surgical procedures (82-562E)
- Health reports (82-003)
- Health trends (11-008E)
- Hospital annual statistics (83-232)
- Hospital statistics, preliminary annual report (83-217)
- Hygiene products, textile industries (34-251, 34-251B)
- Quarterely hospital information system, hospital indicators (83-002)
- Surgical procedures and treatments (82-208)

5.2.2 Classification

Every item purchased by a hospital is recorded for accounting purposes under a specific code published in the Canadian Hospital Accounting Manual (CHAM). This coding and classification system is independent of the HS system. The code given to a product depends on its final destination in the hospital. For instance, alcohol (medical use) will be coded as 29 Drugs - general and 680 Pharmacy, whereas alcohol (laboratory use) will be coded as 40 Other supplies and expenses and 660 Laboratory. The first, two digit code, gives the "nature of expense" whereas the second, 3 digit code, indicate the "expense centre".

The CHAM system is in the process of being replaced by a fully computerized system called MIS (management information system) promoted by the Canadian Hospital Association. This new accounting system will be used by all Canadian hospitals in the future.

Reports on hospital morbidity use an international classification of diseases. The same classification is used by the WHO (World Health Organization).

5.2.3 Data Collection and Treatment

Hospital statistics are obtained by Statscan, through their annual hospital surveys called: "Annual Return of Health Care Facilities - Hospitals, Part One and Part Two".

The number of hospitals reporting varies from year to year. The 1986-87 annual summaries are based on 75% of the universe of all public hospitals, including psychiatric, long-term, etc. Federal government and privately owned hospitals do not report. A professional audit is performed on the data collected. Several provinces are involved with Statscan in the data editing process. Alberta is the most active.

The most recent publication covers the 1986-87 period.

There are 2 to 3 thousand clients from the health care sector for the Statscan publications. Promotional activity is restricted to 1 mailing a year.

5.3 ISTC

5.3.1 Publications

Next to Statscan, ISTC is the most important source of hard data on the Canadian medical devices market.

In 1990, the Market Intelligence division published 16 reports on exports to Canada for the following devices:

- Pacemakers for stimulating heart muscles
- Apparatus based on the use of X-Rays for medical, surgical, dental or veterinary use.
- Therapeutic respiratory apparatus
- Electro-Cardiograph, parts and accessories
- Ultra-violet or infra-red ray apparatus - medical
- Hearing Aids
- Artificial joints and other orthopaedic or fracture appliances
- Other artificial parts of the body
- Other medical appliances, worn, carried or implanted in the body
- Needles (other than tubular metal needles, needles for sutures) catheters, cannulae and the like and parts
- Syringes, with or without needles
- Needles for sutures
- Tubular metal needles
- Other electro-diagnostic apparatus
- Other medical instruments and appliances
- Apparatus based on the use of alpha, beta, or gamma radiation for medical, surgical, dental or veterinary use

Other, 1988 publications include: sheath contraceptives, dental hand instruments, rubber and disposable plastic gloves. Statistics are given by SCG 8 digit code in units and $, for the year 1988. Imports, Canadian production and exports are shown separately. A break-down is given by country of origin. Unit prices are given in Canadian $ by country of origin.

ISTC offers other products such as the BOSS Directory (see Users' Guide) and the inter-firm comparison for productivity improvement.

5.3.2 Classification

ISTC, uses the HS classification. Classification break-downs are discussed with the company requesting the report.

5.3.3 Data Collection and Treatment

The information provided by ISTC's market intelligence service is product specific and is based upon restricted access to Customs import documents and invoice copies obtained from Revenue Canada. These invoices are attached to the B3 forms mentioned earlier in this report.

If there are too many to process, a scientific random sample is used for projection purposes instead of a census of all invoices. The precision of the projections is estimated at ± 5 to 10% for large volume product categories.

Reports as detailed as the above mentioned 1989 publications, are only produced upon request from companies able to demonstrate sufficient evidence that they want to manufacture in Canada.

There are some rules of confidentiality imposed by the Statistics Act, which may result in the absence of statistical data for certain product categories. In cases where:

1 company has 75% of the total market,
2 companies combined, have 85% of the total market,
3 companies combined, have 90% of the total market,

data is considered confidential, and no data is released in the publication.

The $ value of imports in the Market Intelligence reports is a compilation of FOB transfer prices.

5.4 Statistics Canada Custom Studies

This department is not really proactive in the medical devices market research field. They have received only one request to date. It was in the blood products area.

A user of data, may disagree with trade data published by Statscan. In such a case a manual verification is performed. This is considered by Statscan to be a custom study. The company reporting the problem would be charged $5.00/line. The charge can be considerable if a large amount of invoices have to be examined.

Companies must answer the annual survey of manufacturers. Statscan would be agreeable to conduct more surveys for industry, should the request be forthcoming.

5.5 Annual Survey of Manufacturers

The Annual Survey of Manufacturers covers all of the manufacturers in Canada. Each respondent is assigned an "industry" code according to the Standard Industrial Classification. The majority of the manufacturers of medical devices would be found in industry class 3912, "Other Instruments and Related Products Industry", under industry group 391 "Scientific and Professional Equipment Industries".

Survey practices vary from year to year but generally questionnaires are sent to manufacturers with significant output and statistics from the remaining manufacturers are collected from income tax records. The questionnaire is primarily designed to collect "principal statistics"; i.e., the information required to calculate "value added" by manufacturing. Principal statistics include inventories, fuel and electricity, manufacturing inputs and manufacturing outputs. Value added is an estimate of the net contribution to the economy made by manufacturing and it is calculated by subtracting the value of energy and manufacturing inputs from the value of manufacturing outputs and adjusting for inventory change. Information is also collected for employment, goods purchased and sold in the same condition as purchased and a number of other items. The largest manufacturers receive a "long form" which has many questions about specific materials used as inputs and products shipped as outputs.

The latest year for which a complete range of statistics from the Annual Survey of Manufacturers was published is 1986. Principal statistics are available for both 1987 and 1988. The industry publications for 1988 will include, for the first time, HS-based commodity detail for 19088 and estimates of the corresponding detail in 1987, a year for which commodity detail was not compiled. As indicated above, because of differences in industry definitions, the medical devices "industry" cannot be monitored directly from the statistics described above.

Statistics arising from the Annual Survey of Manufacturers are important components of the System of National Accounts. They are also used by analysts in government and private industry as benchmarks for monthly surveys, indicators of economic activity in small areas and for trend analysis.

5.6 Provincial Government Data

It is extremely difficult to locate and to obtain statistical data on medical devices in Canada. The Consultant approached the ISTC health care specialists, the provincial governments (both health and economic development) with limited success.

5.6.1 British Columbia

According to the BC ministry of health, no statistical market data is available.

BC's health care budget for:

1989-1990 was $4.3 billion
1990-1991 is $4.8 billion

The percentage of the budget allocated to medical devices is unknown.

The Consultant managed to obtain, with the help of the local ISTC health care specialist, some aggregate market data for:

- major prosthetics
- other medical/surgical supplies
- contrast media
- all other patient care supplies

5.6.2 Alberta

The annual report of the Alberta Hospitals and Medical Care does not show any hard data on the medical devices market in that province. The Ministry of Health provided some hard data on global expenditure for medical surgical supplies. There is no break-down by product group of sector specialty. No information is obtainable on equipment purchases.

The Alberta Hospital Association shared some group purchasing information with the Consultant. The data could be very useful for suppliers, but it cannot be used for statistical purposes as there are a few unknowns:

- Number of hospitals participating
- Number of beds covered
- Duration of participation
- Level of participation (% consumption obtained through group purchasing)

5.6.3 Saskatchewan

The Consultant reviewed the:

- Annual report of Saskatchewan Health
- Statistical supplement to the annual report
- Annual report of Saskatchewan Medical Care Insurance Association
- Annual report of individual hospitals

No statistical data can be found in any of the above publications on medical devices that would be relevant to this study.

5.6.4 Manitoba

The annual report and the annual statistics issued by Manitoba Health Service Commission do not include any statistical data on medical devices. The Manitoba government spent $1.56 billion on health care for the 1989-90 fiscal year. Salaries account for 60%. The medical devices portion is unavailable.

5.6.5 Ontario

The annual report of the Ontario Ministry of Health does not contain any statistics on the government's expenditure on medical devices. Some information will be obtained at a later date. The Consultant will incorporate the analysis in the final report.

5.6.6 Quebec

The Consultant reviewed the annual report of the Montreal Joint Hospital Institute, the annual statistics of the Ministry of Health and the annual report of the Ministry of Health. None of these publications give market data for medical devices.

The book on annual statistics deals with one category of medical devices: Orthopedic devices such as lower and upper extremity prosthesis, walking aids, wheelchairs and accessories.

The provincial group purchasing organization, CRSSS, has some data on products bought for participating hospitals. Not all products are in the group purchasing plan. 22.5% of the laboratory supplies, 70% of the drugs and 28.3% of the medical surgical supplies are bought by the CRSSS.

5.6.7 Maritimes

Publications by the Health Services Commission have been reviewed. The Consultant could not identify any statistical market data for PEI.

The annual report of Financial Services for New Brunswick gives some consumption data for laboratory supplies, ECG, radiology diagnostics, physical medicine and rehabilitation and respiratory therapy.

The health care hospital budget of Nova Scotia is $675 million. The percentage allocated to supplies is 23% and 2% to equipment. There is no detailed information readily available.

In Newfoundland, medical devices are not a priority sector, therefore, very little information could be found.

5.7 Other Government and Association Sources of Data

5.7.1 NRC - CISTI

The Canadian Institute for Scientific and Technical Information (CISTI) is a division of the National Research Council (NRC). CISTI operates Canada's largest scientific and technical information service.

CAN/OLE (Canadian On-line Enquiry Service) is an on-line information retrieval system used to locate documents from major worldwide scientific and technical abstracting and indexing services. Journal articles, reports, conference proceedings, books, government publications, theses, organizations and associations make up the information contained in CAN/OLE. Statistical data on medical devices would not be identifiable exclusively, but rather such information would be referred to in publications.

CAN/SDI (Canadian Selective Dissemination of Information Service) is a personalized current awareness service. It enables one to stay informed on the most current publications (reports, books, journals, etc.) by receiving printed references referring to the requested subject matter.

5.7.2 Associations

The Consultant approached MEDEC, TIMEC and AQFIM as potential sources of market data.

None of these organizations seem to have a tool they could use to assess Canadian market size and trends. Some had access to consultants' market surveys through provincial government contacts, while others obtained a limited amount of data from local group purchasing organizations.

None of the above mentioned organizations is in a position to comment on the Canadian market.

5.8 Domestic Market Private Sector Sources

The following sections describe Canadian databases pertaining to the medical device sector. Databases are grouped into three categories:

1. Primary database: deals entirely with medical devices from a legal, technical, or business aspect.
2. Secondary database: cover more general subject areas but have significant coverage of medical devices.
3. Tertiary database: contains valuable information on a very narrow aspect of medical devices.

5.8.1 ResCan

Primary Database
Language of database is English and French

The database producer is ResCan Consultants, a market research firm with over 17 years experience in both the human and veterinary industries. The ResCan data base tracks data from purchasing invoices submitted by a sample of hospitals (acute care, general, 50 beds and over) and private labs across Canada. The database tracks 200,000 product items from over 1,000 suppliers.

There is no on-line access. Information is available on an ad-hoc or annual subscription basis depending on the client's request for either type of product:

1. Quarterly Market Audit: market size in units, $, market trends, brand and company market shares
2. Annual Instrumentation Studies: database information is complemented with interviews on present and future placements, acquisions made, etc.
3. Bi-Annual Compendium: listing of suppliers by product, product by suppliers, address and phone numbers.

The database is made up of 20 books. The books are further divided into 250 categories called chapters, which, in turn are subdivided into 2,300 generic product descriptors.

5.8.2 CANTECH

Secondary Database
Language of database is English

The database producer is William G. Hutchison and Company Ltd. Hutchison Research is a market research firm specializing in Canadian advanced technology companies. The CANTECH database profiles over 5,000 Canadian manufacturers of high tech products and providers of high tech services.

Each individual company profile is updated on the anniversary of its completion. Each corporate profile contains information on the firm's name, address, and contact numbers. Ownership status, structure and year of incorporation in Canada are provided. Company size is determined by number of employees, annual sales revenue and R&D expenditure and staff. Business activities are mentioned briefly. A list of executives responsible for key areas is also provided.

Most of the information pertaining to medical device companies is contained under the major technology category entitled, "Medical Equipment" (MED). Some information can be found in "Biotechnology Products and Equipment".

5.8.3 Standards Council of Canada Databases

Secondary Database
Language of database is English and/or French

The database producer is the Standards Council of Canada (SCC). They offer three bilingual databases, available 24 hours a day, for standards users in Canaa and abroad.

The first database is called Canadian Standards (Stannorm). It contains bibliographic information on Canadian Standards published by five accredited standards-writing organizations of the National Standards Systems:

Bureau de normalisation du Québec (BNQ)
Canadian Gas Association (CGA)
Canadian General Standards Boards (CGSB)
Canadian Standards Association (CSA)
Underwriter's Laboratories of Canada (ULC)

The second database is called Reference Standards-Federal. This database contains information on Canadian, foreign, and international standards and standard-type documents referenced in Canadian federal legislation.

The third database is called GATT TBT (Notifications) Draft European Standards. This database contains information on proposed regulations, mandatory standards or certification systems from countries that have signed the GATT Agreement on Technical Barriers to Trade.

5.8.4 Pharmaceutical News Index (PNI)

Secondary Database
Language of database is English

The database producer is UMI/Data Courier. Data Courier is an operating division of University Microfilms International (UMI). Both are owned by Bell and Howell. They specialize in the development, production, marketing and electronic distribution of business information products.

The PNI database contains current and retrospective news about the pharmaceuticals, medical devices, cosmetics, and related health industries, world wide. There are approximately 15-20 thousand references on medical devices per year. Eighteen major US and international news publications are indexed cover - to-cover (includes Clinica World Medical Devices News).

6. Export Market Data

6.1 Japan

In Japan, the medical device industry is actually termed the medical electronic equipment manufacturing industry. A break-down by activity is shown in Table 1.

The production of the medical electronics equipment manufacturing industry is supervised by the Ministry of International Trade and Industry (MITI). The official production statistics for medical equipment and supplies is controlled by the Ministry of Health and Welfare, except for those medical products excepted by the Pharmaceutical Act. The Act concerns the manufacture, import and sales of medical equipment in Japan. The industry is classified according to the MITI industrial code:

Code No. 30 for Electrical Machinery Manufacturing Industry

3061	X-Ray apparatus manufacturing industry
3069	Electronics - applied equipment manufacturing industry

Code No. 32 for Precision Machinery Industry

3216	Precision measuring industry
3017	Analyzer manufacturing industry
3231	Medical equipment and instruments manufacturing industry
3232	Dental instruments and devices manufacturing industry
3234	Medical supply manufacturing industry
3235	Dental supply manufacturing industry

The publication entitled March 1990 Edition of your Market in Japan -- Medical Electronics Equipment, issued by Japan External Trade Organization, provides excellent detail regarding the medical electronics equipment manufacturing industry. Renewal of the edition occurs every five years. The contents include: overview of the industry, market trends, technological level required in Japan, future market outlook, promotion measures for laws and regulations on medical equipment imports, related organizations and importers and exhibitions.

Market trends cover production, export and import trends, market scale and share of imported medical equipment, as well as distribution. Import and export statistics for medical equipment supplies are classified by type based on custom clearances of the Ministry of Finance. The statistics are HS (Harmonized System) based. Major foreign exporters of medical equipment and importers into the Japanese market are listed in the future market outlook section. This section provides both national medical expenses (healthcare budget) and medical facilities in Japan. Contact information is provided in the section under related organizations and importers.

The Ministry of Health and Welfare conducts an annual production survey which is published by the Research Institute for Economics on the pharmaceutical industry.

The survey covers the manufacturers of drugs, quasi-drugs, and medical devices under the Pharmaceutical Act. The contents include: imports/exports, end of year inventory, shipments and production amount (in Yen)

The Ministry of International Trade and Industry (MITI) conduct surveys of production trends for machinery manufacturers, including X-ray, ultrasound, and electromedical device statistics. Production (Yen and units) as well as exports are provided.

The Yano Research Institute published (1990) the Research Report on Market for Equipment for Diagnostic Imaging and Implants in Japan. The report covers:

Imaging: mammography systems, contrast media for digestive system, x-ray equipment in Japan

Implants: heart valves, pacemakers (implant type) and auxiliary equipment for hearts

There is an organization in Japan that was formed for the purpose of helping industrially advanced countries to expand their exports of manufactured products to Japan, thereby contributing to the promotion of international trade and industry. It is called MIPRO (Manufactured Imports Promotion Organization)

MIPRO is engaged in a wide variety of activities which includes:

- Holding and assisting import promotion exhibitions in Japan
- Dissemination of information regarding imported products and the Japanese market
- Monitoring service for export to Japan
- Holding seminars and showing films to promote import

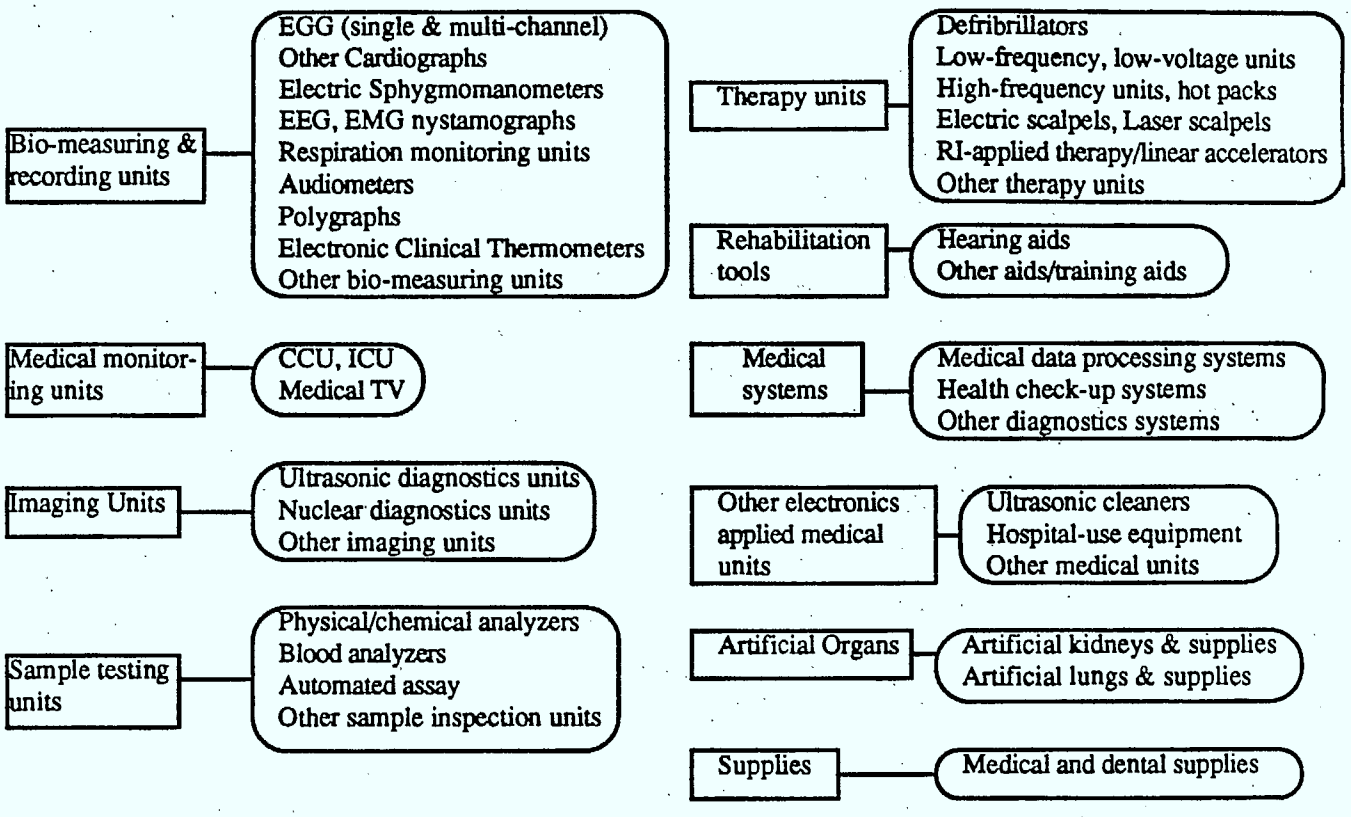
MIPRO often receives inquiries from overseas countries as to what products are selling well in Japan and the reasons why. In order to provide more practical information on the Japanese market, MIPRO produces one report a year. The 1990 edition is entitled Health Care, Market of Health Care Products. The report includes:

- market development of healthcare
- import trends : statistics, dependence, suggestions for increasing market share
- summary of the market : market size
- trends in consumption
- distribution trends : sales strategy
- related regulations and the import system
- suggestions on how to approach the Japanese market
- list of related organizations: government offices, related associations, importers, medical/care equipment manufacturers

The report is an excellent tool in gaining additional insight into the needs and characteristics of the Japanese market.

TABLE : 1

MEDICAL ELECTRONICS EQUIPMENT INDUSTRY
JAPAN



6.2 Israel

The Canadian Embassy, Tel Aviv, Israel, provided references in order to obtain publications on medical devices.

Marketing data for Israel is available from the Department of Trade and Industry, London in a detailed market study on medical equipment entitled Market Report Healthcare and Medical Equipment. This study was commissioned by the British Embassy in December of 1989, however it is available through purchase only.

Various directories of healthcare products are available from the Israel Export Institute, Healthcare Centre.

Data on the healthcare budget is available in Hebrew only. The most recent publication is entitled National Expenditure on Health 1986/87 and Preliminary Estimate for 1987/88, from the Ministry of Health.

It can be concluded that Israel does not have documentation on medical devices readily available. Market research studies have been recommended in order to generate statistics on medical devices.

6.3 Austria

The information sent to ResCan from Austria partly originated from the national statistical bureau, Osterreichisches Statistisches Zentralamt.

Most of the requested statistics on medical devices are not readily available and according to the Canadian Embassy, Vienna, Austria, are almost impossible to obtain.

The healthcare budget for hospitals is documented in the Federal Annual Statistical Yearbook 1989, whereby the titles have an English translation, but the details are all in German.

6.4 Belgium

The Canadian Embassy, Brussels, Belgium, after having contacted the federations active in the field of medical equipment and diagnostics, reported that there are no statistics available for the Belgian market. Four federations grouped under the association BELCOMET conducted an inquiry for the first time in 1990 to learn more about total import, production, and export of medical devices in Belgium. A report documenting the global results is expected to be published early in 1991.

6.5 England

The Canadian High Commission, London, England has reported that there do not appear to be any formal statistics available in the United Kingdom (U.K.). Apparently, one organization (MSPA) is trying to coordinate the use of independent solicitors to collect this kind of information.

The British National Statistics Office of HM Customs and Excise, do not give out information on import/export statistics any longer. The details can now only be obtained through marketing agents for a fee.

The Clinica Fact Book 1990, a yearly publication priced at £95, was mentioned as potentially containing some pertinent information. However, an examination of example sheets covering contents of the book revealed that, detailed information is not provided. The book contains, as the title implies, facts from the United States, Europe (including the U.K.) and other countries (Japan, China, Saudi Arabia, Hungary, etc.). Six medical device segments are identified whereby facts for various countries and the world are given. The segments are: in vitro diagnostics, diagnostic imaging, cardiology, electromedical products, specialties, and ophthamology.

6.6 Italy

After having contacted various sectoral associations in medical devices, the Canadian Consulate General, Milano, Italy, indicated that it is extremely difficult to obtain data which is of any consistence, as the market is very fragmented. No relevant study is available at present. However, some associations are in the process of preparing a relatively thorough market analysis, which will be obtainable no earlier than February or March of 1991.

In responding to our suggestion of contacting Italy's National Statistical Office, the most recent statistics available were forwarded and include (in Italian):

Production and Sales of Medical Articles - 1987
Import/Export figures for the year 1988 by product types and trade partner (country of origin/destination)

The data is classified according to the Harmonized System.

Various journals containing advertising and articles had been sent; while interesting, they proved useless for the purpose of this study.

6.7 Netherlands

The Canadian Embassy, The Hague, Netherlands, provided the most comprehensive package of data sources pertaining to medical devices. Much of the information available locally in the Netherlands is in Dutch.

Data on the total size of the market is difficult to obtain due to "confidentiality" on the part of local industry associations and Central Bureau for Statistics as far as divulging details of production figures. However, other publications reporting statistics and market information are available and summarized below:

Industrial Production Statistics (1987 and 1988) for Medical, Surgical and Dental Instrumentation, Orthopedic Articles and Protheses (Central Bureau voor de Statistiek, Heerlen)

Import and Export Statistics for Medical Products for 1988 and 1989 (Central Bureau voor de Statistick, Heerlen) The products are categorized using the Harmonized System Customs Coding.

The Netherlands: Market Report for Medical Instruments & Equipment (Commercial Dept., British Embassy, The Hague/Department of Trade & Industry, London, 1988)

Surgical Instruments and Medical Disposables: A survey of The Netherlands and Other Major Markets in the European Community (CBI, Rotterdam, 1990)

Profile: Medical Technology (extract from Report ("Instrumenten in Europa Zonder Grensen" by Klynveld Bosboom Hegener for the Association 'Het Instrument' 1990).

Industry Sector Analysis: Laboratory Instrumentation - ASI (US Embassy, The Hague, 1987)

Holland Health Care Industry (Netherlands Ministry of Economic Affairs, 1990)

Fact Sheet on The Netherlands: Health Care (Ministry of Welfare, Health & Cultural Affairs, 1989)

Financieel Overzicht Gezondheidszorg en Maatschappelijk Welzijn -- Financial Overview of Health Care and Public Welfare (Ministry of Welfare, Health and Cultural Affairs)

Health Insurance in The Netherlands (Ministry of Welfare, Health and Cultural Affairs, 1989)

6.8 Sweden

There does not appear to be any statistical data available on medical devices in Sweden. The Canadian Embassy, Stockholm, Sweden could only provide referral to MEDISTAT: Medical Markets in the EEC, a 200 page report costing $530 US. A copy of their order form highlights the content of the report:

- Health sector profile: Healthcare expenditure, provision and resources
- Health care development: Future plans and their impact on the medical market

- Market Analysis: Latest available figures for market size, domestic production, imports, exports, balance of trade in US $ for:

  Electromedical
  X-Ray Apparatus
  Wheelchairs
  Medical Furniture
  Dental Instruments
  Mechano Therapy
  Hearing Aids
  Orthopaedic & Prosthetic Equipment
  Bandages
  Medical Supplies

- Detailed statistics in local currency of imports, exports and balance of trade for over 50 major categories of equipment and supplies.

- Strength of local manufacturing examining domestic producers and the role of major foreign suppliers.

- Market access analysis of public procurement suppliers policies and purchasing procedures.

- Director: Names and addresses of principal hospitals, leading manufacturers, and suppliers.

6.9 France

There does not appear to be any detailed statistical data on medical devices in France. The limited information sent from France is, not surprisingly, in French.

The French Ministry of Health on Hospitalization in France publishes Informations Hospitalières. Special issue number 26, (1990) deals with healthcare expenditure for 7 specific years from 1970 - 1986 for 12 countries. A complete breakdown of France's healthcare expenditure (4 main areas) is provided.

A 5 page report is available from the International Affairs Advisor to the French Hospital Directorate entitled Le Marche Francais de l'Industrie Des Technologies Medicales. The report provides statistics on establishments, allocation of investments, the evolution of the biomedical sector, the evolution of manufacturing sectors, and import/export statistics by country.

6.10 Germany

There does not appear to be available statistical data on medical devices in Germany.

6.11 United States

The Bureau of Census publishes, on an annual basis, US Industrial Outlook. Section number 51 entitled, Medical and Dental Instruments and Supplies, comments on cost containment, medical device legislation, technology, foreign trade, trends, and long term prospects. The various categories for medical instruments include:

- Surgical and Medical
- Surgical Appliances and Supplies
- Dental Equipment and Supplies
- X-ray Apparatus and Tubes
- Electromedical Equipment

Annual Survey of Manufacturers (ASM)
Economic Censuses : Census of Manufacturers

The Census of Manufacturers is conducted every 5 years covering the years ending in 2 and 7 (ie: 1982, 1987) It covers all manufacturing establishments with one paid employee or more. The ASM is conducted in each of the 4 years between the Census of Manufacturers, and covers a probability based sample of approximately 56,000 establishments.

There are 6 Standard Industrial Classification (SIC) Codes which encompass medical devices in both surveys:

3841	Surgical and medical instruments
3842	Surgical appliances and supplies
3843	Dental equipment and supplies
3844	X-ray apparatus and tubes
3845	Electromedical equipment
3851	Ophthalmic goods

For each SIC code the following information is available:

Number of establishments
Employment and payroll
Shipments, cost of materials, and value added
Inventories
Capital expenditures, assets, rental payments, and purchased services
Ratios

6.12 Other International Data

The Consultant reviewed the Statistical Yearbook of the UN and UNESCO. None of these publications contain information on health care budgets or consumption of health care products.

7. End User's Attitude

7.1 Sample Size and Distribution

To uncover the source of domestic and international market data used by medical devices suppliers, the Consultant selected a representative sample of 154 CEO's (from about 800) by using the BRMD and ResCan database.

A questionnaire was designed in both official languages and tested with companies as well as with the Performance Indicators Working Group.

In order to increase the response rate, after the original mailing, two fax messages had to be sent to potential respondents. A total of 48 completed questionnaires have been received. This represents a 31% response rate.

The regional distributing of completed questionnaires is shown on Table 2.

TABLE : 2

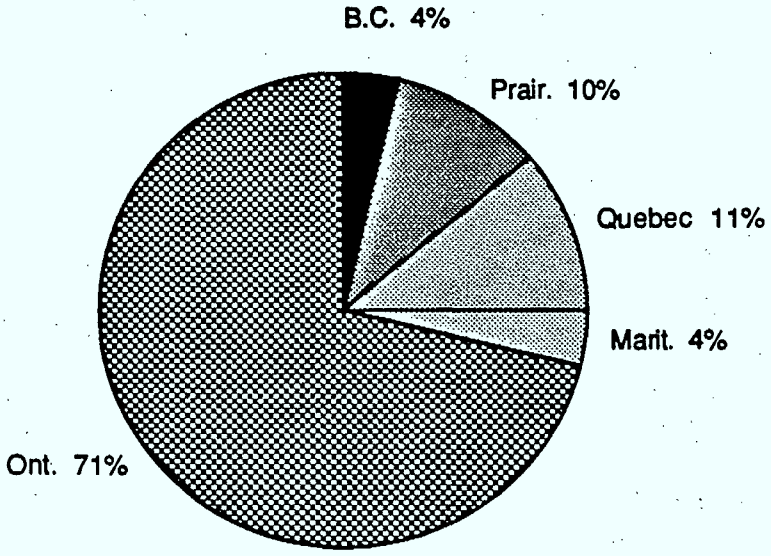
RESPONSE RATE BY REGION

Region	# Sent	# Received	% Responses
B.C.	9	2	22
Alta.	8	4	50
Sas.	2	0	0
Man.	4	1	25
Ont.	96	34	35
Que.	31	5	16
Marit.	4	2	50
TOTAL	154	48	31

The regional distribution of the sample is shown in Table 3.

TABLE : 3

SAMPLE SIZE BY REGIONS

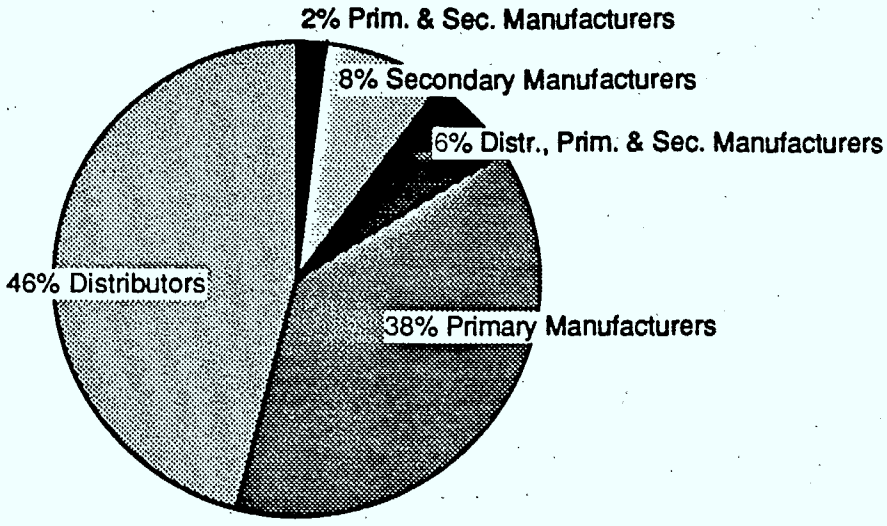


The sample follows fairly closely the regional concentration of industry.

The break-down of the sample by type of companies, is shown in Table 4.

TABLE : 4

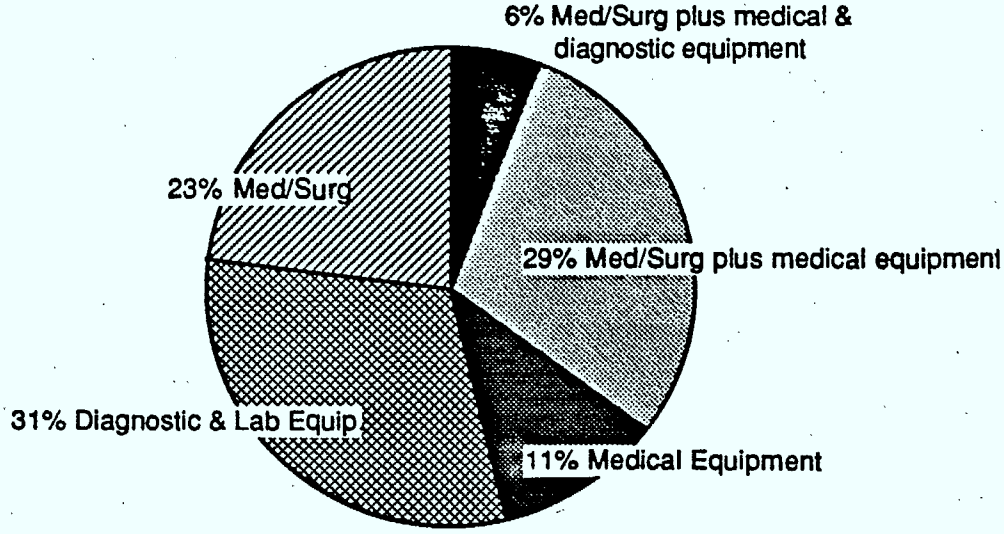
SAMPLE BY COMPANY TYPE



The sample break-down by the field covered is summarized as follows:

TABLE : 5

SAMPLE BY FIELD COVERED



7.2 Respondents' Knowledge of Product Classification Systems

- "Are you aware of any of the following product classification systems? If yes, please comment on the relevance of those you are familiar with".

7.2.1 BRMD

The BRMD has a classification system used for notification purposes. The system is simlar to the one used by the FDA in the U.S.

65% of the respondants are aware of the BRMD classification system, whereas 35% are not. 70% of the Ontario respondents are aware of the system, followed by 60% in Quebec and 25% in Alberta. Of the 31 respondents aware of the BRMD classification, only 9 gave a relevant comment. Only 2 out of the 9 felt that the database is comprehensive and could be an excellent source.

Among the comments the following are relevant to the study:

	# of Incidence
• Complex	1
• Not the same as industry definition	1
• Not up to date, a lot of obsolete information	1
• Very comprehensive, should be excellent source	2
• Notification database	2
• Cannot supply market data	1
• Not relevant for specialiazed products	1

7.2.2 ResCan

The ResCan classification is built around the BRMD/FDA system. It is used to measure markets and market shares.

46% of the respondents are aware of the ResCan classification system whereas 54% are not. 59% of the Ontario respondents are aware of the ResCan classification followed by 20% in Quebec. Of the 22 respondents aware of the ResCan classification, only 8 gave a relevant comment. Two do not understand the classification, and 2 indicated a certain level of usefulness.

Among the comments the following are relevant to the study:

	# of Incidence
• Incomplete, too general	2
• Not up to date	1
• Should be useful in wound care	1
• Level of detail and precision for diagnostic reagents improved in last two years	1
• Need to fix bugs in classification, unsure if sample is representative, but closest so far to meeting needs of industry and market	1
• Do not fully understand classifications	2

7.2.3 HS

It is a universal classification system used by Customs for tariff definition. The system is used by Statscan and ISTC's market intelligence department.

31% of the respondents are aware of the HS classification systems whereas 69% are not.

32% of the Ontario respondents are aware of the HS system. In Quebec it's 40% followed by 25% in Alberta.

Of the 15 respondents familiar with the HS coding, only 4 gave comments that are considered relevant to the study.

Among the comments the following are relevant to the study:

	# of Incidence
• Global	1
• Use only for importation	1
• Use in market research	1
• Good, but too late	1

7.2.4 MEDEC

The national trade association has its own definition of industry and the market segments. (see section 8.1 on page 48)

60% of the respondents are aware of the MEDEC systems, whereas 40% are not.

68% of the Ontario respondents knew of the MEDEC classification, followed by 60% in Quebec and 20% in Alberta. Of the 29 respondents familiar with the MEDEC classification, only 6 gave comments. Of the 6, only 2 found the classification satisfactory.

Among the comments the following are relevant to the study:

	# of Incidence
• Easy to use and understand	1
• Use for implants	1
• Very broad, too general	2
• Most members need training	1
• Not used	1

7.2.5 Universal System

Respondents were asked the following question:

- "Do you see an advantage of having a universal product classification system?"

77% answered yes, 13% answered no and 10% did not comment.

Of the four classifications studied 2% voted for the BRMD, 8% for the ResCan, 6% for the HS, and 8% for the Medec system. 76% did not answer.

Among the comments concerning a universal product classification system, the following are relevant to the study:

	# of Incidence
• Not possible to classify products in sufficient detail for meaningful comparisons; too many different technologies and format to allow direct comparison	1
• ResCan can use industry input to fine-tune product classification	1
• Depends on who the market is measured for and why information is tabulated	1
• ResCan possesses the most complete information	1
• HS would be useful if more detailed; too general	1

7.3 Sources of Market Information

The sources of statistical data to measure the domestic and international markets have been identified. Respondents also indicated their level of satisfaction with the data.

7.3.1 Canadian Market

- "Do you use any statistical market data to monitor your market penetration?"

69% answered yes, while 31% answered no.

The regional distribution of the users of market data is: 54% Ontario, 10% Quebec, 5% Alberta and Nova Scotia.

- "Do you use any statistical market measure before you launch a new product?"

Once again, 69% answered yes, while 31% said no.
100% of the Quebec respondents and 76% of the Ontario respondents are users of market data. The percentage is much lower in the other provinces.

- "What is the source of the data you currently use?"

Internal salesforce has been mentioned 38 times (41%), Statscan 12 times (13%), ISTC import analysis 4 times (4%), US data divided by ten 16 times (17%), and consultant surveys 23 times (25%). Most of the respondents indicated multiple sources of market data used.

Internal salesforce is predominently used by distributors to collect market data, followed by Consultant survey. Primary manufacturers seem to use almost equally the internal salesforce, Statscan, and Consultant studies. Secondary manufacturers do not seem to show preference for any of the data sources studied. For those who indicated to be both distributors and/or primary and secondary manufacturer, internal salesforce is the preferred source, followed by consultants' surveys and US data divided by 10.

The Consultant cannot show any significant difference in the preferences of data sources by field covered.

When examining the preferences of data source by province the internal salesforce is used by 71% of the western respondents. In Ontario, 36% indicated the use of the salesforce, 26% Consultants, 17% US data divided by 10 and 16% StatsCan. In Quebec and the Maritimes, 60% use the salesforce, 20% Consultants and 20% US data divided by 10.

•Comments:

The following comments on sources of Canadian data were made:

	# of Incidence
• Domestic data combined with foreign market would be welcome	1
• Internal is incomplete, Statscan is too old, US does not always apply, Consultants too expensive	1
• Too expensive in general	1
• Use several different sources for accurate picture, most data is flawed in one way or another	1
• None are really valuable	1
• Statscan doesn't break product down into required detail	
• Willing to pay for quality data at any price	1
• Federal data to general, private data too pricey. Level of detail and accuracy in private and federal data has to be questionable.	1

•Ranking of Data Sources

The following table shows the weighted rankings given to the various data sources used by respondents. The highest weight ranking value possible for each parameter is 5, signifying excellence.

There were 38 respondents evaluating Internal Sales-Force, 12 Statscan, 4 ISTC, 16 US divided by 10, and 23 evaluating Consultants' surveys.

TABLE : 6

WEIGHTED RANKING
SOURCES OF DOMESTIC DATA

	US/10	Internal Sales Force	StatsCan	Consultants
Price	3.2	4.0	4.1	2.4
Timeliness of Reporting	3.2	3.3	2.1	3.1
Level of Detail	3.1	3.1	2.5	3.0
Precision	2.8	2.8	2.8	2.9
Ease of Interpretation	3.2	3.4	3.1	3.4
Completeness and Relevance	2.8	3.2	2.8	3.0

For US divided by 10 data, all parameters were ranked more or less around 3.1.

When looking at the internal sales force used as sources of data, "precision" was ranked the lowest at 2.8. Not surprising is the highest ranking of 4 for price when considering that companies feel they can employ the salesforce for both marketing and selling purposes simultaneously.

Statscan's highest ranked parameter was price at 4.1. The timeliness of reporting shows the worst ranking of 2.1.

When Consultants are used as sources of data, companies show a low level of satisfaction with price, as reflected by the weighted ranking of 2.4, the lowest value. However, the ease of interpretation of reports issued by Consultants was given the highest weighted ranking of 3.4.

Ranking of parameters for ISTC have been suppressed due to very low response rate.

- "Do you feel that ISTC and/or the provincial governments should provide companies with regular domestic market data as a service to industry?"

63% answered yes, while 37% said no. This response rate reinforces the opinion voiced by industry delegates attending the workshop on performance indicators in July, 1990. Participants developed a concensus about immediate priorities for ISTC regarding the implementation of performance indicators for the medical devices sector. The following recommendations are extracted from the Memorandum dated October 4, 1990 prepared by Linda Leinan, ISTC, after the workshop:

- Macro and micro performance indicators are both necessary

- Timeliness is critical to collection, consolidation, summarization and provision of this indicator information

- There should be a directory of information sources that would make access and use of performance indicators likely and more appropriate

- The coordination of existing sources of information is likely to be more beneficial than re-doing or investing heavily to supplement current information collection

- In integrating or supplementing present information sources, design the data collection and management prospectively rather than attempting to make a link with historical data. The historical perspective is less likely useful to the industry

- Reinforce standardized nomenclature

- Keep in close contact with the users of the provided information and performance indicators to ensure both validity and utility. Continue to widely communicate the availability, quality and validity of the information, performance indicators, or other products and support made available

- Integrate initiatives regarding sector performance indicators with the provinces' needs for information for strategic development in these sectors

- Consider funding market research on a repayable basis, for example, for a 1% royalty fee. Examination of royalty revenues from this source would be one method of directly accounting for success attributable to sector campaign support

- "If you answered yes, can you comment on what is needed in terms of level of detail, precision of data and timeliness?"

The comments on the level of detail are as follows:

	# of Incidence
• By region, by manufacturers, by product ID number	2
• By region	2
• By product category, by industry, by region	5
• Market shares	2
• Market size and market shares	3
• The more detail the better	2
• Type of surgical procedures	1
• Trends, potential can be shown in gross numbers	1
• By HS class, codes or brand description	1
• Pricing	1
• Units imported, country of origin, company importing, Canadian manufacturer/unit/company name	1
• Market size, usage at product level	1
• Unit purchased, hospitals and private labs, by disease state	1

The comments on the precision of data can be summarized as follows:

	# of Incidence
• ± 5%	3
• ± 10%	3
• good accuracy, minimal error in extrapolation	4
• standard deviation should be shown to know reliability	1

The comments on the timeliness of data are as follows:

	# of Incidence
• Annually	13
• Monthly	1
• Quarterly	3
• Every 6 months	2

- "How much would you pay for domestic market information that you consider useful?"

58% did not answer the question.
10% of the answers were in the range of $100 - 875.
6% were in the range of $1,000 - 3,000.
11% were in the range of $5,000-7,500.
15% were in the range of $10,000 - 30,000.

The range indicated by distributors was from a low of $100 to a high of $25,000.

Primary and secondary manufacturers indicated a low of $300 and a high of $30,000.

Those who fall in the category of distributor/manufacturer indicated a range of $500 to $17,000.

The average being $8,185, and the median $5,000 per year.

7.3.2 Foreign Markets

- "Does your company export medical devices?"

29% answered yes, while 71% answered no.

19% of the total yes answers came from Ontario followed by 6% from Quebec.

- "Do you use any statistics to measure the export market? If yes, please indicate the sources of data in the US / Europe / Japan and Pacific Rim."

Of the 14 companies (29%) who export medical devices only 8 use statistical data to measure the foreign market they want to penetrate.

The data sources indicated by respondents for the USA are:

	# of Incidence
• VPG (Venture Planning Group Inc.)	1
• Boston Biomedical	1
• BBI (Biomedical Business International)	1
• Frosst & Sullivan	1
• Consultant Studies (multiclient/private)	1
• Self generated, customer data	1

The data sources indicated by respondents for Europe are:

	# of Incidence
• Glover and Associates	1
• BBI and other tracking publications	1
• Self generated, internal customer data	1
• Private / multiclient market studies	1
• European Regulatory Agency	1
• Local distributors	1

The data sources for Japan/Pacific Rim used by respondents are:

	# of Incidence
• Fuji Kaizai	1
• Private/multiclient studies	1
• BBI and other trading publications	1
• Local distributors	1
• Ministry of Health	1

- "What is your level of satisfaction with the data you use?"

The weighted rankings are shown in the following table:

TABLE : 7

WEIGHTED RANKING
SOURCES OF FOREIGN DATA

Parameters	USA	European	Japan
Price	3.5	4.0	4.2
Timeliness of Reporting	3.5	3.6	4.0
Level of Detail	3.3	3.6	3.7
Precision	3.8	4.0	4.0
Ease of Interpretation	3.7	4.0	4.2
Completeness and Relevance	4.0	3.8	4.0

Six respondents evaluated the US data sources and 5 those of Europe. The Japanese data sources were evaluated by only 4 respondants. The statistical significance of the above table is very low, due to low response rate.

7.4 Data Concordance

- "If you use several sources of data, domestic and international, do you feel that there is a reasonable compatability, i.e. are you comparing 'apples to apples'."

52% did not answer, 31% said no, and 17% said yes.

The comments received are as follows:

	# of Incidence
• US and Canadian data are very different in some respect	1
• US firms have incomplete Canadian data	1
• Discrepencies found	1
• More or less compatible, not always precise	3
• No compatibility except by luck. Concordance extremely difficult to establish	2
• Product not broken down into detail	1
• Internal data has been most effective	1
• BRMD could be used as a measuring stick to ensure concordance	1

- "What do you do in case you cannot establish data concordance? Adjust the data, develop your own concordance"

Seven respondents indicated that they adjust the data mainly based on industry knowledge and demographics. Eight respondants indicated that they develop their own concordance based on:

- additional survey
- industry knowledge, past history
- distributor information
- in-house and parent company statistics.

7.5 How to Improve User Awareness and Access

Awareness and access cannot be improved until availability is established. Except for Statscan and ResCan, there seems to be no readily available source of information on the Canadian medical devices market.

Statscan uses FOB transfer prices, and is lacking the level of detail needed by industry. The ResCan database has not yet reached full maturity. Therefore the majority of the companies interviewed use the sales force and private/multiclients consultants surveys to gain some knowledge of the Canadian marketplace.

The Canadian multinational medical devices companies are not as data rich as their US parents. The small companies do not even feel the need to collect data the same way as the large companies do.

Major multinational corporations have established their own information collection system throughout the years and seem to jealously hang onto their own data. They know that market information is badly needed, and they feel that having it gives them a competitive edge they are not ready to give up.

Data becomes useful information only after having been understood and applied to business problems such as inventory control, product development and design, pricing policies, physical distribution efficiencies, sales territory design, sales incentive program development, etc. Only large size companies have the financial resources to collect data and keep a market analyst on staff.

There is no need to increase the awareness of data on the part of major corporations. They all know the value of market data, and use it regularly.

Smaller companies however need to learn more about the importance of having and making use of market information. A possible way of educating future users would be to make available some information free of charge through the trade associations and/or TIMEC and follow-up with workshops on how to use market data for planning

ISTC could play an important catalytic role in bringing the parties together to ensure that industry can access market data without restriction. TIMEC and the trade associations should be involved in the dissemination of the data. The MEDEC journal should have a section dealing with the climate of the Canadian (and international if possible) medical devices market. This could raise the level of awareness of data sources as well as utility of data.

8. Pilot Study on Data Concordance

8.1 Product Classifications

In order to calculate world markets, by adding statistical market data from various sources, data concordance must be ensured. Data concordance can only be achieved if all parties involved in data collection measure the same markets, use the same product classification system and the same nomenclature.

In Canada, the Consultant identified 5 types of product classification, two of which (BRMD and ResCan) have commonalities. The MEDEC classification is unique and isolated. The HS classification is universal (discussed on page 12). The BRMD and ResCan classifications have great similarity with the US FDA classification. It seems that BRMD/FDA are in the process of establishing a harmonized universal system which would be cross referenced with the ECRI classification. Hospital statistics are grouped according to CHAM definition (discussed on page 16).

•MEDEC

There are six sectors subdivided into 38 sub-sectors:

ADS - Assistive Devices; includes 9 subsectors with common reimbursement practices.
DIA - Diagnostics: includes 6 sub-sectors that have to meet the same regulatory requirements.
HEQ - Hospital Equipment: includes 8 sub-sectors all subject to group purchasing.
IMP - Implants: includes 6 sub-sectors all part V of the BRMD regulations
MIT - Medical Imaging Therapy: includes 4 sub-sectors that have to follow Canadian radiation standards
MSS - Medical Surgical Supply: includes 5 sub-sectors that are described as volume business

•BRMD/FDA

The FDA classification is published in the Medical Device Register. It shows 19 medical specialities or panels of experts.

The medical products section includes the following major categories with the corresponding two digit code:

- Anesthesiology and pulmonary medicine : 73
- Cardiovascular : 74
- Dental : 76
- Ear, Nose, Throat : 77
- Gastroenterology and urology : 78
- General hospital and personal use : 80
- Neurology : 84
- Obstetrics and gynecology : 85
- Opthalmic : 86
- Orthopedics : 87
- Physical Medicine : 89
- Radiology : 90
- General and plastic surgery : 79

The in-vitro diagnostic product section includes:

- Chemistry : 75
- Hematology : 81
- Immunology : 82
- Microbiology : 83
- Pathology : 88
- Toxicology : 91

There are about 6,000 medical device product names in the Directory of Products listed in alphabetical order. Each device name is followed by a 5-character unique FDA code. The first two digits represent the above classification. The 3 letters that follow represent the finer breakdown .

Example:	*Cane (Physical Medicine)*	*89IPS*
	Support, knee (Physical Medicine)	*89RXS*

The main use of the FDA/BRMD classification is to serve as notification before introduction of new products to the marketplace.

•ResCan

This classification is based on the grouping of products in a 4 level hierarchical system. The highest level is called a book. There are 20 books:

001 Blood Bank
002 Biochemistry
003 Hematology
004 Histology/Cytology
005 Microbiology Devices
006 Serology/Immunology Devices
007 General Laboratory Disposables and Equipment
008 Anesthesiology & Pulmonary
009 Cardiovascular
010 Ear, Nose & Throat
011 Gastroenterology & Urology
012 Neurology
013 Obstetrics & Gynecology
014 Opthalmics
015 Orthopaedics
016 Physical Medicine
017 Radiology & Imaging Devices
018 Surgery
019 Operating Room
020 General Hospital & Personal Use

The next level is called a chapter. Each book is composed of a certain number of chapters which in turn are divided into smaller groups of product called generic descriptors. Individual products, in direct competition with each other, are classified under the same generic descriptor. The ResCan classification is used to measure markets.

BRMD/FDA/ECRI classifications allow for a product to be categorized under several generic descriptors. ResCan has therefore eliminated the overuse of generic descriptors thereby ensuring that a product is categorized exclusively under one generic descriptor.

•ECRI

Generic product descriptors are listed in alphabetical order in 30 main categories:

Anasthesiology
Cardiology
Cardiothoracic Surgery
Clinical Engineering
Clinical Laboratory
Dentistry
Emergency Medecine
Gastroenterology
Gynecology
Health Facility
Implants
Intensive Care Unit
Internal Medicine
Materials Management
Nephrology
Neurology
Neurosurgery
Nursing Services
Obstetrics
Ophthamology
Orthopedics
Otolaryngology
Pathology
Pediatrics
Physical medicine
Proctology
Pulmonary Medicine
Radiology
Surgery
Urology

Each product category is coded by using a 5 digit product code. There are about 3,600 generic product codes. The ECRI system is used in the US as basis for computer-based inventory.

8.2 Cross-Reference MEDEC / RESCAN

To test the flexibility of the ResCan database, the Consultant attempted to cross-reference the MEDEC and the ResCan classifications.

The result was submitted to MEDEC for comments. After having reviewed the cross-references for the assistive devices and hospital equipment sectors, MEDEC indicated that "listing of devices in each sector appear reasonable. Perhaps not complete but undoubtedly included most products. Description terms are satisfactory".

At a later date, similar cross-referencing could be attempted with the HS system used by Statscan and ISTC's market intelligence department.

8.3 Markets Measured

Statistics generated from the ResCan database are restricted, for the time being, to the acute care general hospitals and private medical laboratory markets.

Data published by Statscan and ISTC measure the volume of imports (which is not the same as the real $ market) regardless of the products' final destination. Imported medical devices can be sold to hospitals, but also to a large number of other facilities including nursing homes, doctors' offices, clinics, home health care retail stores, educational institutions, pharmacies, industry and government laboratories.

The ResCan and the Statscan publications do not measure the same markets.

8.4 Result of the Pilot Study

The Consultant examined domestic data from different sources:

- Import statistics according to HS codes
- Hospital statistics according to CHAM codes
- ResCan data according to modified BRMD codes
- Some provincial government data collected through Ministry of Health, coding unknown
- Some market information from MEDEC
- Some market information from provincial group purchasing organizations

In order to establish concordance it is imperative to measure the following:

- Same market
- Same year
- Same number of products
- Same nomenclature

Hospital statistics generated by Statscan deal with the consumption of a sample of public general hospitals only. It does not include medical equipment and laboratory instrumentation. The data is not projected from sample to universe.

The ResCan database provides market data for acute care general hospitals of 50 beds and over and private laboratories. It measures supplies and small equipment.

The other data obtained from the provinces can only be used if detailed information is available for all medical device items used in each province, based on a well defined classification used by each province.

MEDEC, TIMEC and AQFIM do not have any hard data that could be used in this pilot study on concordance.

Statistical data for most of the HS categories is often too general, to the point that concordance with the ResCan database was impossible to perform. In some cases like wheelchairs (HS codes: 8713 - 10 and 8713 - 90) the description is very specific but the markets for which data is produced by Statscan and ResCan are not comparable. The acute care general hospitals measured by ResCan are certainly not the only market for this kind of a product.

Three product groups, suture materials (HS code: 3006 - 10), opacifying preparations, x-ray (HS/SCG code: 3006 - 30 - 10) and pacemakers (HS code 9021 - 50) have been chosen by the Consultants to study the possibility of establishing at least a partial concordance.

<u>Suture Material</u>

- Imports : 1989 in '000 $12,650
- Disappearance cannot be calculated as no information is released for this product category in the publication on shipments.
- ResCan : 1989 in '000 $50,655
- Further concordance with other domestic and international sources could not be achieved due to lack of detail.
- Conclusion: Concordance cannot be established. We do not know the percentage mark-up used by industry on imported products. We do not know what $ volume is locally manufactured.

Opacifying Preparations, X-Ray

- Imports : 1989 in '000 $15,811
- Disappearance cannot be calculated as no information is released for this product category in the publication on shipments
- ResCan : 1989 in '000 $37,355
- Census data from one of the provinces $4,718
- Projected to the total number of beds in Canada $46,921
- Conclusion: Concordance cannot be established between ResCan and Statscan for the reasons mentined under sutures. There is partial concordance between Rescan and the projected total based on the input of one province only. Barium preparations are widely used in each x-ray department. Injectable contrast media is more restricted. The projection methodology is therefore not the same for these two types of opacifying preparations. The provincial census is a total from which injectables cannot be isolated for projection purposes. The Consultant cannot adjust the projection methodology for these two types of products to increase the precision of the estimate.

Pacemakers for stimulating heart muscle

• Imports :	1989 in '000	$13,633
• Exports :	1989 in '000	843
• Shipments:	1986 in '000	5,021
• Disappearance:	in '000	17,811
• ResCan (Canadian market)	1989 in '000	17,396

- Conclusion: A fairly good concordance was established. ResCan may have underestimated the market given that import volumes are expressed in transfer price. Import / export statistics measure the same period. Shipments is 3 years behind. This may have an impact on the precision of the estimate for disappearance.

9. Options For On-going Sector Monitoring

There are two major target audiences for market data; governments and industry. Their use of information may well be different, the need however is the same.

None of the Canadian data sources are complete and fully satisfactory to meet both government and industry needs. The Consultant proposes the following options for ISTC's consideration.

9.1 Government Source

9.1.1 Statistics Canada

To make the Statscan data more useful for monitoring performance and market in the medical devices sector, the following changes should be considered by Statscan.

- Ensure continuity of raw data supply in spite of the possible negative impact of Free Trade on the availability of detailed invoice information.
- Increase the level of detail by attempting a complete cross-referencing with either BRMD / ResCan and/or MEDEC classifications
- Use a standard product nomenclature adapted by the medical devices industry, BRMD and ResCan
- Provide real market data rather than just import statistics . Use industry average selling prices rather than FOB transfer prices. If this is not feasible, provide import data on quantities with SKU, allowing industry users to calculate the corresponding $ market. Provide market share data.
- Keep up to date on classification of new products.
- Ensure that export and shipment data are structured the same way as import data allowing users to easily calculate disappearance.
- Ensure that all three publications (import, export, shipment) are up to date.
- Validate precision of published data with industry users.
- Keep in closer contact with clients, to better respond to demand. Use client feedback to modify the structure of the reports.

Should the above be impossible to achieve, Statscan could approach MEDEC and individual companies to request their cooperation in disclosing sales information that could be used by Statscan to produce market estimates. This method of data collection was tried several times by MEDEC in the past, without too much success. Assuming that industry would accept to provide Statscan with their sales information, several problems will still have to be resolved:

- The universe of companies cannot be considered as homogeneous. A representative sample cannot be taken. Projection is therefore not possible. Statscan will have to obtain the cooperation of all companies catering to this market. (Well over 800)
- Statscan will not be able to validate data provided by industry.
- Product classification cannot be escaped.
- Market shares cannot be produced, as companies would want to ensure confidentiality of their data.
- Implementation has to be completed within a year to permit ISTC to measure the market in year one of the sector initiative.

9.1.2 Industry, Science and Technology Canada

The Market Intelligence division could be another potential source of market data.

ISTC however will have to deal with the same problems as Statscan. The Consultant observed that ISTC is much closer to the medical devices industry, their associations, and to the provincial governments involved in the development of this sector than is Statscan. It is therefore more likely that ISTC would master the task faster than Statscan.

9.2 Private Sector Source

ResCan is the only consulting firm in Canada operating a database on the medical devices market.

To increase the utility of the ResCan database in monitoring market and performance in the medical device sector, the following tasks should be performed by ResCan:

- Create an advisory committee in cooperation with TIMEC and the trade associations to validate product classification and market projections. Based on their feedback, adjust the sample size and distribution.
- Start an annual survey of the major capital equipment market. This should be a quasi census.
- Ensure that quarterly reports are available 8 to 10 weeks after the closing of the quarter.

ResCan measures the market for acute care general hospitals of 50 beds and over and private labs. The sample, in the future, could include the Red Cross and provincial laboratories.

ResCan does not plan to measure other markets such as educational and industry laboratories, pharmacies, doctors' offices, clinics, etc. Therefore, the ResCan database cannot be used to quantify the total Canadian market.

The advantage offered by the database include:

- Continuity of raw data supply is not threatened by Free Trade.
- Market can be measured for an individual product (there are currently 200,000 items in the database) as well as for groups of products. Data is produced bottom-up in a very flexible manner.
- Market shares and average price are available.
- Break-downs can be given by geographical region and type and size of institution.
- There are well established statistical validation methods based on which ResCan will calculate the precision of market projections, and adjust the sample as needed.
- Almost $1.5 million has been invested by the company on computer program development and on establishing a data collection and product classification methodology. Another $400,000 grant was received from NRC.

9.3 Conclusion

- ResCan is in the process of drafting an agreement with TIMEC and the industry associations (mainly MEDEC) on data distribution and educational support for data users.
- The ResCan database requires validation by industry to be fully developed.
- The ISTC Market Intelligence division and ResCan could either merge their data and introduce a new "product" that would cover all markets (institutional, educational, etc.) and have the flexibility of the database, or continue separately in which case industry and governments could continue to monitor the institutional market by using ResCan's database and bring their own adjustments to ISTC and/or Statscan data for the other markets not measured by the database.

10. Users' Guide

This Users' Guide deals with services and sources of medical device data both domestically and internationally for anyone interested in marketing a new product or investing in a new area in Canada or abroad. It includes both public and private sources.

Publications are listed in alphabetical order according to title for the domestic market. Publications for the international market are indicated under their country of origin which is listed in alphabetical order.

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The following is a sample with an explanation of the items listed:

1 Annual Return of Hospitals, Hospital Indicators

2 83-233 3 $8 4 annually

5 1986-87 6 (published 1989)

7 Detailed report on hospitals, ...

1. title of publication
2. Statscan catalogue number, if applicable
3. price
4. frequency of publication
5. year(s) of coverage: latest report
6. year of publication: latest report
7. description

10.1 Domestic Market

10.1.1 Statistics Canada Publications

Annual Return of Hospitals, Hospital Indicators

83-233	$8	annually
1986-87	(published 1989)	

Detailed report on hospitals, broken down by department and procedures: Canada and individual provinces.

Examples:
- Percentage of occupancy
- Cost per day per occupied bed
- Paid hours per total patient-day
- Etc.

Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures

82-562	$30	variable
1986	(published, June 1986)	

Contains the Canadian classification of the various procedures: diagnostic, therapeutic, and surgical. Each procedure is given a code number, which is related to a family number, which in turn, is related to a certain system of the human body.

Example:

Operation on the Eyes	
22	Operation on eyelids
22-0	Incision of eyelid

Canadian Export - Import Alphabetical Index

12-579E	Canada	$35	occasionally
	Other Countries	$48	
1987	(published, December 1987)		

Prepared by Statistics Canada. To be used in conjunction with both the Canadian Export and Import by Commodity (HS based) publications. Provides an alphabetical listing of products and their HS code; does not provide statistics.

Custom Tariffs

RV55-2	$122.60	variable
1989	(ammendments forwarded to subscriber as published)	

Contains tariff descriptions and rates of duty, based on the Harmonized Commodity Description and Coding System (HS).

Exports by Commodity

65-004	Canada	$52.50	monthly
		$525.00	annually
	Other	$63.00	monthly
	Countries	$630.00	annually
	*	Free	
October 1990		(published, December 1990)	

Export statistics are classified and published according to the Harmonized Commodity Description and Coding System (HS). Quantity and value ($'000) are provided by country of origin for the respective month, as well as cumulative totals. 52 HS codes, pertaining to medical devices, have been identified.

Example:	4015 11	Gloves surgical of rubber	Quantity (pairs)	Value ($ '000)
		Exports total	9,390,721	5,711

* Individuals have access free of charge when researching data themselves at their local Statistics Canada office.

Health Reports

82-003	$26	every 3 months
1987-88	(published, October 1990)	

Information is detailed to age, sex, and part of the anatomy affected. Hospitals morbidity is reported, as well as accidents in Canada.

Examples:
- Mental disorders
- Cardiovascular disease
- Cancer, T.B.
- Aging of Canadian population
- Etc.

Publication available through annual subscription only. It gives current data. 3 year history is available.

Health Trends

11-008F $34 every 3 months
Winter 1990

Canadian magazine which discusses social and health habits of Canadians, broken down by age, sex, and reading skills.

Example:
- How/what they eat
- Number of hours of sleep
- Sleeping habits
- Etc.

Hospital Statistics, Preliminary Annual Report

Formerly 83-217
Now 82-003S variable
1988-89 (published 1989)
1990 supplement No. 2, Vol. 2

Provides tabulations, definitions, and other explantory detail on preliminary hospital utilization and expenditure data. It provides total cost for reporting hospitals, by type and size of medical and surgical supplies: Canada and individual provinces.

Imports by Commodity

65-004	Canada	$52.50	monthly
		$525.00	annually
	Other	$63.00	monthly
	Countries	$630.00	annually
	*	Free	
October 1990		(published, December 1990)	

Import statistics are classified and published according to the Harmonized Commodity Description and Coding System (HS). Quantity and value ($'000) are provided by country of origin for the respective month, as well as cumulative totals. 52 HS codes, pertaining to medical devices, have been identified.

Example:	4015 11	Gloves surgical of rubber	Quantity (pairs)	Value ($ '000)
		Imports total	64,231,346	8,785

* Individuals have access free of charge when researching data themselves at their local Statistics Canada office.

Products Shipped by Canadian Manufacturers

31-211	Canada	$60	annually
1984, 85, 86	(published, March, 1990)		

Contains values and quantities of shipments of goods of own manufacture by manufacturing establishments in Canada. The commodity detail is based on the Industrial Commodity Classification (ICC) which is structured on the Standard Commodity Classification. A list of product names corresponding to the three-digit codes of the ICC, arranged in alphabetical order, is included. The unit of measurement, quantity and value ($'000) are provided whenever possible.

Standard Classification of Goods

12-580E	$85	variable
1988	(published, November 1988)	

Provides codes for goods based on the Harmonized Commodity Description and Coding System (HS).

Standard Industrial Classification

12-501E	Canada	$25	variable
	Other Countries	$30	
1980	(published, December 1980)		

Provides a list of industries making up the total economic activity of Canada, their titles, definitions and codes. The classification structure is based on 4 main levels of production by specialization:

1) Divisions
2) Major Groups
3) Minor Groups
4) Units

The medical device industry does not have a code. Medical equipment is categorized under 3912.

Standard Geographical Classification

12-571 to 12-573	12-571 - $55.00	variable
	12-572 - $35.00	
	12-573 - $75.00	
1986	(published 1987)	

Standard Geographical Classification (Cont'd)

The SGC is a system for the identification and coding of three types of geographical areas. These are:

- Province and Territories (PR)
- Census Divisions - counties, regional districts, etc. (CD)
- Census Subdivisions - usually municipalities (CSD)

Also identified are Census Metropolitan Areas (CMA), defined as labor market areas with an urbanized core having a population of 100,000 or more.

Example: Nepean, Ontario

PR	CD	CSD	CCS	CMA
35	06	012	012	505

Surgical Procedures and Treatment

Formerly 82-208
Now 82-003S $15 variable
1987/88 (published, 1989)
1990 supplement, Vol. 2, No. 2

Provides information on each surgical procedure or treatment performed per province.

Examples:
- Separations (discharge or death) and days
- Days stays
- Age group
- etc.

Textile Products Industries

34-251 $32 annually
1986 (reviewed, July 1989)

Contains shipment values (in $'000) by product, SIC and number of establishments manufacturing that particular product.

Example: 881 11 (Industrial commodity classification)
surgical gauze, dressing and sponge pads

	1986	
SIC	Establishments	Value
1994	8	36,358

Textile Products Industries (Cont'd)

34-251B $4 annually
1986 (reviewed, July 1989)
Supplement to 34-251

Contains information on stocks and principal statistics for each product: breakdown by province.

Example:
- Number of establishments
- Number of workers
- Cost of fuel and electricity
- Cost of materials and supplies
- Goods in process
- Finished products
- Etc.

10.1.2 Statistics Canada Contact Information

Statistics Canada
Ottawa, Ontario
K1A 0T6

International Trade / Data Dissemination	Gordon Blaney	613-951-9647
Hospital Data	Deirdre Gillieson	613-951-1635
Production / Shipment	Bob Wright	613-951-3514

10.1.3 B.O.S.S.

The Business Opportunities Sourcing System (B.O.S.S.) publishes various directories from Industry, Science and Technology Canada (ISTC), including:

Directory of Canadian Manufacturers / Products
Directory of Research and Development Laboratories/facilities in Canada
Directory of Canadian Trading Houses
Directory of Canadian Custom Brokers and Freight Forwarders
Directory of Canadian Construction Companies
Directory of Computer Software and Services
Canadian Directory of Marine Shipping

Services Directories:
Consulting Agrologists
Management Consultants
Architects
Surveyors and Mappers
Consulting Engineers

The Directory of Canadian Manufacturers (companies) is published every six months in hard copy and is available at no charge. It is also available on-line via a micro computer. A distribution list is kept whereby regular updates are sent to a client as soon as they become available. The information in the directory is obtained from questionnaires sent to establishments in Canada. The companies are listed alphabetically by name. Each company profile includes:

Company Name
Telex/Telephone/Fax number
Mailing/Street Address
Last time firm completed a questionnaire
Executive Officer
Total staff
Total sales
Parent country
Research and development department (if any)
Export Manager
Exports to (countries)
Interested (countries)
Products

The Directory of Canadian Made Products is also published every six months and is available in hard copy or on-line through a micro computer.

The directory is produced in alphabetical sequence by product name. Under each product the following information is given:

Company Name
Address
Telex/Telephone/Fax Number
If the product is exported

Contact: Business Opportunities Sourcing System (BOSS)
Industry Science and Technology Canada
235 Queen Street
Ottawa, Ontario
K1A 0H5
Telephone: 613-954-5031
Fax: 613-954-1894

10.1.4 CANTECH

Secondary Database
Language of database is English

The database producer is William G. Hutchison and Company Ltd. Hutchison Research is a market research firm specializing in Canadian advanced technology companies. The CANTECH database profiles over 5,000 Canadian manufacturers of high tech products and providers of high tech services.

The database including all data and search software sells for $6,000 on an annual subscription basis. Clients can load CANTECH on their IBM compatible computer (13 mb of hard disk space required) and receive updated information quarterly.

Each individual company profile is updated on the anniversary of its completion. Each corporate profile contains information on the firm's name, address, and contact numbers. Ownership status, structure and year of incorporation in Canada are provided. Company size is determined by number of employees, annual sales revenue and R&D expenditure and staff. Business activities are mentioned briefly. A list of executives responsible for key areas is also provided.

Hutchison is currently negotiating with STM and CANet to get CANTECH on line, since it is not available as such, currently.

The CANTECH National Directory, hard copy, is also available for $295. It is organized by province, and then alphabetically. Companies are indexed, at the back of the directory, according to technology.

Custom directories can be defined by geography (ie: all companies in Metro Toronto) or by technology (ie: all companies involved in medical devices and test and measurement equipment).

Also available are custom Data on Demand search services using CANTECH. Each search is based on criteria supplied by the client, however output can range from mailing labels ($.50 each) to full corporate profiles ($6.50 each).

The database is made up of 18 major technology categories:

AUT	- Factory Automation Equipment
BIO	- Biotechnology Products and Equipment
CHE	- Chemicals
COM	- Computer Hardware
DEF	- Defense/Military Equipment
ENR	- Energy/Environmental Equipment
MAN	- Manufacturing/Processing Equipment
MAT	- Advanced Materials
MED	- Medical Equipment
PHA	- Pharmaceuticals
PHO	- Photonic Equipment
SER	- Advanced Technology Services
SOF	- Computer Software
SUB	- Subassemblies/Subsystems
TAM	- Test & Measurement/Control Equipment
TEL	- Telecommunications Equipment
TRN	- Transportation Equipment
ZZZ	- Other High Technology Equipment

Example:	*CODE*	*GENERIC NAME*	*GENERIC DESCRIPTION*
	MEO-HA-O	Ophthalmic Devices	Devices used to aid eye impairments

Contact: Hutchison Research
King West Business Centre
2 Pardee Avenue
Suite 202
Toronto, Ontario
M6K 3H5

Telephone: (416) 539-9220
Fax: (416) 539-9225

Mr. Pim van der Toorn
General Manager

10.1.5 Industry, Science and Technology Canada Library

The Industry, Science and Technology Canada (ISTC) Library has access to over 400 on-line databases through 12 different systems:

CANADIAN PERIODICAL INDEX	INSIGHT
CAN/OLE	INFO GLOBE
DIALOG	INFOMART
DOBIS	PROFILE
ECONOMIC BULLETIN BOARD	QL SEARCH
FINANCIAL POST	TEXTLINE

The DIALOG service alone offers approximately 340 databases. The database that is of particular interest to medical devices is the Frost and Sullivan Research Report (Index to). Market size and share by product and company are provided.

Since ISTC's Library has access to DIALOG, the Library will cover the cost of searching the database and provide the required printout.

Contact: ISTC Library Information Services — Telephone: 613-954-2728

Micromedia — Telephone: 416-593-5211

10.1.6 Market Intelligence Service

The Market Intelligence Service is offered through Industry, Science and Technology Canada (ISTC). The service offers detailed information on specific product markets. Anyone interested in developing a new product or investing in a new area should examine the market closely.

The information is based upon restricted access to Customs import documents. A product-specific report consists of :

- annual changes and trends in imports
- quantity and value of imports
- ports of entry
- unit import prices
- major foreign countries exporting to Canada
- names of Canadian importers and suppliers
- names of foreign companies exporting to Canada
- Canadian production and exports
- Canadian market summaries
- American imports
- Canadian tariffs
- import market shares of top importers
- imported product breakdowns by type, size, material and price range

Basic market information is available readily while more complex requests are evaluated in terms of potential economic benefits, prior to completion.

Indexes, copies of reports are offered, on request, at no charge.

Contact: Market Intelligence Division
Services to Business Branch
Industry, Science and Technology Canada
235 Queen Street — Telephone: 613-954-4970
Ottawa, Ontario — Fax: 613-954-1894
K1A 0H5

10.1.7 NRC - CISTI

The Canadian Online Enquiry Service (CAN/OLE) is produced by the Canadian Institute for Scientific and Technical Information (CISTI) a division of the National Research Council Canada.

CAN/OLE is an online information retrieval system. It is accessible through the DATAPAC Telecommunications Network. Any dial-up terminal, word processor, or microcomputer which can communicate using ASCII code in full duplex at a speed of 30, 120, or 240 characters per second is compatable with CAN/OLE. Customers pay only for the time spent on the system. Some databases have royalty fees in addition to the basic hourly rate. Royalty fees are also charged for displaying references on some databases. Cost estimates are provided at the terminal to monitor what is being spent.

There are 47 databases available on CAN/OLE including an online training database (ABC1, ABC2). Topics covered include: Physical sciences, Engineering and Materials, Natural Sciences Agriculture and Food, Official Publications, Directories of Organizations and Individuals, Library Catalogues, and Related Topics.
The Canadian Selective Dissemination of Information Service (CAN/SDI) is another service operated and maintained by CISTI in cooperation with five other CAN/SDI centres:

- Agriculture Canada (AG CAN)
- Atomic Energy of Canada Ltd. (AECL)
- Canada Centre for Mineral and Energy Technology (CAN MET)
- Geological Survey of Canada (GSC)
- Sport Information Resource Centre (SIRC)

CAN/SDI is a current awareness service designed to keep individuals informed on the most current journal articles, technical reports, patents, and books. The computer scans references and then prints the appropriate ones that match an individual's profile. The cost of the CAN/SDI service depends on the data bases chosen and the number of references requested. Abstracts (if available) and duplicate references are available for an additional cost.

Contact: CISTI
NRC Canada
Ottawa, Ontario
K1A 0S2

Telephone: (613) 993-1210
Fax: (613) 952-8244

Client Services CAN/OLE, CAN/SDI

The Canadian Scientific Numeric Databases (CAN/SND) is yet another database service provided by CISTI. It consists of machine-readable collections of critically evaluated scientific numeric data, and computer programs to support the various uses of this data.
CAN/SND is available on line worldwide through the nearest data telecommunications network. Charges are based solely on computer resources used.

There are 6 data bases available on CAN/SND:

CRYSTDAT	NIST Crystal Data Identification File
CRYSTIN	Inorganic Crystal Structure Database
CRYSTMET	Crystallographic Data File
CRYSTOR	Cambridge Structural Database
FACT	Facility for the Analysis of Chemical Thermodynamics
SPIR	Search Program for Infrared Spectra

Contact: CISTI
NRC Canada
Ottawa, Ontario
K1A 0S2

Telephone: (613) 993-3294
Fax: (613) 952-8246

Manager, CAN/SND

10.1.8 Pharmaceutical News Index (PNI)

Secondary Database
Language of database is English

The database producer is UMI/Data Courier. Data Courier is an operating division of University Microfilms International (UMI). Both are owned by Bell and Howell. They specialize in the development, production, marketing and electronic distribution of business information products.

The PNI database contains current and retrospective news about the pharmaceuticals, medical devices, cosmetics, and related health industries, world wide. There are approximately 15-20 thousand references on medical devices per year. Eighteen major US and international news publications are indexed cover - to-cover (includes Clinica World Medical Devices News).

PNI is available (on-line) on three systems, BRS, DIALOG, and ORBIT Search Service. Prices range from $100 US per connect hour ($.55 per record) to $150 US per connect hour ($.70 per record). Photocopies of most PNI articles are available at $.15 each page, along with overnight mail fees where applicable. The database is updated weekly with more than 600 records. There is an embargo on some newsletters causing a one month lag time in reporting. Coverage dates back to 1974.

The database provides unique details about the following subject areas:

- Health legislation and policy making
- Statistical data
- Pharmaceutical research
- Over-the-counter prescription markets
- Drug and device recalls
- Litigation and court decisions
- Market analysis
- Biotechnology updates
- R&D in progress
- Veterinary pharmaceuticals
- Livestock disease news
- Personnel changes
- Corporate financial information
- NDA (New Drug Application) approvals
- Acquisitions and mergers
- Government contracts
- Product successes and failures
- Health and beauty aids
- Advertising campaigns
- New product development
- Joint ventures

In addition to PNI, Data Couriers produces Business Dateline, America's regional business press on-line, a tertiary database. It contains 76,000 articles from over 180 business publications covering news on local products, and regional business trends. Most services are updated weekly, and in some cases, monthly (ESTI/HRIN and Mead). Access is available through: BRS, BRS/Colleague, DIALOG, Dow Jones/Retrieval, ETSI/HRIN, Mead, and VU/TEXT. Prices range from $75 US per connect hour ($2.90 per record) to $126 US per connect hour ($4.00 per record).

Contact:	UMI/Data Courier	Telephone:	800-626-2823 US
	A Bell and Howell Company		800-626-0307 Can.
	620 South Third Street		(502) 583-4111
	Louisville, Kentucky	Fax:	(502) 589-5572
	40202 - 2475		

10.1.9 ResCan

Primary Database
Language of database is English and French

The database produced by ResCan Consultants monitors 200,000 product items from 2,000 suppliers. Data from purchasing invoices submitted by a sample of Canadian hospitals (acute care, general, 50 beds and over) and private diagnostic laborotaries is entered daily into their computers.

Rescan Consultants
Division of Armar International Inc.

Only hard copies of information are available either on an ad-hoc or annual subscription basis. Price ranges from $5,000 to $25,000 per year depending on the quantity of information requested. Products offered include:

1. Quarterly Market Audit: market size in units and $, market trends, brand and company market shares

2. Annual Instrumentation Studies: database information is complemented with interviews on present and future placements, acquisition made, etc.

3. Bi-Annual Compendium: listing suppliers by product, product by suppliers, address and phone numbers.

The database is made up of 20 books:

001	Blood Bank	011	Gastroenterology & Urology
002	Biochemistry	012	Neurology
003	Hematology	013	Obstetrics & Gynecology
004	Histology/Cytology	014	Opthalmics
005	Microbiology Devices	015	Orthopaedics
006	Serology/Immunology Devices	016	Physical Medicine
007	General Laboratory Disposables and Equipment	017	Radiology & Imaging Devices
008	Anesthesiology & Pulmonary	018	Surgery
009	Cardiovascular	019	Operating Room
010	Ear, Nose & Throat	020	General Hospital & Personal Use

The books are further divided into 250 categories called chapters, which, in turn are subdivided into 2,300 generic product descriptors. Products are then listed under their respective generic descriptor. An example is given below:

Book	001	Blood Bank Devices
Chapters	006	Blood Bank Sera
	81KSX	Rare Sera
	81UJS	Anti-Human Sera, Blood Bank
	81UJY	Blood Grouping Reagent (ABO, RH)

Contact: Rescan Consultants
388 St. Jacques St. W.
Suite 500
Montreal, Quebec
H2Y 1S1

Telephone: 514-284-3696
Fax: 514-284-0043

Margarita Reti, President

10.1.10 Standards Council of Canada Databases

Secondary Database
Language of database is English and/or French

The database producer is the Standards Council of Canada (SCC). They offer three bilingual databases, available 24 hours a day, for standards users in Canada and abroad.

The first database is called Canadian Standards (Stannorm). It contains bibliographic information on Canadian Standards published by five accredited standards-writing organizations of the National Standards Systems:

Bureau de normalisation du Québec (BNQ)
Canadian Gas Association (CGA)
Canadian General Standards Boards (CGSB)
Canadian Standards Association (CSA)
Underwriter's Laboratories of Canada (ULC)

Information is collected on a daily basis.

A printed directory entitled, National Standards System: Directory and Index of Standards is made available in May of each year for a price of approximately $50.

The second database is called Reference Standards-Federal. This database contains information on Canadian, foreign, and international standards and standard-type documents referenced in Canadian federal legislation.

The third database is called GATT TBT (Notifications) Draft European Standards. This database contains information on proposed regulations, mandatory standards or certification systems from countries that have signed the GATT Agreement on Technical Barriers to Trade. Also includes summaries of draft standards published by the European Committee on Standardization (CEN) and the European Committee on Electrotechnical Standardization (CENELEC).

Information is sourced from notification from Geneva.

The Standards Council of Canada does not charge users for accessing any of the databases. A user pays only for telecommunications charges, which vary depending upon the method of access:

1 DATAPAC packet switched network. User obtains a Network User Identifier (NUI) from Telecom Canada.

2 iNet 2000 network from Telecom Canada, whereby an iNet password is obtained from any local telephone company.

3 CAN/OLE network of CISTI can access only the Canadian Standards database.

Contact: Information Division
Standards Council of Canada
350 Sparks Street, Suite 1200
Ottawa, Ontario
K1P 6N7

Telephone: (613) 238-3222
Fax: (613) 995-4564

10.1.11 Trade Information Enquiry and Retrieval System (TIERS)

The database producer is Statistics Canada.

The TIERS database profiles over 15,000 commodities for imports and exports for approximately 200 countries at a detailed level. The database consists of 1989 and 1990 merchandise trade data. The menu system includes a Harmonized System Coding, (6 digits), quantity, value ($'000), province, year variables, and the most current trade statistics.

TIERS will be updated monthly with data available 48 hours after their release. An IBM PC, XT, AT or PS2 compatible is needed, along with DOS, 350K free ram and 80MB hard disk space for each year of data.

Contact: Statistics Canada
International Trade Division
Ottawa, Ontario
K1A 0T6

Telephone: 613-951-9798
Fax: 613-951-0117

Bansi Arora

10.2 International Market

The International Section of this User's Guide does not contain the following countries due to the non-existence of readily available data on medical devices:

Austria
Belgium
England
Germany
Israel
Sweden

Contacting local consultants within each country is recommended.

10.2.1 France

Informations Hospitalières

Published by the Ministry of Health, special issue No. 26 deals with healthcare expenditure for 7 specific years from 1970 - 1986 for 12 countries.

10.2.2 Italy

Stastiche Di Importazioni / Esportazioni

Contains import / export statistics classified and published according to the Harmonized Commodity Description and Coding System (HS)

Contact: Instituto Centrale de Statistica (ISTAT)
Via Cesare Balbo 16
00184 Rome

10.2.3 Japan

Health Care, Market of Health Care Products

The Manufactured Imports Promotion Organization (MIPRO) had chosen the subject of their annual report for 1990 to cover the market of health care products. The report covers import, distribution, consumption trends and regulations, and organizations among others.

Contact: MIPRO
World Import Mart
P.O. Box 2129
1-3 Higashi-Ikebukuro 3 -Chome
Toshima-ku
Tokyo, Japan 170

Telephone: 03-988-2791
Fax: 03-988-1629

March 1990 Edition of your Market in Japan - Medical Electronics Equipment

Provides complete coverage of the medical electronics equipment manufacturing industry: medical equipment and supplies; market trends, technological level, outlook, regulations on imports, and organizations.

Contact: Japan External Trade Organization
2-5, Tor anomon 2-Chome
Minato-ku
Tokyo 105, Japan
Telephone: 03-582-5170
Fax: 03-582-7508

10.2.4 Netherlands

Fact Sheet on The Netherlands: Health Care

This contains information on the various healthcare policies, sources of financing, and the cost of the healthcare and personal social service.

Contact: Ministry of Welfare, Public Health and Cultural Affairs

Financieel Overzicht Gezondheidszorg en Maatschappelijk Welzijn -- Financial Overview of Health Care and Public Welfare

The most complete publication providing full financial information on the health care sector.

Contact: Ministry of Welfare, Public Health and Cultural Affairs

Health Insurance in The Netherlands

Provides insight into coverage of medical expenses in the Netherlands for treatments and services.

Contact: Ministry of Welfare, Public Health and Cultural Affairs
P.O. Box 5406
2280 HK RIJSWIJK
Telephone: 070 407 911

Holland Health Care Industry

A comprehensive package of services and products in the field of medical and pharmaceutical technology.

Contact: Netherlands Foreign Trade Agency (EVD)
Ministry of Economic Affairs
Bezuidenhout se weg 151/181
2594 AG Den Haag
The Netherlands

Import and Export Statistics for Medical Products for 1988 and 1989

The products are categorized using the Harmonized Commodity Description & Coding System (HS)

Industrial Production Statistics (1987 and 1988) for Medical, Surgical and Dental Instrumentation, Orthopedic Articles and Protheses

These are the only categories of medical products for which production statistics are available. Total domestic production for 1987 and 1988 is given.

Contact: Centraal Burjeau vapor de Statistiek
Klousterwegl
Postbus 4481
6401 C2 Heerlen
Telephone: 045 73 66 66
Fax: 045 72 74 40

Industry Sector Analysis: Laboratory Instrumentation - ASI

Provides market assessment, competitive situation, market access, significant trade events, best prospects, and minimal statistical data for laboratory instrumentation in the Dutch market.

Contact: U.S. Embassy
The Hague

Profile: Medical Technology

A 2 page summary offering strengths and weaknesses of companies concentrating on consumer goods and companies concentrating on investment goods.

Contact: Klynveld Bosbuam Hegener

Surgical Instruments and Medical Disposables: A survey of The Netherlands and Other Major Markets in the European Community

The report is presented in two parts. The first part discusses the demand, supply, market segments and market access for medical disposables and surgical instruments in the Netherlands. The second part of the report deals with the European market. A breakdown of the three main product caterogies is provided:

1) Wadding, Gauze Bandages, Napkins, Sanitary Towels, and Similar Articles
2) Syringes, Needles, Cannolea, Catheters, and Similar Articles
3) Other Medical, Surgical and Veterinary Instruments and Applicants

Contact: CBI
P.O. Box 30009
3001DA
Rotterdam, The Netherlands
Fax: 010-4114081

The Netherlands: Market Report for Medical Instruments & Equipment

This report looks at the prospects for companies to market their products in the Netherlands. It gives an insight into the structure and framework of the Dutch health service and decentralized agencies. Market trends and fluctuations are examined. Exhibitions, medical societies, health care publications, as well as some manufacturers are listed.

Contact: Commercial Department
British Embassy
The Hague

10.2.5 United States

Annual Survey of Manufacturers

Conducted every year except for those years ending in 2 and 7 (ie: excluding 1982 and 1987). Probability-based sample of approximately 56,000 establishments. (For description see Economic Censuses: Census of Manufacturers)

Economic Censuses: Census of Manufacturers

Conducted during those years ending in 2 and 7 (ie: 1982 and 1987).

Medical device data is covered under six Standard Industrial Classification (SIC) codes:

3841	Surgical andd medical instruments
3842	Surgical appliances and supplies
3843	Dental equipment and supplies
3844	X-ray apparatus and tubes
3845	Electromedical equipment
3851	Ophthalmic goods

Information per establishment is provided such as numbers, employment, shipments, expenditures, inventories, etc.

U.S. Industrial Outlook

Section 51, Medical and Dental Instruments and Supplies

Provides information on cost containment, medical device legislation, technology, foreign trade, trends, and long term prospects.

Contact: U.S. Department of Commerce
Bureau of Census Telephone: 301-763-1503

Philippe Morris

10.2.6 List of Consultants / Associations

Belgium (Association)

BELCOMET
c/o Fabrimetal
Rue des Drapiers
1050 Bruxelles

Telephone: 32 2 510 23 11
Fax: 32 2 510 23 01

Mr. Rambout

Israel (Consultant)

MOP - Consulting and Medical Projects Development
29 Kazan Street
Raanana, Israel
43611

Telephone: 972 52 450594
Fax: 972 52 918374

Mr. Fred Zinger

Netherlands (Consultant)

IMC
Achter Emer 17
4824 ZA BREDA

Telephone: 076 411964
Fax: 076 419643

R. Van de Graaf

Sweden (Consultant)

Draco AB
Box 34
221 00 Lund
Sweden

Telephone: 46 16 60 00
Fax: 46 11 35 78

Galenus AB
Dragarbrunnsgatan 63
753 20 Uppsala
Sweden

Telephone: 18 12 06 40

Italy (Consultant)

Pharma Group
Sede Legale - Direzione e Uffici
Via Larga
31-220122
Milano, Italy

Telephone: 02 806595
Fax: 02 8058107

Mr. Mario Ladina

10.3 World Market

Clinica Fact Book, 1990

£ 95
$ 185 (US)

This yearly publication provides facts on healthcare expenditure, establishments, medical device markets, laboratory tests, etc. The book provides statistics for both worldwide and individual countries.

Contact: Publications Ltd.
18120 Hill Rise
Richmond, Surrey
TW1 06UA
Telephone: 01-948-3262

Medistat, Medical Markets in Western Europe

$ 930 (US) - Volume I & II

Over 300 pages of detailed facts, figurs and analysis of the medical markets in 17 individual countries. The report contains 5 sections : health sector profile, healthcare development, market analysis, market access, and directory. Monthly publications are also available.

Contact: WMI Publications Ltd.
MDIS House
8 Eastagate Square
Chichester, West Sussex
PO19 1JN
United Kingdom
Telephone: 0243-533 322
Fax: 0243-533 418

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Statistics Canada Publications

Other Services

International Market Publications

11. Proposal for Industry-Wide Market Survey in Years One and Five of the Sector Initiative

11.1 Introduction

11.1.1 Problem Definition

Over a number of years, both government and industry have recognized the significant imbalance of trade that has plagued the Canadian medical sevices industry. Of the approximate $2.4 billion in purchases of medical devices by Canadian hospitals, laboratories, clinics, doctors' offices, etc. in 1990, over 85% were imported versus domestically manufactured. If no major government / industry strategic initiatives are undertaken during the years to come, the level of manufacturing commitment by both small Canadian owned firms as well as multinationals will continue to decline, and result in a weakened industry more dependent on foreign resources and directions.

ISTC seems to be determined to find a way to reverse the current trend.

Information will be needed during the course of the sector campaign, especially in year one and five, to measure the impact of the campaign. The study on Performance Indicators, prepared by ResCan uncovered the lack of data that would be relevant, detailed, timely and complete

11.2 Objectives

Conduct a complete study of the Canadian market and industry in year one and five of the sector campaign.

The study should meet the needs of:

- ISTC
- Provincial governments
- Industry
- TIMEC
- Trade Associations
- others, such as RD or financial community

The study will cover a wide range of topics, such as:

- Market size
- Market trends
- Market break-down by type of institutions
- Climate of competition
- Opportunity identification

It will deal with questions on imports, exports, shipments, employment, status of R&D and company market shares.

11.3 Study Objectives

In order to meet the study objectives, the Consultant will undertake the following tasks:

- Establish the total current market in Canada in terms of units and $ for a chosen sub-sector. (definition MEDEC, ResCan or a cross-referenced version of both classifications)
- Report on the principal segmentation of the market:
  - hospitals and other publicly owned institutions
  - private labs and other privately owned facilities
- Report on the geographical segmentation of the market
- Give a break down by generic product groups and individual products within each of the categories
- Evaluate current and emerging climate of competition
- Analyze buyers' attitude towards Canadian made products
- Identify obstacles faced by newcomers in trying to penetrate this market
- Report on imports, exports and shipments
- Report on employment (manufacturing vs R&D) and on R&D expenditures as % of sales
- Comments, recommendations

The Consultant will provide the services of professional market researchers, computer specialists and other staff to carry out the survey, to satisfy the objectives listed above.

11.4 Methodology

11.4.1 General

Available statistics, publications and research work will be identified as background information. In addition to a review of the ResCan library, current data will be collected from all Canadian sources judged as relevant to the survey.

The Consultant's database and extensive experience in institutional and medical market research will be the base of the questionnaire and sample design.

Market segmentation by type of product, cross-referencing with MEDEC's definition can be done easily by the Consultant's team of medical doctors.

11.4.2 Data Retrieval

Institutional market data on medical devices, supplies and small equipment can be retrieved from the ResCan database.

The following information will be extracted:

- market size in $ by product category within the chosen sub-sector
- market size in SKU and $ by product, brand and company market share
- market trends
- average prices
- regional break-downs

11.4.3 Validation

Data retrieved from the ResCan data base will be validated with CEO's of major companies catering to the sub-sector studied. Depending on the sub-sector chosen, the # of personal and/or telephone interviews can be between 10 and 25.

11.4.4 Data Collection

- Primary data collection on end users' attitude towards Canadian made products, and obstacles faced by newcomers to break into this market, employment and R&D expenditures as % of sales.

- Provincial governments will be contacted to obtain data on epidemiological trends, and government healthcare budgets.

Pilot Study:

Within the selected sample, the Consultant will conduct a number of personal interviews to evaluate the questionnaire design. Only tested questionnaires will be used for interviewing.

Data Analysis and report writing

The Consultant will integrate the questionnaire and interviews with end users, manufacturers, distributors, and general information and statistics retrieved for the database to build the profile of the sub-sector studied.

The report will describe the method of approach, detail the assumptions, document fully all sources of information and lay out the problems and limitations of the survey.

The Consultant will develop two types of questionnaires to be used during interviews with various categories of respondents *.

- public (hospitals, clinics, provincial labs, red cross, government laboratories, educational laboratories)

- private (diagnostic labs, x-ray and other clinics, industry lab, doctor's office, pharmacy, home health care retail stores)

The first is on attitudes alone and will be addressed to the institutional users. A total of 250 questionnaires will be sent by mail to the public sector facilities. (If the sub-sector chosen contains major capital equipment, the survey questionnaire may have to be expanded to include questions on purchases, age of currently used equipment, etc.)

The second is on attitudes as well as consumption. 500 questionnaires will be sent by mail to the private sector users. The Consultant will conduct a region by region survey of the market.

Secondary Data Collection

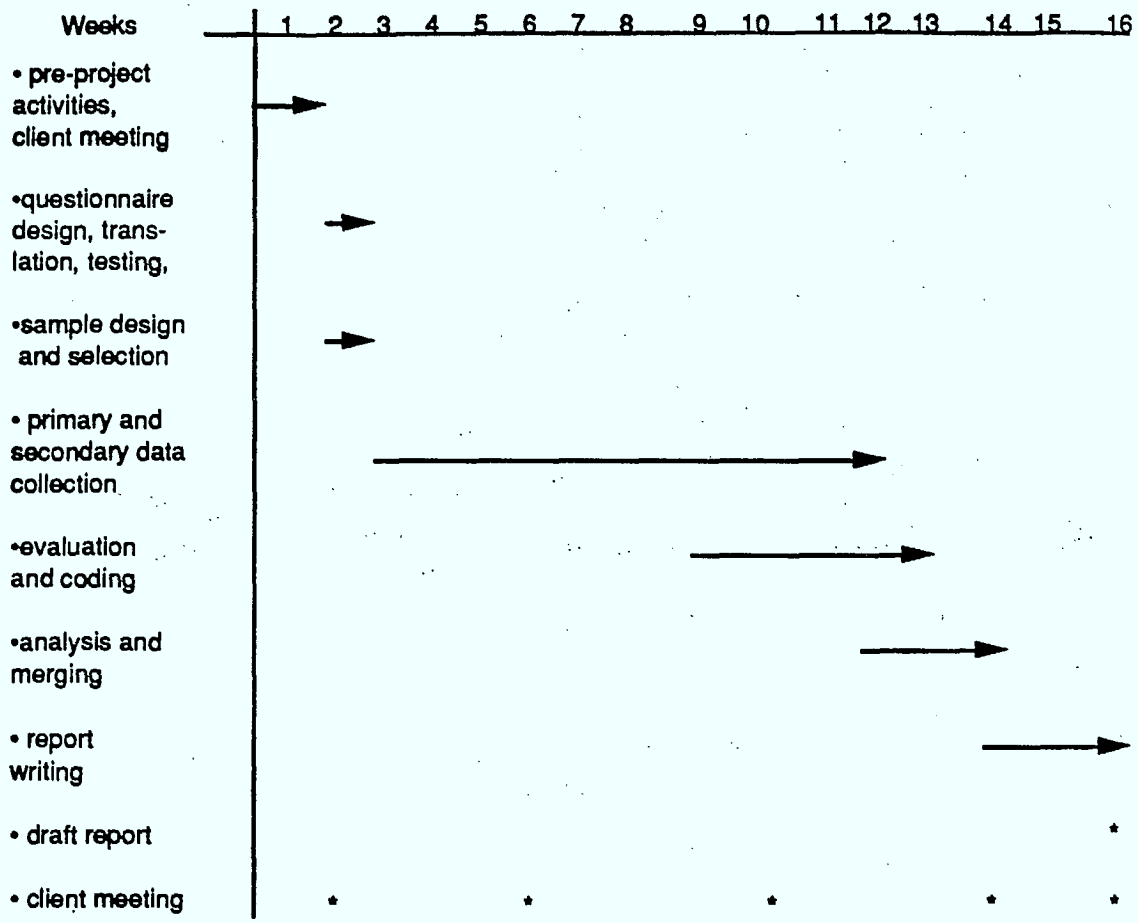
Statscan and ISTC's market intelligence departments will be contacted to obtain information on imports, exports, shipments, and transfer prices. A cross reference must be done on classifications.

A draft report will be submitted for discussion, and will be followed by a final report.

*List of public and private sector users depends on the sub-sector chosen.

11.5 Time Schedule

The research project will take 4 months:



11.6 Price of the Study

The price of the study cannot be determined without knowing the sub-sector to be surveyed.

11.7 Other Subjects to be Covered

- Study Team
- Company Qualification
- CV's