Abstract: There is described a medical apparatus for use in negative pressure wound therapy. The apparatus comprises: a fluid collection vessel having a fluid inlet for receiving fluid; a pump operable to pump air out of the fluid collection vessel so as to draw fluid into the fluid collection vessel via the fluid inlet; a power supply for powering the pump; and an attachment member for releasably attaching the entire apparatus directly to a patient. There is also described a medical system incorporating the medical apparatus. The medical system further comprises a wound dressing and a fluid conduit. The fluid conduit has a first end coupled to the wound dressing and a second end for coupling to the fluid inlet of the fluid collection vessel so as to convey fluid from the wound dressing to the fluid collection vessel when the pump is in operation.
FIELD OF THE INVENTION

The present invention relates to a medical apparatus for use in negative pressure wound therapy.

BACKGROUND OF THE INVENTION

Medical systems exist for collecting fluids or liquids such as body fluids from patients. One example is a negative pressure wound therapy system for collecting exudates from a wound. Such systems generally comprise a suction pump assembly with a control system to regulate negative pressure (see, for example, the Venturi system available from Talley Group Limited, www.talleygroup.com), as well as a dressing system to allow removal of exudates from a wound by suction. The two are connected via a conduit of convenient length. The dressing is used to isolate, protect and seal the wounded area so that healing and recovery are promoted.

The present invention seeks to provide an alternative medical apparatus for use in negative pressure wound therapy which provides various advantages over those of the prior art.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there is provided a medical apparatus for use in negative pressure wound therapy. The apparatus comprises: a fluid collection vessel having a fluid inlet for receiving fluid; a pump operable to pump air out of the fluid collection vessel so as to draw fluid into the fluid collection vessel via the fluid inlet; a power supply for powering the pump;
and an attachment member for releasably attaching the entire apparatus directly to a patient.

Thus, the claimed apparatus is sufficiently small, light and compact to be attached directly to the patient (e.g. to the patient's skin) by means of the attachment member. In this way, the patient has far greater mobility (e.g. is able to be ambulatory) whilst receiving negative pressure wound therapy. In contrast, the pump and fluid collection vessel assemblies of the prior art are either not portable at all due to their size and/or weight, or are sufficiently large and weighty that they need to be carried around by a patient in a carry case or pouch. Hence, the present apparatus provides a more portable and convenient solution. Furthermore, the claimed apparatus is suitable for the treatment of shallow wounds, whereas existing systems are designed for the treatment of large and deep wounds.

Advantageously, the apparatus further comprises a housing for encasing the fluid collection vessel, the pump and the power supply. In this embodiment, the attachment member is coupled to the housing. The housing may be sealed shut during manufacture. Inclusion of a is one way of ensuring that the fluid collection vessel, the pump and the power supply are all part of a single device for attachment to the patient, rather than being separate components.

Advantageously, the attachment member comprises an adhesive layer. This could be on the back of the housing, or could be on a member which protrudes from the housing, e.g. an attachment strap, tab, wrap or wing. The adhesive layer could be in the form of adhesive tape. Alternatively, the attachment member comprises a Velcro strap. This form
of attachment member would be particularly useful for attaching to a limb of the patient.

Advantageously, the apparatus is designed to be disposable. In particular, the entire apparatus is intended to be disposed of after a single use on a single patient. Thus, the power supply can be for limited duration and the fluid collection vessel can have a relatively small capacity compared to existing canisters used in negative pressure wound therapy. Advantageously, the power supply is operable to power the pump for up to about 48 hours. Advantageously, the fluid collection vessel has a capacity of about 6 cubic centimetres. This capacity is chosen to be suitable for unobtrusive attachment to patient and for 48 hours collection of exudates from an average shallow wound.

- Advantageously, the fluid inlet comprises a short tapered tube for coupling to a flexible fluid conduit. This is a cheap simple way of making a water-tight connection between the fluid collection vessel and a flexible fluid conduit. Thus, the device is quick and easy to use.

Advantageously, the apparatus further comprises an alarm for indicating when the power supplied to the pump by the power supply has dropped below a predetermined level. The alarm may be visible (e.g. flashing LED) and/or audible (e.g. beeping tone). This is a safety feature.

According to a second aspect of the present invention, there is provided a medical system for use in negative pressure wound therapy. The system comprises: a medical apparatus according to the first aspect of the invention; a wound dressing; and a fluid conduit having a first end coupled to the wound dressing and a second end for coupling to the fluid inlet of the fluid collection vessel so as to
convey fluid from the wound dressing to the fluid collection vessel when the pump is in operation.

Advantageously, the first end of the fluid conduit is permanently coupled to the wound dressing. This decreases the number of connections which need to be made by a user on applying the system to a patient's wound.

Advantageously, the fluid conduit is flexible. This allows for ease of connection of the second end to the fluid inlet of the fluid collection vessel.

Advantageously, the fluid conduit has a length of up to about 250 mm. This relatively short conduit reduces the risk of kinking and entanglement.

According to a third aspect of the present invention, there is provided a medical system for use in negative pressure wound therapy. The system comprises: a wound dressing; a fluid collection reservoir coupled to the wound dressing; a pump operable to pump fluid from the wound dressing into the fluid collection reservoir; a power supply for powering the pump; and an attachment member for releasably attaching the entire system directly to a patient.

Other preferred features of the present invention are set out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 schematically illustrates a patient undergoing negative pressure wound therapy using a system according to one embodiment of the present invention;
Figure 2a is a schematic representation of a medical apparatus for use in negative pressure wound therapy according to one embodiment of the present invention; Figure 2b shows the medical apparatus of Figure 1a with a top portion of the housing removed; and Figure 3 shows a system for negative pressure wound therapy according to another embodiment of the present invention: Figure 3a is a plan view of the system, Figure 3b is an end view, Figure 3c is a side view, and Figure 3d is a perspective view.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Figure 1 schematically shows a patient 1 wearing a portable system 2 for negative pressure wound therapy. In particular, the system 2 is being used to provide negative pressure wound therapy for a shallow wound (not shown) on the front of the patient's left thigh.

The system 2 comprises a wound dressing 3, a fluid conduit 4 and a medical apparatus 10. The wound dressing 3 covers the wound on the patient's leg. The fluid conduit 4 extends out of the wound dressing 3 and is used to convey fluid (e.g. exudates) from the wound to the medical apparatus 10. A conventional shallow wound dressing 3 and fluid conduit 4 may be used. The wound dressing 3 is porous, allowing take-up of exudates from the wound. In one embodiment, the wound dressing 3 includes adhesive tabs that enable it to be attached directly to the patient's skin so as to form an air tight seal and a durable means of attachment. The fluid conduit 4 is flexible and is embedded into the wound dressing 3 to transport exudates away from the wound site. It is desirable, but not essential, that the wound dressing 3 and the fluid conduit 4 are permanently
fixed together so as to reduce the number of connections that need to be made when the system is set up. The medical apparatus 10 is described in further detail below with reference to Figures 2a and 2b.

As shown in Figure 2a, the medical apparatus 10 comprises a housing 12 and two adhesive attachment tabs 14 for attaching the housing 12 to the patient's skin. The housing 12 is substantially box-shaped with rounded corners. The attachment tabs 14 extend out from either side of the housing 12 for ease of attachment around a limb of the patient, for example. As well as being easy to attach, the attachment tabs 14 are designed to be fairly easily detached from a patient's skin so that the apparatus 10 may be easily repositioned, or so that the apparatus 10 may be easily removed after use without the need for any additional tools or equipment. In one embodiment, the attachment tabs 14 comprise a layer of adhesive on the underside such that they self-adhere to the patient's skin. For example, the attachment tabs 14 may comprise adhesive tape. The adhesive is such that the attachment tabs 14 may be later detached from the patient's skin without causing damage thereto. Thus, adhesives similar to those used on conventional sticking plasters would be appropriate for this purpose.

In the embodiment of Figure 2a, the housing 12 has a length L of approximately 90mm, a width W of approximately 60mm and a depth D of approximately 15mm. Thus, the housing 12 is very compact and only protrudes 15mm from the patient's skin surface such that it does not restrict the patient's movement and is fairly unobtrusive in use. Given the length, width and depth measurements stated above, the volume within the housing 12 is of the order of 80 cubic centimetres in this embodiment. In alternative embodiments,
smaller housings may be used so long as there is sufficient space within the housing for the relevant components (e.g. pump, fluid collection vessel, printed circuit board and power supply, as described below). Alternatively, larger housings may be used so long as the housing is sufficiently compact and light so as to be easily attached to the patient's skin without restricting the patient's movement to any significant degree.

The housing 12 has a top portion 12a and a bottom portion 12b. Figure 2b shows the apparatus 10 with the top portion 12a of the housing 12 removed to show the contents thereof. For simplicity, the attachment tabs 14 are not shown in Figure 2b. As shown in Figure 2b, the housing 12 contains a fluid collection vessel 16, a pump 18, a power supply 20 and a printed circuit board 22. Thus, the fluid collection vessel 16, the pump 18, the power supply 20, and the printed circuit board 22 are all integral to the apparatus 10 and are all formed into a single device. In other words, the apparatus 10 is self-contained since, for example, no external power source is required.

The fluid collection vessel 16 is a watertight container which acts as a repository for collected fluid (e.g. exudates) from the patient's wound. The fluid collection vessel 16 has a fluid inlet 24 which extends out of the housing 12 for this purpose. In use, this fluid inlet 24 is coupled to the fluid conduit 4 that extends from the wound dressing 3. The fluid collection vessel 16 is not accessible by users, it is integral to the apparatus 10 and is not designed to be opened or removed. The volume of the fluid collection vessel 16 is sufficient for about 48 hours of negative pressure wound therapy. For example, in one embodiment, the fluid collection vessel 16 has a capacity of
about 6 cubic centimetres, but capacities of up to 10 cubic centimetres are also envisaged. A solidifying agent (not shown) is provided within the fluid collection vessel 16 to solidify any fluid collected therein. The solidifying agent occupies about 2 cubic centimetres of the capacity of the fluid collection vessel 16.

The pump 18 is not accessible by users, it is integral to the apparatus 10 and is not designed to be replaced or removed. The pump 18 is coupled to the fluid collection vessel 16 by means of a port (not shown). The port enables the pump 18 to draw air out of the fluid collection vessel 16 in use. The drawn air then passes through the pump 18 and out of a pump exhaust port 26 to the atmosphere. The exhaust port 26 therefore allows vented air to pass out of the housing 12. Thus, the action of the pump 18 is able to create a "negative pressure" (i.e. a pressure below atmospheric pressure) within the fluid collection vessel 16. In this way, a pressure gradient is created between the wound site and the fluid collection vessel 16 which draws fluid from the wound dressing 3, along the fluid conduit 4 and into the fluid collection vessel 16. The pump 18 is selected such the sub-atmospheric pressures it creates are between allowable clinical levels.

A volume of activated carbon (not shown) is provided for anti-bacterial control. The carbon may be located, for example, between the fluid collection vessel 16 and the pump 18. A hydrophobic filter (not shown) is present in the vicinity of the port so as to prevent exudates from leaving the fluid collection vessel 16 and damaging the pump 18. In one embodiment, a chamber (not shown) is provided between the fluid collection vessel 16 and the port that leads to the pump 18. The anti-bacterial filtration media (e.g.
carbon) and the hydrophobic filter may be disposed in the chamber in this embodiment.

The pump 18 is powered by means of the power supply 20. The power supply 20 is not accessible by users, it is integral to the apparatus 10 and is not designed to be removed, recharged or replaced. In Figure 1b, the power supply comprises a pair of batteries. The batteries have sufficient power to allow pump 18 to operate for 48 hours. In a preferred embodiment the batteries are of the Lithium type.

A flexible membrane switch 28 is provided on the housing 12 to allow a user to switch the pump 18 on and off. An LED and/or an audible alarm (not shown) may also be provided.

The printed circuit board 22 controls the apparatus 10. In particular, the printed circuit board 22 is operable to switch the pump on and off in response to signals from the switch 28. In addition, the printed circuit board 22 may be operable to provide continuous operation of the LED when power is supplied to the pump 18, and may be further operable to provide intermittent operation of the LED when the battery power is less than that required for achieving the requisite sub-atmospheric pressure. The printed circuit board 22 may also be operable to sound the audible alarm and/or switch off the pump 18 when the battery power is less than that required for achieving the requisite sub-atmospheric pressure. The printed circuit board 22 is not accessible by users, it is integral to the apparatus 10 and is not designed to be removed.

The entire system 2 for negative pressure wound therapy is designed to be disposable. In particular, both the apparatus 10 and the combined wound dressing 3 and fluid
conduit 4 assembly should be disposed of after a single use on a single patient. Thus, the apparatus 10 is changed and discarded at the same time as the combined wound dressing 3 and fluid conduit 4 assembly. In contrast, because of their size and associated cost, conventional negative pressure would therapy systems tend to be re-usable, with the attendant infection control risks and need for decontamination between users. The collection vessel and wound dressing components of conventional systems are disposable. However, each of these components is suitable for a different duration of use, so the present system, which is completely disposable after a single use, is more practical and convenient and easy to use since everything is disposed of at the same time.

The housing 12 of the apparatus 10 is not intended to be opened by a user. In one embodiment, the housing 12 is sealed closed during manufacture (of course, the pump exhaust port 26 and the fluid inlet 24 in the housing 12 are not sealed closed). Thus, the individual components housed inside the housing 12 (e.g. the fluid collection vessel 16 and the power supply 20) cannot be easily accessed for replacement, etc. Since the apparatus 10 is disposable, the power supply 22 for the pump 18 need only last for a limited period of time, and need not be rechargeable. For example, in the embodiment of Figures 2a and 2b above, the power supply 22 is sufficient to power the pump continuously for about 48 hours. Similarly, only a fairly small capacity pump 18 is required. For a shallow wound with moderate exudates, the 6 cubic centimetre capacity of the fluid collection vessel 16 is sufficient for about 48 hours of pumping. Due to the disposable nature of the system 2, all
the components are relatively cheap, such that both the apparatus 10 and the system 2 are relatively low cost.

In use, the wound dressing 3 is affixed to the patient's skin so as to form a seal around the wounded area. The apparatus 10 is then affixed to the patient's skin by means of the attachment tabs 14. The apparatus 10 should be affixed to the patient's skin in a position that is both close to the wound site and does not restrict the patient's movement. Thus, the fluid collection vessel 16, the pump 18 and the power supply 20 are together secured to the patient's skin.

As mentioned above, one end of the fluid conduit 4 is preferably already affixed to the wound dressing 3 in an appropriate manner when the wound dressing 3 is removed from its sterilised packaging. Therefore, the only connection which needs to be made by a user is that the free end of the fluid conduit 4 should be fluidically coupled to the fluid inlet 24 of the fluid collection vessel 16 of the apparatus 10. In one embodiment (not shown), the fluid inlet 24 comprises a connector in the form of a short, rigid, tapered tube extending out of the housing 12 such that the outer diameter of the tube decreases with distance from the housing 12. This tapered tube may then be attached to the fluid conduit 4 to form an airtight seal in one easy action without the need for tools. In particular, this attachment is achieved by pressing the tapered tube tightly into the bore at the free end of the fluid conduit 4. If the fluid conduit 4 is manufactured from a relatively soft material (e.g. silicon), then this press-fit forms an effective seal between the fluid inlet 24 and the fluid conduit 4 that is
easily connected by a user. Thus, the present system 2 may be very quickly applied to the patient's wound.

Because the apparatus 10 is attached directly to the patient 1 in the vicinity of the wound site, the fluid conduit 4 is relatively short and therefore remains in close proximity to the patient's skin in use. For example, a typical length for the fluid conduit 4 is between about 150mm and 250mm in one embodiment of the present invention. This is in contrast to conventional drain tube in conventional negative pressure wound therapy systems which are relatively long (greater than 1500mm) and are prone to kinking and entanglement. Thus, the present system 2 reduces the possibility of kinking and entanglement of the drain tube.

Another advantage of the fluid conduit 4 is that the apparatus 10 need not be applied to the patient's skin in the direct vicinity of the wound site. For example, this is advantageous in cases where the wound is in a position that is likely to be lain on by the patient. In such cases, the apparatus 10 may be disposed slightly further from the wound site in a more convenient location so as not to inhibit the patient's ability to lie down or move.

Having attached both the wound dressing 3 and the apparatus 10 to the patient's skin, and having connected the fluid conduit 4 therebetween, the system is put into operation by pressing the switch 28 on the apparatus 10. This causes the pump 18 to start pumping so as to create a negative pressure within the fluid collection vessel 16 such that exudates are drawn from the wound dressing 3, along the fluid conduit 4, and into the fluid collection vessel 16.

The system 2 will continue to operate until such time as the apparatus 10 is switched off manually by a user by
means of the switch 28, or until such time as the power supplied to the pump 18 by the power supply 20 drops below a predetermined threshold value. If the supplied power does drop below the predetermined threshold value, the printed circuit board activates an audible alarm and/or flashing LED and will turn off the pump 18. This is a safety feature which ensures that the pump 18 is not run at too low a power which might result in the created vacuum no longer being within allowable clinical levels.

A second embodiment of a negative pressure wound therapy system 100 is shown in Figure 3. The system 100 is substantially flat (e.g. having a maximum depth of, say 10mm) and comprises a number of layers as shown by the end and top views of Figures 3b and 3c. The system 100 as a whole is similar in overall appearance to a large adhesive plaster or sticking plaster (e.g. Band-Aid) used for covering minor cuts. It is intended that the system 100 be used on shallow wounds that have a small to moderate amount of discharge (e.g. exudates). The system 100 is entirely self-contained in that it requires no external power supply or connections to external drain tubes or the like. This removes the possibility of a disconnection or a misconnection causing a malfunction in the operation of the system 100 (i.e. the system is virtually fool-proof). In addition, the system 100 is intended to be completely disposable after a single use on a single patient.

In this embodiment, the system 100 includes a number of layers. A top layer includes a micro-vacuum pump 102, a flexible battery 104, a fluid reservoir 106 for fluids such as exudates, a flexible microchip 108, an automatic leak detector 110, and an on/off switch 114 (see the plan view in
Figure 3a). A second layer underneath the first layer comprises a filter 116. A third layer underneath the second layer includes a heat/cold pack 112, and a sealant film 118. A fourth layer includes a medicated wound pocket or dressing 120 with integrated drain tube. No further components are required, so the system is completely self-contained.

The micro-vacuum pump 102 is switched on and off by means of the on/off switch 114. The flexible battery 104 powers the pump 102.

The reservoir 106 is flexible and highly absorbent. Advantageously, the reservoir is see-through so that a care-giver or patient may easily observe how full it is and/or the colour/texture of the collected exudates.

There is a hydrophobic filter between the pump 102 and the reservoir 106. In addition, there is a check valve between the reservoir 106 and the dressing 120 to prevent any back flow or return of exudates to the wound area. This allows wound healing to progress in a better and accelerated manner.

As well as controlling the pump 102, the flexible microchip 108 may be used to record data collected from the wound bed site.

The automatic leak detector 110 comprises leak detection globe gauze and alerts the care-giver or patient if there is leak at the dressing level. The alert may be by means of a visual indicator and/or an audible alarm.

The dressing 120 may include anti-bacterial agents or any type of medication (e.g. silver) which might assist in wound healing. There are no external tube connections or wires/electrodes in the wound dressing 120.

The sealant film 118 is a self-sealant silicone gel sheet or equivalent material suitable for use on human skin.
It enables the system 100 to be easily applied, adjusted, realigned or removed from the patient's skin. Silicone gel is particularly advantageous since it has self-adhesive characteristics as well as a comfortable weight and smooth feel which help to reduce any pain associated with applying or removing the system 100 from the patient's skin. In addition, silicone gel is extremely flexible, translucent, non-toxic and durable. The translucent nature of silicone allows for improved visibility of the wound by a care-giver or patient.

The self-contained nature of the system 100 (i.e. the lack of external connections) enables the system to be quickly and easily applied to a wound. Furthermore, the patient retains total mobility and ease and comfort of movement throughout the treatment. Furthermore, the simplicity of the system 100 enables a care-giver to manage the entire system 100 in one quick glance of observation.

In use, the system 100 is supplied in sterilized packaging. A caregiver simply removes the system 100 from the packaging and applies it directly to a shallow wound. In particular, the dressing 120 is inserted directly into or onto the open wound. The surrounding sealant film 118 is then pressed down lightly at the periphery of the dressing 120 so to form an airtight and watertight seal as the silicone self-adheres directly to the patient's skin around the wound. This process takes only a few seconds or minutes, rather than many minutes if a conventional negative pressure wound therapy system were to be used.

Once applied to the wound, the system 100 may be switched on by means of the on/off button 114. The pump 102 is therefore activated such that exudates begin to be drawn into the reservoir 106 via suction in order to promote
faster healing of the wound site by means of the enhanced wound drainage.

The reservoir 106 is made of clear material so that a patient or care-giver can observe if the reservoir 106 is full, or if there are traces of blood in the exudates within the reservoir 106. In these circumstances, or in case of pain, the care-giver or patient may switch off the system 100 by means of the switch 114. The clear material of the sealant film 118 further enables a care-giver or patient to see the progress of wound healing much more clearly than with conventional negative pressure wound therapy systems.

It is envisaged that the self-contained, compact, lightweight and easy to use nature of the apparatus 10 and systems 2 and 100 described herein makes them suitable for military/combat applications (e.g. on the battlefield) or other emergency medical situations where it is necessary to apply the treatment as quickly as possible whilst potentially keeping the patient mobile at the same time. For example, a soldier could carry a system 2 or 100 at all times so as to be able to seal and treat a shallow wound quickly and easily in a combat situation. Any bleeding would also be contained by the system.

Although preferred embodiments of the invention have been described, it is to be understood that these are by way of example only and that various modifications may be contemplated. For example, the wound dressing 3, the fluid conduit 4 and the apparatus 10 of the first embodiment could be combined into a single self-contained device for attachment to the patient. This would create a system similar to the second embodiment (Figure 3) but somewhat less compact.
CLAIMS:

1. A medical apparatus for use in negative pressure wound therapy, the apparatus comprising:
   a fluid collection vessel having a fluid inlet for receiving fluid;
   a pump operable to pump air out of the fluid collection vessel so as to draw fluid into the fluid collection vessel via the fluid inlet;
   a power supply for powering the pump; and
   an attachment member for releasably attaching the entire apparatus directly to a patient.

2. The apparatus of claim 1 further comprising a housing for encasing the fluid collection vessel, the pump and the power supply, wherein the attachment member is coupled to the housing.

3. The apparatus of claim 1 or claim 2 wherein the attachment member comprises an adhesive layer.

4. The apparatus of claim 1 or claim 2 wherein the attachment member comprises a Velcro strap.

5. The apparatus of any preceding claim wherein the apparatus is designed to be disposable.

6. The apparatus of any preceding claim wherein the power supply is operable to power the pump for up to about 48 hours.
7. The apparatus of any preceding claim wherein the fluid collection vessel has a capacity of about 6 cubic centimetres.

8. The apparatus of any preceding claim wherein the fluid inlet comprises a short tapered tube for coupling to a flexible fluid conduit.

9. The apparatus of any preceding claim further comprising an alarm for indicating when the power supplied to the pump by the power supply has dropped below a predetermined level.

10. A medical system for use in negative pressure wound therapy, the system comprising:
    the medical apparatus of any preceding claim;
    a wound dressing; and
    a fluid conduit having a first end coupled to the wound dressing and a second end for coupling to the fluid inlet of the fluid collection vessel so as to convey fluid from the wound dressing to the fluid collection vessel when the pump is in operation.

11. The system of claim 10 wherein the first end of the fluid conduit is permanently coupled to the wound dressing.

12. The system of claim 10 or claim 11 wherein the fluid conduit is flexible.

13. The system of any of claims 10 to 12 wherein the fluid conduit has a length of up to about 250 mm.
14. A medical system for use in negative pressure wound therapy, the apparatus comprising:
   a wound dressing;
   a fluid collection reservoir coupled to the wound dressing;
   a pump operable to pump fluid from the wound dressing into the fluid collection reservoir;
   a power supply for powering the pump; and
   an attachment member for releasably attaching the entire system directly to a patient.

15. A medical apparatus substantially as herein described with reference to Figures 2a and 2b of the accompanying drawings.

16. A medical system substantially as herein described with reference to Figure 1 of the accompanying drawings.

17. A medical system substantially as herein described with reference to Figures 3a to 3d of the accompanying drawings.