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Canadian Market Opportunities— Import Profile



Government
of Canada

Regional Industrial
Expansion

Gouvernement
du Canada

Expansion industrielle
régionale

Canada

HEMODIALYSIS EQUIPMENT AND PARTS

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These offices are listed on the last
page of this publication.

REFERENCE SOURCES

Department of Regional Industrial Expansion
Statistics Canada
Revenue Canada
Supply and Services Canada

EXPLANATORY NOTES

Valuation

Imports are generally recorded at the values established for customs duty purposes according to the provisions of the Customs Act. Customs values are identical to selling prices for most transactions between non-affiliated firms, but customs values exceed selling prices for many transactions between affiliated firms. All values are reported in Canadian dollars and do not include duty.

Average Growth Rate

Growth rates are calculated on the basis of annual compounding.

Rounding

Figures may not add due to rounding.

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CANADIAN MARKET OPPORTUNITIES - IMPORT PROFILE

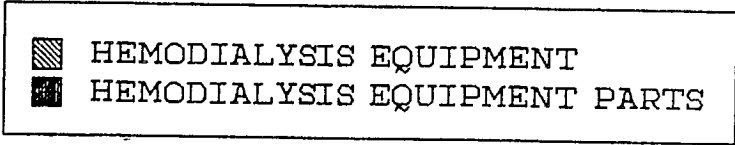
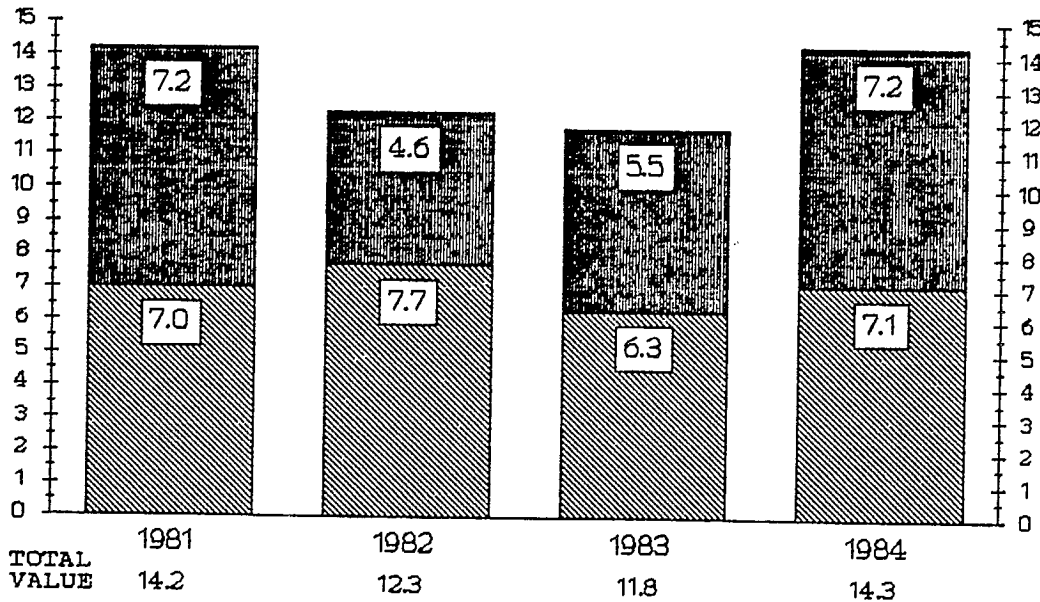
HEMODIALYSIS EQUIPMENT AND PARTS

This report is one of a continuing series designed to increase business awareness of the potential existing for domestic production and to stimulate Canadian business to further explore potential opportunities in both the Canadian and export markets. It is important to emphasize that this report does not attempt any assessment as to the feasibility of manufacturing or competing in a particular market and should be treated as an indicator or starting point for the manufacturer or entrepreneur.

Hemodialysis equipment and parts as described in this report are found under two import commodity codes (Canadian International Trade Classification): 706-89-11 "Artificial kidney machine" and 706-89-18 "Artificial kidney machine parts."

IMPORT TRENDS: OVERVIEW

VALUE (MILLION \$)



VALUE OF IMPORTS BY MAJOR FOREIGN COUNTRY OF EXPORT

HEMODIALYSIS EQUIPMENT (706-89-11)

<u>Foreign Country of Export</u>	<u>1981</u>	<u>1982</u>	<u>1983</u>	<u>1984</u>	Average Annual Growth Rate	Per cent Change	10-Month Imports Jan. to Oct.	
					<u>1981-1984</u>	<u>1983-1984</u>	<u>1984</u>	<u>1985</u>
					%	%		
UNITED STATES Value (\$000)	3 805	5 111	3 276	3 677	-1	12	3 061	3 366
FRANCE Value (\$000)	86	260	1 395	1 250	144	-10	1 061	706
WEST GERMANY Value (\$000)	713	721	1 130	808	4	-28	796	2 441
SWEDEN Value (\$000)	1 179	393	294	651	-18	121	289	265
ITALY Value (\$000)	7	143	89	248	228	179	204	901
OTHER Value (\$000)	1 202	1 032	156	492	-26	215	492	809
<hr/>								
TOTAL Value (\$000)	6 992	7 660	6 340	7 126	1	12	5 903	8 488

Imports of hemodialysis equipment remained relatively steady between 1981 and 1984 with an average annual growth rate of one per cent. Ten-month comparative data for 1984 and 1985 show a significant 44 per cent increase in total imports. In general, the European producers are moving ahead of the United States in terms of quality standards. This is reflected in the increased value of imports from West Germany and Italy during the first 10 months in 1985. Several of the U.S. producers are having their products made in Italy as quality is high and labour costs are lower than those in the U.S.

The United States has consistently been the major exporter to Canada, accounting for 52 per cent of the total value of imports in both 1983 and 1984, followed by France with 22 per cent in 1983 and 18 per cent in 1984.

VALUE OF IMPORTS BY MAJOR FOREIGN COUNTRY OF EXPORT:

HEMODIALYSIS EQUIPMENT PARTS (709-89-18)

<u>Foreign Country of Export</u>	<u>1981</u>	<u>1982</u>	<u>1983</u>	<u>1984</u>	Average	Per cent	10-Month	
					Annual		Change	Imports
					Rate		Jan. to Oct.	1985
					1981-1984	1983-1984	1984	1985
					%	%		
UNITED STATES Value (\$000)	6 041	3 282	3 503	3 419	-17	-2	2 818	3 425
ITALY Value (\$000)	121	322	1 033	2 091	159	102	1 859	799
WEST GERMANY Value (\$000)	203	208	183	882	63	382	640	745
SWEDEN Value (\$000)	109	83	329	291	39	-12	268	363
JAPAN Value (\$000)	430	515	63	234	-18	271	202	107
OTHER Value (\$000)	264	192	405	266	0	-34	245	470
TOTAL Value (\$000)	7 168	4 602	5 516	7 183	0	30	6 032	5 909

Imports of hemodialysis equipment parts fell significantly by 36 per cent between 1981 and 1982 (from \$7.2 million to \$4.6 million). The decrease was accounted for by the recessionary economic situation at that time. By 1984, however, the total value of imports recovered to its 1981 level. Ten-month comparative data for 1984 and 1985 indicate little change overall or by individual country of export.

The United States was the major exporter to Canada between 1981 and 1984. However, its share of total imports has dropped from 84 per cent in 1981 to 48 per cent in 1984. During the same period, the import market shares of both Italy and West Germany have increased (from two to 29 per cent for Italy, and from three to 12 per cent for West Germany). Italian producers are increasingly manufacturing parts for both U.S. equipment designers and equipment of Italian origin. It should be noted that although France is the second major exporter to Canada of Hemodialysis Equipment only a minimal amount of parts have been imported from that country.

IMPORT MARKET CONCENTRATION
(BY % OF TOTAL 1984 VALUE)

<u>Top 5</u> <u>Importers</u>	<u>Top 10</u> <u>Importers</u>	<u>Top 20</u> <u>Importers</u>	<u>Top 30</u> <u>Importers</u>
77	87	93	94

The 10 major importers accounted for 87 per cent of the total value of imports in 1984. Six of these were wholesalers of professional equipment and supplies. Nine companies are located in Ontario.

NOTE: "Top importers" are the known importers with the largest imports by value in 1984.

TYPE AND LOCATION OF THE 30 TOP KNOWN IMPORTERS - 1984
(94% OF TOTAL IMPORT VALUE)

	<u>MANUFACTURERS</u>		<u>WHOLESALEERS</u>		<u>OTHER</u>		<u>TOTAL</u>	
	<u>No. of</u> <u>Importers</u>	<u>Value</u> <u>(\$000)</u>	<u>No. of</u> <u>Importers</u>	<u>Value</u> <u>(\$000)</u>	<u>No. of</u> <u>Importers</u>	<u>Value</u> <u>(\$000)</u>	<u>No. of</u> <u>Importers</u>	<u>Value</u> <u>(\$000)</u>
Ontario	4	671	9	7 885	3	325	16	8 881
Québec	-	-	7*	4 120*	4	263	11*	4 383*
Atlantic Provinces	-	-	-	-	-	-	-	-
Western Provinces	-	-	-	-	3	172	3	172
TOTAL	4	671	16	12 005	10	760	30	13 436

Per cent of 1984 total value	5%	84%	5%	94%
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* Québec and Atlantic Provinces aggregated to preserve confidentiality.

There were 63 known importers of hemodialysis equipment and parts in 1984, of whom the top 30 accounted for 94 per cent of the total import value. Of these 30 importers, 16 were wholesalers of professional equipment and supplies whose total imports represented 84 per cent of the import total. Seven of the top 30 importers were hospitals. The 16 Ontario importers accounted for 62 per cent of the total imports.

Of the 63 known importers, 14 imported both hemodialysis equipment and parts, 13 imported only equipment and 36 imported only parts.

CANADIAN PRODUCTION

There are currently no Canadian manufacturers of hemodialysis equipment or parts. There is, however, one Canadian manufacturer of interperitoneal dialysis devices. This company is located in Ontario. Statistics Canada does not publish specific production data for dialysis equipment and parts which are included with "Dental, optical, surgical and medical instruments and apparatus."

EXPORTS

Statistics Canada does not publish export data for dialysis equipment and parts. They are included in the export class "Medical and related instruments, equipment and parts, not elsewhere specified."

MARKET SUMMARY

The Products

There are two common types of dialysis--i.e. hemodialysis (HD) and intermittent peritoneal dialysis (IPD). The former modality involves removing the blood from a patient and pumping it through a dialyzer unit in which blood toxins are exchanged into another fluid (the dialysate), through a semi-permeable surface. Peritoneal dialysis involves introducing a dialysate into the peritoneal cavity, allowing natural tissues to exchange blood toxins, and then draining and discarding the dialysate. This report examines hemodialysis equipment and parts only.

There are three major components of a hemodialysis system:

- 1) Water purification, dialysate preparation and delivery to the exchange unit (the dialyzer);
- 2) The dialyzer; and
- 3) The blood pumping unit which delivers blood from the patient, to the dialyzer and returns it to the patient.

Both the dialysate formulation and flow rate are electronically monitored and alarms indicate deviations from pre-set levels. Similarly, blood flow rates are monitored and alarms indicate deviations from normal, pre-set limits.

Peritoneal dialysis involves the implantation of a semi-permanent catheter into the patient's peritoneal cavity. At a specified time, dialysate solution contained in a plastic bag is allowed to flow by gravity into the peritoneal cavity. The solution is then drained through the same catheter and discarded.

Technology

A major element of a dialysis system is the requirement of pure water, normally accomplished by filtration or reverse osmosis procedures. Suitable chemicals are added to form the dialysate and the concentrations are controlled by measurement of chloride ion concentration. Pressure, flow rate and chloride ion concentration alarms are built into the delivery system of the dialysate to the dialyzer.

Dialyzers constructed of hollow fibres are the current popular type. The technology of construction is closely held by a small number of companies, worldwide. In addition, there is but one source, worldwide, for the synthetic fibre material which is most commonly used to construct dialyzers. A dialyzer, with its multiple tubes, resembles the construction of a miniature tube and shell heat exchanger.

Pumping of dialysate is done by centrifugal pumps. Pumping of blood is done by a peristaltic pump. Detectors and alarms indicate abnormalities in flow rates or pressures and/or blood leakage. Specialized PVC is used for both blood and dialysate handling.

A small intravenous pump is used to introduce heparin into the patient's blood stream.

MARKET SUMMARY (CONTINUED)

Regulatory Environment

All equipment and supplies for dialysis treatments must be certified safe by the Bureau of Medical Devices of the Department of Health and Welfare. Records supporting the certification must be maintained, and as well, equipment must meet the requirements (with respect to current leakage) of the Food and Drug Act.

The Canadian Standards Association maintains standards for the equipment used for hemodialysis, and it is likely that hospitals would require that equipment meet these standards.

In the United States, the Food and Drug Administration states that all equipment and supplies are considered Class II devices and must meet the mandatory standards which have been developed. In addition, suppliers must be registered and maintain certain specified records. Such standards include precise marking and labelling requirements, information to be included in instruction manuals, accuracy of blood flow rate measurement and alarm settings, accuracy of flow rate measurement of dialysate, etc.

Apparent Domestic Market

There are some 2 500 Canadians undergoing HD on a regular basis (generally two or three times weekly). In addition, many other patients undergo HD for brief periods. Approximately half as many, some 1 300 patients, undergo some form of IPD on a regular basis.

On a per province basis, the Canadian Renal Failure Registry indicated the following numbers of persons undergoing dialysis treatment in 1984.

	<u>B.C.</u>	<u>Alta.</u>	<u>Sask.</u>	<u>Man.</u>	<u>Ont.</u>	<u>Que.</u>	<u>N.B.</u>	<u>N.S.</u>	<u>P.E.I.</u>	<u>Nfld.</u>	<u>Totals</u>
Hemodialysis	371	200	62	131	840	723	66	73	-	98	2 566
Peritoneal Dialysis	215	64	43	66	633	208	33	18	-	32	1 312

For the last several years, the annual imports of hemodialysis delivery systems (including water purification systems which are always required) has remained steady at approximately \$7 million. Annual imports of the disposable dialyzers and other parts has also remained at some \$7 million. Chemicals necessary for dialysate preparation provide an annual market of \$5 million.

Both HD delivery systems and all dialyzers are entirely imported. The dialysate chemicals are generally purchased from Canadian manufacturers.

Over the last few years, the growth rate of the market for equipment, parts and supplies for hemodialysis has been close to zero, since the rate of kidney disease remains fairly stable. Increasing population would no doubt increase the demand for hemodialysis treatment as will the expected increase in average age of the population over the next twenty or thirty years.

Only recently, cardiac care facilities in some centres have begun to use hemodialysis to alleviate certain heart conditions both prior to and after heart surgery. This procedure may well accelerate demand for additional hemodialysis equipment.

MARKET SUMMARY (CONTINUED)

Tariffs and Other Trade Considerations

Dialysis equipment and supplies enter Canada free of duty. No federal or provincial sales taxes are levied on such devices. The U.S. imposes a duty of 4.7 per cent ad valorem on equipment and supplies entering the U.S.

Competitive Factors

There are many suppliers for this market (some hospitals have advised as many as 26), and there is very aggressive competition among suppliers. There are at least 10 U.S. manufacturers of dialysate delivery systems and more than 15 U.S. suppliers of the artificial kidneys (dialyzers). The currently preferred construction of dialyzers is by means of a bundle of hollow fibres constructed of Cuprothane, a type of rayon. Such rayon is only produced by one plant in the world and there are only five or six manufacturers in the world with the technology to produce hollow fibres from Cuprothane fibres. These few manufacturers provide the requirements of all other suppliers. In addition, the construction of dialyzers, based on hollow fibres, is covered by patents held by Dupont Inc. and Monsanto Inc. in the United States. Opportunities exist, however, for Canadian companies with the financial strength and/or the technological background to enter the dialysis equipment market.

There is also an opportunity in Canada for the production of a machine to wash dialyzers as there is an increasing amount of reuse of dialyzers. Techniques for cleaning and re-sterilization of these devices have been developed, and there is an increasing tendency for hospitals to reuse dialyzers a number of times (up to six or seven times). New dialyzers cost approximately \$20 to \$25 each.

This report was prepared by:

the Market Development Branch
in collaboration with the
Health Care Products Division,
Chemicals Directorate,
Resource Processing Industries Branch.

DEPARTMENT OF REGIONAL INDUSTRIAL EXPANSION

CANADIAN TARIFFS, 1985

Tariff Item	Description	% of Total Import Value (1984)	TARIFF TREATMENT				
			British Prefer- ential Tariff	U.K. and Ireland	Most Favoured Nation Tariff	General Tariff	General Prefer- ential Tariff
			%	%	%	%	%
47600-01	X-ray apparatus and X-ray film; microscopes, illuminating devices and stands for use therewith; the following surgical, dental, veterinary and diagnostic articles: instruments; sterilizers; cobalt-therapy units; anaesthesia, surgical suction and oxygen administering apparatus including motive power and wall outlets but not piping systems. Parts of all the foregoing; electric light lamps designed for use with all the foregoing; portable cases and containers for all the foregoing	53	Free	Free	Free	Free	Free
47810-01	Aural, nasal, mastectomy and other medical or surgical prostheses, other than dental prostheses; materials for use in reconstructive surgery, other than dental surgery; ileostomy, colostomy and urinary appliances or articles, other than infants' pants and diapers, designed to be worn by an individual; materials and articles required therewith for proper application and maintenance	40	Free	Free	Free	Free	Free

Tariff Arrangements and Foreign Countries of Export:

MOST FAVOURED NATION: UNITED STATES, FRANCE, WEST GERMANY, SWEDEN, ITALY, JAPAN

ENQUIRIES CONCERNING TARIFFS SHOULD BE DIRECTED TO THE NEAREST CUSTOMS AND EXCISE OFFICE OR TO:

TARIFF PROGRAMS
REVENUE CANADA
CUSTOMS AND EXCISE
OTTAWA, ONTARIO
K1A 0L5
TEL: (613) 996-9478

CANADIAN IMPORTERS

Importers of Hemodialysis Equipment and Parts as indicated in this report in 1984 are listed below in alphabetical order. The number in brackets following the names of the importers indicate the specific products they are importing as follows: (1) Hemodialysis Equipment; and (2) Hemodialysis Equipment Parts. The list includes all importers except individuals and a minimal number of importers whose names were not available.

<u>Name</u>	<u>Address</u>	<u>Name</u>	<u>Address</u>
129170 Canada Inc./Micro Ancapsulation Technologie Inc.(2)	St-Laurent, Qué.	Provincial Government Minister of Finance(1)(2)	Victoria, B.C.
Amicon Canada Limited(2)	Oakville, Ont.	Provincial Medical Supplies Ltd.(2)	St. John's, Nfld.
Becton Dickinson Canada Inc.(1)(2)	Mississauga, Ont.	Ray Laborie & Associés Inc.(1)	Brossard, Qué.
Bionetics Ltd.(2)	St-Laurent, Qué.	Royal Columbian Hospital(2)	New Westminster, B.C.
Cardiomed Supplies Inc.(1)(2)	Stouffville, Ont.	Royal Inland Hospital(2)	Kamloops, B.C.
Cardiovision Supplies Inc.(1)(2)	Gormley, Ont.	Royal Victoria Hospital(1)(2)	Montréal, Qué.
Centre Hospitalier de Verdun(1)	Montréal, Qué.	Seagold Industries(2)	Burnaby, B.C.
Cobe Canada Limited(1)(2)	Scarborough, Ont.	St. Joseph's Hospital(1)(2)	Hamilton, Ont.
Cordis Brent Inc.(1)(2)	Toronto, Ont.	St. Michael's Hospital(2)	Toronto, Ont.
Critikon Canada Inc.(2)	Markham, Ont.	St. Paul's Hospital(2)	Vancouver, B.C.
Culligan of Canada Ltd.(2)	Mississauga, Ont.	Sydney City Hospital(1)	Sydney, N.S.
Dupont Canada Inc.(2)	Mississauga, Ont.	Terumo Corporation Canada(1)	Boisbriand, Qué.
Dynetech Ltd.(2)	Toronto, Ont.	The Health Sciences Centre(2)	Winnipeg, Man.
Eiscint Canada Limited(2)	Markham, Ont.	The Izaak Walton Killam Hospital for Children(2)	Halifax, N.S.
Équipement de Physiothérapie P. Gélinas Ltée(2)	Westmount, Qué.	The Wellesley Hospital(2)	Toronto, Ont.
Extracorporeal Inc.(1)(2)	Markham, Ont.	Toronto Western Hospital(1)	Toronto, Ont.
Foothills Provincial General Hospital(2)	Calgary, Alta.	Travenol Canada Inc.(1)	Mississauga, Ont.
Gambro Canada Ltd.(1)(2)	Mississauga, Ont.	University of Alberta Hospital(2)	Edmonton, Alta.
Hamilton Civic Hospitals(2)	Hamilton, Ont.	Vancouver General Hospital(1)(2)	Vancouver, B.C.
Health Sciences Centre Hospital(1)	Vancouver, B.C.	Vial Medical Ltée(2)	St-Léonard, Qué.
Hôpital Général d'Ottawa(2)	Ottawa, Ont.	Vicraft Plastics Ltd.(2)	Scarborough, Ont.
Hôpital Maisonneuve-Rosemont(1)	Montréal, Qué.	Victoria Hospital Corporation(1)(2)	London, Ont.
Hôpital Notre-Dame(2)	Montréal, Qué.		
Hospal Ltée(1)(2)	St-Léonard, Qué.		
Hotel Dieu Hospital(1)	Kingston, Ont.		
Institut Armand Frappier(1)	Laval-des-Rapides, Qué.		
London Health Association(1)	London, Ont.		
McGaw Manufacturing, Div. of McGaw Supply Ltd.(2)	Brantford, Ont.		
Medical Mart Supplies Ltd.(2)	Mississauga, Ont.		
Medionics International Inc.(2)	Markham, Ont.		
Millipore Ltd.(2)	Mississauga, Ont.		
Montréal General Hospital(1)(2)	Montréal, Qué.		
Petwa Canada Ltd.(2)	Calgary, Alta.		
Petwa Deionization Inc.(2)	Calgary, Alta.		
Province of Nova Scotia(1)(2)	Halifax, N.S.		

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