WO 98/04303 A1 describes monitoring the flow resistance of an infusion line by measuring pressure, for example in order to detect an occlusion of the administration line. The disclosure focuses on coping with noise sources, such as patient movement, breathing, etc. Further, effects of the use of several IV infusion sets in parallel are described.

U.S. 2006/272421 A1 describes detecting intravascular pressure, wherein a membrane can dampen the oscillations relating to cardiovascular system of a patient. The described concepts are also applicable to intravenous infusion.

Summary

Embodiments of the present invention provide an IV infusion set that alleviates or minimizes the above-mentioned drawbacks. Embodiments of the present invention provide an infusion line that alleviates or minimizes the above-mentioned drawbacks. Embodiments of the present invention provide a process for detecting the pressure of a medical fluid in an IV infusion set that alleviates or minimizes the above-mentioned drawbacks.

An IV infusion set, an infusion line, and/or a process according to one or more of the appended embodiments, taken singly or in any combination, attain at least one of the above-indicated advantages.

According to a first aspect of the present invention, there is provided an IV infusion set, comprising a patient access configured to connect to a vascular system of a patient, a source of medical fluid, an infusion line having at least one first end configured to connect to the source of medical fluid

and at least one opposite second end configured to deliver the medical fluid towards the patient access, the infusion line defining at least a medical fluid path developing from the first end of the infusion line to the patient access, the second end of the infusion line being connected to the patient access, the source of medical fluid being coupled to the first end of the infusion line and configured to supply medical fluid to the infusion line, an infusion apparatus arranged on the infusion line, a sensor configured to emit a pressure signal indicative of a pressure of a medical fluid in the infusion line, and a control unit configured to receive the pressure signal and to determine a patient signal indicative of a vital signal of the patient based on the pressure signal. The infusion apparatus includes a pump. The IV infusion set further comprises a compliance element configured to attenuate pressure variations of medical fluid the infusion line, and a resistance element configured to reflect pressure waves moving along the infusion line. The sensor is arranged on the infusion line at a position downstream from the resistance element with respect to a direction of fluid flow along the infusion line from the medical fluid source towards the patient access. Optionally, the infusion line includes a main infusion line with or without one or more auxiliary infusion lines connected to a main infusion line.

In an embodiment, the infusion line includes a main infusion line and at least one auxiliary infusion line connected to the main infusion line. The at least one auxiliary infusion line has at least one first end configured to connect to an

auxiliary source of medical fluid and at least one opposite second end configured to deliver the medical fluid towards the main infusion line. The auxiliary infusion line defines at least a medical fluid path developing from the first end of the auxiliary infusion line to the patient access. The source of medical fluid is coupled to the first end of the auxiliary infusion line and configured to supply medical fluid to the auxiliary infusion line. The IV infusion set further comprises the auxiliary source of medical fluid, and an auxiliary infusion apparatus arranged on the auxiliary infusion line.

In an embodiment, the IV infusion set further comprises at least one auxiliary sensor configured to emit an auxiliary pressure signal indicative of a pressure of a medical fluid in the at least one auxiliary infusion line.

In an embodiment, the IV infusion set further comprises, for each of the at least one auxiliary infusion lines, an auxiliary compliance element configured to attenuate pressure variations of medical fluid in the respective auxiliary infusion line, and an auxiliary resistance element configured to reflect pressure waves moving along the respective auxiliary infusion line. The compliance element and the resistance element are arranged on the main infusion line and the auxiliary compliance element and the auxiliary resistance element are arranged on the auxiliary infusion line. Optionally, the auxiliary compliance element and the auxiliary resistance element are arranged on the auxiliary infusion line proximate the connection to the main infusion line.

In an embodiment, the compliance element is arranged downstream from the pump with respect to the direction of fluid flow along the infusion line from the medical fluid source towards the patient access.

In an embodiment, the compliance element is arranged upstream from the resistance element with respect to the direction of fluid flow along the infusion line from the medical fluid source towards the patient access.

In an embodiment, the resistance element includes a flow restrictor to restrict flow of medical fluid along the infusion line through resistance element.

In an embodiment, the compliance element has an inlet port and an outlet port for the medical fluid and defines a portion of the medical fluid path.

In an embodiment, the compliance element comprises a drip chamber.

In an embodiment, the IV infusion set further comprises an additional drip chamber arranged downstream from the medical fluid source with respect to the direction of fluid flow along the infusion line from the medical fluid source towards the patient access. Optionally, the additional drip chamber is arranged upstream from the pump with respect to the direction of fluid flow along the infusion line from the medical fluid source towards the patient access.

In an embodiment, the resistance element comprises a hollow body interposed along the infusion line to allow passage of the medical fluid, the hollow body having a fluid passage section

smaller than a fluid passage section of the infusion line defining a section restriction for the medical fluid flow.

In an embodiment, the hollow body defines a portion of the medical fluid path.

In an embodiment, the hollow body includes a slender hollow body.

In an embodiment, the hollow body is made of a material more rigid than the material of the infusion line. In an embodiment, the hollow body has a longitudinal axis coincident with a longitudinal axis of the infusion line and a circular passage section smaller than a passage section of the infusion line.

In an embodiment, the resistance element is directly connected to an outlet of the compliance element.

In an embodiment, the resistance element comprises a needle. Optionally, the resistance element includes one of: a 16 G needle, an 18 G needle, a 20 G needle, a 22 G needle, a 24 G needle, and a 27 G needle.

In an embodiment, the IV infusion set further comprises a second resistance element.

In an embodiment, the second resistance element is arranged on the infusion line upstream from the compliance element with respect to the direction of fluid flow along the infusion line from the medical fluid source towards the patient access.

In an embodiment, the second resistance element comprises a second hollow body interposed along the infusion line to allow passage of the medical fluid, the second hollow body having a

fluid passage section smaller than a fluid passage section of the infusion line defining a section restriction for the medical fluid flow.

In an embodiment, the second hollow body defines a portion of the medical fluid path.

In an embodiment, the second hollow body includes a slender hollow body.

In an embodiment, the second hollow body is made of a material more rigid than the material of the infusion line.

In an embodiment, the second resistance element is directly connected to an inlet of the compliance element.

In an embodiment, the second resistance element comprises a needle. Optionally the second resistance element includes one of: a 16 G needle, an 18 G needle, a 20 G needle, a 22 G needle, a 24 G needle, and a 27 G needle.

In an embodiment, the second resistance element includes a flow restrictor.

In an embodiment, the patient signal is indicative of any one of: a peripheral venous pressure, a heart rate of a patient, a respiratory rate of a patient.

In an embodiment, the pump is positive displacement pump configured to operate on the external of a tube portion of the infusion line to convey medical fluid along the direction of fluid flow. Optionally, the pump includes one of a peristaltic pump and a finger pump.

In an embodiment, the resistance element is arranged downstream from the pump with respect to the direction of fluid flow along the infusion line from the medical fluid source towards the patient access.

In an embodiment, the IV infusion set further comprises an attachment element placed in correspondence of the first end of the infusion line, the source of medical fluid comprising a container, the attachment element being configured to fluidly couple the infusion line with the container of medical fluid. Optionally, the container includes one of a bag and a bottle.

In an embodiment, the IV infusion set further comprises a flow regulator configured to selectively restrict a fluid flow passage inside the infusion line, said flow regulator being configured to progressively squeeze a portion of the infusion line thereby reducing the fluid flow passage. The fluid flow regulator is optionally configured to progressively squeeze a portion of the infusion line based on manual operation by a user.

In an embodiment, the infusion line includes a pressure coupling configured to be coupled and to cooperate with the sensor to allow the sensor to estimate the pressure signal.

In an embodiment, the pressure coupling comprises a flat and elastic membrane configured to deform based on a pressure of the fluid flowing inside the infusion line.

In an embodiment, the pressure coupling comprises a rigid body including an inlet port to receive an inlet tubing portion of the infusion line and an outlet port to receive an outlet

tubing portion of the infusion line, the rigid body defining an inner housing divided by the flat and elastic membrane into a first chamber in fluid communication with both inlet and outlet port and a second air chamber isolated the first chamber.

In an embodiment, the sensor includes a transducer to detect a parameter indicative of a pressure signal along the infusion line and provide an electric signal function of the detected parameter.

In an embodiment, the sensor further includes a measurement module configured to receive the electric signal from the transducer and to determine the pressure signal based on the electric signal.

In an embodiment, the sensor is coupled to an injection port.

In an embodiment, the injection port comprises a first section in fluid communication with an internal volume of the infusion line, a second section including an external volume, the sensor being coupled to the external volume and configured to generate a secondary pressure signal based on a pressure in the external volume, and a membrane separating the first section from the second section. The control unit is configured to receive the secondary pressure signal and to determine the pressure signal based on the secondary pressure signal.

According to a second aspect of the present invention, there is provided an infusion line for medical fluid, the infusion line comprising at least one first end configured to connect to a source of medical fluid, at least one opposite second end configured to connect to a patient access, the infusion line

defining a medical fluid path developing from the first end of the infusion line to the patient access, a compliance element configured to attenuate pressure variations of medical fluid in the infusion line, and a resistance element configured to reflect pressure waves moving along the infusion line. Based on a direction of fluid flow of the medical fluid through the infusion line from the first end towards the second end, the resistance element is arranged downstream from the compliance element and upstream the second end. Optionally, the infusion line includes a main infusion line and/or one or more auxiliary infusion lines connected to a main infusion line.

In an embodiment, the infusion line further comprises a sensor configured to emit a signal indicative of a pressure of the medical fluid in the infusion line. The sensor is arranged downstream from the resistance element and upstream the second end.

In an embodiment, the resistance element includes a flow restrictor to restrict flow of medical fluid along the infusion line through resistance element.

In an embodiment, the compliance element has an inlet port and an outlet port for the medical fluid and defines a portion of the medical fluid path.

In an embodiment, the compliance element comprises a drip chamber.

In an embodiment, the infusion line further comprises an additional drip chamber arranged downstream from the first end with respect to the direction of fluid flow.

In an embodiment, the resistance element comprises a hollow body interposed along the infusion line to allow passage of the medical fluid, the hollow body having a fluid passage section smaller than a fluid passage section of the infusion line defining a section restriction for the medical fluid flow.

In an embodiment, the hollow body defines a portion of the medical fluid path.

In an embodiment, the hollow body includes a slender hollow body.

In an embodiment, the hollow body is made of a material more rigid than the material of the infusion line.

In an embodiment, the resistance element is directly connected to an outlet of the compliance element.

In an embodiment, the resistance element comprises a needle. Optionally, the resistance element includes one of: a 16 G needle, an 18 G needle, a 20 G needle, a 22 G needle, a 24 G needle, and a 27 G needle.

In an embodiment, the infusion line further comprises a second resistance element.

In an embodiment, the second resistance element is arranged on the infusion line upstream from the compliance element with respect to the direction of fluid flow along the infusion line.

In an embodiment, the second resistance element comprises a second hollow body interposed along the infusion line to allow passage of the medical fluid, the second hollow body having a fluid passage section smaller than a fluid passage section of

the infusion line defining a section restriction for the medical fluid flow.

In an embodiment, the second hollow body defines a portion of the medical fluid path.

In an embodiment, the second hollow body includes a slender hollow body.

In an embodiment, the second hollow body is made of a material more rigid than the material of the infusion line.

In an embodiment, the second resistance element is directly connected to an inlet of the compliance element.

In an embodiment, the second resistance element comprises a needle. Optionally, the second resistance element includes one of: a 22 G needle and a 27 G needle.

In an embodiment, the second resistance element includes a flow restrictor.

In an embodiment, the infusion line further comprises an attachment element placed in correspondence of the first end of the infusion line, the attachment element being configured to connect to a source of medical fluid comprising a container, the attachment element being configured to fluidly couple the infusion line with the container of medical fluid. Optionally, the container includes one of a bag and a bottle.

In an embodiment, the infusion line further comprises a flow regulator configured to selectively restrict a fluid flow passage inside the infusion line, the flow regulator being configured to progressively squeeze a portion of the infusion

line thereby reducing the fluid flow passage. The fluid flow regulator is optionally configured to progressively squeeze a portion of the infusion line based on manual operation by a user.

In an embodiment, the infusion line includes a pressure coupling configured to be coupled and to cooperate with the sensor to allow the sensor to estimate the pressure signal.

In an embodiment, the pressure coupling comprises a flat and elastic membrane configured to deform based on a pressure of the fluid flowing inside the infusion line.

In an embodiment, the pressure coupling comprises a rigid body including an inlet port to receive an inlet tubing portion of the infusion line and an outlet port to receive an outlet tubing portion of the infusion line, the rigid body defining an inner housing divided by the flat and elastic membrane into a first chamber in fluid communication with both inlet and outlet port and a second air chamber isolated the first chamber.

In an embodiment, the sensor includes a transducer to detect a parameter indicative of a pressure signal along the infusion line and provide an electric signal function of the detected parameter.

In an embodiment, the sensor further includes a measurement module configured to receive the electric signal from the transducer and to determine the pressure signal based on the electric signal.

In an embodiment, the sensor is coupled to an injection port.

In an embodiment, the injection port comprises a first section in fluid communication with an internal volume of the infusion line, a second section including an external volume, the sensor being coupled to the external volume and configured to generate a secondary pressure signal based on a pressure in the external volume, and a membrane separating the first section from the second section. The control unit is configured to receive the secondary pressure signal and to determine the pressure signal based on the secondary pressure signal.

Disclosed herein is a process for detecting the pressure of a medical fluid in an IV infusion set, the IV infusion set being realized in accordance with the first aspect, the process comprising controlling, by the control unit, the pump to convey medical fluid along the infusion line in the direction of fluid flow, receiving the pressure signal from the sensor, determining, by the control unit, the patient signal indicative of a vital signal of the patient based on the pressure signal.

In an embodiment, the infusion line is made of a flexible material (or includes portions made of flexible material).

In an embodiment, the infusion line is made of a bendable and/or squeezable plastic material.

In an embodiment, the resistance element comprises a hollow body interposed along the infusion line to allow passage of the medical fluid, the infusion line having a substantially circular fluid passage cross section and the hollow body having a fluid passage cross section smaller than the fluid passage cross section of the infusion line defining a section

restriction for the medical fluid flow, the hollow body defining an elongated portion of the medical fluid path.

In an embodiment, the resistance element comprises a hollow body interposed along the infusion line with an elongated fluid passage to allow passage of the medical fluid, the hollow body receiving fluid from a portion of the infusion line, conveying the fluid along the elongated fluid passage and delivering fluid to a subsequent portion of the infusion line, at least an inlet of, and preferably all, the elongated fluid passage having a fluid passage cross section smaller than a fluid passage cross section of the infusion line.

In an embodiment, the infusion line is (substantially or at least partly) transparent.

Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of at least an embodiment of the invention, illustrated by way of non-limiting example in the accompanying figures of the drawings.

Brief Description of the Drawings

The description will now follow, with reference to the appended figures, provided by way of non-limiting example, in which:

Figure 1A schematically shows a first known IV infusion set;

Figure 1B schematically shows a second known IV infusion set including a main infusion line and an auxiliary infusion line;

Figure 2 schematically shows a known IV infusion set and illustrates effects that may occur during measurement of line

pressure in an IV infusion line in accordance with prior art designs;

Figure 2A shows a diagram illustrating frequency/amplitude for different flow rates;

Figure 2B shows a diagram illustrating frequency/amplitude for different flow rates;

Figure 3 schematically shows a known IV infusion set and illustrates effects that may occur during measurement of line pressure in an IV infusion line in accordance with prior art designs;

Figure 3A shows a diagram illustrating frequency/amplitude occurring in IV infusion sets with and without drip chamber;

Figure 3B shows several diagrams respectively illustrating example signals indicative of pump pressure and patient venous pressure;

Figures 3C and 3D show prior art designs for placing a sensor on an IV infusion line;