

## ANNEX 1 TO STATEMENT OF REASONS

1. A device (10) for delivering fluid to a Type I diabetic patient, comprising:
  - an exit port assembly (70) adapted to connect to a transcutaneous patient access tool;
  - a dispenser for (40) causing fluid from a reservoir (30) to flow to the exit port assembly;
  - a local processor (50) connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based on flow instructions;
  - a wireless receiver (60) connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and
  - a housing (20) containing the exit port assembly, the dispenser, the local processor, and the wireless receiver;

wherein the housing is free of user input components for providing flow instructions to the local processor, ~~and~~ wherein the transcutaneous patient access tool is integrated into the exit port assembly, and wherein the reservoir (30) is contained in the housing (20) and has a volume in the range of 2 to 3 ml.

2. A system including a fluid delivery device (10) for delivering fluid to a patient and a remote control device (100) separate from the fluid delivery device, the fluid delivery device comprising:

an exit port assembly (70) adapted to connect to a transcutaneous patient access tool;  
a dispenser for (40) causing fluid from a reservoir (30) to flow to the exit port assembly;  
a local processor (50) connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based on flow instructions;  
a wireless receiver (60) connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and  
a housing (20) containing the exit port assembly, the dispenser, the local processor, and the wireless receiver;

wherein the housing is free of user input components for providing flow instructions to the local processor, wherein the transcutaneous patient access tool is integrated into the exit port assembly,

the remote control device (100) including:

a remote processor;

user interface components (120) connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and

a transmitter (130) connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device;

and further comprising a proximity alarm.

3. A kit including a system including a plurality of fluid delivery devices (10) for delivering fluid to a patient and a single remote control device (100) separate from the fluid delivery devices.

the fluid delivery devices comprising:

an exit port assembly (70) adapted to connect to a transcutaneous patient access tool;

a dispenser for (40) causing fluid from a reservoir (30) to flow to the exit port assembly;

a local processor (50) connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based on flow instructions;

a wireless receiver (60) connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and

a housing (20) containing the exit port assembly, the dispenser, the local processor, and the wireless receiver;

wherein the housing is free of user input components for providing flow instructions to the local processor, wherein the transcutaneous patient access tool is integrated into the exit port assembly,

the remote control device (100) including:

a remote processor;

user interface components (120) connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and

a transmitter (130) connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device;

wherein each fluid delivery device (10) includes a bar code (26) and the remote control device (100) includes a barcode scanner (140).

- ~~2-4.~~ A device, system or kit according to claim 1, 2 or 3, wherein the flow instructions cause a predetermined rate of fluid flow for a predetermined period.
- ~~3-5.~~ A device, system or kit according to claim 24, wherein the predetermined rate of fluid flow comprises a basal rate.
- ~~4-6.~~ A device, system or kit according to claim 1, 2 or 3, wherein the flow instructions cause a predetermined volume of fluid to flow for a predetermined period.
- ~~5-7.~~ A device, system or kit according to claim 46, wherein the predetermined volume comprises a bolus volume.
- ~~6-8.~~ A device, system or kit according to claim 1, 2 or 3, wherein the local processor (50) is programmed to cause a flow of fluid comprising pulse volumes.
- ~~7-9.~~ A device, system or kit according to any preceding claim, further comprising at least one user interface component accessible from an exterior of the housing (20) for occluding flow to the exit port assembly.
- ~~8-10.~~ A device, system or kit according to any preceding claim, further comprising a power supply (80) for supplying electrical power to the local processor.
- ~~9-11.~~ A device, system or kit according to claim 810, wherein the power supply (80) is integrated with the device.
- ~~10-12.~~ A device, system or kit according to claim 810, wherein the power supply (80) comprises a replaceable battery.
- ~~11-13.~~ A device, system or kit according to any preceding claim, wherein the receiver (60) utilizes radio frequency signals.
- ~~12-14.~~ A device, system or kit according to any preceding claim, further comprising a transmitter connected to the local processor (50) for transmitting information from the local processor to a separate, remote control device.
- ~~13-15.~~ A device, system or kit according to any preceding claim, wherein the housing (20) is free of user output components for providing information from the local processor.

~~14.~~ A device according to any preceding claim, further comprising a reservoir (30) and the dispenser (40) controls fluid flow from the reservoir (30) to the exit port assembly (70).

~~15-16.~~ A device according to claim 14, wherein the reservoir (30) contains a therapeutic fluid.

~~16-17.~~ A device according to claim 14 or ~~15-16~~, further comprising a fill port connected to the reservoir (30).

~~17-18.~~ A device according to claim 14, ~~15-16~~ or ~~16-17~~, wherein the reservoir (30) is made of a flexible material and collapses as emptied.

~~18-19.~~ A device according to claim 1 or any of claims ~~14-16~~ to ~~17-18~~, wherein the reservoir (30) is thermally insulated.

~~19-20.~~ A device according to claim 1 or any of claims ~~14-16~~ to ~~18-19~~, wherein the reservoir (30) is pressurized.

~~20-21.~~ A device according to claim ~~19-20~~, further comprising a spring (34) compressing the reservoir (30).

~~21-22.~~ A device according to claim 1 or any of claims ~~14-16~~ to ~~20-21~~, further comprising a second reservoir (90) connected to the exit port assembly (70).

~~22-23.~~ A device according to claim 1 or any of claims ~~14-16~~ to ~~21-22~~, further comprising:  
an expandable bolus accumulator (185) connected to the reservoir (30); and  
at least one user interface component accessible from an exterior of the housing (20) for opening fluid flow between the bolus accumulator and the exit port assembly (70).

~~23-24.~~ A device, system or kit according to any of claims 1 to ~~13-15~~, wherein the dispenser (40) includes an expandable accumulator (43), an inlet valve (41) controlling flow from a reservoir into the accumulator and an outlet valve (42) controlling flow between the accumulator and the exit port assembly.

~~24-25.~~ A device, system or kit according to any of claims 1 to ~~13-15~~ or ~~23-24~~, wherein the dispenser (40) comprises a pump for pumping fluid from a reservoir (30) to the exit port assembly (70).

25-26. A device, system or kit according to any of claims 1 to 13-15, 23-24 or 24-25, further including at least one sensor connected to the local processor (50) and comprising at least one of an occlusion detector (22), a reservoir volume transducer (37), a reservoir empty detector, (222) a leak detector, a pressure transducer (221), a fluid contact detector, an impedance monitor, a voltage detector, a photodetector, and a vibration monitor.

26-27. A device, system or kit according to any of claims 1 to 13-15 or 23-24 to 25-26, further comprising an alarm (223) connected to the local processor (50).

27-28. A device, system or kit according to any of claims 1 to 13-15 or 23-24 to 26-27, further comprising adhesive (201) on an exterior of the housing (20).

28-29. A device, system or kit according to claim 27-28, wherein the adhesive (201) is provided in at least one continuous band surrounding the exit port assembly (70).

29-30. A device, system or kit according to any of claims 1 to 13-15 or 23-24 to 28-29, wherein the exit port assembly (70) is mounted in a recessed portion of the housing (20).

30-31. A device, system or kit according to any of claims 1 to 13-15 or 23-24 to 29-30, wherein the housing (20) is flexible.

31-32. A device, system or kit according to claim 30-31, wherein the housing (20) includes hinge sections (23).

32-33. A device, system or kit according to any of claims 1 to 13-15 or 23-24 to 31-32, wherein the housing (20) includes a window (22).

33-34. A device, system or kit according to any of claims 1 to 13-15 or 23-24 to 32-33, wherein the housing (20) includes vent holes (38).

34-35. A device, system or kit according to any of claims 1 to 13-15 or 23-24 to 33-34, wherein the local processor (50) and the receiver (60) are encapsulated in an electromagnetic shielding material.

35-36. A device, system or kit according to claim 34-35, wherein the receiver (60) includes an antenna (61) extending out of the electromagnetic shielding material.

~~36-37.~~ A device, system or kit according to any of claims 1 to ~~13-15~~ or ~~23-24~~ to ~~3536~~, wherein the local processor (50) includes programming which can be updated by a remote control device (100).

~~37-38.~~ A system including a fluid delivery device (10) according to claim 1 or any of claims ~~4~~ ~~4~~ to ~~13-15~~ or ~~23-24~~ to ~~3637~~, and further comprising a remote control device (100) separate from the fluid delivery device and including:

- a remote processor;
- user interface components (120) connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and
- a transmitter (130) connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device.

~~38-39.~~ A system according to claim ~~3738~~, further comprising a proximity alarm.

~~39-40.~~ A kit including a system according to claim ~~37-38~~ or ~~3839~~, further including a single remote control device (100) and a plurality of fluid delivery devices (10).

~~40-41.~~ A kit according to claim ~~3940~~, wherein each fluid delivery device (10) includes a bar code (26) and the remote control device (100) include a barcode scanner (140).

~~41-42.~~ A device, system or kit according to claim 1, ~~2 or 3~~, wherein the local processor (50) is further programmed to provide flow information; and wherein the housing (20) is free of user output components for providing the flow information from the local processor to a user.

~~42-43.~~ A device, system or kit according to claim ~~4142~~, wherein the local processor (50) is programmed to receive at least some of the flow instructions from a separate, remote control device (100).

~~43-44.~~ A system including a fluid delivery device (10) according to claim ~~41-42~~ or ~~4243~~, and further comprising a remote control device (100) separate from the fluid delivery device and including:

- a remote processor;
- user output components (110) connected to the remote processor for allowing a user to receive flow information; and

a receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.

44.45. A system for delivering a fluid to a patient, comprising:

(a) a fluid delivery device (10) according to claim 1 for attachment to a skin surface of a patient; and

wherein the local processor (50) is programmed to cause a flow of fluid to the exit port assembly (70) based at least in part on received flow instructions, and further programmed to provide flow information, the fluid delivery device further comprises:

a wireless transmitter connected to the local processor (50) for transmitting the flow information from the local processor; and the housing contains the wireless transmitter; and

(b) a remote control device (100) separate from the fluid delivery device and including,

user input components (120) for receiving user inputs,

user output components (110) for providing user outputs,

a remote processor connected to the user input components and programmed to provide the flow instructions based on the user inputs, and connected to the user output components to provide user outputs based on the flow information,

a wireless transmitter (130) connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device, and

a wireless receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.

## ANNEX 2 TO STATEMENT OF REASONS

5 maintenance of the device for four or more years to justify the expenditure. Also due to the cost, replacement devices are not easily available or practical. Any damage to the device, such as that caused by it being dropped, result not only in the costs of repair or replacement, but also in a period of discontinued therapy. The high cost of the device is a concern of healthcare providers who approve and prescribe the use of the device, limiting the expansion of the patient populations and therapies for which the devices can be used.

10 WO 00/29047 published 25 May 2000 discloses a device and a method for supplying medicaments by a mobile, portable, non-implantable means with wireless operation or programming. WO 00/10628 published 2 March 2000 discloses an infusion system with remote programming, bolus estimator and vibration alarm capabilities and containing a fluid that is expelled through an outlet in a reservoir and housing, and then into a body of a user through tubing and a set. US4559037 published 17 December 1985 discloses a device for pre-programmable infusion of liquids. EP1177802 published 6 February 2002 and falling under Article 54(3) European Patent Convention discloses a self-contained drug infusion device with a disposable portion and a reusable portion remotely connected to the disposable portion.

20 US 5,800,420 discloses devices for the delivery of liquid drugs to a subject, in particular, "closed loop" insulin delivery devices.

25 None of the above disclose a programmable and adjustable infusion system that is precise and reliable and can offer clinicians and patients a small, low cost, light weight, simple to use alternative for parenteral delivery of liquid medicines.

### SUMMARY OF THE INVENTION

30 A device for delivering fluid to a patient in accordance with the invention is provided in claim 1. A system including a fluid delivery device for delivering fluid to a patient and a remote control device separate from the fluid delivery device is provided in claim 2. A kit including a system including a plurality of fluid delivery devices for delivering fluid to a patient and a single remote control device separate from the fluid delivery devices is provided in claim 3.

35 The applicant has determined that a sophisticated ambulatory infusion device that can be programmed to reliably deliver variable flow profiles of liquid medications, yet is small, light weight and low cost, is needed. Smaller and lighter devices are easier to