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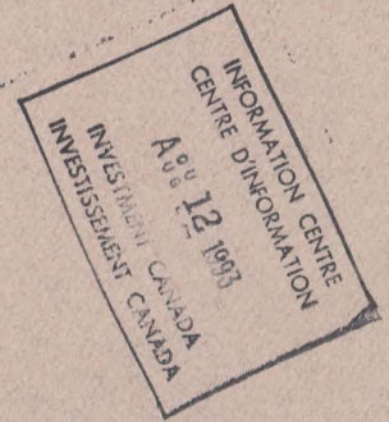
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THE CASE

FOR

INVESTING

IN CANADA



THE CANADIAN
MEDICAL DEVICES
INDUSTRY



INVESTMENT
CANADA

INVESTISSEMENT
CANADA

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THE CANADIAN MEDICAL DEVICES INDUSTRY
THE CASE FOR INVESTING IN CANADA

March 1993

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1.0 EXECUTIVE SUMMARY

The Canadian medical devices industry is a diverse, expanding sector which is increasingly serving global markets with high value-added products. Canada's business and research climate strongly supports the medical devices industry. In recent years, Canadian scientists, doctors and engineers have made important contributions to the fields of surgery, diagnostics, medicine, and biomedical engineering. In the area of health-care delivery, the Canadian system is viewed by many as the best in the world.

Today, the Canadian medical devices industry comprises 800 firms, of which approximately 90% are Canadian-owned. Thirty per cent of the \$900 million domestic output is exported, primarily to the United States. Despite its relatively small population, Canada is one of the world's leading consumers of medical devices with domestic consumption of \$2.5 billion, nearly 80% of which is supplied by imports, primarily from the U.S.

Technological innovation is a powerful tool used by the industry to enhance its global competitive position. Canada's technology base is solid and extensively supported by both the public and private sectors; its components include both small and large companies and a world-class network of universities and hospitals, as well as government laboratories such as the National Research Council. Canadian R&D centres and many universities have made numerous important contributions to the medical devices field.

Canada's R&D infrastructure has grown rapidly in the past decade. Total R&D expenditure has more than quadrupled in the last 15 years. In 1992, Canada's total expenditure on R&D stood at \$10 billion, a level that is considered competitive with other G7 countries, when defence-related spending is excluded.

Canada is in an advantageous position to provide medical devices companies with access to innovative products and technologies. As a result of the most generous R&D tax credit policy in the industrialized world, Canada is a very attractive location for large companies to leverage their R&D investment.

Canada offers foreign medical devices companies a range of economic and business advantages including competitive tax rates, a well-educated and productive labour force, easy access to the American market, and well-developed support industries such as microelectronics, advanced industrial materials, and biotechnology.

Canada's regulatory system is widely recognized for its high standards. Moreover, it is especially well-suited for medical devices companies engaged in global marketing, as medical devices manufactured in Canada for export must simply comply with the regulations of the importing country.

The Canadian medical devices industry is in an ideal position to achieve rapid economic and technological growth. Canada provides a superior environment in which enterprising, internationally-oriented firms can develop and manufacture medical device products for the global marketplace.

2.0 THE CANADIAN MEDICAL DEVICES INDUSTRY

2.1 Industry Overview

By the end of 1992, there were over 800 Canadian manufacturers of medical devices employing over 20,000 people. Of these manufacturers, approximately 90% are Canadian-owned. Many of the Canadian companies are technology-based and niche market oriented, exporting a large percentage of their products.

A significant number of these Canadian-owned companies have leading-edge technologies and unique, innovative devices. Areas of particular strength include cardiovascular, medical imaging, in vitro diagnostics, orthopaedic and assistive devices.

The following provides additional facts on the Canadian devices industry.

- Market size of C\$2.5 billion annually
- One of the world's top 10 markets for medical devices
- Per capita consumption in Canada is comparable to per capita consumption in the U.S.
- One-fifth of consumption is produced domestically
- 30% of all domestic manufacturing is exported, primarily to the U.S. (53%) and to the EC (23%)
- 35% of all companies have between 20 and 100 employees and 5% have more than 250 employees
- 60% of Canadian manufacturers have sales exceeding \$1 million
- Canadian manufacturing covers 1,500 classes of devices
- Ontario and Québec together account for 72% of shipments. Western and Atlantic Canada account for 22% and 6% respectively

Canadian devices production has grown steadily over the past 15 years. The dollar value of production has more than tripled since 1978, reaching an estimated \$900 million in 1992.

2.2 Multinational Investment in Canada

Two international economic forces - the globalization of markets and the rationalization of production - have not left the Canadian medical devices industry unaffected. In the search for continued viability and competitiveness, Canadian firms have recognized that the development and penetration of niches in the world marketplace is of utmost importance.

Several U.S. and European multinationals have been making increasingly important contributions to the Canadian devices industry. Companies such as Baxter, American Cyanamid, Johnson and Johnson, and Shields have identified advantages in forming strategic alliances with emerging companies in the health-care industry. Such arrangements range from collaborative R&D to equity participation to distribution agreements.

In the face of their corporate headquarters' quest for strategic changes in response to the influences of globalization and rationalization, Canadian subsidiaries have actively pursued distinct mandates to ensure their future prosperity. One avenue taken has been to manufacture high-technology niche products to capitalize on the flexibility and cost effectiveness of Canadian plants. Another approach has been to capture significant benefits by repositioning the Canadian plant production for export markets.

A multinational company which selects Canada as an export base has at its command a strong technology base, a less litigious environment, and a favourable regulatory climate. These factors, combined with government programs, all translate into significant cost savings.

Some of the Canadian subsidiaries that have worked with international manufacturing mandates include:

- | | |
|----------------------|-----------------------------|
| • Baxter | parenteral solutions |
| • Becton Dickinson | vinyl gloves |
| • 3M | artificial ligaments |
| | tapes |
| | cardiac electrodes |
| • Smith & Nephew | bandages |
| • Johnson & Johnson | closure devices |
| • Davis & Geck | sutures |
| • Everest & Jennings | wheelchairs |
| • Medtronic | pacemakers |
| • Graphic Controls | electrodes |
| | video printer products |
| • Mallinckrodt | diagnostics |
| • Amso | hospital/laboratory washers |
| • Luxo Lamp | medical examination lights |

3.0 CANADIAN TECHNOLOGICAL CAPABILITIES

3.1 Overview

Canada has developed an extensive infrastructure to support research and development in many fields including medical devices. The following provides some information on R&D in Canada:

- Canada's total expenditure in 1992 on R&D amounted to approximately \$10 billion.
- Private companies account for 53% (1992) of all R&D activity in Canada, the remainder being conducted at universities, hospitals and government laboratories.
- Direct government expenditure in 1992 was approximately \$3.7 billion.
- Canada spends 1.43% of its GDP on R&D - comparable to **non-defence** spending by the U.S. and other G7 countries.
- Human resources devoted to R&D increased from 106,760 in 1987 to 111,990 in 1989 - an increase of 4.9%.
- 55% of Canadians engaged in R&D activities were scientists or engineers, 25% were technicians and the remainder were support staff.
- In 1990, a total of \$1 billion was spent on Canadian health-care research, of which approximately 8% was directly applicable to medical devices.
- Metropolitan Toronto is considered the third largest centre for medical devices R&D in North America.

3.2 Medical Device Research and Development

Health care is at the top of Canada's science and technology agenda. Canada is recognized as a world leader in the field of medicine and in the delivery of health care. It has also been the site of pioneering achievements in diagnostics and treatment in areas such as neuroscience, diabetes, and cardiology. Some significant developments are listed below.

- Discovery of insulin (1921-22) by Banting, Best and Collip at the University of Toronto
- Development of world's first heart pacemaker at the Toronto General Hospital (1950)
- The installation of the first cobalt 60 cancer therapy unit at Victoria Hospital (London, Ontario, 1951)
- Introduction of the world's first artificial kidney
- First use of the intra-aortic balloon pump in heart surgery (Toronto)
- Development of a catheter ablation technique to treat arrhythmias (Institut de Cardiologie de Montréal)
- Development of brain mapping techniques to enhance the understanding of localized functions of the brain (Montréal)
- Discovery of the carcinoembryonic antigen, produced by cancers of the colon, and development of the first immunological blood test for the presence of cancer (Montréal)
- Discovery of the gene that causes cystic fibrosis (Hospital for Sick Children, Toronto, 1989)
- Development of the use of L-DOPA in the treatment of Parkinson's disease

The thrust of Canada's science and technology initiative has resulted in health-care research which is leading-edge and which is focused on developing niche products with global appeal.

A network of 16 universities with medical faculties and over 85 hospital and clinical trial facilities provides the focus for innovation in the design, development, and testing of medical devices in Canada. The majority of the R&D initiatives under way in Canada can be classified into six broad sectors, with specific niches within each sector as the focus of attention. Table 3.1 provides some detail of the six sectors of activity.

Table 3.1 Medical Devices Sectors in Canada

<p style="text-align: center;">Cardiovascular</p> <ul style="list-style-type: none"> • catheters • circulatory assist devices • defibrillators • heart valves • imaging • pacemakers • stents • vascular grafts 	<p style="text-align: center;">Diagnostics</p> <ul style="list-style-type: none"> • biotechnology - in vitro • EKG/EEG/magnetic resonance • imaging • instrumentation • robotics • 3-D ultrasound
<p style="text-align: center;">Orthopaedics/Prosthetics Orthotics</p> <ul style="list-style-type: none"> • artificial joints/ligaments • biocompatible/bio-active coating materials • surgical instrumentation • testing devices • myoelectric control 	<p style="text-align: center;">Assistive Devices</p> <ul style="list-style-type: none"> • aids to daily living (ADLs) • communications and control aids • seating • postural support • robotics • transfer/mobility devices
<p style="text-align: center;">Medical Imaging</p> <ul style="list-style-type: none"> • high resolution • mapping and reconstruction • radiation scatter • storage and transmission • 3-D modelling 	<p style="text-align: center;">Biomaterials</p> <ul style="list-style-type: none"> • anti-infective coatings • biodegradable/non-biodegradable • blood compatible materials • hard surfaces • soft tissue compatible materials

3.3 University R&D

Table 3.2 Medical Devices R&D at Canadian Universities

University	Cardiovascular	Diagnostics	Orthopaedics	Assistive	Imaging	Biomaterials
British Columbia			X	X	X	
Simon Fraser		X	X		X	
Alberta	X	X			X	
Calgary	X	X	X		X	
Manitoba		X		X	X	
Western	X		X		X	
Waterloo				X	X	
McMaster	X					
Toronto	X		X	X	X	X
Queen's			X			X
Ottawa	X		X		X	X
Montréal	X		X		X	X
McGill	X		X	X		
Sherbrooke					X	
Laval	X				X	X
New Brunswick			X	X	X	
Dalhousie	X	X	X			X
Memorial		X	X	X		

Please see Appendix I for additional details.

3.4 Centres of Excellence Network

Table 3.3 University Centres of Excellence in Health-Care Research

Program	Focus of Research
Canadian Aging Research Network University of Toronto	Assistive devices for home health care of elderly and disabled
Canadian Bacterial Diseases Network University of British Columbia	Antibiotics and other therapeutics, vaccines and diagnostics
Canadian Genetic Diseases Network University of British Columbia	Genes that directly cause or predispose humans to disease
Neural Regeneration and Recovery Network McGill University	Molecular level research involving neuronal survival, regrowth, reconnection
Protein Engineering Network University of British Columbia	Investigation of proteases involved in infectious diseases and growth factors involved in wound healing and cancer
Inspiraplex Respiratory Health Network McGill University	Prevention, diagnosis, treatment and rehabilitation for cystic fibrosis, asthma and other respiratory diseases
Institute of Robotics and Intelligent Systems Precarn Associates	Advanced R&D in robotics and artificial intelligence

For additional information, please see Appendix II.

3.5 Institutional R&D

Table 3.2 **Medical Devices R&D at Canadian Institutes**

Centre	Cardiovascular	Diagnostics	Orthopaedics	Assistive	Biomaterials
ARCOR				X	
Fisher Rehabilitation			X	X	
Institut de Cardiologie	X				
Institut de Réadaptation			X	X	
Institut de Recherches Cliniques	X	X			
MacMillan Rehabilitation			X	X	
Ottawa Heart Institute	X	X			X
Ryerson Polytechnical			X	X	

Please see Appendix III for additional details.

4.0 BUSINESS FACTORS FAVOURING INVESTMENT

4.1 Overview

Canada offers a number of competitive advantages for investment in the medical devices industry. One of Canada's principal advantages is its favourable regulatory environment. A research and development or manufacturing facility located in Canada deals with fewer regulatory procedures relative to the U.S.

Canada is a very attractive location for companies to leverage their R&D investment - given the generous R&D tax incentive policy, the collaboration of governments, research institutions, hospitals and universities in research and development initiatives, and with access to the innovative products and technologies of the medical devices and related industries. Canada has the most generous tax treatment of R&D in the industrialized world.

There are a number of additional factors that combine to create a superior business environment in Canada. These factors include, but are not limited to, competitive corporate tax rates, a well-trained labour force with competitive wages, access to the North American market, government support for the industry, and well-developed support industries such as microelectronics, advanced industrial materials, and biotechnology.

These advantages are summarized as follows:

- Favourable regulatory environment
- Competitive taxation system
- Low cost and/or cost-shared R & D
- Availability of skilled professionals
- Cost-competitive labour
- Support industries
- Access to international markets
- Government support programs

4.2 Regulation and Litigation

Canada's medical regulatory system is widely recognized for its high standards. Medical devices products are regulated in accordance with the Food and Drugs Act and administered by the Field Operations Directorate and the Bureau of Radiation and Medical Devices (BRMD) divisions of the Health Protection Branch of Health and Welfare Canada.

The Canadian system is characterized by a program of voluntary compliance for the majority of medical devices products. Whereas certain products do require pre-market approval (Schedule V devices such as permanent implants, and intra-ocular lenses), the remaining medical device categories simply require notification of the BRMD within 10 days of first commercial sale. According to a recent study conducted by Arthur D. Little, Canadian regulatory requirements placed on medical equipment are viewed as being "relatively quick and transparent".

In addition, medical devices manufacturers located in Canada are not required to obtain domestic regulatory approval for export products. Canadian exporters must maintain data on file to substantiate the claim that the products are in compliance with the import country's regulatory requirements. The Little study also states: "Canada clearly has a regulatory advantage over the U.S. in the exporting of medical devices".

The Canadian business environment is significantly less litigious than that of the United States. In general, the Canadian legal system does not promote the use of legal means to receive compensation for medical malpractice. A study in the *New England Journal of Medicine* indicates that Canadian physicians are one-fifth as likely to be sued as American physicians¹.

4.3 Taxation

The Canadian corporate taxation system is highly competitive, providing specific advantages for companies with manufacturing or R&D activities in Canada. Tax in Canada is collected at both the federal and provincial levels.

The federal budget tabled on February 25, 1992 reduced the overall corporate tax rate to 22% effective January 1, 1993, and to 21% effective January 1, 1994. Several recent provincial budgets have emulated the federal initiative by reducing both small business and corporate tax rates.

The proposed federal corporate rate of 22%, coupled with an average provincial manufacturing and processing tax of 13%, offers an average combined tax rate of 34% in Canada. As illustrated

¹ 1991. Coyte et al. "Medical Malpractice The Canadian Experience". *The New England Journal of Medicine*. 324:89-93.

1991. Dr. Arthur D. Little, "Strategic Analysis of the Medical Devices Industry in Canada"

in Table 4.1, the combined tax rate for Canada compares very favourably to the average corporate taxation rates in the United States and other industrial countries².

In a concerted effort to further improve Canada's international competitive position, the federal budget also included a number of other changes affecting business taxation. The **capital cost allowance rate** for manufacturing and processing machinery acquired after February 25, 1992 was increased from 25% to 30%. At the same time, the government announced that it is prepared to negotiate reciprocal tax treaties with its trading partners to reduce the **withholding tax rate** on direct dividends to 5%. Negotiations with the Government of the United States have commenced.

Table 4.1: Combined Corporate Manufacturing Income Tax Rates

Country/City	Combined Tax Rate (%)
Canada	34.0 (Average)
United States	
- California	40.1
- Illinois	37.2
- Michigan	35.5
- New York	40.3
- Pennsylvania	46.2
	39.6
France	
- Paris	42.0
Italy	
- Milan	47.8
United Kingdom	
- London	33.0
Japan	
- Tokyo	51.6
Germany	
- Dusseldorf	51.8

Source: Industry, Science and Technology Canada, Oct. 1992, and Samson, Belair/Deloitte & Touche Tohmatsu International.

² Source: The budget Papers, Department of Finance, February 25, 1992, Industry, Science and Technology Canada and Samson, Belair - Deloitte & Touche Tohmatsu International, Oct., 1992.

4.4 Research and Development Tax Incentives

According to Deloitte & Touche and the Conference Board, Canada offers the most generous tax treatment of R&D in the industrialized world. This tax treatment makes Canada particularly attractive for large companies seeking to maximize their R&D investment.

Federal R&D Expense Deduction

R&D expenditures are generally separated into current expenditures, which include salaries of scientific and technical personnel and the cost of materials used, and capital expenditures, which include the cost of equipment and facilities. Although most countries allow current expenditures to be deducted from income in the year they are incurred, there are differences in the ability to write off capital expenditures for R&D purposes in the year they are incurred.

Canada provides a large R&D performer with the option of immediate write-off of capital R&D expenditure or deferral for claim in a future year.

Federal R&D Tax Credit

In addition to the expense deduction, the federal government also allows a 20% **investment tax credit** on R&D expenditures. This tax credit may then be used to offset up to 75% of federal taxes payable. In addition, qualifying Canadian-controlled private corporations (CCPCs) are eligible for a 100% refundable tax credit on current expenditures at the rate of 35%.

In addition, industry is now entitled to claim 65 cents on each dollar of direct R&D salary expenses when calculating intramural R&D overhead costs eligible for investment tax credits. Another recent change allows for a new partial investment tax credit for capital equipment shared by the corporate R&D group with other segments of the business including production and quality control operations.

The competitive federal R&D tax credit system in Canada is complemented by further tax credit incentives that exist in some provinces.

As shown in Table 4.2, Canada offers a very favourable tax treatment of R&D in comparison to other countries in the G-7.

**Table 4.2: International Comparison
After-Tax Cost of \$1 R&D Expenditure**

Country	After-Tax Cost (\$)
Canada	
Newfoundland	0.423
Nova Scotia	0.358
New Brunswick	0.430
Prince Edward Island	0.437
Québec	0.447
Ontario	0.461
Manitoba	0.477
Saskatchewan	0.494
Alberta	0.540
British Columbia	0.502
United States	
California	0.582
Illinois	0.628
Japan	0.494
Italy	0.554
United Kingdom	0.650

Source: Jacek Warda. *International Competitiveness of R&D Tax Incentives*. The Conference Board of Canada, May 1990.

4.5 R&D Leveraging

A high degree of industry-university interaction has developed in Canada. University researchers actively seek private sector contracts to supplement their public or para-public funding. Industry-university contacts have increased the scientific community's openness and willingness to work with industry at developing commercially viable products.

For the medical devices industry, combining university expertise with various matching programs and R&D tax credit incentives allows a company to further leverage its Canadian R&D spending. The value of every R&D dollar spent in a university by a private company in Canada can be equivalent to a real expenditure of **six dollars**.

The following chart provides an example of the benefits of Canadian R&D spending. The university contribution is assumed to include researcher and graduate student time, facilities, equipment and materials. Estimates indicate that a university contribution is equivalent to one-half the combined monetary contribution of both the private sector and government.

Company expenditure	\$100,000
Government matching	100,000
University contribution	<u>100,000</u>
Total Budget	\$300,000

Assuming that the R&D is carried out in Québec, the after-tax cost of the \$100,000 of R&D expenditure would be \$44,700. In Ontario, the cost would be \$46,100. **Thus, a private corporation working jointly with a university need only spend approximately \$45,000 in order to obtain an R&D budget equivalent to \$300,000.** Similar leveraging is found in all other provinces.

4.6 Skilled and Cost Competitive Labour

Canada is rich in its availability of highly talented research professionals. Canadian physicians and hospitals are considered to be among the best in the world. The practice of medicine in Canada is similar to that in the U.S., making Canada an excellent location for clinical work related to medical devices.

Canadian post-secondary institutions with engineering and science departments, and a strong network of 16 world-class universities with medical faculties, produce a steady flow of new graduates every year. Table 4.3 provides a breakdown of graduates from Canadian universities and colleges in the fields of engineering, sciences and the health professions.

**Table 4.3: University Graduates, 1991
Discipline and Degree**

Discipline	B.Sc./B.Eng.	M.Sc./M.Eng./Ph.D.	Total
Chemical Engineering	623	197	820
Electrical Engineering	1,905	555	2,460
Mechanical Engineering	1,836	321	2,157
Other Engineering	2,760	1,066	3,826
Chemistry	972	385	1,357
Computer Science	2,231	375	2,606
Physics	683	348	1,031
Biochemistry	827	87	914
Biology	4,049	464	4,513
Health Professionals	7,548	1,361	8,909
Total	23,434	5,165	28,593

Source: Statistics Canada

Professional and secretarial wages compare favourably with those in the U.S. and other G7 nations.

Table 4.4:

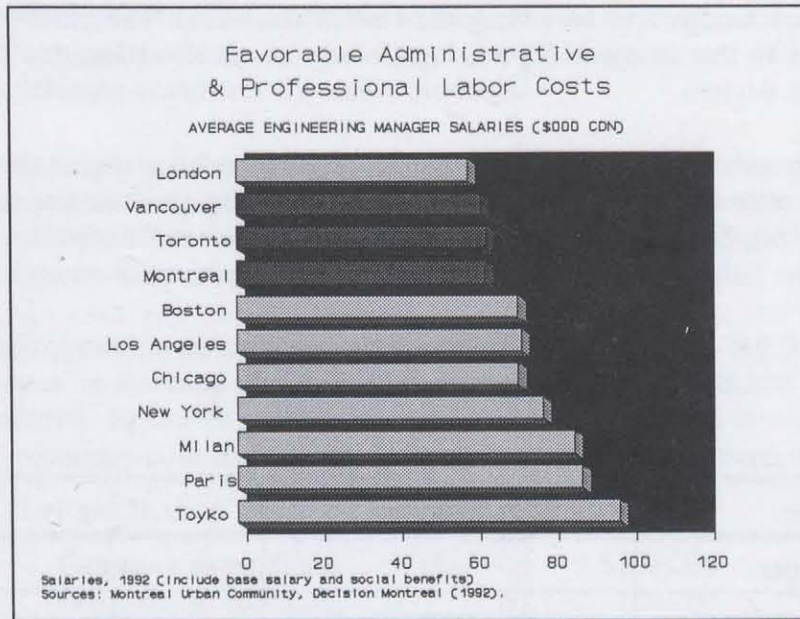
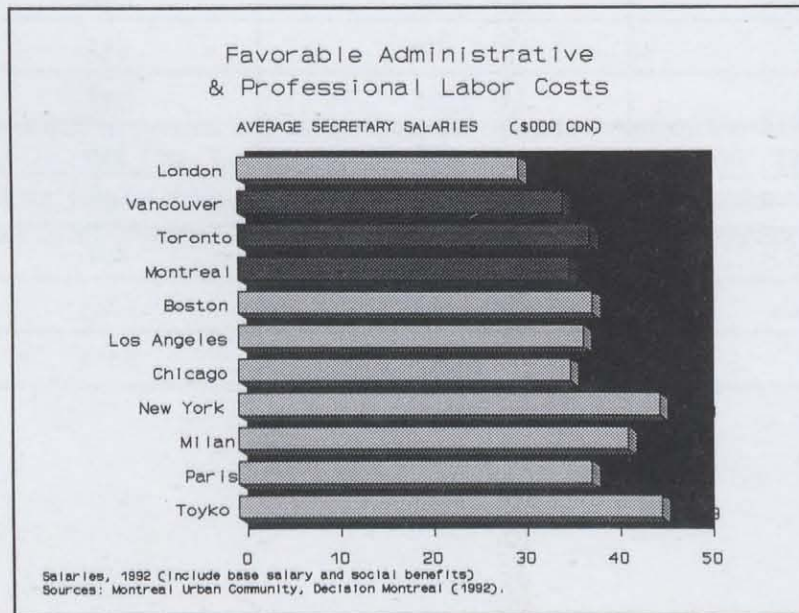


Table 4.5:



Note: Includes payments made directly to worker, pay for time worked and not worked, bonuses, special payments and the cost of payments made in kind, and employer contributions legally required, contractual and private benefit plans.

4.7 Support Industries

The base technologies considered necessary to develop new medical devices, such as advanced materials, microelectronics, biotechnology, and pharmaceuticals, have also received focused government attention in Canada. This effort has resulted in an accumulation of world-class technologies and technical expertise within Canadian companies, research institutes and universities in the field.

ADVANCED INDUSTRIAL MATERIALS

The applications of advanced industrial materials to the medical devices industry are far-reaching: ceramics for prostheses, carbon/carbon composites for cardiovascular and prosthetic applications, and graphite composites in X-ray applications.

Canadian industry consists of a wide range of firms dedicated to the production of functional and structural advanced materials. There are over 50 manufacturers in Canada in the area of advanced ceramics alone. These range from IBM, which produces hybrid ceramic circuits, to Hamilton Porcelain, which produces ceramic parts made of alumina, zirconia, and boron nitride powders.

PHARMACEUTICALS

The Canadian pharmaceutical industry is well-developed, showing real growth of approximately 6% per year for prescription drugs and 3% for over-the-counter products. Average after-tax profit on capital employed is approximately 20% and a return on sales of 8.3%.

Central Canada accounts for 85% of the pharmaceutical sector's manufacturing establishments, Ontario and Québec accounting for 50% and 35% respectively. With an asset base of over \$2.0 billion, pharmaceutical companies in Ontario and Québec spend over \$300 million in direct research and development each year.

It is important to note that R&D expenditures in medical devices qualify under the R&D commitments made to Canada by Canadian research-based pharmaceuticals manufacturers.

BIOTECHNOLOGY

In the last 10 years, Canada has developed a rapidly growing biotechnology industry which compares favourably with that of other OECD countries. In 1992, over 400 biotechnology firms employing over 9,500 people in Canada were involved in developing and commercializing relatively new techniques in genetic engineering, monoclonal antibodies, and plant and animal tissue culture as well as novel fermentation processes. The rate of creation of new firms is approximately 10% per annum.

Thirty-eight per cent of Canadian companies actively involved in biotechnology are concentrated in the health-care sector. In 1991, total revenues were \$1.3 billion, out of which \$500 million was spent on R&D. The projected growth of revenues in this sector is 50% per annum.

TELECOMMUNICATIONS

Canada's telecommunications industry has consistently demonstrated technological leadership on a global scale. In 1990, the industry employed 55,000 people and generated annual revenues of \$7.4 billion, of which over 37% were the result of exports, primarily to the U.S. and Europe.

The strength of the Canadian telecommunications industry lies in its strong R&D capabilities. On average, both small and large firms spend well in excess of 10% of their sales on R&D. Northern Telecom, primarily through Bell-Northern Research, spends approximately \$750 million annually on research and development.

SOFTWARE AND INFORMATICS

The Canadian informatics and software industry is one of the fastest growing in the economy. Ranked among the 10 largest in the world, Canada's software products market is estimated at \$1.25 billion for 1992 and expected to exceed \$2 billion by 1997. The industry consists of approximately 5,600 firms which employ 35,000 people. Although highly successful software producers can be found in every province, they are concentrated in Ontario, Québec, Alberta, and British Columbia. Canada's strengths lie in the development of specialized software applications and customized software. Several innovative packages in health care, education, and geographic information systems have achieved international recognition.

MICROELECTRONICS

The Canadian microelectronics industry is small but has numerous pockets of excellence. The industry has an estimated output value of \$500 million of which two thirds was used for in-house consumption. Canada's microelectronics industry is recognized as world-class calibre. Over the years, the communications industry has served as the catalyst for the microelectronics sector. The presence of Bell-Northern Research and other research labs created the critical mass for the first generation of semiconductor and silicon companies. Today, this competence is well-distributed across the country due to the achievement by Canadian-based firms of prominent positions in several niche markets. Over 70% of the industry's manufactured production not destined for domestic use in communications equipment is exported to the United States, Europe and Japan.

4.8 Government Support

Both the provincial and federal levels of government have taken strong initiatives in encouraging the growth of the medical devices industry in Canada. There has been a demonstrated willingness to work closely with industry and R&D institutions alike in order to provide solid infrastructure and support.

A wide array of programs exist in Canada which provide significant cost and scientific advantages to the Canadian medical devices industry. Whether companies prefer tax credits, grants, assistance for research and development or training programs, the various levels of government have programs which can assist in augmenting the financial resources of the company concerned.

A number of business activities may be eligible for government support, including:

- Feasibility Studies
- Research and Development
- Engineering Support
- Capital Investment
- Export Marketing
- Employee Training

Details of both federal and provincial assistance programs are provided in Appendix IV.

4.9 Access to International Markets

CANADA-U.S. FREE TRADE AGREEMENT (FTA)

The 1989 Canada-U.S. Free Trade Agreement has increased and secured access to Canada's largest trading partner, the U.S.A. The FTA builds on a long history of economic co-operation between the two countries. Prior to January 1, 1989, 80% of Canadian exports entered the U.S. market duty free. Tariffs on the remaining 20%, which meet the FTA's North American content requirements, are being progressively phased out over a 10-year period. In fact, ongoing bilateral negotiations and consultations with domestic industry have accelerated the tariff removal schedule on hundreds of products.

There are several provisions in the FTA which aim to reduce many of the non-tariff barriers which exist in the North American medical devices industry. Standards in manufacturing, testing and certification will be harmonized wherever possible.

Also under the FTA, Canadian products will receive equal treatment on most sales to U.S. government departments. Travel and temporary residency in the U.S. will be eased for Canadian professionals.

NORTH AMERICAN FREE TRADE AGREEMENT (NAFTA)

The North American Free Trade Agreement among Canada, the United States and Mexico which will be implemented on January 1, 1994 will create the largest free trade zone in the world.

Guaranteed access to a market of 360 million with a combined GNP of US\$5,934 billion will make Canada an ideal choice for technology-dependent, niche-oriented operations.

5.0 BUSINESS OPPORTUNITIES

5.1 Overview

Companies are continually looking for new opportunities where unique technologies exist and where the business climate is favourable. The following section lists a few of the mechanisms which are available to foreign companies wishing to take advantage of technology and business related opportunities in the Canadian medical devices industry.

5.2 Restructuring for Globalization

Both globalization and free trade in North America have changed the way that multinationals view their markets and operations. Many multinationals are encouraging their subsidiaries to become more specialized manufacturers of a narrower range of products for domestic as well as international markets.

Canadian subsidiaries such as Becton Dickinson, 3M, Baxter and Mallinckrodt have developed geographical manufacturing mandates, resulting in production for international markets.

These companies serve as examples of how operations in Canada can take advantage of favourable and harmonized regulatory practices, world-class clinical trials, close relationships with research institutes and hospitals, and competitive labour costs, in order to prosper under the new global market conditions.

Such operations, particularly those with strong technological capabilities and, which manufacture for niche markets are ideals for success within a multinational framework.

5.3 Strategic Alliances with Canadian Firms

Of Canada's 800 medical devices manufacturers, many smaller Canadian medical devices firms are actively seeking strategic alliances to enhance their market opportunities in the global arena.

- These companies have unique product and manufacturing technologies, which offer a range of potential strategic business opportunities for multinationals.
- Many of these companies are new spin-off operations from university-led technologies that were developed for commercialization.
- Companies often have established links to Canadian university and hospital systems, allowing for quick and cost-effective development of new medical devices from the prototype stage, through clinical testing, to final design and commercialization.
- These operations often have compact R&D teams that have improved communication and fast turnaround capabilities.
- Successful companies can access government assistance programs that effectively leverage the cost of product development and manufacturing.
- They often possess niche technology capabilities that offer new product opportunities with global potential.
- They have a good working knowledge of the Canadian regulatory environment with respect to product clinical trials and product approvals to suit both domestic and international regulatory requirements.

5.4 Product Development Through University/Technology Centres

Canada's scientific community is considered world-class. In the fields of medical devices, pharmaceuticals, advanced materials, and microelectronics, Canadian institutional scientists have unique technologies and can claim a number of "world firsts".

When these academic strengths are combined with hospital and clinical test facilities that are also at the leading edge, a "critical mass" of specialist expertise provides an ideal environment for advanced research and product development activity.

The advantages of working with Canadian technology centres include:

- focused approach toward innovations in medical devices
- desire to develop and commercialize products through strategic partnerships with industry
- free and open communication between clinicians with varied skills in many departments and hospitals
- access to world-class researchers and scientists in the enabling and basic sciences at the universities within the network
- highly supportive provincial governments providing environment and assistance programs that encourage product development

Table 5.1 provides an outline of the various technology centres operating in six medical devices sectors. Additional technology centres may be involved in R&D activity in these sectors.

Table 5.1 Canadian Technology Centres

<p style="text-align: center;">Cardiovascular</p> <ul style="list-style-type: none"> • University of Alberta • University of Calgary • Dalhousie University • Institut de Cardiologie de Montréal • Institut de Recherches Cliniques de Montréal • Université Laval • McGill University • McMaster University • Université de Montréal • University of Ottawa Heart Institute • University of Toronto (CCR) • University of Western Ontario 	<p style="text-align: center;">Medical Imaging</p> <ul style="list-style-type: none"> • University of Alberta • University of British Columbia • University of Calgary • Université Laval • University of Manitoba • Université de Montréal • University of New Brunswick • Université de Sherbrooke • University of Ottawa • Simon Fraser University • University of Toronto • University of Waterloo • University of Western Ontario
<p style="text-align: center;">Orthopaedics/Prosthetics Orthotics</p> <ul style="list-style-type: none"> • University of British Columbia • University of Calgary • Dalhousie University • Institut de Réadaptation • McGill University • Memorial University • Université de Montréal • University of New Brunswick • University of Ottawa • Queen's University • Ryerson Polytechnical Institute • Simon Fraser University • University of Toronto • University of Western Ontario 	<p style="text-align: center;">Assistive Devices</p> <ul style="list-style-type: none"> • ARCOR • University of British Columbia • Fisher Rehabilitation Engineering Centre • Institut de Réadaptation • Institut de Recherche Cliniques de Montréal • Hugh MacMillan Rehabilitation Centre • University of Manitoba • McGill University • Memorial University • University of New Brunswick • Ryerson Polytechnical Institute • University of Toronto • University of Waterloo • University of Western Ontario
<p style="text-align: center;">Diagnostics</p> <ul style="list-style-type: none"> • University of Alberta • University of Calgary • Dalhousie University • Institut de Cardiologie de Montréal • Université Laval • University of Manitoba • Memorial University • Institut de Recherches Cliniques de Montréal • Simon Fraser University 	<p style="text-align: center;">Biomaterials</p> <ul style="list-style-type: none"> • Dalhousie University • Université Laval • Université de Montréal • University of Ottawa • Ottawa Heart Institute • Queen's University • University of Toronto • University of Western Ontario

Please see Appendices I and III for additional details.

5.5 New Companies/Divisions

Canada's attractive technological and regulatory environment provides ideal conditions in which small high-tech companies or autonomous high-tech operating divisions of multinationals can flourish. The advantages are many:

- the new company/division can be established close to a network specializing in a selected technological niche in order to access the network's scientific and technology resources, and its skilled base of scientists
- maintenance of low overheads by taking advantage of the high standard of facilities already in place
- the cost of technology and product development can be reduced by taking advantage of R&D tax credits and government assistance programs
- international markets can be accessed more quickly

5.6 Product/Technology Licensing

Technology licensing is recognized as an invaluable tool for launching products and generating revenue for institutions, which, in turn, funds ongoing research and development work. Canada has many innovative ideas emerging from its product development institutional system. Governments also recognize that the licensing of technology can be beneficial as part of a larger effort to build Canada's medical devices industry.

For the multinational, acquiring technology or product licensing agreements offers many advantages, not least of which is the possibility of the speedy global commercialization of new innovative products.

APPENDIX I

UNIVERSITY RESEARCH IN MEDICAL DEVICES

UNIVERSITY OF ALBERTA, Edmonton, Alberta

UNIVERSITY OF BRITISH COLUMBIA, Vancouver, British Columbia

UNIVERSITY OF CALGARY, Calgary, Alberta

DALHOUSIE UNIVERSITY, Halifax, Nova Scotia

UNIVERSITÉ LAVAL, Québec, Québec

UNIVERSITY OF MANITOBA, Winnipeg, Manitoba

McMASTER UNIVERSITY, Hamilton, Ontario

McGILL UNIVERSITY, Montréal, Québec

MEMORIAL UNIVERSITY, St. John's, Newfoundland

UNIVERSITÉ DE MONTRÉAL, ÉCOLE POLYTECHNIQUE, Montréal, Québec

UNIVERSITY OF NEW BRUNSWICK, Fredericton, New Brunswick

UNIVERSITY OF OTTAWA, Ottawa, Ontario

QUEENS UNIVERSITY, Kingston, Ontario

UNIVERSITY OF SHERBROOKE, Sherbrooke, Québec

SIMON FRASER UNIVERSITY, Burnaby, British Columbia

UNIVERSITY OF TORONTO, Toronto, Ontario

UNIVERSITY OF WATERLOO, Waterloo, Ontario

UNIVERSITY OF WESTERN ONTARIO, London, Ontario

UNIVERSITY OF ALBERTA, Edmonton, Alberta

Medical devices research and development at the University of Alberta is conducted in a multi-faculty mode and through specific centres.

Biomedical Design Centre

The principal mandate of the Biomedical Design Centre is to develop instrumentation and devices which promote advanced research in the medical sciences. Examples of devices which are currently under development include:

- instrumentation designed for the quantitative harvesting, processing and analysis of human pancreatic islet cells for transplantation
- robotic systems for the performance of high-risk clinical reactions
- extended precision image analysis processors

Heritage Research on Cardiovascular Diseases

Both basic and clinical scientists conduct research for this group at the University of Alberta. The areas of their current work include:

- the genesis of ventricular fibrillation and the factors determining successful defibrillation
- pathophysiologic studies of myocardial ischemia and re-perfusion injury
- studies of the perinatal changes of the heart and circulation
- application of molecular biologic technique to membrane transport in cardiac cells, especially in relation to calcium binding proteins and to the sodium/proton exchange protein
- study of the substrate utilization of the developing heart and the diabetic heart.

A major achievement within this group has been the development by Drs. F. Witkowski and P. Penkoske of non-polarizable, miniature silver-silver chloride electrodes which can be used in cardiac monitoring equipment. The new electrode permits stable transmural direct current unipolar electrogram recordings without disturbance of electrical activity. Applications are anticipated for many medical, industrial and scientific situations requiring small, non-polarizable, ion-sensitive electrodes.

Islet Cell Transplantation Group

The islet transplantation group is comprised of both basic and clinical scientists who are actively involved in diabetes research, from finding a better treatment to finding a cure. The R&D projects with possible commercial application include:

- development of an automated machine for islet isolation
- encapsulation of islets
- development of a glucose sensor for use in the artificial endocrine pancreas

Surgical-Medical Research Institute

The Surgical-Medical Research Institute is a multi-user facility that is used by both basic and clinical researchers from the University of Alberta. The facility offers surgical suites for large and small animal research, a biochemistry department with clinical monitoring, computing and photographic capabilities, and an electron microscope facility for TEM and SEM processing. The R&D projects with possible commercial application include:

- development of new equipment for laparoscopic surgery
- development of a tunable YAG laser
- testing drugs for pharmacokinetics
- anti-rejection drug therapy for graft rejection

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UNIVERSITY OF BRITISH COLUMBIA (UBC), Vancouver, British Columbia

The major provincial centre for medical and medical devices R&D, UBC conducts more than \$14 million in biotechnology research annually. A major focus of research at UBC is:

Positron Emission Tomography (PET)

- PET scanning and its applications to neurodegenerative disorders. PET scanners are used to carry out biochemical examinations in patients suffering from numerous brain disorders such as Alzheimer's disease, Huntington's disease, and other disorders including schizophrenia and depression.

Activities in the area of medical devices include:

- therapeutic diaper to reduce incidence of dysplasia in newborns
- kit and method for forming a temporary hip joint prosthesis
- device for the measurement of magnetic output of telephones
- telephone teaching and training device for hearing-aid users
- portable visual communication and captioning device
- temporary antibiotic loaded knee joint prosthesis for the management of infection
- brush-tip pin (BTP) array electrode set for detecting bioelectric signals
- computer-controlled head-fixation device for use with medical scanning devices
- portable infrared communication system
- computerized driver assessment module to evaluate the driving potential of disabled individuals

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UNIVERSITY OF CALGARY, Calgary, Alberta

The University of Calgary's primary areas of research are conducted by a number of specific groups of researchers, including:

- Neurosciences Research Group
- Cardiovascular Research Group
- Joint Injury and Diseases Research Group
- The Respiratory Diseases Research Group

The Neurosciences Research Group (NRG)

The NRG is an interdisciplinary group with research interest in:

- cellular properties of nerve cells and nerve networks
- neural control of movement
- growth and development of the nervous system
- neuro-degenerative diseases

NRG's development interests focus on the following:

- a non-invasive computer imaging system to provide on-line, high-resolution images of cortical activity. The system employs a novel and totally non-invasive technique for examining changes in the intrinsic optical properties of cortical tissues in order to map out areas of activity.
- an in vitro technique to produce human neural progenitor cells for clinical and basic applications.
- a portable distortion-product emission device for the determination of frequency specific hearing function.

The Cardiovascular Research Group (CVRG)

The CVRG's research programs focus on:

- activation of cardiac contraction
- the heart as a pump
- the interplay between cardiac/pericardiac structures and the venous system
- cardiac electrophysiology (basic and clinical)
- evaluation of novel anti-arrhythmic drugs
- evaluation of pacemaker/defibrillator designs and devices

The CVRG's development programs focus on:

- non-invasive measurements of ventricular function
- anti-arrhythmic therapy

Joint Injury and Diseases Research Group

This group conducts multidisciplinary research into the causes and treatments of joint injuries and arthritis. Examples of current research projects are :

- mechanical tests of joints and joint tissue
- immunohistochemistry and image analysis of joint tissues
- serological tests of disease
- cell systems for studies of arthritis
- molecular biology of connective tissues
- development of instruments to measure bone and joints (in vivo and in vitro)

Major achievements of the Joint Injury and Diseases Research Group include:

- instrument to quantify mechanical behaviour of small soft tissue samples
- surgical instrument design
- measurement of joint function
- software for analysis of biomedical tests, image analysis and clinical data bases
- studies on transplantation of ligaments and cartilage (biomechanical, morphological, mechanical)
- biochemical markers of diseases

The Respiratory Diseases Research Group (RDRG)

The RDRG explores collectively topics ranging from abnormalities in lung function and control of breathing to neurotransmitters responsible for breathing and micro-mechanics of the lung.

Medical device development includes:

- a nasal airway positive pressure system to treat sleep apnea sufferers

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DALHOUSIE UNIVERSITY, Halifax, Nova Scotia

Working with the Victoria General Hospital, Dalhousie University is actively engaged in both the development and the testing of technologies related to medicine and medical devices. At present, research interests lie in the areas of cardiology, digestive disorders, infectious diseases, genito-urinary disorders, oncology, diagnostic imaging, and respirology and rheumatology.

Of particular interest at Dalhousie University, is the field of orthopaedics. Two current research studies include:

- a five-year study to examine the merits of two types of artificial hip replacement devices. The jointly funded \$480,000 study is examining the function of cemented versus uncemented hip prostheses.
- a \$500,000 project, to be conducted jointly by a scientific team from Dalhousie and the Technical University of Nova Scotia, to improve the stability of wheelchairs.

Other ongoing projects involve the development and functional/clinical evaluation of devices such as:

- heart valve replacement
- new ultra-sensitive ELISA methods
- quantitative assays for various neuropeptides
- apheresis techniques
- X-ray hip frame
- implant technology
- transplantation products
- radiotherapy systems

The Centre for Clinical Research

The Centre, under development at the Victoria General Hospital, will act as a focus of facilities, administration, and support systems through which varied research programs will be driven.

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UNIVERSITÉ LAVAL, Québec, Québec

Université Laval is a world-class centre of biomaterial, prosthetic, and implant research. Headed by Dr. Robert Guidoin, the Biomaterials Institute at the university is actively involved in research in the following areas:

- evaluation of prosthetic materials and synthetic or biologically-treated polymers; specific focus is on biostability and biofunctionality
- accelerated tissue regeneration for vascular grafts
- hemodynamics of cardiovascular grafts and heart valves
- development of an ultrasonic intravascular imagery system for cardiovascular surgery

The Institute is extensively involved in collaborative projects with major industry players in the areas of:

- vascular grafts
- medical textiles
- cardiac valves
- sutures
- ultrasonic imaging

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UNIVERSITY OF MANITOBA, Winnipeg, Manitoba**The Biomedical Engineering Laboratory**

The laboratory works closely with the Department of Electrical and Mechanical Engineering to ensure that any new developments in the areas of scanning, tunnelling microscopy, fibre-optics communications, VLSI (Very Large Scale Integrator) devices, integrated optics, and sensors and displays which might have an impact on biomedical engineering advances can be incorporated into the research projects quickly. Examples of recent special projects and developments are:

- lung ventilator device
- cerebrospinal fluid anti-syphon shunt
- amplitude modulation stethoscope
- software programs
 - lung sound definition
 - apnea event detection and analysis
- computer controlled electrical stimulator for pain control, neuromuscular contraction, etc.
- wheelchair ergometer
- balance trainer
- seat-pressure monitor
- non-invasive system to monitor intravascular volume and oxygen content

Other medical device R&D work under way at the University of Manitoba includes:

- neuroscience research to achieve functional recovery and regeneration
- applied clinical research in gerontology
- radiopharmaceuticals and nuclear medicine research aimed at developing products and quality control procedures for use in nuclear medicine
- pulmonary biology, pathobiology, and respirology research

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McMASTER UNIVERSITY, Hamilton, Ontario

McMaster University has focused its medical devices research efforts in the area of cardiovascular devices. The departments of Bio-Engineering and Bio-Medical Sciences are currently involved in:

- development of new automated techniques into clinical electromyography (EMG)

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McGILL UNIVERSITY, Montréal, Québec

McGill University in Montréal has long been considered to be one of the premier medical schools in the world. Although only a fraction of the medical R&D effort at McGill is directed at devices, efforts in this area include:

- completely implanted electrical systems for muscle stimulation following nerve injury and repair
- orthopaedic surgical devices including the design of joint replacement implants, joint braces, internal and external fracture fixation devices, spine stabilizing instruments, etc.
- cardiac assist devices
- dental prosthetic devices such as titanium endosteous implants
- electrical stimulation of the bladder and urinary prosthetic devices
- cochlear implants
- patient transport devices

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MEMORIAL UNIVERSITY, St. John's, Newfoundland

Medical research at Memorial University is wide in scope and based upon the work of research groups which have been established in immunology, molecular biology, neuroscience, oncology, and clinical epidemiology. In addition to these groups, examples of current areas of research include hypertension, kidney disorders, arthritis, cancer, genetic disorders, heart disease, and transplantation. Specific projects under way include:

- development of inexpensive, computer-controlled equipment to work with monoclonal antibodies
- development of models of human auditory processes
- investigation of antibody/drug interactions in the treatment of lung cancer (project with Searle and West Midlands Health Authority, U.K.)
- periosteal grafting for cruciate ligament tear
- new total hip design

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UNIVERSITÉ DE MONTRÉAL, ÉCOLE POLYTECHNIQUE, Montréal, Québec

The Technology Development Centre at the École Polytechnique in Montréal and the Institute of Biomedical Engineering are associated with the University of Montréal. The Institute specializes in cardiovascular research and in research related to the application of biomechanics and biomaterials to orthopaedics and rehabilitation.

Research work focuses on:

- **Electrical activity of the heart.** Studies on basic mechanisms of arrhythmia generation and electrical propagation in cardiac tissue. In order to conduct various theoretical and experimental studies, several tools have been developed; for example: a set of mathematical models for simulation covering from cell properties to electrocardiographic generation on a torso, instrumentation for cardiac mapping, multi-lead ST segment monitoring and RF ablation of arrhythmogenic sites.
- **Joint biomechanics and biomaterials.** Studies on basic properties as well as neuromuscular control of joints. The activities necessitate the use of computer models as well as testing and measurements instrumentation in order to develop artificial tissues and prostheses. Examples of specific projects: a multi-functional hand prosthesis, artificial ligament testing machine, computer visualisation technologies to develop 3-D modelling and reconstruction of the spine.
- **Biochemical systems, images and instrumentation.** Studies on the kinematic of cardiac muscle and blood flow in coronary arteries using imaging techniques, specifically echocardiography, cineangiography and cineventriculography. In addition to cardiac mapping, an impedance imaging tomograph is under development. It is mainly to be used to give new information to the studies of the electrical activity of the heart. However, other applications are possible: pneumology, neurology and rehabilitation.

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UNIVERSITY OF NEW BRUNSWICK (UNB), Fredericton, New Brunswick

The Institute of Biomedical Engineering at the University of New Brunswick is involved in a complete spectrum of activities in biomedical engineering. These activities range from basic research in biomedical engineering to the design and development of myoelectric control systems for artificial arms.

The Institute has gained international recognition for its involvement in the development of myoelectric control systems for artificial arms. Collaborating with Hugh Steeper Ltd. of England, and Liberty Mutual Lab of the U.S.A. Researchers at UNB completed a novel five-state myoelectric control system for a multifunction prosthesis, small enough to be tested on patients.

Other research projects at the Institute of Biomedical Engineering include:

- elbow disarticulation prosthesis development
- spinal cord monitoring
- signal processing
- human gait analysis
- radiation scatter imaging
- a VLSI (Very Large Scale Integrator) telemetry implant for myoelectric control

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UNIVERSITY OF OTTAWA, Ottawa, Ontario

The Institute of Medical Engineering at the University of Ottawa, drawing from 30 principal investigators from the Faculties of Medicine and Engineering, has a mandate to enhance the process of technology transfer of biomedical inventions and techniques to industry. Current areas of interest for the institute include ophthalmology, cardiology, orthopaedics, neurology, general surgery, anaesthesia, paediatrics, medical imaging techniques and reproductive biology.

Some of the institute's major achievements include:

- development of an automatic sleep staging apparatus
- cardiovascular devices, including implantable pacemakers, defibrillators and heart assist systems
- ISIS project for transmission and storage of high-quality medical images
- medical signal processing applied to apnea monitoring
- orthopaedic implant development
- new techniques for evoked potential data analysis

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QUEEN'S UNIVERSITY, Kingston, Ontario

Queen's University is one of Canada's leading research institutions in the medical devices area. Biomedical research at Queen's University has a strong focus on orthopaedics. The work of Drs. Sorbie and Wevers in the areas of biomechanics and prostheses at Queen's has gained international repute. Queen's is also an active participant in the Ontario Centre for Materials Research (OCMR).

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UNIVERSITY OF SHERBROOKE, Sherbrooke, Québec

Medical devices research and development at the University of Sherbrooke is primarily conducted through the *Centre de Recherche Clinique* (Clinical Research Centre, CRC) of the Centre Hospitalier Universitaire de Sherbrooke (CHUS).

Clinical Research Centre (CRC)

The principal mandate of the CRC is to develop clinical research in biomedical sciences including the development of instrumentation and devices applied to medical activities.

Devices under development include:

- Surgical Instrumentation
 - a multi-function valve for general surgery

- Imaging Instrumentation
 - detectors and methods of detection
 - positron emission tomography (PET)
 - image reconstruction and analysis

- Development of new radiopharmaceuticals and photosensitizers

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SIMON FRASER UNIVERSITY (SFU), Burnaby, British Columbia

Extensive research and development efforts in the area of medical devices is currently under way at SFU, in particular within the schools of Engineering Science and Kinesiology. Recently, a new Institute of Micromachining and Microfabrication has been established. A key focus of the institute is the development of devices at the sub-nanogram scale for biomedical application. Two devices that have been developed are a scale for measuring a single cell, even while it is growing, and a blood pressure device that can be read with the naked eye, has no moving parts and requires no power supply.

Other devices under development at SFU include:

- device to align lower limb prostheses
- portable EKG
- device to assess hand stiffness by measuring finger joint torque and angle

Other research areas at SFU include:

- robotics for use in medical applications
- prosthetic arms
- spinal reflexes in neuromuscular development
- biology of aging
- systems models in physiology
- biomechanics and electrophysiological kinesiology
- ultrasound and other imaging techniques to assess tissue masses

Simon Fraser also offers a Biomedical Student Co-op Program to provide companies with access to qualified students. There is also a co-op program for Engineering Science which has a biomedical engineering specialized area of study.

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UNIVERSITY OF TORONTO, Toronto, Ontario

The largest academic medical centre in North America, the University of Toronto's Faculty of Medicine operates 14 centres of specialization, such as the Banting and Best Diabetes Centre, the Positron Emission Tomography Centre and the Ontario Light and Laser Research Centre and the Centre for Biomaterials.

Some of the major areas of research undertaken by the approximately 150 scientists involved with medical devices research are implants, contrast agents, medical imaging, cell imaging, doppler ultrasound, angiography, angioplasty, vascular grafts, prosthetic devices, clinical testing of new machines, aids for the elderly, clinical evaluation of new devices, and rehabilitation technology (seating, hearing, vision, communications).

Centre for Biomaterials

Established in 1986, the Centre for Biomaterials is supported by the combined efforts of the faculties of Medicine, Dentistry, Pharmacy, Applied Science and Engineering. The centre has played a key co-ordinating role since 1987 in the Biomaterials Area Program within the Ontario Centre for Materials Research (OCMR), one of seven Centres of Excellence funded by the Province of Ontario.

Major research areas currently being undertaken by members of the centre are as follows:

1. Blood-Interfacing Implants

- development of non-thrombogenic materials for blood-interfacing applications; surface modification of polymeric materials
- mechanical and biochemical characterization of natural and modified tissues for construction of tissue-derived implants for cardiovascular use

2. Bone-Interfacing Implants

- surface modification of metals for bone-interfacing biomaterials in orthopaedics and dentistry
- development and assessment of surface coatings (porous coatings, plasma-sprayed coatings, sol-gel coatings)
- studies of "bio-active" ceramics
- development of new biodegradable composite biomaterials
- studies of the bone-biomaterial interface using unique in vivo and in vitro methods
- design and development of dental and orthopaedic implants

3. Drug Delivery Systems

- development of biodegradable and bioerodable controlled drug delivery materials
- micro-encapsulation of human mammalian cells for controlled delivery of pharmaceutical agents

4. Material Processing/Design Characterization

- studies on dental restorative materials
- mechanical testing of biomaterials and tissues
- prototype fabrication of metal and ceramic biomaterials
- surface analysis of biomaterials and certain surface-modified tissues
- development of novel diagnostics as well as implants

5. Biocompatibility Testing/Evaluation

- studies on biodegradation of metal, polymer and ceramic biomaterials with a focus on ion release and analysis of trace elements within host tissues
- biocompatibility assessment using novel in vitro methods
- development of new test methods for assessing the biological and engineering characteristics of biomaterials
- examination of tissue-biomaterial interfaces using various high-resolution and lower power microscopic techniques

Centre for Cardiovascular Research

The Centre for Cardiovascular Research (CCR) is a joint venture between the Toronto General Hospital, Mount Sinai Hospital and the University of Toronto. Established in 1989, the CCR is a world-renowned institution in the area of cardiovascular care and research. The centre has been responsible for the development and/or use of many "firsts" in the cardiovascular field - such as blood thinners, cardiac pacemakers, modern lung and heart-lung transplantation and balloon electrical stimulation and ablation of cardiac arrhythmias. The CCR focuses primarily on three areas of research:

1. Atherosclerotic Cardiovascular Disease

- human research cardiac catheterization
- vascular research
- hemostasis and thrombosis research
- lipid and atherosclerosis research
- cardiovascular cell culture
- large animal surgery
- vascular surgery
- biomedical engineering vascular research

2. Myocardial Hypertrophy and Failure

- molecular cardiology
- non-invasive research
- clinical cardiovascular physiology
- cardiovascular pharmacology
- surgical innovations

3. Arrhythmias and Sudden Death

- development of balloon electric shock ablation (BESA)
- 3-D spatial reconstruction of cardiac electric events causing lethal arrhythmias
- investigation of abnormalities in the metabolism of heart muscle cell membrane lipids
- effect of variations in nervous tone on onset, pattern and termination of cardiac arrhythmias

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UNIVERSITY OF WATERLOO, Waterloo, Ontario

The University of Waterloo is active in the development of new medical devices through several research groups at the university, including:

- Centre for Applied Health Research
- Centre for Contact Lens Research
- Centre for Sight Enhancement
- Centre for Occupational Health and Safety
- Gait Laboratory

These research groups are undertaking device development in a number of areas, including:

- computer imaging software
- confocal scanning microscope
- geriatric assists
- gait assessment

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Associate Director
Technology Transfer and Licensing Office
UNIVERSITY OF WATERLOO
Waterloo, Ontario
CANADA, N2L 3G1

Tel: 519-888-4058
Fax: 519-746-3575

UNIVERSITY OF WESTERN ONTARIO (UWO), London, Ontario

The University of Western Ontario works in close collaboration with University Hospital and the John Robarts Research Institute as part of Clinical Research London. Over 35 faculty members are involved in biomedical engineering research which has direct or indirect relation to medical devices. Medical devices R&D activity at UWO takes place in several scientific groups:

Biomedical Engineering

- patient controlled analgesic device (version III)
- heart valve with an expansile stent
- HIS bundle ablator
- fibrillator system
- cardiac interval timer
- cardiac electrophysiology system with cardiac trending computer
- cardiac fibrillation computer
- gas supply pressure alarm (oxygen monitor)

Circulatory Assist Device Laboratory:

- optimal storage temperature for donor
- organ transport
- investigation of pulsatile and non-pulsatile flow for ventricular assist devices

EEG Department/Epilepsy Unit:

- automated electroencephalograph (EEG)
- electrode fabrication (3 devices)
- ECOG electrode array
- software
 - EEG patient data base
 - appointment scheduler
 - epilepsy patient data base
 - long-term EEG monitoring
 - EEG analysis

Imaging Research Laboratory:

- volume CT scanner
- ultra-high resolution
- computer controlled physiological flow pump
- velocity calibration system
- 3-D colour Doppler ultrasound imaging device
- 3-D ultrasound of the prostate
- 3-D ultrasound for cardiac mapping
- 3-D ultrasound for fetal imaging
- automated detection and quantification of MS lesions
- ECG TTL signal converter

Orthopaedic Research Laboratory:

- self-aligning knee
- pin-loading device
- arthroscopy instruments

Contact: Dr. Gregor Reid
Director of Research Services
UNIVERSITY OF WESTERN ONTARIO
Office of Research Services
Stevenson-Lawson Building
London, Ontario
CANADA, N6A 5B8

Tel: 519-661-2161
Fax: 519-661-3907

APPENDIX II

FEDERAL NETWORKS OF CENTRES OF EXCELLENCE

THE CANADIAN AGING RESEARCH NETWORK (CARNET), Toronto, Ontario

**CANADIAN BACTERIAL DISEASES NETWORK (CBDN),
Vancouver, British Columbia**

CANADIAN GENETIC DISEASES NETWORK, Vancouver, British Columbia

**N.R. NETWORK FOR NEURAL REGENERATION AND FUNCTIONAL RECOVERY,
Montréal, Québec**

**PROTEIN ENGINEERING NETWORK OF CENTRES OF EXCELLENCE (PENCE),
Vancouver, British Columbia**

**INSPIRAPLEX -
THE RESPIRATORY HEALTH NETWORK OF CENTRES OF EXCELLENCE,
Montréal, Québec**

**INSTITUTE OF ROBOTICS AND INTELLIGENT SYSTEMS
Nepean, Ontario**

THE CANADIAN AGING RESEARCH NETWORK (CARNET)

University of Toronto, Toronto, Ontario

CARNET brings together Canada's leading researchers in the field of aging, including experts from various disciplines such as social psychologists, sociologists, geriatricians and economists. These researchers are developing a number of integrated research programs to investigate conditions which foster methods of promoting independence and productivity in an aging society.

Four linked research programs based at the Universities of Toronto, Guelph, and Manitoba, make up CARNET.

The Products and Services research group conducts research on the development of new and innovative products and services for an aging population, including home-care services which enhance independent living of the elderly.

Two other research groups, the Work and Eldercare research group and the Cognitive Function research group, explore areas outside that of medical devices.

The Infrastructure group provides supportive research to the other research groups by stimulating linking of the research activities across the groups. The Infrastructure group also conducts research focused on policy implications of CARNET research findings. The Infrastructure group includes the Universities of Alberta, Concordia, McMaster, Montréal, Trent, Victoria, Waterloo and Western Ontario.

CARNET has two major corporate partners:

ARCOR - The Canadian Aging and Rehabilitation Product Development Corporation is based in Winnipeg, Manitoba. ARCOR is a non-profit corporation whose main purpose is to establish national and international capabilities for business and research in aging and rehabilitation.

The other major corporate partner is Corporate Health Consultants (CHC), based in Mississauga, Ontario. CHC is a leading company in the area of employee assistance providing nationwide eldercare services.

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Network Manager
CARNET
University of Toronto, Centre for Studies of Aging
455 Spadina Avenue, Suite 305
Toronto, Ontario
CANADA, M5S 2C8
Tel: 416-978-7910 Fax: 416-978-4771

CANADIAN BACTERIAL DISEASES NETWORK (CBDN)

University of British Columbia, Vancouver, British Columbia

CBDN focuses on all major areas of bacterial diseases research including antibiotics and other therapeutics, vaccines and diagnostics for human, fish, food animals and plants. A strong base in fundamental science provides an environment that fosters research collaboration and a willingness to adapt the network's capabilities to specific problems and the needs of our industry partners.

Participating centres include the Universities of Victoria, British Columbia, Alberta, Calgary, Saskatoon, Guelph, Laval and the federal laboratories, LCDC and NRC. CBDN industry partners include AGTI, Astra Pharma Inc., Beckman Instruments, Biophotonics, BioStar, Biosignal, Micrologix Biotech Inc., StressGen Biotechnologies Corp., Syndel Laboratories, SynPhar Laboratories Inc., and Synthetic Peptides Inc.

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Communications Officer
CBDN
351 - 2125 East Mall (UBC Campus)
Vancouver, British Columbia
CANADA, V6T 1Z4

Tel: 604-822-4040
Fax: 604-822-6938

CANADIAN GENETIC DISEASES NETWORK

University of British Columbia, Vancouver, British Columbia

The network studies the genes that directly cause or predispose humans to disease. The goal is to determine the biological function of each of the relevant genes and to discover how mutation in each causes disease. This research, involving nationwide collaborations among 25 research groups, will lead to major breakthroughs and commercial opportunities in the areas of DNA diagnostics and therapeutics.

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Managing Director
NCE GENETICS
Room 348 - 2125 East Mall
University of British Columbia
Vancouver, British Columbia
CANADA, V6T 1Z4

Tel: 604-822-7886
Fax: 604-822-7945

N.R. NETWORK FOR NEURAL REGENERATION AND FUNCTIONAL RECOVERY

The N.R. Network brings together over 100 neuroscientists and over 50 national trainees from 14 of the top universities across Canada. It is the largest of the 15 Centres of Excellence created by the NCE program of the Government of Canada and is the largest funded at \$25.5 million over four years.

The network focuses on two broad fields of neural disorders:

1. Molecular Field

- neuronal survival and protection
- neurotrophic factors
- growth inhibitory molecules
- regrowth and reconnection in the damaged nervous system
- new gene technology

2. Device Field

- neuromuscular technology
- pharmacological therapy
- kinesiological evaluation and fitting

Industrial arrangements include BioMech Designs Ltd., Minimed Technologies, Leaf Electronics Ltd., MDS Health Group Ltd., Industries Auteca Ltd., and others.

Contact: Warren C. Bull
Executive Director
N.R. NETWORK
1650 Cedar Avenue, Room L7-132
Montréal, Québec
CANADA, H3G 1A4

Tel: 514-937-6011 ext. 2519
Fax: 514-934-8216

PROTEIN ENGINEERING NETWORK OF CENTRES OF EXCELLENCE (PENCE)

University of British Columbia, Vancouver, British Columbia

The network researches the relationship between the molecular structure and function of proteins by chemical and biological synthesis of systematically modified proteins. With the potential of developing new drugs or vaccines, the network's current research includes investigation of the proteases involved in infectious diseases and with the family of growth factors involved in wound healing and cancer.

The network brings together Canadian scientists from the Universities of Alberta, British Columbia and Toronto; from the National Research Council; from the Pulp and Paper Research Institute, and seven industrial partners. Close industrial collaboration gives the network excellent potential for technology transfer.

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 PENCE
 Administrative Centre
 University of British Columbia
 Room 345, 2125 East Mall
 Vancouver, British Columbia
 CANADA, V6T 1Z4

Tel: 604-822-6821
Fax: 604-822-2005

**INSPIRAPLEX -
THE RESPIRATORY HEALTH NETWORK OF CENTRES OF EXCELLENCE**

McGill University, Montréal, Québec

The network's research aims to improve prevention, diagnosis, treatment and rehabilitation for people with cystic fibrosis, asthma or other respiratory diseases. Products include the Proportional Assist Ventilator, a rapid lung viral diagnostic kit, devices to evaluate pulmonary functions and dynamic quantitative imaging technologies.

Industrial affiliates are Merck-Frosst Canada Inc., Engineering Interface Ltd., Respironics Inc. and Medix Pharmaceuticals Ltd. Participating universities are the Universities of British Columbia, Calgary, Saskatchewan, Manitoba, McMaster, McGill, Montréal, Laval and the Hospital for Sick Children's Research Institute in Toronto.

Contact: Anne Vézina
INSPIRAPLEX - RESPIRATORY HEALTH NETWORK
McGill University
Montréal, Québec
CANADA

Tel: 514-845-5750
Fax: 514-845-6740

INSTITUTE OF ROBOTICS AND INTELLIGENT SYSTEMS

Precarn Associates, Nepean, Ontario

The network of 135 academic professors at 18 Canadian universities operates as a component of a consortium of 32 companies whose mission is to carry out advanced R&D in robotics and artificial intelligence. Research is well-advanced in the use of micro-robots for retinal and brain surgery.

Contact: Mr. Gordon MacNabb
President
PRECARN ASSOCIATES INC.
30 Colonnade Road
Nepean, Ontario
CANADA, K2E 7J6

Tel: 613-727-9576
Fax: 613-727-5672

APPENDIX III

MEDICAL DEVICES R&D AT INSTITUTES AND HOSPITALS

ARCOR, Winnipeg, Manitoba

FISHER REHABILITATION ENGINEERING CENTRE, Victoria, British Columbia

IZAAK W. KILLAM CHILDREN'S HOSPITAL, Halifax, Nova Scotia

HUGH MacMILLAN REHABILITATION CENTRE, Toronto, Ontario

INSTITUT DE RECHERCHES CLINIQUES DE MONTRÉAL (IRCM), Montréal, Québec

THE INSTITUT DE CARDIOLOGIE DE MONTRÉAL (ICM), Montréal, Québec

MEDICAL DEVICE DEVELOPMENT CENTRE, Vancouver, British Columbia

UNIVERSITY OF OTTAWA HEART INSTITUTE, Ottawa, Ontario

THE INSTITUT DE RÉADAPTATION DE MONTRÉAL, Montréal, Québec

RYERSON POLYTECHNICAL INSTITUTE, Toronto, Ontario

ARCOR, Winnipeg, Manitoba

ARCOR is a not-for-profit joint venture between the governments of Canada and Manitoba that provides a range of services to companies with products that will enhance the quality of life and facilitate independent living for seniors and individuals with disabilities. These services include:

- a market responsive product development, product design and mechanical prototyping capability which allows new product concepts to be transformed into actual prototypes
- testing and evaluation of aging and rehabilitation products for health-care providers, industry and institutions
- applied research, including market research and related consulting services
- access to aging and rehabilitation experts, consumers and research facilities to assist business in developing, testing and marketing new products
- brokerage services to facilitate existing and new firms wishing to start or expand manufacturing for distribution throughout the international market

ARCOR is currently involved in the development of several new products, which includes:

- patient transfer/lift system for home use
- innovative motor design for mobility devices such as scooters and wheelchairs

ARCOR is one of two industry partners involved in the Canadian Aging and Rehabilitation Network of Centres of Excellence.

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President
ARCOR
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CANADA, R3B 1N9

Tel: 204-943-9400
Fax: 204-943-4088

FISHER REHABILITATION ENGINEERING CENTRE, Victoria, British Columbia

The Fisher Rehabilitation Engineering Centre, located at the Queen Alexandra Centre for Children's Health, is responsible for medical devices and delivery process research and development, primarily in the areas of:

- seating systems
- orthotics
- robotics
- communications

There are a number of specific projects that are currently under way at the centre, including:

- pressure measurement devices for measuring the interface pressure of seated individuals
- CAD/CAM techniques for the design and fabrication of wheelchair seat cushions
- evaluation of the effects of anteriorly tipped seating on various functions
- CAD/CAM techniques for orthotics
- improvement of hip abduction orthoses
- evaluation of wheelchair mounted manipulative devices and robotics

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FISHER REHABILITATION ENGINEERING CENTRE
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CANADA, V8N 1V7

Tel: 604-721-6779
Fax: 604-721-6815

IZAAK W. KILLAM CHILDREN'S HOSPITAL, Halifax, Nova Scotia

Affiliated with Dalhousie University, the Izaak W. Killam Children's Hospital is the principal paediatric tertiary care centre for Atlantic Canada. The hospital is committed to achieving a leadership role in preventing accident, trauma, and illness and in delivering internationally recognized standards of child health care.

Recent projects undertaken at the hospital involving medical devices include:

- gait disorder measuring device
- investigation of pacemaker leads
- telephone transmission of electrocardiograms (EKGs)

Contact: Dr. Robert Bortolussi
Chief of Research
Research Office
IZAAK W. KILLAM CHILDREN'S HOSPITAL
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Halifax, Nova Scotia
CANADA, B3J 3G9

Tel: 902-428-8520
Fax: 902-492-0997

HUGH MacMILLAN REHABILITATION CENTRE, Toronto, Ontario

One of the world's premier centres in the field of rehabilitation engineering, research and development, the centre's initiatives currently under way embrace the following:

- postural support and seating devices
- systems for mobility and transportation of persons with physical disabilities
- microcomputer applications for communications and control
- powered upper extremity prosthetics
- orthotic systems
- development and evaluation of therapeutic strategies

The centre also serves as the headquarters for the Ontario Rehabilitation Technology Research and Development Consortium, which links Ontario university researchers with clinicians, consumers and manufacturers relating to the areas of seating, mobility, communications, hearing vision, prosthetics, orthotics and respiration.

Contact: Dr. Morris Milner
 Vice-President, Research and Development
 HUGH MacMILLAN REHABILITATION CENTRE
 350 Rumsey Road
 Toronto, Ontario
 CANADA, M4G 1R8

Tel: 416-425-6220
Fax: 416-425-6591

INSTITUT DE RECHERCHES CLINIQUES DE MONTRÉAL (IRCM), Montréal, Québec

IRCM is a world-renowned research centre involved in a variety of areas including biomedical engineering, clinical pharmacology, hypertension, lipoproteins and atherosclerosis, neuroscience, cancer and immunology.

The centre is engaged in a number of international collaborations with, among others, Johns Hopkins, Yale, Harvard, and Columbia Universities in the U.S., with Oxford and Cambridge in the U.K., as well as the Institut Pasteur in Paris.

In the area of biomedical engineering, work at IRCM can be grouped into the following areas:

- digital signal processing of heart sounds
- Doppler-echocardiography of blood flow
- computer processing of biological images
- new electronic stethoscope
- diagnostic kit for apolipoprotein E phenotyping by immuno-fixation from total plasma for evaluating cardiovascular risk factors

Contact: Hélène Akzam
 Secretary General
 INSTITUT DE RECHERCHES CLINIQUES DE MONTRÉAL
 110, avenue des Pins ouest
 Montréal, Québec
 CANADA, H2W 1R7

Tel: 514-987-5768
Fax: 514-987-5679

THE INSTITUT DE CARDIOLOGIE DE MONTRÉAL (ICM), Montréal, Québec

The work of this leading cardiovascular institute incorporates clinical trials, research and development, teaching and patient care. The Institut de Cardiologie has pioneered cardiac diagnostic techniques using cardiac catheterization. This work led to Canada's first coronary angioplasty in 1980, and the first valvuloplasty in 1987. The ICM is also actively involved in several areas of cardiovascular physiology and clinical pharmacology. The institute has become a global leader in the treatment of cardiac arrhythmias using a new form of catheter ablation.

Current programs include:

- diagnosis and management of restenosis after coronary angioplasty as well as evaluation of progression of coronary atherosclerosis using quantitative coronary angiography
- study of anti-platelet agents and their use in acute ischemia and myocardial infarction
- extensive work in the area of electrophysiology
- use of holospectral imaging in nuclear medicine for scatter subtraction
- implantable defibrillators
- coronary stents
- endovascular echocardiography
- atherectomy

The institute also houses a Biomedical Engineering laboratory which conducts extensive research aimed at improving echo-Doppler diagnostic feature extraction methods and evaluates new diagnostic directions in cardiac valve disease diagnosis.

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Public Affairs
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Fax: 514-593-2540

MEDICAL DEVICE DEVELOPMENT CENTRE, Vancouver, British Columbia

The Medical Device Development Centre is located in the Jack Bell Research Centre, adjacent to the Vancouver General Hospital (VGH). The centre is a joint venture between VGH, British Columbia Institute of Technology (BCIT), the University of British Columbia (UBC) and Simon Fraser University (SFU). The centre provides a facility and an environment where clinical access, academic and technological skill, and industrial and business expertise can be united to develop medical devices and procedures leading to commercialization.

Engineering Services

Mechanical, electrical and electronic, biomedical and computer engineering services are available through the centre from VGH, UBC, SFU and BCIT. These include:

- UBC/SFU computing services
- UBC/SFU/BCIT technology services, such as mechanical, plastics, electronics, etc.
- VGH Biomedical Engineering services - services from other B.C. hospitals can also be arranged
- VGH/UBC clinical experiment design and analysis capabilities

Clinical Services

Through VGH (and by special arrangement, through other Vancouver hospitals) animal and human clinical testing are available to sponsored projects. Assistance with the rigorous experimental and ethical approval process can be provided through the centre.

Contact: **JACK BELL RESEARCH CENTRE**
 211-2660 Oak Street
 Vancouver, British Columbia
 CANADA, V6H 3Z6

Tel: 604-875-4810
Fax: 604-875-4497

UNIVERSITY OF OTTAWA HEART INSTITUTE, Ottawa, Ontario

The University of Ottawa Heart Institute at the Ottawa Civic Hospital is the first institute in the world to combine patient treatment, rehabilitation, research, and education at one facility. A number of programs are currently under way involving close interaction between scientists, clinicians, engineers, and other health-care professionals. Because the Heart Institute is integrated into a patient treatment and rehabilitation environment, rapid and efficient testing of new products and ideas is greatly facilitated.

Some of the research thrusts of the institute include:

- the pioneering work of Dr. Adolpho de Bold on Atrial Natriuretic Factor (ANF), a natural diuretic produced by the atria of the heart that has implications for the treatment of hypertension, heart failure and other cardiac diseases;
- the Taichman Laboratory, which is one of the few muscle mechanics laboratories using the human cardiac muscle model to test new drugs and devices;
- innovative polymeric materials are under development for a wide variety of uses from extracorporeal circuits and sutures to implantable vascular grafts and artificial hearts; the Institute has recently patented a new biomaterial which is more blood compatible than any existing material;
- the six-year, \$25 million international research program to develop an implantable Electrohydraulic Ventricular Assist Device (EVAD) which started in 1990 has already led to the development of spin-off technologies including a transcutaneous energy transfer system. The EVAD project will be the first step in a research program to develop a permanent artificial heart;
- studies of new non-invasive diagnostic measures aimed at providing new methods to identify high-risk patients;
- long-term study of prosthetic heart valves;
- investigation of lipids and their role in heart disease;
- the Medical Devices Evaluation Centre;

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Director of Development
UNIVERSITY OF OTTAWA HEART INSTITUTE
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CANADA, K1Y 4E9

Tel: 613-761-4794
Fax: 613-729-3937

THE INSTITUT DE RÉADAPTATION DE MONTRÉAL, Montréal, Québec

Founded in 1949, the Institut de réadaptation de Montréal (IRM) specializes in the readaptation of physically handicapped individuals with particular emphasis on rehabilitation, orthotics and prosthetics. The IRM has specific expertise in the area of development and manufacture of technical aids, including:

- customized sport prostheses
- wheelchair control systems

The IRM is affiliated with the Université de Montréal and has been heavily involved in the development of a multi-functional hand prostheses.

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6300, rue Darlington
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Fax: 514-340-2149

RYERSON POLYTECHNICAL INSTITUTE, Toronto, Ontario

Through the Faculty of Engineering and Applied Sciences, Ryerson is involved in collaborative projects with a number of institutes in the Toronto region, including:

- Sick Children's Hospital
- Toronto Western Hospital
- Hugh MacMillan Medical Centre

Ryerson has technical capabilities well-suited for medical devices development:

- prototype design and development
- robotic and laser technologies
- ultrasound
- rehabilitation engineering

There are a number of medical devices projects that are currently under way at the institute, including:

- cardiac mapping
- blood flow in zero gravity environments
- devices for handicapped individuals
- electronic devices
- improvement of hip abduction orthoses
- evaluation of wheelchair mounted manipulative devices and robotics

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 Toronto, Ontario
 CANADA, M5B 2K3

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Fax: 416-979-5336

APPENDIX IV

GOVERNMENT SUPPORT PROGRAMS

RESEARCH AND DEVELOPMENT

**INDUSTRY, SCIENCE AND TECHNOLOGY CANADA
MEDICAL DEVICES TECHNOLOGY ASSESSMENT PROGRAM
STRATEGIC TECHNOLOGIES PROGRAM (STP)
MICROELECTRONICS SYSTEMS DEVELOPMENT PROGRAM (MSDP)
INNOVATION ASSISTANCE PROGRAM (IAP)**

**NATIONAL RESEARCH COUNCIL (NRC)
THE MEDICAL RESEARCH COUNCIL (MRC)
NATURAL SCIENCES AND ENGINEERING RESEARCH COUNCIL (NSERC)
NATIONAL HEALTH RESEARCH AND DEVELOPMENT PROGRAM (NHRDP)**

REGIONAL ECONOMIC DEVELOPMENT

**INDUSTRY, SCIENCE AND TECHNOLOGY CANADA
WESTERN ECONOMIC DIVERSIFICATION (WED)
NORTHERN ONTARIO DEVELOPMENT FUND (FEDNOR)
CANADA-QUÉBEC SUBSIDIARY AGREEMENT ON THE ECONOMIC
DEVELOPMENT OF THE REGIONS OF QUÉBEC
ATLANTIC CANADA OPPORTUNITIES AGENCY (ACOA)**

EXPORT FUNDING AND DEVELOPMENT PROGRAMS

**PROGRAM FOR EXPORT MARKET DEVELOPMENT (PEMD)
EXPORT DEVELOPMENT CORPORATION (EDC)**

EMPLOYMENT AND TRAINING PROGRAMS

THE CANADIAN JOBS STRATEGY

PROVINCIAL PROGRAMS

**BRITISH COLUMBIA
ALBERTA
ONTARIO
QUÉBEC
ATLANTIC CANADA**

RESEARCH AND DEVELOPMENT

FEDERAL PROGRAMS

Industry Science and Technology Canada

ISTC is the Government of Canada's most predominate economic development agency and is involved in promoting industrial research and development through various programs

The Agency has developed a new program, MEDTAP, that specifically addresses the requirements of the medical devices sector. MEDTAP contributions may cover up to 50% of total project costs to a maximum of \$350,000. These contributions are generally subject to repayment via a royalty on sales.

Medical Devices Technology Assessment Program (MEDTAP)

MEDTAP is a program to help firms adapt and incorporate new technical developments into exceptional medical device products that have the potential to succeed in global markets. MEDTAP is sponsored by ISTC and is delivered in partnership with the National Research Council (NRC). MEDTAP is focusing on projects where the primary issue is the application and scale-up of technology.

Medical Devices Technology Assessment Program (MEDTAP)

Health Care Products Directorate
Industry, Science & Technology Canada
235 Queen Street
Ottawa, Ontario
K1A 0H5
Tel: 613-954-3077
Fax: 613-954-4209

ISTC also offers R&D incentives through other programs such as the **Strategic Technologies Program (STP)**, the **Microelectronics Systems Development Program (MSDP)**, and the **Innovation Assistance Program (IAP)**. Assistance generally takes the form of a repayable or non-repayable contribution of up to 50% of project costs up to a maximum of \$2 million (\$300,000 for IAP). Short descriptions of each of these programs are as follows:

Strategic Technologies Program (STP)

STP encourages industry-led alliances to undertake research, development and application projects and offers financial assistance of up to \$2 million for projects in three disciplines: advanced materials, biotechnology, and information technologies. Medical devices projects based on any of the above technologies are eligible for STP funding. The STP program is an initiative that covers up to half the eligible costs of R&D or technology application undertaken by alliances among companies, universities, and/or research institutes.

The Strategic Technologies Program (STP)
c/o Biotechnology Directorate
Chemicals and Bio-Industries Branch
Industry, Science & Technology Canada
235 Queen Street
Ottawa, Ontario K1A 0H5
Tel: 613-954-3020
Fax: 613-952-4209

Microelectronics Systems Development Program (MSDP)

MSDP is a \$60 million program administered by ISTC whose objective is to support the development of advanced microelectronics and information technologies systems. Projects in the areas of health informatics, X-ray transmission, bedside monitoring, and telecommunications are eligible for 50% funding up to a maximum of \$5 million.

The Microelectronics and Systems
Development Program (MSDP)
c/o Programs and Planning Directorate
Information Technologies
Industry Branch
Industry, Science & Technology Canada
235 Queen Street
Ottawa, Ontario K1A 0H5
Tel: 613-996-7155
Fax: 613-995-5773

Innovation Assistance Program (IAP)

IAP is restricted to Québec and provides up to \$300,000 to fund industrial research programs in most sectors. Because the medical devices area has been identified as strategically important, projects in this area receive preferential treatment.

Innovation Assistance Program (IAP)
Federal Office of Regional Development (Québec)
Tel: 1-800-263-4689
Fax: 283-7557

National Research Council (NRC)

The NRC is Canada's primary science and technology resource. The council also provides extensive support to private companies through the **Industrial Research Assistance Program (IRAP)**. The NRC offers the advantage of world-class scientific and engineering support. The NRC is open to various types of arrangements with Canadian-based companies:

- R&D projects co-funded by the NRC
- customized R&D projects
- specific testing and analysis
- collaborative R&D
- access to major engineering facilities and installations

NRC-IRAP
National Research Council Canada
Building M-55
Montreal Road
Ottawa, Ontario
K1A 0R6
Tel: 613-993-1790
Fax: 613-952-1079

Medical Research Council (MRC)

The MRC is a government corporation dedicated to the promotion and assistance of basic, applied, and clinical research in the health sciences, and in the training of and development of the Canadian health-care research pool.

The council has four types of programs to assist in defraying the direct costs of biomedical research. These programs offer assistance for individual or collaborative research activities. Grant programs are available for equipment, operations, clinical trials, product development, industrial fellowships and special projects.

The MRC is moving towards increased collaboration with industry. A new industry/university program has been established to fund such alliances.

The Medical Research Council of Canada (MRC)

Jeanne Mance Building

20th Floor

Tunney's Pasture

Ottawa, Ontario

K1A 0W9

Tel: 613-954-1958

Fax: 613-954-6653

Natural Sciences and Engineering Research Council (NSERC)

NSERC's aim is to promote collaboration between universities, the private sector, and research oriented federal government departments. Projects can range from a short-term endeavour to advance a specific technology, to longer-term research in a technology of direct interest to a company or to product commercialization.

In general, NSERC will match corporate contributions for co-operative R&D partnerships. Industrial Research Chairs can provide a company with the benefit of working directly with a strong team of senior university researchers on technology of strategic interest. The council will share the costs of the salary of one or more research professors and their research associates as well as make contributions to equipment, infrastructure and operating support.

Under the Industrial Research Fellowships program, NSERC will share the salary of a recent doctoral graduate to work in a company for the first two years of employment.

National Sciences and Engineering Research Council of Canada (NSERC)
200 Kent Street
Ottawa, Ontario
K1A 1H5
Tel: 613-996-1898
Fax: 613-992-5337

National Health Research and Development Program (NHRDP)

The National Health Research and Development Program aims to support scientific activities designed to provide information pertinent to the achievement of Canadian health goals. Eligible activities include research projects, studies, and demonstration and evaluation projects. Currently, particular emphasis is placed on delivery of health care, preventative medicine, rehabilitation, communicable disease control, and risk assessment.

The National Health Research and Development Program
Health Services and Promotion Branch
Jeanne Mance Building
de l'Eglantine Street
Tunney's Pasture
Ottawa, Ontario
K1A 1B4
Tel: 613-954-8554
Fax: 613-954-6363

REGIONAL ECONOMIC DEVELOPMENT

FEDERAL PROGRAMS

The Government of Canada supports regional industrial development through a comprehensive network of programs. These programs are administered by Industry, Science and Technology Canada (ISTC) and are applicable, on a regional basis, across the country. Through ISTC, investors in Canada are eligible for financial contributions towards the acquisition of new equipment and machinery as well as engineering and other direct costs associated with start up, expansion or modernization.

Industry, Science and Technology Canada
Headoffice
C.D. Howe Building
235 Queen Street
Ottawa, Ontario
K1A 0H5
Tel: 613-995-8900

Western Economic Diversification (WED)

WED encourages economic development in Western Canada (British Columbia, Alberta, Saskatchewan and Manitoba) by providing repayable financial assistance to projects deemed strategically important in terms of products, markets technology or balance of trade. The medical devices sector has been identified as a priority strategic sector.

The Western Economic Diversification (WED)
Canada Place
1500-9700 Jasper Ave.
Edmonton, Alberta
T5J 4H7
Tel: 403-495-4164
Fax: 403-495-6876

Northern Ontario Development Fund (FEDNOR)

FEDNOR provides contributions and loan insurance for capital projects and contributions for marketing, innovation, and related studies intended to generate significant new income and employment opportunities in northern Ontario.

FedNor Head Office
302 Queen Street East
Sault Ste. Marie, Ontario
P6A 1Z1
Tel: 705-942-1347
Fax: 705-942-5434

Canada-Québec Subsidiary Agreement on the Economic Development of the Regions of Québec

This program is designed to assist manufacturing companies in improving their competitiveness on an international level. Assistance is also available for start-ups and for construction of new manufacturing facilities. Funding can be obtained for feasibility studies and capital investment. Assistance of up to \$2 million per project is available.

Business Service Centre (FORD(Q))
Suite 3800, 800 Victoria Square
P.O. Box 247
Montréal, Québec
H4Z 1E8
Tel: (514) 283-7557

Atlantic Canada Opportunities Agency (ACOA)

ACOA provides assistance towards the establishment, development, and promotion of companies in Atlantic Canada. Financial assistance is available for capital investment as well as research and development. The program offers six types of assistance to commercial operations: loan insurance, interest buy downs, studies, innovation assistance, new facility establishment, expansion/modernization, and new product expansion.

The Atlantic Canada Opportunities Agency (ACOA)
644 Main Street
P.O. Box 6051
Moncton, New Brunswick
E1C 9J8
Tel: 506-851-2271
Fax: 506-851-7403

EXPORT FUNDING AND DEVELOPMENT PROGRAMS

FEDERAL PROGRAMS

The federal government has put in place programs and mechanisms designed to provide financial assistance to companies planning to export products manufactured in Canada. Assistance can range from cost sharing on promotional activities to export credits. Also eligible for funding is the hiring of senior level specialists in international marketing and the carrying out of market development studies.

Program for Export Market Development (PEMD)

PEMD assists Canadian exporters in a number of activities including:

- visits
- trade missions
- trade shows and exhibitions
- establishing permanent sales offices abroad
- bidding on specific foreign projects
- establishing export consortia

Contributions are generally repayable on the basis of sales generated. PEMD is jointly administered by Industry, Science and Technology Canada (ISTC) and External Affairs and International Trade Canada (EAITC).

The Program for Export Marketing Development (PEMD)

Export and Investment Programs Division

External Affairs and International Trade

125 Sussex Drive

Ottawa, Ontario

K1A 0G2

Tel: 613-996-7155

Fax: 613-995-5773

Export Development Corporation (EDC)

The services of EDC can be used by Canadian companies to provide advisory, insurance, guarantee, and financing facilities in order to improve their ability to sell their products abroad. Firms of any size can obtain 90% coverage against non-payment for political or commercial reasons. Bank guarantees are available, and financing at favourable rates can be provided to the purchaser of Canadian goods for up to 85% of the contract value of the sale.

Export Development Corporation (EDC)

151 O'Connor Street

P.O. Box 655

Ottawa, Ontario

K1A 1K3

Tel: 613-598-2992

Fax: 613-237-2690

EMPLOYMENT AND TRAINING PROGRAMS

FEDERAL PROGRAMS

The Canadian Government, as a result of its commitment to increase the productivity of the labour force, has set up initiatives designed to ensure that labour skills correspond to changing technology. These initiatives provide very significant financial assistance for companies wishing to train workers.

The Canadian Jobs Strategy

The Canadian Jobs Strategy is a set of programs launched by the federal government to better respond to the needs of the Canadian labour market. The strategy was developed following extensive consultation with both the private sector and provincial governments. It is designed to provide the Canadian labour force with the training required to effectively compete with and adapt to technological and market changes. It is also designed to provide the private sector with the financial assistance required to provide workers with both classroom and on-the-job training.

Employment and Immigration Canada
National Headquarters
Place du Portage, Phase IV
140 Promenade du Portage
Hull, Québec
Tel: 819-994-2949

PROVINCIAL PROGRAMS

Provincial programs may be used by a medical devices firm in addition to the support received from federal programs. Each province has created individual programs tailored to suit its industrial strategy. Following is a listing of some of the programs available through the provincial governments.

British Columbia

The British Columbia Health Research Foundation supports a number of awards programs for health research in British Columbia. Emphasis is placed on the use of funds for the encouragement of clinical research projects and studies aimed at evaluating the effectiveness of health-care programs.

Alberta

The Alberta Heritage Foundation for Medical Research (AHFMR) was established in 1979 with a \$300 million endowment from the Alberta Government. In 1988, approximately \$50 million was awarded under its various scientific programs. The Foundation funds scientific research and development through a program of grants and awards designed to recruit, support, and train a critical mass of careers scientists in Alberta.

The AHFMR also administers the two tiered Technology Transfer Program, which assists medical researchers and firms in their efforts to commercialize promising research results. There are also a variety of assistance programs for marketing, training, and specific research projects in areas such as electronics, biotechnology and advanced industrial materials.

Ontario

The Province of Ontario has developed a series of programs that can assist business in a number of ways such as tax incentives, project financing, small business advice, industry/university research programs, etc. The Government of Ontario has allocated funds to promote R&D and manufacturing activities.

Québec

Funding for R&D and capital investment can be obtained through la Société de développement industriel du Québec (SDIQ). SDIQ programs can take the form of interest-free or interest-reduced loans and, in some cases, may take the form of non-repayable contributions.

In addition, the province has established a Technology Development Fund, a program designed to provide financing for up to 50 per cent of R&D project costs. The fund requires that submissions be made by R&D consortia which include two or more companies and at least one university.

The Government of Québec, in addition to providing training grants and subsidies, has recently set up a highly successful training tax credit which is very similar to its R&D tax credit program.

Atlantic Canada

Each of the Atlantic provinces has established programs to assist the private sector with industrial or technology-based projects. These include repayable contributions, interest-free or interest-reduced loans, tax incentives, as well as business consulting.

There are also a number of R&D organizations in Atlantic Canada, such as the Research Council of Nova Scotia, which provide technical facilities and services to the private sector.

