Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).
Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a catheter with an ultrasound assembly, and more particularly, to a catheter with an ultrasound assembly which reduces the exposure of at least one lumen within the catheter to ultrasound energy.

Description of Related Art

[0002] US 5,081,993 relates to an ultrasonic probe. The catheter has an exterior surface. A transducer element is provided. A number of lumen within a tip attached to the catheter are provided.

[0003] EP 0 774 276 A2 upon which the preamble of claim 1 is based relates an apparatus for transurethrally applied focused ultrasound therapy. A probe is coupled with an elongate catheter body, the probe has a transducer. The probe supports the transducer. The transducer is mounted on a quarter wave plate.

[0004] It is frequently desirable to use a catheter to deliver various media to treatment sites within the body. The delivered media frequently includes drugs, medications, microbubbles and other therapeutically beneficial compounds. For instance, catheters are frequently used to treat thrombi which have formed in the cardiovascular vessels of the body. These catheters are used to deliver solutions containing dissolution compounds directly to the thrombus. Many catheters include an ultrasound transducer for delivering ultrasound energy to media which has been delivered to the treatment site. The ultrasound energy in combination with the delivered media and/or the ultrasound energy can enhance the desired therapeutic effects.

[0005] The media are typically delivered to the treatment site through lumens in the catheter. These lumens frequently must pass near the ultrasound transducer. As a result, the media can be exposed to the ultrasound energy before the media is delivered to the treatment site. This exposure can reduce the therapeutic effect of the media. For instance, when the delivered media is microbubbles, the microbubbles can be burst within the lumen before the microbubbles are delivered. The therapeutic effect from microbubbles can be a result of the microbubbles bursting after delivery to the treatment site. Bursting the microbubbles before they are delivered to the treatment site can deprive the treatment site of this therapeutic effect.

[0006] Many catheters suitable for the delivery of media and microbubbles are frequently positioned within a patient using over-the-guide wire placement techniques. When these techniques are used, it is frequently desirable to leave the guidewire within a catheter during the delivery of the media and the ultrasound energy. However, the presence of the guidewire within the catheter can alter the frequency of the ultrasound energy produced by the ultrasound transducer. As a result, the frequency of the ultrasound energy actually produced by the ultrasound transducer may be different than the desired frequency.

[0007] There is a need for a catheter including an ultrasound assembly which reduces the exposure of lumens within the catheter to ultrasound energy delivered from the ultrasound transducer.

SUMMARY OF THE INVENTION

[0008] The present invention is defined in claim 1.

[0009] An object for an embodiment of the invention is providing a catheter for delivering ultrasound energy to a treatment site within a vessel.

[0010] Another object for an embodiment of the invention is providing a catheter for delivering ultrasound energy and another media to a treatment site within a vessel.

[0011] Yet another object for an embodiment of the invention is providing a catheter for delivering ultrasound energy and media to a treatment site within a vessel while reducing the exposure of the media to the ultrasound energy while the media is transported through the catheter.

[0012] Yet another object for an embodiment of the invention is providing a catheter for delivering ultrasound energy to a treatment site within a vessel while reducing the effects of a guidewire positioned in a lumen of the catheter on the frequency of the ultrasound energy.

[0013] A further object for an embodiment of the invention is providing a catheter including an ultrasound transducer adjacent to a chamber which extends along the longitudinal length of the ultrasound transducer.

[0014] Yet further object for an embodiment of the invention is providing a catheter including an ultrasound transducer adjacent to a chamber which extends along the longitudinal length of the ultrasound transducer and is filled with a low acoustic impedance material.

[0015] An even further object for an embodiment of the invention is providing a catheter including an ultrasound transducer adjacent to an evacuated chamber which extends along the longitudinal length of the ultrasound transducer.

[0016] A catheter is disclosed. The catheter includes an elongated body with an exterior surface and an ultrasound transducer with a longitudinal length. A support member supports the ultrasound transducer at the exterior surface of the elongated body and defines a chamber adjacent to the exterior surface of the elongated body. The chamber reduces transmission of ultrasound energy from the ultrasound transducer into the elongated body along the longitudinal length of the ultrasound transducer.

[0017] Another embodiment of the catheter includes an elongated body with an exterior surface and an ultra-
sound transducer with a longitudinal length. A support member supports the ultrasound transducer at the exterior surface of the elongated body. The support member at least partially defines a chamber adjacent to the exterior surface of the elongated body. The chamber extends continuously along the longitudinal length of the ultrasound transducer.

[0018] Another embodiment of the catheter includes an elongated body with an exterior surface and at least partially defining a chamber adjacent to the exterior surface of the elongated body. An ultrasound transducer is positioned on an opposite side of the chamber from the elongated body. The chamber extends on an opposite side of the chamber from the elongated body. A balloon is coupled with the elongated body.

[0019] Another embodiment of the catheter includes an elongated body defining at least a portion of a chamber and an ultrasound transducer positioned on an opposite side of the chamber from the elongated body. A balloon is coupled with the elongated body.

[0020] An ultrasound assembly for use with a catheter is also disclosed. The assembly includes an elongated body with an exterior surface and an ultrasound transducer with a longitudinal length. A support member supports the ultrasound transducer at the exterior surface of the elongated body and at least partially defines a chamber adjacent to the exterior surface of the elongated body. At least one assembly end is configured to be coupled with the catheter.

[0021] Another embodiment of the ultrasound assembly includes an elongated body with an exterior surface and an ultrasound transducer with a longitudinal length. A support member supports the ultrasound transducer at the exterior surface of the elongated body and at least partially defines a chamber adjacent to the exterior surface of the elongated body. The chamber extends continuously along the longitudinal length of the ultrasound transducer.

[0022] Yet another embodiment of the ultrasound assembly includes an elongated body defining at least a portion of a chamber and an ultrasound transducer positioned on an opposite side of the chamber from the elongated body. At least one assembly end is configured to be coupled with the catheter.

BRIEF DESCRIPTION OF THE FIGURES

[0023]

Figure 1A is a cross section of an ultrasound assembly according to the present invention.
Figure 1B is a cross section of an ultrasound assembly according to the present invention.
Figure 1C illustrates a support member with integral supports.
Figure 1D illustrates a support member which is supported by an outer coating.
Figure 2A is a cross section of a catheter which includes an ultrasound assembly module which is independent of a first catheter component and a second catheter component.

Figure 2B illustrates the first and second catheter components coupled with the ultrasound assembly module.
Figure 2C is a cross section of an ultrasound assembly which is integral with a catheter.
Figure 3A is a cross section of an ultrasound assembly configured to radiate ultrasound energy in a radial direction. The wires which drive the ultrasound transducer pass through a utility lumen in the catheter.
Figure 3B is a cross section of an ultrasound assembly configured to radiate ultrasound energy in a radial direction. The lines which drive the ultrasound transducer pass through line lumens in the catheter.
Figure 3C is a cross section of an ultrasound assembly configured to longitudinally radiant ultrasonic energy. The distal portion of one line travels proximally through the outer coating.
Figure 3D is a cross section of an ultrasound assembly configured to longitudinally transmit ultrasound energy. The distal portion of one line travels proximally through a line lumen in the catheter.
Figure 4A is a sideview of a catheter including a plurality of ultrasound assemblies.
Figure 4B is a cross section of an ultrasound assembly included on a catheter with a plurality of utility lumens.
Figure 4C is a cross section of an ultrasound assembly included on a catheter with a plurality of utility lumens.
Figure 5A is a sideview of a catheter including a balloon.
Figure 5B is a cross section of a catheter with a balloon which include an ultrasound assembly.
Figure 5A is a sideview of a catheter with a balloon positioned distally relative to an ultrasound assembly.
Figure 6A is a sideview of a catheter with an ultrasound assembly positioned distally relative to a balloon.
Figure 6B is a sideview of a catheter with an ultrasound assembly positioned distally relative to a balloon.
Figure 6A is a sideview of a catheter with an ultrasound assembly positioned at the distal end of the catheter.
Figure 7A is a sideview of a catheter with a media delivery port positioned between an ultrasound assembly and a balloon.
Figure 7B is a sideview of a catheter with an ultrasound assembly positioned between a media delivery port and a balloon.
Figure 7C is a cross section of a catheter with an ultrasound assembly positioned at the distal end of the catheter.
Figure 8A is a sideview of a catheter including a media delivery port and an ultrasound assembly positioned between first and second balloons.
Figure 8B is a sideview of a catheter including a media delivery port and an ultrasound assembly posi-
tioned between first and second balloons. Figure 8C is a cross section of a balloon included on a catheter having a first and second balloon. Figure 9A illustrates ultrasound transducers connected in parallel. Figure 9B illustrates ultrasound transducers connected in series. Figure 9C illustrates ultrasound transducers connected with a common line. Figure 10 illustrates a circuit for electrically coupling temperature sensors. Figure 11 illustrates a feedback control system for use with a catheter including an ultrasound assembly. Figure 12A illustrates an ultrasound assembly positioned adjacent a treatment site and microbubbles delivered via a utility lumen. Figure 12B illustrates an ultrasound assembly positioned adjacent a treatment site and a media delivered via a media delivery port. Figure 12C illustrates an ultrasound assembly positioned adjacent a treatment site and a media is delivered via a media delivery port while a guidewire is positioned in a utility lumen. Figure 12D illustrates a catheter including a balloon positioned adjacent a treatment site. Figure 12E illustrates a catheter including a balloon expanded into contact with a treatment site. Figure 12F illustrates a catheter with an ultrasound assembly outside a balloon positioned at a treatment site. Figure 12G illustrates the balloon of Figure 12F expanded into contact with a vessel so as to occlude the vessel. Figure 12H illustrates a catheter with an ultrasound assembly outside a first and second balloon positioned at a treatment site. Figure 12I illustrates the first and second balloon of Figure 12H expanded into contact with a vessel so as to occlude the vessel.

DETAILED DESCRIPTION

[0024] The present invention relates to a catheter including an ultrasound assembly. The catheter includes an elongated body with at least one utility lumen extending through the elongated body. The utility lumens can be used to deliver various media to a treatment site and/or to receive a guidewire so the catheter can be guided to the treatment site. The ultrasound assembly can include an ultrasound transducer which can transmit ultrasound energy. A support member can support the ultrasound transducer adjacent an outer surface of the elongated body so as to define a chamber between the ultrasound transducer and the elongated body. [0025] The chamber can be filled with a material which creates a low acoustic impedance to reduce the exposure of at least one utility lumen within the elongated body to ultrasound energy delivered from the ultrasound transducer. For instance, the chamber can be filled with a material which absorbs, reflects or prevents transmission of ultrasound energy through the chamber. Alternatively, the chamber can be evacuated to reduce transmission of ultrasound energy through the chamber. [0026] The support member can have ends which extend beyond the ultrasound member. As a result, the chamber can be positioned adjacent the entire longitudinal length of the ultrasound transducer and can extend beyond the ends of the ultrasound transducer. This configuration maximizes the portion of the ultrasound transducer which is adjacent the chamber. Increasing the portion of ultrasound transducer adjacent to the chamber can reduce the amount of ultrasound energy transmitted to the utility lumens. The ultrasound assembly can include an outer coating over the ultrasound transducer. Temperature sensors can be positioned in the outer coating adjacent to ultrasound transducer. This position of the temperature sensors feedback regarding the temperature adjacent to the ultrasound transducers where the thermal energy has a reduced opportunity to dissipate. As a result, the temperature sensors provide a measure of the temperature on the exterior surface of the transducer. [0027] Figures 1A-1B illustrates a catheter 10 including an ultrasound assembly 12 according to the present invention. The catheter 10 includes an elongated body 14 with a utility lumen 16 extending through the elongated body 14. The utility lumen 16 can receive a guidewire so the catheter 10 can be threaded along the guidewire. The utility lumen 16 can also be used for the delivery of media which includes drugs, medication, microbubbles and other compounds which provide a therapeutic effect. [0028] The ultrasound assembly 12 includes an ultrasound transducer 18. Suitable ultrasound transducers 18 include, but are not limited to, PZT-4D, PZT-4, PZT-8 and cylindrically shaped piezoceramics. When the ultrasound transducer 18 has a cylindrical shape, the ultrasound transducer 18 can encircle the elongated body 14 as illustrated in Figure 1B. The ultrasound assembly 12 also includes a support member 20. Suitable support members 20 include, but are not limited to, polyimide, polyester and nylon. The support member 20 can be attached to the ultrasound transducer 18. Suitable means for attaching the ultrasound transducer 18 to the support member 20 include, but are not limited to, adhesive bonding and thermal bonding. The ultrasound assembly 12 can also include an outer coating 22. Suitable outer coatings 22 include, but are not limited to, polyimide, parylene and polyester. [0029] The support member 20 supports the ultrasound member 20 at an external surface 24 of the elongated body 14 such that a chamber 26 is defined between the ultrasound transducer 18 and the external surface 24 of the elongated body 14. The chamber 26 preferably has a height from .25-10 \( \mu \text{m} \), more preferably from .50-5 \( \mu \text{m} \) and most preferably from .0-1.5 \( \mu \text{m} \). The support
member 20 can be supported by supports 28 positioned at the ends 30 of the support member 20 as illustrated in Figure 1B. The supports 28 can be integral with the support member 20 as illustrated in Figure 1C. The outer coating 22 can serve as the supports as illustrated in Figure 1D.

[0030] The ends 30 of the support member 20 can extend beyond the ends 32 of the ultrasound transducer 18. The supports 28 can be positioned beyond the ends 32 of the ultrasound transducer 18. As a result, the chamber 26 can extend along the longitudinal length 34 of the ultrasound transducer 18, maximizing the portion of the ultrasound transducer 18 which is adjacent to the chamber 26. The chamber 26 can be filled with a medium which absorbs ultrasound energy or which prevents transmission of ultrasound energy. Suitable gaseous media for filling the chamber 26 include, but are not limited to, helium, argon, and nitrogen. Suitable solid media for filling the chamber 26 include, but are not limited to, silicon and rubber. The chamber 26 can also be evacuated. Suitable pressures for an evacuated chamber 26 include, but are not limited to, negative pressures to -760 mm Hg.

[0031] One or more temperature sensors 36 can be positioned in the outer coating 22. The temperature sensors 36 can be positioned adjacent the ultrasound transducer 18 to provide feedback regarding the temperature adjacent the ultrasound transducer 18.

[0032] The ultrasound assembly 12 can be a separate module as illustrated in Figures 2A-2B. In Figure 2A, the catheter 10 includes a first catheter component 40 and a second catheter component 42 and an ultrasound assembly module 38. The first and second catheter components 40, 42 include component ends 44 which are complementary to the ultrasound assembly module ends 46. The component ends 44 can be coupled with the ultrasound assembly module ends 46 as illustrated in Figure 2B. Suitable means for coupling the component ends 44 and the ultrasound assembly module ends 46 include, but are not limited to, adhesive, mechanical and thermal methods. The ultrasound assembly 12 can be integral with the catheter 10 as illustrated in Figure 2C. Further, the outer coating 22 can have a diameter which is larger than the diameter of the elongated body 14 as illustrated in Figure 1A or can be flush with the external surface 24 of the elongated body 14 as illustrated in Figures 2A-2C.

[0033] The ultrasound assembly 12 can be electrically coupled to produce longitudinal vibrations of the ultrasound transducer 18 as illustrated in Figures 3A-3B. A first line 48 is coupled with an outer surface 50 of the ultrasound transducer 18 while a second line 52 is coupled with an inner surface 54 of the ultrasound transducer 18. The first and second lines 48, 52 can pass proximally through the utility lumen 16 as illustrated in Figure 3A. Alternatively, the first and second lines 48, 52 can pass proximally through line lumens 56 within the catheter 10 as illustrated in Figure 3B. Suitable lines for the ultrasound transducer 18 include, but are not limited to, copper, gold and aluminum. Suitable frequencies for the ultrasound energy delivered by the ultrasound transducer 18 include, but are not limited to, 20 KHz to 2 MHz.

[0034] The ultrasound assembly 12 can be electrically coupled to produce longitudinal vibrations of the ultrasound transducer 18 as illustrated in Figures 3C-3D. A first line 48 is coupled with a first end 58 of the ultrasound transducer 18 while a second line 52 is coupled with a second end 60 of the ultrasound transducer 18. The distal portion 62 of the second line 52 can pass through the outer coating 22 as illustrated in Figure 3C. Alternatively, the distal portion 62 of the second line 52 can pass through line lumens 56 in the catheter 10 as illustrated in Figure 3D. As discussed above, the first and second lines 48, 52 can pass proximally through the utility lumen 16.

[0035] Figure 4A illustrates a catheter 10 including a plurality of ultrasound assemblies. The catheter 10 includes an electronics coupling 64, a plurality of media delivery ports 66 and a media inlet port 68. The electronics coupling 64 is designed to be coupled with electronics (not shown) which receive signals from the temperature sensors 36. Figures 4B-4C are cross sections of a catheter 10 with a second utility lumen 16A coupled with the media delivery ports 66. The second utility lumen 16A can also be coupled with the media inlet port 68 illustrated in Figure 4A. The media inlet port 68 is designed to be coupled with a media source (not shown). Media can be transported from the media source and through the media delivery ports 66 via the second utility lumen 16A.

[0036] The catheter 10 can include a balloon 70 as illustrated in Figure 5A. The balloon 70 can be constructed from an impermeable material or a permeable membrane or a selectively permeable membrane which allows certain media to flow through the membrane while preventing other media from flowing through the membrane. Suitable membranous materials for the balloon 70 include, but are not limited to cellulose, cellulose acetate, polyvinylchloride, polyolefin, polyurethane and polysulfone. When the balloon 70 is constructed from a permeable membrane or a selectively permeable membrane, the membrane pore sizes are preferably 5 A-2 µm, more preferably 50 A-900 A and most preferably 100 A-300 A in diameter.

[0037] As illustrated in Figure 5B, an ultrasound assembly 12, a first media delivery port 66A and a second media delivery port 66B can be positioned within the balloon 70. The first and second media delivery ports 66A, 66B are coupled with a second utility lumen 16A and third utility lumen 16B. The second and third utility lumens 16A, 16B can be coupled with the same media inlet port 68 or with independent media inlet ports 68. When the first and second media delivery ports 66A, 66B are coupled with different media inlet ports 68, different media can be delivered via the second and third media delivery ports 66A, 66B. For instance, a medication media can be delivered via the third utility lumen 16B and an expansion media can be delivered via the second utility lumen...
The ultrasound assembly 12 can be positioned between the first and second balloons 70A, 70B. A second media delivery port 66B can optionally be positioned between the first and second balloons 70A, 70B. In Figure 8A the second media delivery port 66B is positioned distally relative to the ultrasound assembly and in Figure 8B the ultrasound assembly is positioned distally relative to the second media delivery port 66B.

As illustrated in Figure 7A, the catheter 10 includes a second utility lumen 16A coupled with a first media delivery port 66A. The second utility lumen 16A can be used to deliver an expansion media and/or a medication media to the balloon 70. When the balloon 70 is constructed from a permeable membrane, the medication media and/or the expansion media can pass through the balloon 70. Similarly, when the balloon 70 is constructed from a selectively permeable membrane, particular components of the medication media and/or the expansion media can pass through the balloon 70. Pressure can be used to drive the media or components of the media across the balloon 70. Other means such as phoresis can also be used to drive the media or components of the media across the balloon 70.

As illustrated in Figures 7A-7C, the ultrasound assembly 12 may be positioned between the first and second balloons 70A, 70B. The ultrasound assembly 12 can be positioned between the first and second balloons 70A, 70B. In Figure 7A the ultrasound assembly 12 is positioned distally relative to the ultrasound assembly 12 and the second media delivery port 66B are positioned distally relative to a balloon 70, however, the balloon 70 can be positioned distally relative to the ultrasound assembly 12 and the second media delivery port 66B. In Figure 7A the ultrasound assembly 12 is positioned distally relative to the ultrasound assembly 12 and the second media delivery port 66B and in Figure 7B the second media delivery port 66B is positioned distally relative to the ultrasound assembly 12.

As illustrated in Figures 7A-7C, the catheter 10 includes a first media delivery port 66A and a second media delivery port 66B. The second utility lumen 16A can be used to deliver an expansion media and/or a medication media to the balloon 70. When the balloon 70 is constructed from a permeable membrane, the medication media and/or the expansion media can pass through the balloon 70. Similarly, when the balloon 70 is constructed from a selectively permeable membrane, particular components of the medication media and/or the expansion media can pass through the balloon 70. Pressure can be used to drive the media or components of the media across the balloon 70. Other means such as phoresis can also be used to drive the media or components of the media across the balloon 70.

As illustrated in Figure 6C, the ultrasound assembly 12 can be positioned between the first and second balloons 70A, 70B. The ultrasound assembly 12 may be positioned at the distal end of the ultrasound assembly 12 and in Figure 6B the ultrasound assembly 12 is positioned distally relative to the ultrasound assembly 12. When the ultrasound transducers 18 are connected in parallel, the ultrasound transducers 18 receive power simultaneously whether the ultrasound transducers 18 are in series or in parallel. When the ultrasound transducers 18 are in series, less current is required to produce the same power from each ultrasound transducer 18 than when the ultrasound transducers 18 are connected in parallel. The reduced current allows smaller lines to be used to provide power to the ultrasound transducers 18 and accordingly increases the flexibility of the elongated body 14. When the ultrasound transducers 18 are connected in parallel, an ultrasound transducer 18 can break down and the remaining ultrasound transducers 18 will continue to operate.
line 74. A particular ultrasound transducer 18 can be individually activated by closing a switch 76 to complete a circuit between the common line 72 and the particular ultrasound transducer’s 18 return line 74. Once a switch 76 corresponding to a particular ultrasound transducer 18 has been closed, the amount of power supplied to the ultrasound transducer 18 can be adjusted with the corresponding potentiometer 78. Accordingly, an catheter 10 with N ultrasound transducers 18 requires only N+1 lines and still permits independent control of the ultrasound transducers 18. This reduced number of lines increases the flexibility of the catheter 10. To improve the flexibility of the catheter 10, the individual return lines 74 can have diameters which are smaller than the common line 72 diameter. For instance, in an embodiment where N ultrasound transducers 18 will be powered simultaneously, the diameter of the individual return lines 74 can be the square root of N times smaller than the diameter of the common line 72.

As discussed above, the ultrasound assembly 12 can include at least one temperature sensor 36. Suitable temperature sensors 36 include, but are not limited to, thermistors, thermocouples, resistance temperature detectors (RTD)s, and fiber optic temperature sensors 36 which use thermalchromic liquid crystals. Suitable temperature sensor geometries include, but are not limited to, a point, patch, stripe and a band encircling the ultrasound transducer 18.

When the ultrasound assembly 12 includes a plurality of temperature sensors 36, the temperature sensors 36 can be electrically connected as illustrated in Figure 10. Each temperature sensor 36 can be coupled with a common line 72 and then include its own return line 74. Accordingly, N+1 lines can be used to independently sense the temperature at the temperature sensors 36 when N temperature sensors 36 are employed. A suitable common line 72 can be constructed from Constantine and suitable return lines 74 can be constructed from copper. The temperature at a particular temperature sensor 36 can be determined by closing a switch 76 to complete a circuit between the thermocouple’s return line 74 and the common line 72. When the temperature sensors 36 are thermocouples, the temperature can be calculated from the voltage in the circuit. To improve the flexibility of the catheter 10, the individual return lines 74 can have diameters which are smaller than the common line 72 diameter.

Each temperature sensor 36 can also be independently electrically coupled. Employing N independently electrically coupled temperature sensors 36 requires 2N lines to pass the length of the catheter 10.

The catheter 10 flexibility can also be improved by using fiber optic based temperature sensors 36. The flexibility can be improved because only N fiber optics need to be employed sense the temperature at N temperature sensors 36.

The catheter 10 can be coupled with a feedback control system as illustrated in Figure 11. The temperature at each temperature sensor 36 is monitored and the output power of an energy source adjusted accordingly. The physician can, if desired, override the closed or open loop system.

The feedback control system includes an energy source 80, power circuits 82 and a power calculation device 84 coupled with each ultrasound transducer 18. A temperature measurement device 86 is coupled with the temperature sensors 36 on the catheter 10. A processing unit 88 is coupled with the power calculation device 84, the power circuits 82 and a user interface and display 90.

In operation, the temperature at each temperature sensor 36 is determined at the temperature measurement device 86. The processing unit 88 receives a signal indicating the determined temperatures from the temperature measurement device 86. The determined temperatures can then be displayed to the user at the user interface and display 90.

The processing unit 88 includes logic for generating a temperature control signal. The temperature control signal is proportional to the difference between the measured temperature and a desired temperature. The desired temperature can be determined by the user. The user can set the predetermined temperature at the user interface and display 90.

The temperature control signal is received by the power circuits 82. The power circuits 82 adjust the power level of the energy supplied to the ultrasound transducers 18 from the energy source 80. For instance, when the temperature control signal is above a particular level, the power supplied to a particular ultrasound transducer 18 is reduced in proportion to the magnitude of the temperature control signal. Similarly, when the temperature control signal is below a particular level, the power supplied to a particular ultrasound transducer 18 is increased in proportion to the magnitude of the temperature control signal. After each power adjustment, the processing unit 88 monitors the temperature sensors 36 and produces another temperature control signal which is received by the power circuits 82.

The processing unit 88 can also include safety control logic. The safety control logic detects when the temperature at a temperature sensor 36 has exceeded a safety threshold. The processing unit 88 can then provide a temperature control signal which causes the power circuits 82 to stop the delivery of energy from the energy source 80 to the ultrasound transducers 18.

The processing unit 88 also receives a power signal from the power calculation device 84. The power signal can be used to determine the power being received by each ultrasound transducer 18. The determined power can then be displayed to the user on the user interface and display 90.

The feedback control system can maintain the tissue adjacent to the ultrasound transducers 18 within a desired temperature range for a selected period of time. As described above, the ultrasound transducers 18 can
be electrically connected so each ultrasound transducer 18 can generate an independent output. The output maintains a selected energy at each ultrasound transducer 18 for a selected length of time.

In Figure 12E, the balloon 70 is expanded into position with the balloon adjacent the treatment site 92. In Figure 12D, a catheter 10 including a balloon 16 is also reduced. The delivery of ultrasound energy 98 into the utility lumen 16 is reduced, the change be before, after, during or intermittently with the delivery of the media. The ultrasound energy 98 can serve to drive the media across the membrane via phonophoresis or can enhance the therapeutic effect of the media.

In lieu of the series of power adjustments described above, a profile of the power delivered to each ultrasound transducer 18 can be incorporated in the processing unit 88 and a preset amount of energy to be delivered may also be profiled. The power delivered to each ultrasound transducer 18 can be adjusted according to the profiles.

In Figure 12F a catheter 10 with an ultrasound assembly 12 outside a balloon 70 is positioned at the treatment site 92 so the ultrasound assembly 12 is adjacent the treatment site 92. A fluid within the vessel flows past the balloon as indicated by the arrow 106. In Figure 12G, the balloon 70 is expanded into contact with the vessel 94. The balloon 70 can be constructed from an impermeable material so the vessel 94 is occluded. As a result, the fluid flow through the vessel 94 is reduced or stopped. A medication media is delivered through the utility lumen 16 and ultrasound energy 98 is delivered from the ultrasound assembly 12. In embodiments of the catheter 10 including a media delivery port 66 outside of the balloon 70 (i.e. Figures 7A-7C), the medication media can be delivered via the media delivery port 66. Further, a first medication media can be delivered via the media delivery port 66 while a second medication media can be delivered via the utility lumen 16 or while a guidewire is positioned within the utility lumen 16. The ultrasound energy 98 can be delivered from the ultrasound assembly 12 before, after, during or intermittently with the delivery of the media. The occlusion of the vessel 94 before the delivery of the media can serve to prevent the media from being swept from the treatment site 92 by the fluid flow. Although the balloon 70 illustrated in Figures 12F-12G is positioned proximally relative to the ultrasound assembly 12, the fluid flow through the vessel 94 can also be reduced by expanding a single balloon 70 which is positioned distally relative to the ultrasound assembly 12.

In Figure 12H a catheter 10 including a first balloon 70A and a second balloon 70B is positioned at a treatment site 92 so the ultrasound assembly 12 is positioned adjacent the treatment site 92. A fluid within the vessel 94 flows past the balloon 70 as indicated by the arrow 106. In Figure 12I, the first and second balloons 70A, 70B are expanded into contact with the vessel 94. The first and second balloons 70A, 70B can be constructed from an impermeable material so the vessel 94 is occluded proximally and distally of the ultrasound assembly 12. As a result, the fluid flow adjacent the treatment site 92 is reduced or stopped. A medication media is delivered through the media delivery port 66 and ultrasound energy 98 is delivered from the ultrasound assembly 12. The ultrasound energy 98 can be delivered from the ultrasound assembly 12 before, after, during or intermittently with the delivery of the media. The occlusion of the vessel 94 before the delivery of the media can serve to prevent...
the media from being swept from the treatment site 92 by the fluid flow.

[0065] The catheters disclosed above can include radiopaque markers to aid in positioning the catheter relative to the treatment site 92.

[0066] The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications, combinations and variations will be apparent to practitioners skilled in this art.

Claims

1. A catheter (10), comprising:
   an elongated body (14) with an exterior surface (24);
   an ultrasound transducer (18) with a longitudinal length (34); and
   a support member (20) located at the exterior surface of the elongated body for supporting the ultrasound transducer, the support member at least partially defining a chamber (26), the chamber being defined between the ultrasound transducer and the exterior surface of the elongated body, the chamber reducing transmission of ultrasound energy from the ultrasound transducer into the elongated body along the longitudinal length of the ultrasound transducer;
   characterised in that the catheter comprises a utility lumen (16) for delivery of media to a treatment site which extends through the elongated body.

2. The catheter according to claim 1, wherein the chamber extends continuously along the longitudinal length of the ultrasound transducer.

3. The catheter according to claim 1, wherein the ultrasound transducer is adjacent the chamber, the catheter further comprising:
   a coating (22) adjacent an external surface of the ultrasound transducer; and
   at least one temperature sensor (36) coupled with the coating.

4. The catheter of claim 3, wherein the at least one temperature sensor is positioned within the coating.

5. The catheter of claim 1, claim 2 or claim 3, wherein the chamber is filled with a low acoustic impedance material.

6. The catheter of claim 1, claim 2 or claim 3, wherein the chamber is air filled.

7. The catheter of claim 1, claim 2 or claim 3, wherein the chamber is filled with nitrogen.

8. The catheter of claim 1, claim 2 or claim 3, wherein the chamber is evacuated.

9. The catheter of claim 1 or claim 2, further comprising:
   a coating (22) adjacent an external surface of the ultrasound transducer; and
   at least one temperature sensor (36) coupled with the coating.

10. The catheter of claim 9, wherein the at least one temperature sensor is positioned within the coating.

11. The catheter of claim 9, wherein the coating includes parylene.

12. The catheter of claim 1 or claim 2, further comprising:
   at least one temperature sensor (36); and
   a feedback control system for adjusting a power delivered to the ultrasound transducer in response to a signal from the at least one temperature sensor.

13. The catheter of claim 1 or claim 2, further comprising:
   a support (28) positioned between the support member and the elongated body.

14. The catheter of claim 13, wherein the support is integral with the support member.

15. The catheter of claim 1, further comprising:
   a coating and supporting the support member.

16. The catheter of claim 2, further comprising:
   a coating adjacent the ultrasound transducer and supporting the support member.

17. The catheter of claim 1, or claim 2 or claim 3, further comprising:
   an expandable balloon (70) enclosing the ultrasound transducer.

18. The catheter of claim 1, wherein the utility lumen comprises one of a plurality of utility lumen extending through the ultrasound transducer.

19. The catheter of claim 2 or claim 3, wherein the utility lumen comprises one of a plurality of utility lumen (16) extending through the elongated body.
20. The catheter of claim 1, claim 2 or claim 3, wherein the ultrasound transducer includes ends (32) and the chamber extends beyond the ends of the ultrasound transducer.

21. The catheter of claim 3, further comprising: at least one support positioned between the support member and the elongated body.

22. The catheter of claim 21, wherein the at least one support are integral with the support member.

23. The catheter of claim 3, further comprising:

a coating adjacent the ultrasound transducer and supporting the support member.

24. The catheter of claim 3, further comprising:

an ultrasound isolation member positioned in the chamber.

25. The catheter according to claim 1, further comprising:

a balloon (70; 70a; 70B) coupled with the elongated body.

26. The catheter according to claim 1, wherein the elongated body defines at least a portion of the chamber, the chamber having a first side adjacent the elongated body and a second side opposite the first side, and the ultrasound transducer is positioned on the second side of the chamber, the catheter further comprising a balloon (70) coupled with the elongated body.

27. The catheter of claim 25 or claim 26, wherein:

the balloon encircles the ultrasound transducer.

28. The catheter of claim 25 or claim 26, wherein:

the balloon is distally positioned on the elongated body relative to the ultrasound transducer.

29. The catheter of claim 25 or claim 26, wherein:

the balloon is proximally positioned on the elongated body relative to the ultrasound transducer.

30. The catheter of claim 25 or claim 26, further comprising:

a second utility lumen (16B); and a media delivery port (66B) coupled with the second utility lumen and positioned external to the balloon.

31. The catheter of claim 25 or claim 26, further comprising:

a second balloon (70A; 70B) coupled with the elongated body.

32. The catheter of claim 31, further comprising:

a second utility lumen; (16B); and a media delivery port (66B) coupled with the second utility lumen and positioned external to the balloon.

Patentansprüche

1. Katheter (10), der aufweist:

 einen länglichen Körper (14) mit einer äußeren Oberfläche (24), einen Ultraschalltransducer (18) mit einer longitudinalen Länge (34) und ein Trägersteil (20), das an der äußeren Oberfläche des länglichen Körpers angeordnet ist für das Tragen des Ultraschalltransducers, wobei das Trägersteil zumindest teilweise eine Kammer (26) definiert, welche zwischen dem Ultraschalltransducer und der äußeren Oberfläche des länglichen Körpers definiert ist, wobei die Kammer die Übertragung von Ultraschallenergie von dem Ultraschalltransducer in den länglichen Körper entlang der longitudinalen Länge des Ultraschalltransducers reduziert, dadurch gekennzeichnet, daß der Katheter ein sich durch den länglichen Körper erstreckendes Nutzlumen (16) für die Zuführung von Medien an eine Behandlungsstelle aufweist.

2. Katheter nach Anspruch 1, wobei die Kammer sich kontinuierlich entlang der longitudinalen Länge des Ultraschalltransducers erstreckt.

3. Katheter nach Anspruch 1, wobei der Ultraschalltransducer zu der Kammer benachbart ist und wobei der Katheter weiterhin aufweist eine Beschichtung (22), die an eine äußere Oberfläche des Ultraschalltransducers angrenzt, und zumindest einen Temperatursensor (36), der mit der Beschichtung verbunden ist.


5. Katheter nach Anspruch 1, Anspruch 2 oder Anspruch 3, wobei die Kammer mit einem Material ge-
ringer akustischer Impedanz gefüllt ist.

6. Katheter nach Anspruch 1, Anspruch 2 oder Anspruch 3, wobei die Kammer mit Luft gefüllt ist.

7. Katheter nach Anspruch 1, Anspruch 2 oder Anspruch 3, wobei die Kammer mit Stickstoff gefüllt ist.

8. Katheter nach Anspruch 1, Anspruch 2 oder Anspruch 3, wobei die Kammer evakuiert ist.

9. Katheter nach Anspruch 1 oder Anspruch 2, der weiterhin aufweist:
   
   eine Beschichtung (22), die zu einer äußeren Oberfläche des Ultraschalltransducers benachbart ist, und
   zumindest einen Temperatursensor (36), der mit der Beschichtung verbunden ist.

10. Katheter nach Anspruch 9, wobei der zumindest eine Temperatursensor innerhalb der Beschichtung positioniert ist.

11. Katheter nach Anspruch 9, wobei die Beschichtung Parylen entträgt.

12. Katheter nach Anspruch 1 oder Anspruch 2, der weiterhin aufweist:
   
   zumindest einen Temperatursensor (36) und
   ein Rückkopplungssteuerungssystem für das Einstellen einer Energie, die dem Ultraschalltransducer in Reaktion auf ein Signal von dem zumindest einen Temperatursensor zugeführt wird.

13. Katheter nach Anspruch 1 oder Anspruch 2, der weiterhin aufweist:
   
   einen Halter (28), der zwischen dem Trägerteil und dem länglichen Körper positioniert ist.


15. Katheter nach Anspruch 1, der weiterhin aufweist:
   
   eine Beschichtung, die das Träger teil trägt.

16. Katheter nach Anspruch 2, der weiterhin aufweist:
   
   eine Beschichtung, die zu dem Ultraschalltransducer benachbart ist und das Träger teil trägt.

17. Katheter nach Anspruch 1, Anspruch 2 oder Anspruch 3, der weiterhin aufweist:
   
   einen aufweitbaren Ballon (70), der den Ultraschalltransducer umschließt.

18. Katheter nach Anspruch 1, wobei das Nutzlumen eines aus einer Mehrzahl von Nutzlumina, die sich durch den Ultraschalltransducer erstrecken, aufweist.


20. Katheter nach Anspruch 1, Anspruch 2 oder Anspruch 3, wobei der Ultraschalltransducer Enden (32) beinhaltet und sich die Kammer über die Enden des Ultraschalltransducers hinaus erstreckt.

21. Katheter nach Anspruch 3, der weiterhin aufweist:
   
   zumindest einen Halter, der zwischen dem Träger teil und dem länglichen Körper positioniert ist.

22. Katheter nach Anspruch 21, wobei der zumindest eine Halter mit dem Träger teil einstückig ausgebildet ist.

23. Katheter nach Anspruch 3, der weiterhin aufweist:
   
   eine Beschichtung, die an den Ultraschalltransducer angrenzt und das Träger teil trägt.

24. Katheter nach Anspruch 3, der weiterhin aufweist:
   
   ein Ultraschallisolierungsteil, das in der Kammer positioniert ist.

25. Katheter nach Anspruch 1, der weiterhin aufweist:
   
   einen Ballon (70; 70a; 70B), der mit dem länglichen Körper verbunden ist.

26. Katheter nach Anspruch 1, wobei der längliche Körper zumindest einen Teil der Kammer definiert, wobei die Kammer eine erste Seite, die zu dem länglichen Körper benachbart ist, und eine zweite Seite, die der ersten Seite gegenüberliegt, aufweist, und der Ultraschalltransducer auf der zweiten Seite der Kammer positioniert ist und der Katheter weiterhin aufweist einen Ballon (70), der mit dem länglichen Körper verbunden ist.

27. Katheter nach Anspruch 25 oder Anspruch 26, wobei:
28. Katheter nach Anspruch 25 oder Anspruch 26, wo-
bei:

der Ballon den Ultraschalltransducer umgibt.

29. Katheter nach Anspruch 25 oder Anspruch 26, wo-
bei:

der Ballon auf dem länglichen Körper relativ zu
dem Ultraschalltransducer distal angeordnet ist.

30. Katheter nach Anspruch 25 oder Anspruch 26, der
evertherin aufweist:

ein zweites Nutzlumen (16B) und
einen Medienzuführunganschluß (66B), der
mit dem zweiten Nutzlumen verbunden und au-
ßerhalb des Ballons angeordnet ist.

31. Katheter nach Anspruch 25 oder Anspruch 26, der
evertherin aufweist:

 einen zweiten Ballon (70A; 70B), der mit dem
länglichen Körper verbunden ist.

32. Katheter nach Anspruch 31, der weiterhin aufweist:

ein zweites Nutzlumen (16B) und
einen Medienzuführunganschluß (66B), der
mit dem zweiten Nutzlumen verbunden und au-
ßerhalb des Ballons angeordnet ist.

Revendications

1. Cathéter (10), comprenant :

un corps allongé (14) avec une surface extérieu-
re (24) ;
un transducteur à ultrasons (18) avec une lon-
gueur longitudinale (34) ; et
un élément de support (20) situé au niveau de
la surface extérieure du corps allongé pour sup-
porter le transducteur à ultrasons, l’élément de
support définissant au moins partiellement une
chambre (26), la chambre étant définie entre le
transducteur à ultrasons et la surface extérieure
du corps allongé, la chambre réduisant la trans-
mission d’énergie à ultrasons provenant du
transducteur à ultrasons dans le corps allongé
suivant la longueur longitudinale du transduc-
teur à ultrasons, caractérisé en ce que le ca-
théter comprend une lumière d’utilité (16) pour
l’administration de produits à un site de traite-
ment qui s’étend à travers le corps allongé.

2. Cathéter selon la revendication 1, dans lequel la
chambre s’étend en continu suivant la longueur lon-
gitudinale du transducteur à ultrasons.

3. Cathéter selon la revendication 1, dans lequel le
transducteur à ultrasons est adjacent à la chambre,
le cathéter comprenant en outre
un revêtement (22) adjacent à une surface externe
du transducteur à ultrasons ;
et
au moins un capteur de température (36) couplé au
revêtement.

4. Cathéter selon la revendication 3, dans lequel le au
moins un capteur de température est positionné à
l’intérieur du revêtement.

5. Cathéter selon la revendication 1, la revendication
2 ou la revendication 3, dans lequel la chambre est
remplie d’un matériau à faible impédance acousti-
que.

6. Cathéter selon la revendication 1, la revendication
2 ou la revendication 3, dans lequel la chambre est
remplie d’air.

7. Cathéter selon la revendication 1, la revendication
2 ou la revendication 3, dans lequel la chambre est
remplie d’azote.

8. Cathéter selon la revendication 1, la revendication
2 ou la revendication 3, dans lequel la chambre est
évacuée.

9. Cathéter selon la revendication 1 ou la revendication
2, comprenant en outre :

un revêtement (22) adjacent à une surface ex-
terne du transducteur à ultrasons ;
et
au moins un capteur de température (36) couplé
au revêtement.

10. Cathéter selon la revendication 9, dans lequel le au
moins un capteur de température est positionné à
l’intérieur du revêtement.

11. Cathéter selon la revendication 9, dans lequel le re-
vêtement comprend du parylène.

12. Cathéter selon la revendication 1 ou la revendication
2, comprenant en outre :

au moins un capteur de température (36) ; et
un système de commande de retour destiné à
régler une puissance délivrée au transducteur
à ultrasons en réponse à un signal provenant du au moins un capteur de température.

13. Cathéter selon la revendication 1 ou la revendication 2, comprenant en outre :

un support (28) positionné entre l’élément de support et le corps allongé.

14. Cathéter selon la revendication 13, dans lequel le support est intégré à l’élément de support.

15. Cathéter selon la revendication 1, comprenant en outre :

un revêtement supportant l’élément de support.

16. Cathéter selon la revendication 2, comprenant en outre :

un revêtement adjacent au transducteur à ultrasons et supportant l’élément de support.

17. Cathéter selon la revendication 1, la revendication 2 ou la revendication 3, comprenant en outre :

un ballonnet extensible (70) enfermant le transducteur à ultrasons.

18. Cathéter selon la revendication 1, dans lequel la lumière d’utilité comprend une lumière d’une pluralité de lumières d’utilité s’étendant à travers le transducteur à ultrasons.

19. Cathéter selon la revendication 2 ou la revendication 3, dans lequel la lumière d’utilité comprend une lumière d’une pluralité de lumières d’utilité (16) s’étendant à travers le corps allongé.

20. Cathéter selon la revendication 1, la revendication 2 ou la revendication 3, dans lequel le transducteur à ultrasons comprend des extrémités (32) et la chambre s’étend au-delà des extrémités du transducteur à ultrasons.

21. Cathéter selon la revendication 3, comprenant en outre :

au moins un support positionné entre l’élément de support et le corps allongé.

22. Cathéter selon la revendication 21, dans lequel le au moins un support est intégré à l’élément de support.

23. Cathéter selon la revendication 3, comprenant en outre :

un revêtement adjacent au transducteur à ultrasons et supportant l’élément de support.

24. Cathéter selon la revendication 3, comprenant en outre :

un élément d’isolation à ultrasons positionné dans la chambre.

25. Cathéter selon la revendication 1, comprenant en outre :

un ballonnet (70 ; 70a ; 70b) couplé au corps allongé.

26. Cathéter selon la revendication 1, dans lequel le corps allongé définit au moins une partie de la chambre, la chambre ayant un premier côté adjacent au corps allongé et un second côté opposé au premier côté, et le transducteur à ultrasons est positionné sur le second côté de la chambre, le cathéter comprenant en outre un ballonnet (70) couplé au corps allongé.

27. Cathéter selon la revendication 25 ou la revendication 26, dans lequel :

le ballonnet encercle le transducteur à ultrasons.

28. Cathéter selon la revendication 25 ou la revendication 26, dans lequel :

le ballonnet est positionné de manière distale sur le corps allongé par rapport au transducteur à ultrasons.

29. Cathéter selon la revendication 25 ou la revendication 26, dans lequel :

le ballonnet est positionné de manière proximale sur le corps allongé par rapport au transducteur à ultrasons.

30. Cathéter selon la revendication 25 ou la revendication 26, comprenant en outre :

une seconde lumière d’utilité (16B) ; et un orifice d’administration de produits (66B) couplé à la seconde lumière d’utilité et positionné à l’extérieur du ballonnet.

31. Cathéter selon la revendication 25 ou la revendication 26, comprenant en outre :

un second ballonnet (70A ; 70B) couplé au corps allongé.
32. Cathéter selon la revendication 31, comprenant en outre :

une seconde lumière d’utilité (16B) ; et
un orifice d’administration de produits (66B) couplé à la seconde lumière d’utilité et positionné à l’extérieur du ballonnet.