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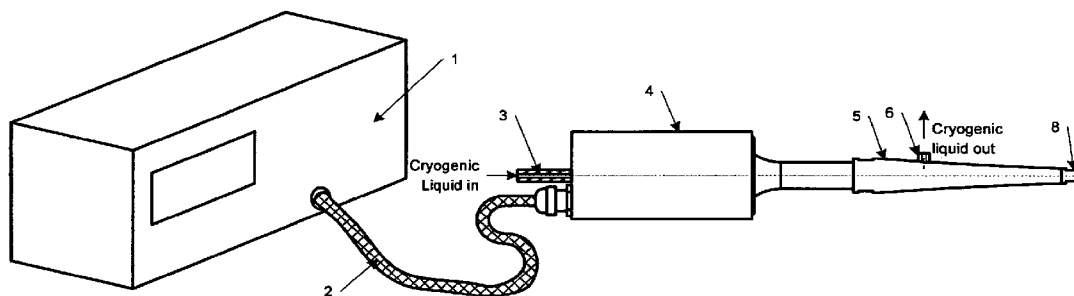
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(54) Title: APPARATUS AND METHODS FOR PAIN RELIEF USING ULTRASOUND WAVES IN COMBINATION WITH CRYOGENIC ENERGY



(57) Abstract: The method and device of the present invention for pain relief using ultrasound waves in combination with, cryogenic energy includes a generator and a transducer to produce ultrasonic waves and a cryogenic source to produce cryogenic energy. Ultrasound waves are delivered to the target in combination with cryogenic energy. Ultrasound waves and cryogenic energy can be delivered to the target from the radial side of the ultrasound horn and/or tip or can be delivered from the distal end of the ultrasound tip. Cryogenic energy can also be delivered directly to the target through a central orifice. Ultrasound energy can also be delivered through a cryogenic spray at the distal end. The use of ultrasound waves in combination with cryogenic energy can provide an analgesic effect.



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APPARATUS AND METHODS FOR PAIN RELIEF USING ULTRASOUND WAVES IN COMBINATION WITH CRYOGENIC ENERGY

BACKGROUND OF THE INVENTION

Field of the Invention:

5 The present invention relates to pain relief. In particular, the present invention relates to apparatus and methods for pain relief using ultrasound waves in combination with cryogenic energy.

Description of the Related Art:

10 The use of ultrasound as a source of heat to treat pain is well known in the art. Heat generated by ultrasound is utilized to treat pain by either ablating the nociceptive nerve and nerve endings responding to the pain (for example Patent No. 5,433,739 to Sluijter et al and Patent No. 6,073,051 to Sharkey et al) or by warming the target tissue (for example Patent No. 50460,595 to Hall et al and Patent No. 5,413,550 to Castel). The former method treats pain by permanently removing the body's ability to sense pain in the treated area. It has been suggested
15 that damage to tissue surrounding the target tissue to be ablated by ultrasonic energy can be reduced by cooling the ultrasound electrode (Patent No. 5,186,181 to Franconi et al). While removing the ability to sense to pain may provide short-term therapeutic benefits, it can cause long term harm by preventing the patient from detecting the development of new pathologies or the worsening of existing pathologies in the treated area. Unable to sense the pain associated
20 with pathologic changes, the patient will delay seeking treatment thereby lowering the patient's prognosis.

 Treating pain by heating the target tissue with ultrasonic energy has been proven effective. Assuming the therapeutic effects of ultrasound administration are tied to a thermal effect, these methods attempt to raise the temperature of the target tissue anywhere from 1 to 4
25 degree Celsius; deep pain and chronic pain are treated with higher temperatures (Patent No. 5,413,550 to Castel). Heating target tissue, however, runs the risk of burning the patient or otherwise producing patient discomfort. Furthermore, studies investigating the therapeutic effects of ultrasound suggest that analgesic effects are not dependent upon the thermal effects of ultrasound. (Hsieh. Effects of ultrasound and diclofenac phonophoresis on inflammatory pain

relief: suppression of inducible nitric oxide synthase in arthritic rats. *Physical Therapy* 2006; 86: 39 – 49; Young and Dyson. Effect of therapeutic ultrasound on the healing of full-thickness excised skin lesions. *Ultrasonics* 1990; 28: 175 – 180; Dino et al. The significance of membrane changes in the safe and effective use of therapeutic and diagnostic ultrasound. *Physics in Medicine and Biology* 1989; 34: 1543 – 1552.) Thus the use of ultrasound as an analgesic heat source is misguided and exposes the patient to unnecessary risks.

The use of cold temperatures to provide pain relief is also well-known. The most frequent use is the standard ice-pack that is used in everyday homes. The analgesic effect cool temperature provides stems from the cooling of neuronal tissue that causes the neuronal tissue to cease functioning. The use of cold temperatures for pain relief has evolved into a different format: cryogenics are now used to cool or freeze neuronal tissue such as nerves to produce an analgesic effect. The freezing of the tissue, however, provides a more dramatic effect than the simple cooling of neuronal tissue. Nerves are destroyed because the freezing of nerve cell bodies kills the cell body. For example, U.S. Pat. No. 6,761,715 to Carroll discloses a system and method for cooling or freezing neuronal tissue in order to induce lesions and produce cryoanalgesia. Additionally, U.S. Pat. No. 5,571,147 to Sluijter et al. discloses a general method of denervation of nerves to relieve back pain using both heating and cryogenic methods. While these methods may result in an analgesic effect, the drawback of these methods is that they result in the destruction of nerves. The present invention does not involve the destruction of tissues, cell, or nerves through heating, freezing, etc to provide pain relief.

U.S. Pat. Application No. 2002/0165529 to Danek discloses a system and method that utilizes cryogenic energy in combination with other sources of energy such as ultrasound or microwave to prevent collateral damage to the surface layer because of the high temperatures used. U.S. Pat. Application No. 2003/0014098 to Quijano et al. also uses cryogenic energy to protect peripheral tissue from applied thermal energy. The present invention does not use cryogenic energy to prevent collateral damage; the cryogenic energy used in the present invention is for an additional therapeutic purpose for pain relief.

Therefore, there is a need for a method and device that utilize both ultrasound energy and cryogenic energy in combination to provide effective pain relief that does not result in destruction of tissues, cells, or nerves.

SUMMARY OF THE INVENTION

The present invention is directed towards an apparatus and methods for pain relief using ultrasound waves in combination with cryogenic energy. Apparatus and methods in accordance with the present invention may meet the above-mentioned needs and also provide additional advantages and improvements that will be recognized by those skilled in the art upon review of the present disclosure.

The present invention comprises an ultrasonic generator, an ultrasonic transducer, an ultrasound horn, an ultrasound tip, and a cryogenic energy supply source. Ultrasonic waves are utilized in combination with cryogenic energy to provide more effective pain relief.

Ultrasonic energy is delivered directly to the surface area intended to be treated for pain. Delivery can occur either through the radial side of the sonotrode (the ultrasound horn and tip) or through the distal end of the ultrasound tip. Ultrasound energy provides a pain relief effect because it positively influences nerve endings, massages tissues, and stimulates cells.

Cryogenic energy is delivered in combination with ultrasound energy. Cryogenic liquid or gas ("cryogenic energy") can be circulated through the delivery system, thus causing the temperature of the sonotrode to decrease. The use of cryogenic energy also provides a cooling effect on the target either through a cooled sonotrode or through cryogenic energy delivered to the surface through an orifice on the ultrasound tip. The use of cryogenic energy can have two important effects. First, cryogenic energy provides pain relief itself. This results from the recognized therapeutic effect of cooling a surface area with, for example, an ice pack. It should be noted that, unlike other cryogenic treatment methods, the cooling effect with the cryogenic energy according to the present invention is not meant to freeze or destroy any tissues, cells, nerve endings, etc. The use of concurrent cryogenic pain relief can also increase the effectiveness of the ultrasound pain relief effect. Second, a cooled sonotrode can prevent the temperature of the target tissue from reaching high levels as a result of using ultrasonic energy. When ultrasound energy is delivered to a target area, heat is generated that raises the temperature of the target. This rise in temperature can result in the destruction of tissues, cells, and nerve endings. Heat energy has been used in conjunction with ultrasound to provide pain relief, but that pain relief is simply the result of the destruction of the nerve ending. However, the use of

cryogenic energy to provide a cooling effect according to the present invention prevents this increase in temperature, and therefore protects nerve endings, tissues, cells, etc from destruction.

The invention is related to the apparatus and methods of using ultrasound waves in combination with cryogenic energy to provide an analgesic effect.

5 One aspect of this invention may be to provide a method and device for more effective pain relief.

Another aspect of the invention may be to provide a method and device for more efficient pain relief.

10 Another aspect of the invention may be to provide pain relief that does not destroy tissues, cells, or nerve endings.

These and other aspects of the invention will become more apparent from the written descriptions and figures below.

BRIEF DESCRIPTION OF THE DRAWINGS

The present Invention will be shown and described with reference to the drawings of preferred embodiments and clearly understood in details.

5 **Figure 1** is a perspective view of an ultrasound and cryogenic pain relief apparatus for use according to the present invention.

Figure 2 is a cross-sectional view of an ultrasound and cryogenic pain relief apparatus.

Figure 3 is a detailed cross-sectional view of the sonotrode section of an ultrasound and cryogenic pain relief apparatus that has a rear cryogenic energy entry port, a radial cryogenic energy exit port, and a distal end central orifice.

10 **Figure 4** is a detailed cross-sectional view of the sonotrode section of an ultrasound and cryogenic pain relief apparatus that has a rear cryogenic energy entry port, a radial cryogenic energy exit port, and no distal end central orifice.

15 **Figure 5** is a detailed cross-sectional view of the sonotrode section of an ultrasound and cryogenic pain relief apparatus that has radial cryogenic energy entry and exit ports, and a distal end central orifice.

Figure 6 is a detailed cross-sectional view of the sonotrode section of an ultrasound and cryogenic pain relief apparatus that has radial cryogenic energy entry and exit ports, and no distal end central orifice.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is an apparatus and methods for pain relief using ultrasound waves in combination with cryogenic energy. Preferred embodiments of the present invention in the context of an apparatus and methods are illustrated in the figures and described in detail
5 below.

Fig. 1 illustrates an ultrasound and cryogenic pain relief apparatus that has an ultrasonic generator **1**, a power supply cord **2**, a cryogenic energy entry port **3**, an ultrasonic transducer **4**, an ultrasonic horn **5**, a cryogenic energy exit port **6**, and an ultrasonic tip **8**.

Fig. 2 illustrates a cross-sectional view of an ultrasound and cryogenic pain relief
10 apparatus shown in **Fig. 1** that has an ultrasonic transducer **4** that is mechanically connected to the ultrasound horn **5** by threading or other material **11**. The preferred embodiment consists of an ultrasonic transducer **4** that is mechanically connected to an ultrasound horn **5**; alternative embodiments could have the ultrasonic transducer **4** directly connected to the ultrasound horn **5** to comprise a single piece without a mechanical interface. The ultrasound horn **5** is
15 mechanically connected to the ultrasound tip **8** by threading or other material **7**. The preferred embodiment consists of an ultrasound tip **8** that is directly connected to the ultrasound horn **5** by a mechanical interface; alternative embodiments could have the ultrasound tip **8** directly connected to the ultrasound horn **5** to comprise a single piece without a mechanical interface. Cryogenic fluid is inserted into the cryogenic energy entry port **3**. The cryogenic energy moves
20 through the entry orifice **12** and into the air chamber **10**. The cryogenic energy then goes through the exit orifice **13** and out of the exit port **6** that is located on a radial side of the ultrasound horn **5**. A tube or other material can replace the entry orifice **12** and the exit orifice **13**. This embodiment of the apparatus also contains a central orifice **9** of ultrasound tip **8**. One example of a cryogenic energy to use is liquid nitrogen; other cryogenic liquids, gases, etc can
25 also be similarly effective.

Fig. 3 is a detailed cross-sectional view of the sonotrode section of the ultrasound and cryogenic pain relief apparatus system shown in **Fig. 2** with an ultrasound horn **5** that is mechanically connected to the ultrasound tip **8** by threading or other material **7**. The preferred embodiment consists of an ultrasound horn **5** that is mechanically connected to the ultrasound
30 tip **8**; alternative embodiments could have the ultrasound tip **8** directly connected the ultrasound

horn 5 to comprise a single piece that does not require a mechanical interface. The ultrasound horn 5 is mechanically connected to the ultrasonic transducer (not shown) by threading or other material 11. The preferred embodiment consists of an ultrasound horn 5 that is mechanically connected to the ultrasonic transducer (not shown) by threading or other material 11; alternative
5 embodiments could have the ultrasound horn 5 directly connected to the ultrasonic transducer (not shown) to comprise a single piece that does not require a mechanical interface. Cryogenic fluid is inserted into the cryogenic energy entry port (not shown). The cryogenic energy moves through the entry orifice 12 and into the air chamber 10. The cryogenic energy then moves through the exit orifice 13 and out of the exit port 6 that is located on a radial side of the
10 ultrasound horn 5. A tube or other material can replace the entry orifice 12 and the exit orifice 13. This embodiment contains a central orifice 9 of ultrasound tip 8.

Fig. 4 is a detailed cross-sectional view of the sonotrode section of an ultrasound and cryogenic pain relief apparatus system that does not contain a central orifice. The sonotrode section consists of an ultrasound horn 5 that is mechanically connected to the ultrasound tip 14
15 by threading or other material 16. The preferred embodiment consists of an ultrasound horn 5 that is mechanically connected to the ultrasound tip 14; alternative embodiments could have the ultrasound tip 14 directly connected to the ultrasound horn 5 to comprise a single piece that does not require a mechanical interface. The ultrasound horn 5 is mechanically connected to the ultrasonic transducer (not shown) by threading or other material 11. The preferred embodiment
20 consists of an ultrasound horn 5 that is mechanically connected to the ultrasonic transducer (not shown) by threading or other material 11; alternative embodiments could have the ultrasound horn 5 directly connected to the ultrasonic transducer (not shown) to comprise a single piece that does not require a mechanical interface. Cryogenic fluid is inserted into the cryogenic energy entry port (not shown) where the cryogenic energy moves through the entry orifice 12
25 and into the air chamber 15. The cryogenic energy then moves through the exit orifice 13 and out of the exit port 6 that is located on a radial side of the ultrasound horn 5. A tube or other material can replace the entry orifice 12 and the exit orifice 13. There is no central orifice in this embodiment. The preferred embodiment has an ultrasound tip 14 without a central orifice. An alternative embodiment is depicted in Fig. 3 where the ultrasound tip 8 has a central orifice
30 9.

Fig. 5 is a detailed cross-sectional view of the sonotrode section of an ultrasound and cryogenic pain relief apparatus that has a cryogenic energy entry port **20** on a radial side of an ultrasound horn **17** - as compared to a cryogenic entry port located on the transducer as shown in **Fig. 2**. The sonotrode section consists of an ultrasound horn **17** that is mechanically
5 connected to the ultrasound transducer (not shown) by threading or other material **26**. The preferred embodiment consists of an ultrasound horn **17** that is mechanically connected to the ultrasound transducer (not shown); alternative embodiments could have the ultrasound horn **17** directly connected to the ultrasound transducer (not shown) to comprise a single piece that does not require a mechanical interface. The sonotrode section also consists of an ultrasound horn **17**
10 that is mechanically connected to the ultrasound tip **23** by threading or other material **22**. The preferred embodiment consists of an ultrasound horn **17** that is mechanically connected to the ultrasound tip **23**; alternative embodiments could have the ultrasound horn **17** directly connected to the ultrasound tip **23** to comprise one single piece that does not require a mechanical interface. Cryogenic fluid is inserted into the cryogenic energy entry port **20** that is
15 located on a radial side of the ultrasound horn **17**. The cryogenic energy moves through the entry orifice **21** and into the air chamber **25**. The cryogenic energy then moves through the exit orifice **19** and out of the exit port **18** that is located on a radial side of the ultrasound horn **17**. The preferred embodiment consists of an exit port **18** located on the direct opposite side of the ultrasound horn **17** than the entry port **20** with both the exit port **18** and entry port **20** positioned
20 at ninety-degrees to the axis of the sonotrode. Alternate embodiment could have an entry port **20** and exit port **18** positioned at any other location on the ultrasound horn **17** or positioned at any other angle to the axis of the sonotrode. The entry orifice **21** and the exit orifice **19** are both located off-center in the ultrasound horn **17**. A tube or other material can replace the entry orifice **21** and the exit orifice **19**. This embodiment contains a central orifice **24** of ultrasound
25 tip **23**.

Fig. 6 is a detailed cross-sectional view of the sonotrode section of an ultrasound and cryogenic pain relief apparatus that has a cryogenic energy entry port **20** on a radial side of ultrasound horn **17**. The sonotrode section consists of an ultrasound horn **17** that is mechanically connected to the ultrasound tip **28** by threading or other material **27**. The
30 preferred embodiment consists of an ultrasound horn **17** that is mechanically connected to the ultrasound tip **28**; alternative embodiments could have the ultrasound horn **17** directly

connected to the ultrasound tip 28 to comprise a single piece that does not require a mechanical interface. Cryogenic fluid is inserted into the cryogenic energy entry port 20 that is located on a radial side of the ultrasound horn 17. The cryogenic energy moves through the entry orifice 21 and into the air chamber 29. The cryogenic energy then moves through the exit orifice 19 and out of the exit port 18 that is located on a radial side of the ultrasound horn 17. The preferred embodiment consists of an exit port 18 positioned on the direct opposite side of the ultrasound horn 17 than the entry port 20 with both the exit port 18 and the entry port 20 positioned at ninety-degrees to the axis of the sonotrode. Alternate embodiment could have an entry port 20 and exit port 18 positioned at any other location on the ultrasound horn 17 or positioned at any other angle to the axis of the sonotrode. The entry orifice 21 and the exit orifice 19 are both located off-center in the ultrasound horn 17. A tube or other material can replace the entry orifice 21 and the exit orifice 19. This embodiment does not contain a central orifice. The preferred embodiment does not have a central orifice; alternative embodiment could contain a central orifice as shown in Fig. 5. The preferred embodiment of an ultrasound pain treatment apparatus does not contain a central orifice, as depicted in Fig. 4 and Fig. 6.

The frequency range for the ultrasound waves is 15 kHz to 40 MHz, with a preferred frequency range of 20 kHz – 60 kHz, and the recommended frequency value is 30 kHz. The amplitude of the ultrasound waves can be 1 micron and above, with a preferred amplitude range of 10 microns to 250 microns, and with a most preferred amplitude range of 20 microns to 70 microns, and the recommended amplitude value is 50 microns. The time of treatment and the number of treatments will vary based on a variety of factors. These factors include the type of pain being treated (chronic, acute, phantom, etc), the source of the pain (cut, bruise, burn, etc), the periodicity of the symptoms, the duration of the pain, the reaction of the patient to the treatment, etc.

Ultrasonic waves are delivered in combination with cryogenic energy to provide more effective pain relief. Cryogenic energy is the cryogenic material such as cryogenic liquid, cryogenic gas, etc that is inserted into the ultrasound and cryogenic pain relief apparatus. Ultrasound waves and cryogenic energy can be delivered either concurrently or sequentially. Ultrasound waves can be delivered either through the radial side of the sonotrode or through the distal end of the ultrasound tip. Cryogenic energy can be delivered either through the radial side of the sonotrode with radial ultrasound waves, or cryogenic energy can be delivered distally with

longitudinal waves. A central orifice can be used to deliver cryogenic energy directly to the target so that the longitudinal ultrasound waves can be delivered to the target through a cryogenic spray. The preferred method of treatment is to deliver radial ultrasound waves from the radial side of the sonotrode and to also deliver cryogenic energy from the radial side of the sonotrode. Ultrasound waves delivered alone from the radial side of the sonotrode can also provide pain relief.

Although specific embodiments and methods of use have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that any arrangement that is calculated to achieve the same purpose may be substituted for the specific embodiments and methods shown. It is to be understood that the above description is intended to be illustrative and not restrictive. Combinations of the above embodiments and other embodiments as well as combinations of the above methods of use and other methods of use will be apparent to those having skill in the art upon review of the present disclosure. The scope of the present invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

CLAIMS

I claim:

- 1) A method for pain relief by using ultrasound waves in combination with cryogenic energy, comprising the steps of:
 - 5 a) delivering ultrasonic energy to the target area;
 - b) wherein ultrasound waves are delivered in combination with cryogenic energy; and
 - c) wherein the ultrasound energy and cryogenic energy have an intensity capable of providing an analgesic effect.
- 2) The method according to claim 1, further including the step of generating the ultrasonic energy with particular ultrasound parameters indicative of an intensity capable providing an
10 analgesic effect.
- 3) The method according to claim 1, further including the step of the cryogenic source generating cryogenic energy capable of providing an analgesic effect.
- 4) The method according to claim 1, wherein the frequency is in the range of 15 kHz-40 MHz.
- 15 5) The method according to claim 1, wherein the preferred frequency is in the range of 20 kHz-60 kHz.
- 6) The method according to claim 1, wherein the recommended frequency value is 30 kHz.
- 7) The method according to claim 1, wherein the amplitude is at least 1 micron.
- 8) The method according to claim 1, wherein the preferred amplitude is in the range of 10
20 microns -- 250 microns.
- 9) The method according to claim 1, wherein the most preferred amplitude is in the range of 20 microns -- 70 microns.
- 10) The method according to claim 1, wherein the recommended amplitude value is 50 microns.
- 11) The method according to claim 1, wherein the ultrasonic energy and the cryogenic energy
25 are delivered for a duration of time based on a variety of factors such as the type of pain being treated, the source of the pain, the periodicity of the symptoms, the duration of the pain, the reaction of the patient, etc.

- 12) The method according to claim 1, wherein the ultrasonic energy and cryogenic energy are delivered from the radial side of the sonotrode.
- 13) The method according to claim 1, wherein the ultrasonic energy and the cryogenic energy are delivered through the distal end of the ultrasound tip.
- 5 14) The method according to claim 13, wherein the ultrasound energy is delivered to the target through a cryogenic spray.
- 15) The method according to claim 1, wherein cryogenic energy is delivered before, during, or after the delivery of the ultrasound energy.
- 16) An apparatus for pain relief by using ultrasound waves in combination with cryogenic energy, comprising:
- 10 a) a generator and a transducer for generating ultrasonic energy;
- b) a cryogenic liquid or gas source for generating cryogenic energy;
- c) wherein the ultrasound horn and/or tip delivers ultrasonic waves in combination with cryogenic energy to the target; and
- 15 d) wherein the ultrasound energy and cryogenic energy have an intensity capable of providing an analgesic effect.
- 17) The apparatus according to claim 16, wherein the generator and transducer generate the ultrasound energy with particular ultrasound parameters indicative of an intensity capable of providing an analgesic effect.
- 20 18) The apparatus according to claim 16, wherein the cryogenic liquid or gas source generate cryogenic energy capable of providing an analgesic effect.
- 19) The apparatus according to claim 16, wherein the frequency is in the range of 15 kHz-40 MHz.
- 20) The apparatus according to claim 16, wherein the preferred frequency is in the range of 20 kHz-60 kHz.
- 25 21) The apparatus according to claim 16, wherein the recommended frequency value is 30 kHz.
- 22) The apparatus according to claim 16, wherein the amplitude is at least 1 micron.

- 23) The apparatus according to claim 16, wherein the preferred amplitude is in the range of 10 microns – 250 microns.
- 24) The apparatus according to claim 16, wherein the most preferred amplitude is in the range of 20 microns – 70 microns.
- 5 25) The apparatus according to claim 16, wherein the recommended amplitude value is 50 microns.
- 26) The apparatus according to claim 16, wherein the ultrasonic energy and cryogenic energy are delivered for a duration of time by using a timer based on a variety of factors such as the type of pain being treated, the source of the pain, the periodicity of the symptoms, the
10 duration of the pain, the reaction of the patient, etc.
- 27) The apparatus according to claim 16, wherein the transducer, such as a Langevin transducer, contains a radiation surface having a surface area dimensioned/constructed for achieving delivery of the ultrasonic energy and cryogenic energy to the target with an intensity capable of providing an analgesic effect.
- 15 28) The apparatus according to claim 16, wherein the transducer contains a longitudinal radiation surface where the shape of the radiation surface is a sphere, a rectangular prism, a flat surface, a curved surface, or another comparable shape or combination of shapes.
- 29) The apparatus according to claim 16, wherein the shape of the peripheral boundary of the radiation surface is circular, elliptical, rectangular, polygonal, or another comparable shape
20 or combination of shapes.
- 30) The apparatus according to claim 16, wherein the shape of the peripheral boundary of the radiation surface is intended to achieve delivery of the ultrasonic energy and the cryogenic energy to the target with an intensity capable of providing an analgesic effect.
- 31) The apparatus according to claim 16, wherein the transducer is driven by a continuous or
25 pulsed frequency.
- 32) The apparatus according to claim 16, wherein the transducer is driven by a fixed or modulated frequency.

- 33) The apparatus according to claim 16, wherein the driving wave form of the transducer is selected from the group consisting of sinusoidal, rectangular, trapezoidal and triangular wave forms.

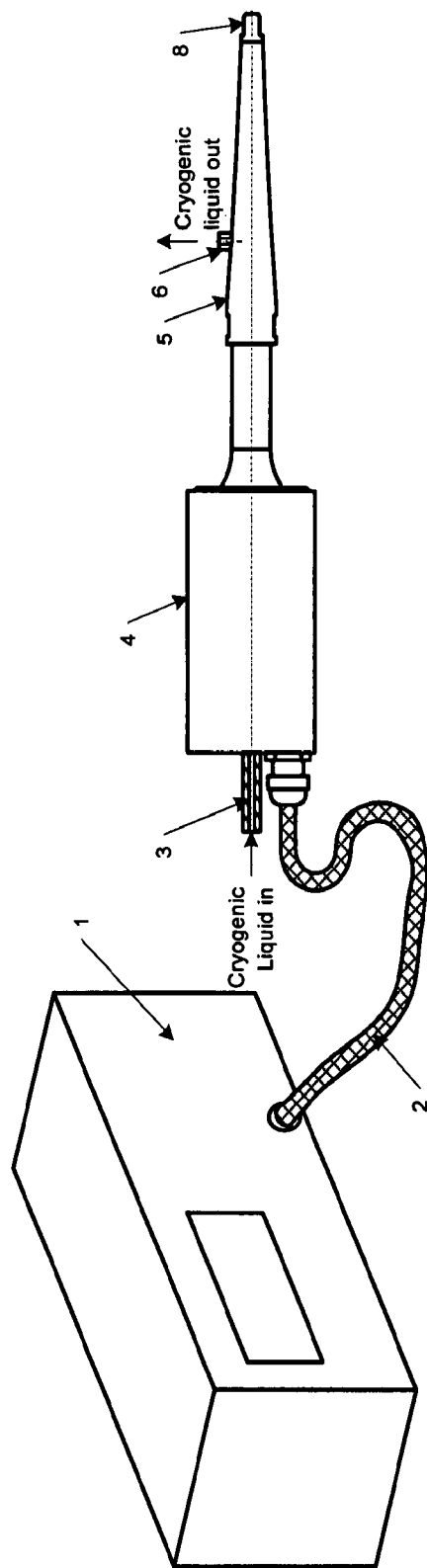


Fig. 1

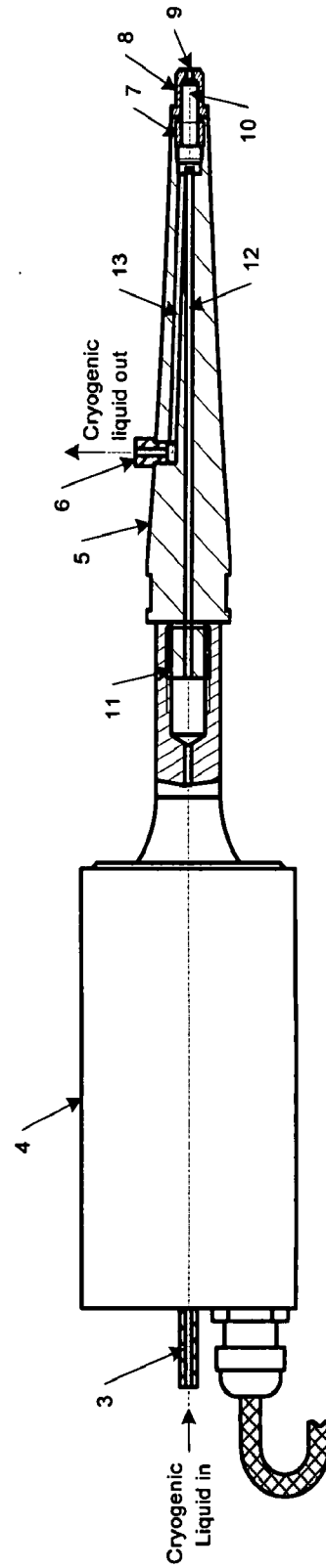


Fig. 2

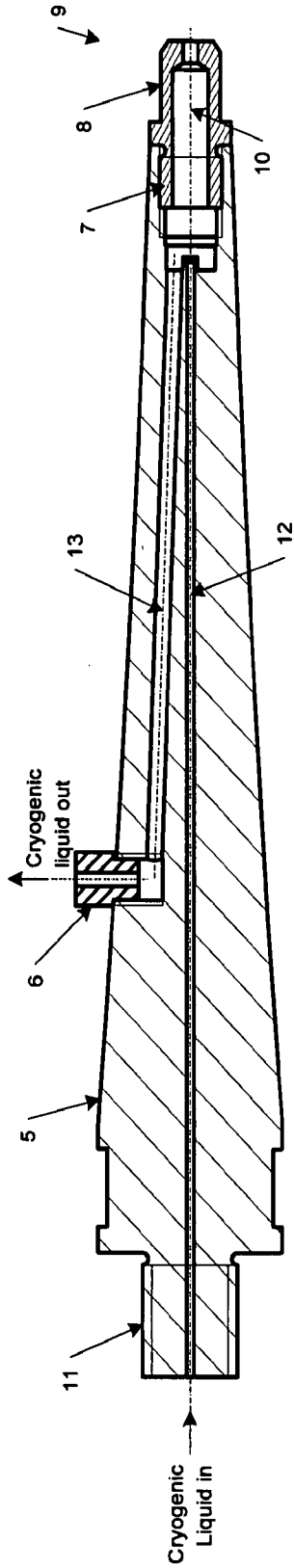


Fig. 3

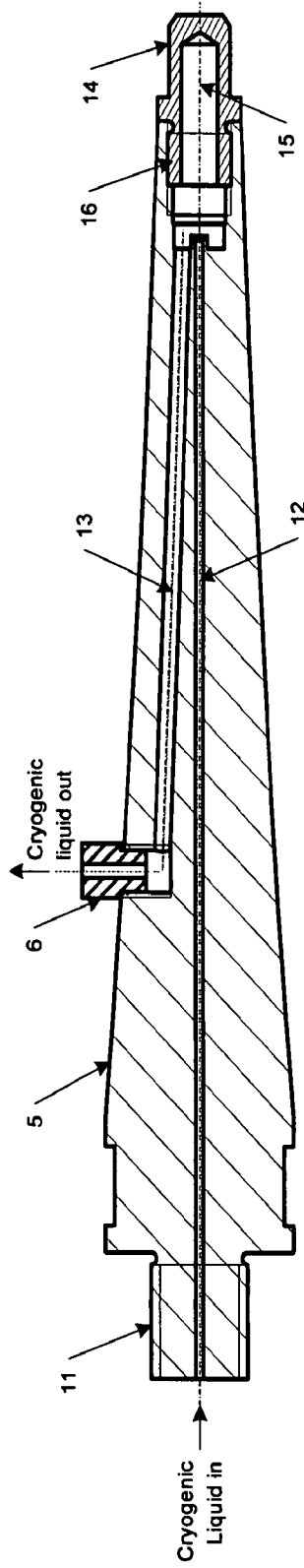


Fig. 4

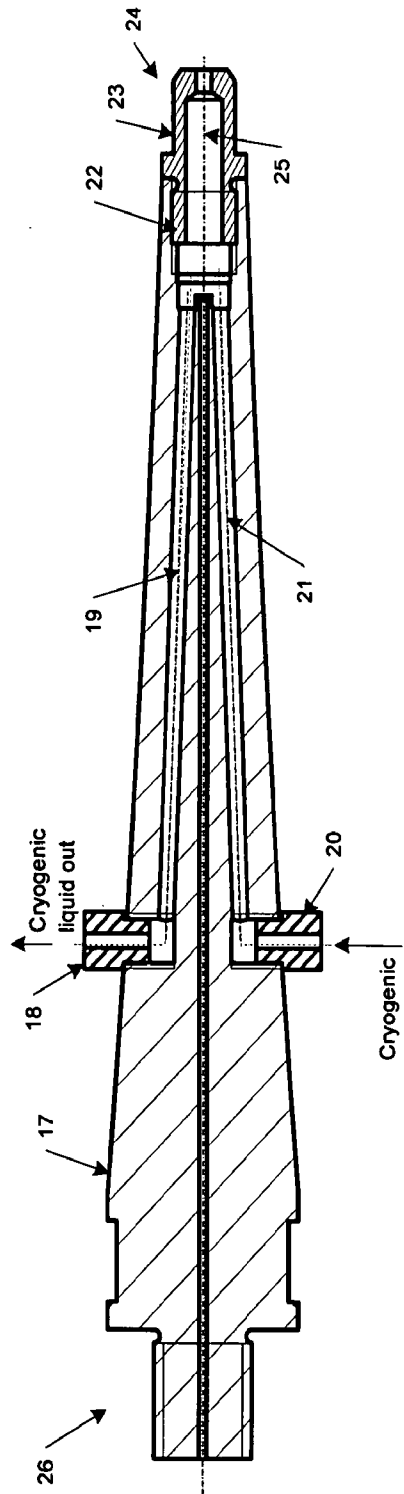


Fig. 5

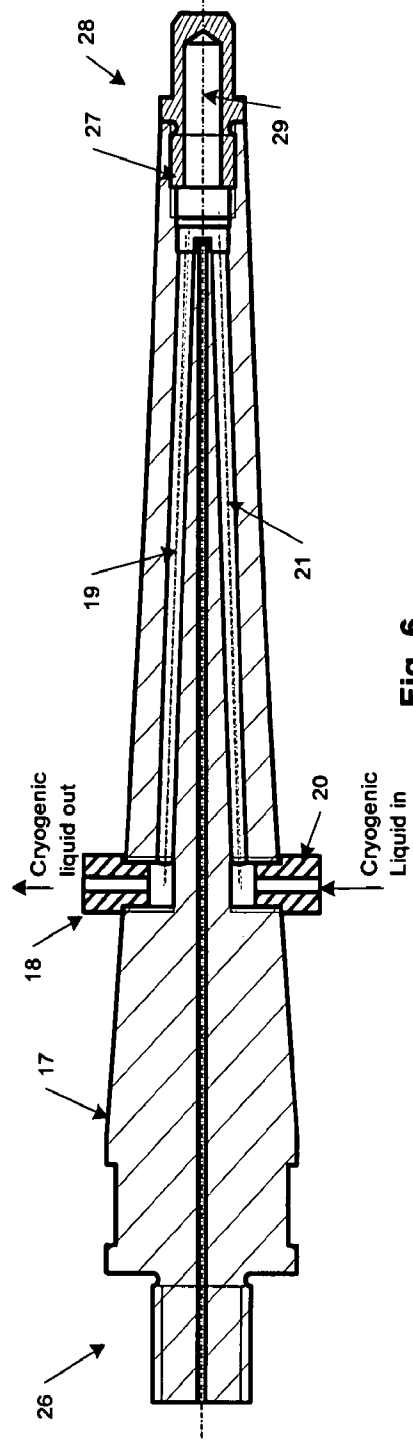


Fig. 6