

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY"

- 9.1 Trade/Proprietary Name: Disetronic Multifuse™ Pump System
- 9.2 Common/Usual Name: Peristaltic Infusion Pump and Accessories
- 9.3 Classification Name: Infusion Pump/Intravascular Administration Set
- 9.4 Comparison to Currently Marketed Devices

The Disetronic Multifuse Infusion Pump is functionally equivalent to the Disetronic Panomat and Dolomat Infusion Pumps and the SIMS Deltec CADD-PLUS, CADD-PCA and CADD-TPN.

9.5 Device Description

9.5.1 Discussion

The Disetronic Multifuse pump is a small, battery-operated peristaltic infusion pump that is suited for ambulatory hospital and home use. The pump is extremely versatile. It has been designed to allow the health provider program the pump to provide one of several types of infusion therapies. The pump can be configured as a continuous rate infusion pump with demand bolus capability, a variable rate infusion pump with demand bolus capability, a Patient Controlled Analgesia (PCA) pump, a Total Parenteral Nutrition (TPN) pump or an intermittent infusion pump. The health provider can further customize the pump for a specific patient by allowing or excluding optional programming steps, limiting allowable ranges, adjusting the rate at which boluses are infused and adjusting alarm and display features. These control functions can only be performed by using the Multifuse Computer Software. This proprietary control software runs on IBM compatible personal computers in the Windows® environment and communicates with the pump through an optical interface. The pump can be re-programmed as required for different patients. This versatility enables the health care provider minimize the different types of pumps and still provide for almost all infusion therapies.

9.5.2 Physical Description

The base housing holds the pumping mechanism, electronics, and batteries. This housing is sealed against water to help prevent internal damage. The front panel on this housing has a dot-matrix LCD display, four input buttons, and two LED status indicator lights. Specific infusion parameters can be programmed using the input buttons on the front panel. There is also an optical interface on the panel for two way communication with a computer or modem.

The Multifuse pump uses four AA-size main batteries. It also accepts rechargeable batteries or can be powered with an available AC adapter. The pump has a separate back-up battery to maintain the pump's memory while the main batteries are being changed or if they become depleted.

The pump infuses fluid by means of a sterile disposable tubing cassette that snaps into the pump. The cassette has a short section of pumping tube which is squeezed by the pump mechanism

to cause the pumping action. The cassettes are available with several different diameters of pumping tubing which offer different flow rate ranges. The cassette has an optical code corresponding to the tube's diameter which is read by the pump's electronics to safely and automatically adjust the flow rate range. The cassette has an air detection chamber, a pressure detection chamber, and an anti-freeflow valve. The air and pressure detection chambers work together with detectors in the pump housing. The cassettes are available in a number of different configurations including different lengths, connectors, filters, injection ports, etc.

A cover for the cassette snaps in place to protect the cassette and sensors during use. This cover also provides a back-up plate against which the pumping mechanism squeezes the flexible tubing.

The tubing cassette connects to a bag-type reservoir which holds the liquid medication. This reservoir may be any suitable standard IV bag or Disetronic Multifuse Reservoirs. The Multifuse reservoirs are made to fit into one of the pump's reservoir holders. These holders slide into a dovetail on the housing and can be changed to the appropriate size. The reservoir holders help protect the reservoir, improve the portability, and may also be locked for security.

Other accessories available for use with the Multifuse include an AC adapter, a belt carrying clip, various carrying pouches, a remote bolus button, and a modem.

9.5.3 Pumping Method and Flow Characteristics

The basic pumping method used in the Disetronic Multifuse Pump is an elastic tube acted upon by three squeezing fingers. The first and third of these fingers, together with the tube, act as valves. The middle finger, together with the tube, is a volume displacement chamber. The tube is positioned between the fingers and a platen. This platen acts as a back-up plate against which the tubing is squeezed. The fingers are moved by a camshaft and motor in a specific sequence so that the tube passively fills from the upstream side and is actively emptied into the downstream side. This is done repetitively to effect an accurate, relatively constant flow.

The Disetronic Multifuse Pump delivers a small, accurate volume each cycle of the pumping mechanism. Different flow rate ranges are obtained with different diameters of elastic tubing. The low range cassette dispenses 100 μ -liters and the high range cassette 250 μ -liters per cycle, respectively.

Each complete output cycle is further resolved into approximately 25% segments by the position sensing electronics. By doing so, the size of, and thus the time between, incremental infusion volumes is one-fourth as small as with complete cycles. Thus, the actual incremental volumes are 25 μ -liters and 62.5 μ -liters for the low and high range cassettes, respectively. This is particularly valuable at low flow rates and helps to improve the continuity of flow. Although the 25% segments are approximated, the overall flow accuracy is not affected due to the accuracy of each complete cycle.

For low flow rates, the pump delivers the one-fourth cycle volume each incremental output and calculates the time, in multiples of one minute, necessary to achieve the correct flow rate. For higher flow rates, the pump delivers an incremental volume every one minute. The volume of these increments is calculated to achieve the correct flow rate.

Bolus volumes are calculated and delivered directly based on the necessary number of cycles or parts of cycles. Therefore, the bolus volume accuracy is independent of its flow rate.

9.5.4 Flow profiles

The Disetronic Multifuse Pump has five different basic modes of infusion profiles, or types that can be selected. These are called the C-type (Continuous), V-type (Variable), PCA-type (Patient Controlled Analgesia), INT-type (Intermittent), and TPN-type (Total Parenteral Nutrition). Each of these profiles can be modified by adding or eliminating certain characteristics to meet the specific needs of the patient. The basic parameters of these types are:

Continuous Infusion	constant rate output
Infusion Rate	rate at which drug is infused
Infusion Volume	volume to be infused
Infusion Time	time duration of therapy
KVO Rate	rate of infusion to maintain an open vein between infusions or boluses
Start Delay	time delay before therapy begins
Cycle Time	time for each therapy for repetitive therapies
Demand Bolus	amount of a patient demand bolus
Physician Bolus	amount of a bolus programmed by the physician to be automatically delivered

9.6 Indications for Use

The Disetronic Multifuse Pump with its accessories is intended for the controlled delivery of parenteral fluids, including patient controlled analgesia (PCA), in both the hospital and home care environments.

9.7 Testing

The Disetronic Multifuse Infusion Pump has been designed and tested in accordance with IEC 601-2-24 of the:

INTERNATIONAL ELECTROTECHNICAL COMMISSION
TECHNICAL COMMITTEE No. 62: ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE
SUB-COMMITTEE 62D: ELECTROMEDICAL EQUIPMENT
Draft Date: August 29, 1994
Part 2: Particular requirements for safety of infusion pumps and controllers.

IEC 601-2-24 incorporates the requirements of IEC 601-1 for all general safety requirements including IEC 801-2 and 801-3 for Electromagnetic Interference (EMI) and Electrostatic Discharge (ESD).

The electronic and mechanical design is not unique and therefore the specifications fully address pump performance.

9.8 Software

Disetronic has adhered to all software development procedures and Good Quality Assurance procedures. All test results demonstrate that the system specifications and functional requirements were met.

9.9 Biocompatibility

The drug contact materials are either used in devices legally marketed in the USA for similar intended uses or comply with ISO 10993-1: 1992 (E) - Externally communicating device, Blood path - Indirect, Prolonged use (< 24 hours to 30 days)

9.10 Conclusion

Based on the functional comparison, design equivalency and the functional and safety testing, Disetronic has determined that the Multifuse Infusion Pump and accessories are substantially equivalent to devices currently marketed in the United States.