

CLAIMS

1. A sensing device for a one-time use medical device comprising;
 - a support component having a support surface for mounting thereon one
 - 5 or more electrically connected switches configured to actuate at a first pre-configured pressure and at a second pre-configured pressure,
 - the one or more electrically connected switches comprising a first pressure switch, wherein the one or more electrically connected switches forms a sensor array adapted to sense expansion or contraction of the expandable tubing,
 - 10 a length of expandable tubing for passing a fluid therethrough secured to the support surface by a securing means, and
 - a pressure concentrator positioned between the first pressure switch and a portion of the length of expandable tubing, the pressure concentrator having an upper surface in physical contact with the portion of the length of expandable
 - 15 tubing, and a lower surface in physical contact with the first pressure switch, the pressure concentrator being shaped to concentrate pressure from expansion or contraction of the expandable tubing to the first pressure switch, wherein the concentrator is configured to modulate the pressure actuation threshold of the first pressure switch to the first pre-configured pressure.
 - 20
2. The sensing device of claim 1 wherein;
 - the one or more electrically connected switches comprise one or more pressure switches having two or more pressure actuation thresholds configured to actuate
 - at a first pre-configured pressure and at a second pre-configured pressure, and

the first and second pre-configured pressures of the sensor array are capable of providing a stepped output at the two or more pressure actuation thresholds upon expansion or contraction of the expandable tubing.

5

3. The sensing device of claim 1 wherein the first a pressure switch has two or more pressure actuation thresholds configured to actuate at a first pre-configured pressure and at a second pre-configured pressure.

4. The sensing device of claim 1 comprising: a pressure concentrator holder configured to maintain the placement of the pressure concentrator in contact with the first pressure switch or the portion of the length of expandable tubing and wherein;
5 the support component comprises a printed circuit board,
the support surface is provided by a surface of the printed circuit board, and
the pressure concentrator holder is formed integrally with the printed circuit board.

10

5. The sensing device of claim 1 1 comprising a second pressure switch having one or more pressure actuation thresholds, wherein the first pressure switch has two or more pressure actuation thresholds and the second pressure switch has one or more pressure actuation thresholds and is configured to
15 actuate at a third pre-configured pressure.

6. The sensing device of claim 1 comprising at least one additional electrically connected switch having a pressure deactuation threshold, and which is configured to deactuate at an additional pre-configured pressure upon
20 contraction of the expandable tubing.

7. A sensing device for a one-time use medical device comprising;
a support component having a support surface for mounting thereon one or more
electrically connected switches configured to actuate at a first pre-configured
5 pressure and at a second pre-configured pressure,
a length of expandable tubing for passing a fluid therethrough, secured to the
support surface by a securing means,
the one or more electrically connected switches comprising a first pressure
switch, wherein the one or more electrically connected switches forms a sensor
10 array adapted to sense expansion of the expandable tubing, and at least one
additional electrically connected switch having a pressure deactuation threshold,
which is configured to deactuate at an additional pre-configured pressure upon
contraction of the expandable tubing.
- 15 8. The sensing device of claim 7 wherein the at least one additional
electrically connected switch comprises;
a first additional pressure switch, and
a pressure concentrator positioned between the first additional pressure switch
and a portion of the length of expandable tubing, the pressure concentrator
20 having an upper surface in physical contact with the portion of the length of
expandable tubing, and a lower surface in physical contact with the first
additional pressure switch, the pressure concentrator being shaped to
concentrate pressure from contraction of the expandable tubing to the first
additional pressure switch, wherein the concentrator is configured to modulate

the pressure actuation threshold of the first additional pressure switch to the additional pre-configured pressure.

9. The sensing device of claim 7 wherein the securing means comprises a
5 tube housing defining a cavity for placing at least a section of the length of
expandable tubing therein, and a fastener or bonding agent for securing the tube
housing to the support surface to maintain the placement of a portion of the
length of expandable tubing in contact with the one or more electrically
connected switches.

10

10. The sensing device of claim 7 wherein the tube housing comprises;
a wall having an external surface and an internal surface,

the wall extending longitudinally wherein the internal surface of the wall defines a longitudinal cavity for placing at least a section of the length of expandable tubing lengthwise therein,

the wall terminating at opposing ends of the longitudinal cavity in an opening

5 configured to allow the expandable tubing to pass therethrough,

the wall having at least one protrusion along the length of two opposing lengthwise edges of the wall,

wherein a portion of the internal surface of the wall at the protrusions is in contact with the support surface and is secured thereto.

10

11. A method for detecting a pressure change within a medical infusion line of a one-time use medical device comprising the steps of;

obtaining a sensing device according to claim 1 or 7,

connecting the medical infusion line with the length of expandable tubing,

15 passing a fluid through the medical infusion line and the length of expandable tubing,

changing the pressure of the fluid within the medical infusion line,

expanding or contracting the expandable tubing,

applying pressure to an electrically connected switch by the expandable tubing,

20 applying sufficient pressure to reach a pressure actuation or a deactuation threshold,

actuating or deactuating at a pre-configured pressure,

outputting actuation or deactuation at the pressure actuation or deactuation threshold and

25 pre-empting an occlusion in the medical infusion line.

12. A method of manufacturing a sensing device according to claim 1 or 6 comprising the steps of;
obtaining;

5 a support component having one or more electrically connected switches mounted thereon,

a length of expandable tubing, and

a securing means,

maintaining the length of expandable tubing in physical contact with the one or

10 more electrically connected switches, and

securing the length of expandable tubing to the support component by securing the securing means to the support surface.