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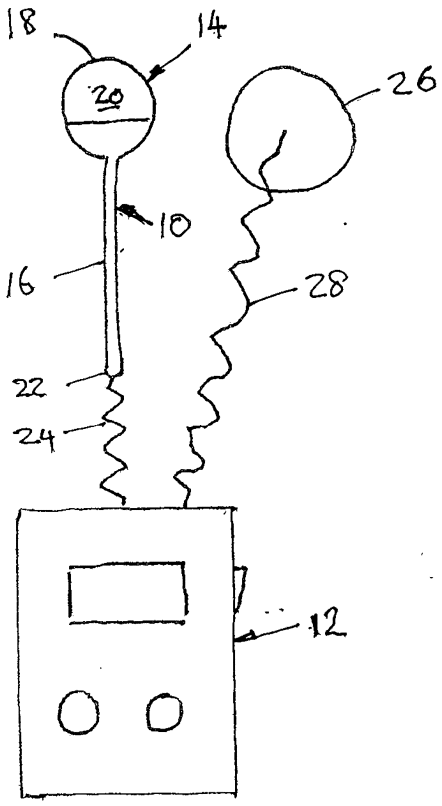
(58) Field of Search:
INT CL **A61N**
Other: **EPODOC, WPI, Patent Fulltext**

(54) Title of the Invention: **Improvements in and relating to electrodes for medical stimulating devices**
Abstract Title: **Electrodes for medical stimulating devices.**

(57) An electrically conducting electrode 10 for connection to an electronic power supply 12 to deliver a stimulating signal for management and/or treatment of neurological or muscular pain. The electrode 10 comprises one or more active or stimulating surfaces 18, each shaped as a hemisphere with a diameter between 2-12 mm. Where each active surface 18 is covered by, or coated with, a layer of an electrically conducting hydrogel 20. Hydrogel layer 20 may be removably replaceable. Active surface 18 may be formed at an end of a rigid stem 16. Electrode 10 may be formed or shaped to fit or treat a specific anatomy part. Also a matrix, or array, comprising a plurality of electrodes 10 mounted on a stiff or semi-stiff backing, with the electrodes 10 provided with a connection for connection to an electronic power supply 12, and where the backing may be electrically conducting with an insulating coating between the electrode's active surface 18 and where the electrodes' active surfaces 18 may be in the form of separate buttons or inserts mounted on a thermo-formable, or curable backing comprising a substrate, or woven or non-woven material.



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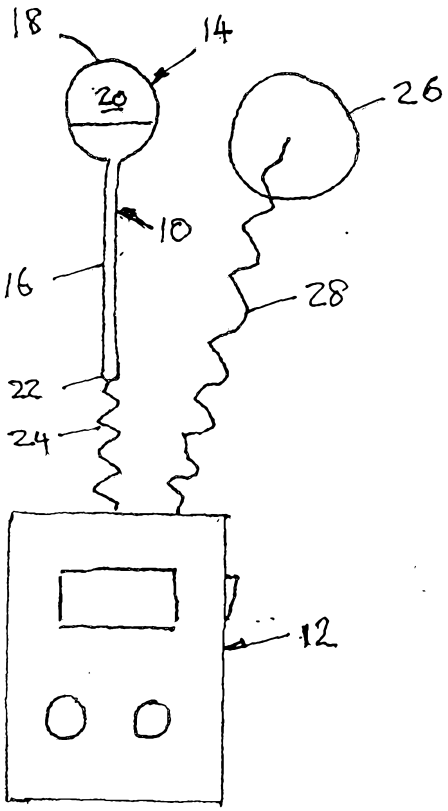

FIG 1

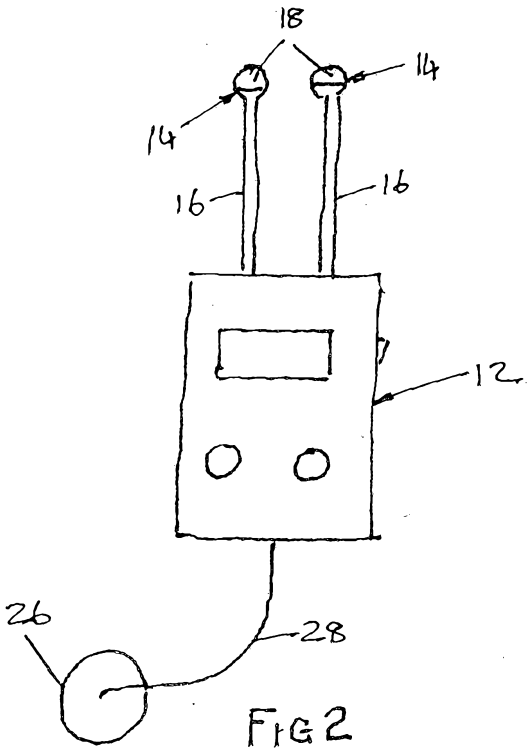

FIG 2

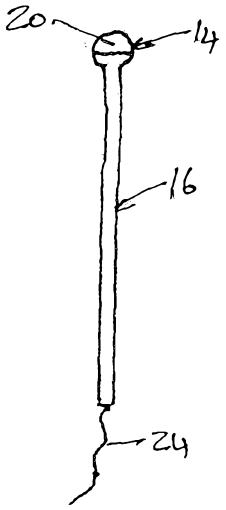

FIG 3

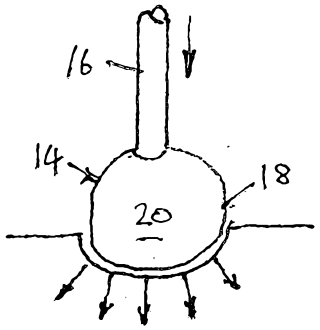

FIG 4

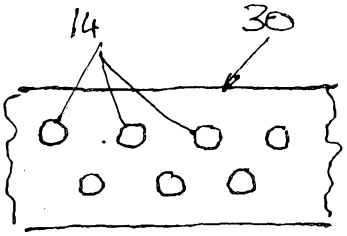

FIG 5

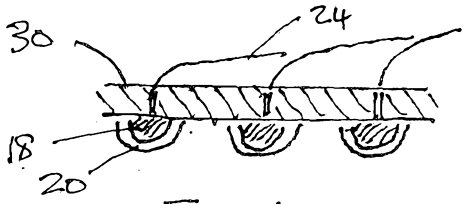

FIG 6

IMPROVEMENTS IN AND RELATING TO ELECTRODES FOR MEDICAL STIMULATING DEVICES

This invention relates to stimulating devices for treatment of acute or chronic pain or for improvement of function by means of the application of an electrical stimulating signal, and specifically to improvements in the electrodes for such stimulating devices.

In my previous patent applications, Nos. GB2435217 and GB2521240, I have shown that the application of firm pressure to stimulating electrodes while a stimulating signal is applied can greatly improve the effectiveness of the treatment and the outcome for the patient.

Nevertheless, patients can experience discomfort at the point of application of the stimulating signal, or it may not be comfortable for them to undergo treatments where a higher stimulating current might be more effective.

In accordance with the invention an electrically-conducting electrode for connection to an electronic power supply arranged in use to deliver a stimulating signal for the management and/or treatment of neurological or muscular pain or improvement of function comprises one or more active surface(s) each shaped substantially as a hemisphere (as herein defined) and whose diameter is between 2 and 12 mm, and each active or stimulating surface of the electrode is covered by or coated with a layer of an electrically-conducting hydrogel or similar soft conducting gel-like material.

A hemisphere as herein defined comprises substantially a hemisphere, though it may be elongated or flattened to improve its penetration, or it may be ellipsoid in shape, or be polygonal in section with a rounded active surface.

In general, the diameter of the electrode(s) will be chosen according to the desired application; a larger diameter where a single electrode is to be used, a smaller diameter where access is restricted, or where the electrodes are provided as an array or matrix for treatment of an enlarged area.

The layer of the hydrogel may be from half a millimetre to 5mm thick, though preferably from three quarters of a millimetre to 3 mm, and ideally 1 to 2mm thick. A hydrogel is typically a polymer–water substrate comprising up to 90% water. Owing to its water content the gel is soft and flexible as well as being a good electrical conductor that can also provide a low electrical resistance in contact with skin. Such gels may also adhere lightly to the skin, thus allowing for easy removal and re-use. In this specification the term 'hydrogel' refers to any similar gel or substance that may possess such properties.

An advantage of the invention is that the provision of a soft conducting layer of hydrogel over the active surface(s) of the electrode(s) greatly increases the comfort of the patient and may permit prolonged treatment. The soft hydrogel can also increase the acceptable stimulating current. In addition, it distributes the firm pressure that is applied during treatment more evenly and decreases the resistance between the electrode and the patient's skin, which may be yet further reduced by the application of contact solution. It should be noted that a single electrode may have more than one active surface.

More specifically, the hydrogel layer or coating may permit a current of up to 20mA to be applied to mucosal tissues, and up to 40mA to be applied to normal skin. The aim of the treatment is often to obtain maximum penetration of the stimulating signal to treat pain or for improvement of function (or to improve penetration over that presently or otherwise available).

The electrode(s) in accordance with the invention may also be used with a variety of existing apparatus to improve penetration by permitting improved contact and conductivity and/or permitting an increased current to be used, or for the apparatus to be used over a wider range of functions to treat pain or improve function.

The electrodes in accordance with the invention may either be disposable or disposable after multiple uses. The hydrogel coating may be formed over the electrode(s), or over multiple stimulating surfaces of the electrodes, or provided as a removable and replaceable layer or shell of hydrogel over the electrode(s) thus allowing the electrodes to be reused indefinitely.

In one embodiment, the electrode may be formed at the end of a stem. The stem, which can provide a convenient handle for a practitioner to grasp in order to apply the desired pressure to the electrode with a lead for connection to the power supply, or may be adapted to plug directly into the power supply whereby the latter can be gripped to exert the desired pressure. The other electrode may be of the same configuration, or alternatively may comprise a patch that is applied to the patient's skin at a suitable location.

The electronic power supply may advantageously be provided with a number of frequency and power ranges. The frequency ranges will preferably cover the range 1 to 100Hz and the range 1 to 10kHz so that the frequency can best be chosen to suit the patient and the type of pain they are suffering from or to improve function.

Equally, the power ranges provided on the power supply may be up to 1mA, 1 to 10mA, 1 to 20mA and say 1 to 50mA.

In order that the power supply and the electrodes that comprise a stimulating device may be taken home for prolonged use by a patient without supervision, once the power and frequency settings have been adjusted by a practitioner, they may be locked, or accessible only to a small range of adjustment.

For use on normal skin it has been found that an electrode where the diameter of the active surface is between 5 and 10mm produces good results.

However, for mucosal tissue, for example in the nose, the diameter of the active surface may be as small as 2 and 3mm. Smaller electrodes may also be used where they are arranged as an array or a matrix for treating a larger area.

Where the electrode is at the tip of a rigid stem, the length of the stem is conveniently 5 to 10cm.

For some applications where the pain or treatment to improve function requires treatment over an enlarged area, an array or matrix of, say, up to six or more electrodes mounted on a stiff or semi-rigid backing may be used. If the electrodes are mounted on a softer backing additional pressure may be applied to the electrodes by means of a strap or brace. The backing may conveniently be held in place by means

of a strap, cuff, brace or using Velcro (Registered TM 3M Inc.) or adhesive tape or strap. The electrodes are provided with connection(s) for connection to the power supply. The electrodes may be of the same or alternating polarities, or a grounding patch may be provided. The diameter of the electrodes may conveniently be 5mm ±1mm for optimum effect.

The electrodes are generally formed of a conducting metal or other electrical conductor, e.g. a plastics material having a conducting coating. A single electrode may be provided with a matrix comprising a plurality of active surfaces as described above, each such active surface separated by an insulating layer so that there is no electrical contact between the active surfaces. Such an electrode may be shaped or adapted specifically to treat or fit the part of the anatomy to be treated.

Specifically, the active surfaces of the electrodes that will generally be in the form of separate buttons or inserts may be mounted on a thermo-formable or curable backing material. The backing material may be a substrate or a woven or non-woven material that can be thermos-formed or air or chemically cured to assume a shape that it will in use retain. It can thus be pre-shaped over the site to be treated, and then heated or otherwise treated to cure the re resin in order to achieve the desired shape or form. If the substrate or material is electrically-conducting, it needs to be covered or coated with an insulating layer between the active surfaces.

The invention extends to a method for treating chronic or acute pain or to improve function comprising applying one or more electrodes as described above to an affected area, applying a firm pressure sufficient to cause indentation of the skin, and applying a stimulating signal either in the range 1 to 100Hz or in the range 1 to 10kHz.

The method includes choosing the stimulating current from one of the ranges up to 1mA, 1-10mA, 1 to 20mA or 1 to 50mA to allow a practitioner to select the desired current according to the characteristics of the area to be treated and the response of the patient.

Equally the electrodes in accordance with the invention may be used advantageously with many existing apparatus for providing stimulating signals for treatment of pain or improvement of function.

Various wave forms and wave patterns may be used with the electrodes and are well described both in my and others' earlier patent applications and in the literature.

The wording and sense of the claims is hereby incorporated into the specification.

The invention will now be specifically described by way of example and illustration with reference to the accompanying drawings, in which:

Figure 1 is a sketch of an electrode in accordance with the invention connected to an electronic power supply;

Figure 2 is a sketch of an alternative arrangement for two electrodes in accordance with the invention connected to an electronic power supply;

Figure 3 is a sketch of an electrode in accordance with a small head, suitable for treating nasal pain, or pain accessed through other orifices;

Figure 4 shows pressure applied to an electrode against the skin;

Figure 5 is a sketch of an array of electrodes for treating a larger area of pain or to improve function; and

Figure 6 is a sketch of a section through an array or matrix of electrodes, such as that shown in Figure 5.

Figure 1 shows an electrically-conducting electrode 10 in accordance with the invention for connection to an electronic power supply 12 arranged in use to deliver a stimulating signal for the treatment of neurological or muscular pain, or to improve function. The electrode 10 comprises a spherical tip 14 at the end of an elongated stem 16 and has an active surface 18 shaped substantially as a sphere whose diameter is approximately 10mm. The active surface 18 and beyond is covered with or coated with a layer of electrically-conducting hydrogel 20, 1 to 2mm thick. The distal end 22 of the stem 16 is provided with a conducting lead 24 for connection to the power supply 12.

The power supply 12 is shown diagrammatically and may be chosen from a number of available units that are capable of meeting the frequency, power and waveform profiles.

While the tip 14 is described as being spherical, it may be substantially spherical either with a flatter tip than spherical, or a slightly more pointed tip, though it must not be sharp.

The soft conducting layer 20 of hydrogel greatly increases the comfort of the patient, and may permit prolonged treatment. The soft hydrogel can also increase the acceptable stimulating current. In addition, it distributes the firm pressure that is advantageously applied during treatment more evenly. This decreases the resistance between the electrode and the patient's skin, which may be further reduced by the application of contact solution. The risk of burning even sensitive skin is thus effectively eliminated.

The electrodes in accordance with the invention may either be disposable, disposable after a certain number of uses or provided with a removable layer 20 of hydrogel which may last for 10 to 20 uses before it needs to be replaced. The hydrogel layer is between 1 and 2mm in thickness. In cases where it is removable, it is more likely to be nearer 2mm thick, and is stretched gently to fit snugly over the electrode(s). It may also be coated to stick to the electrode(s)

The hydrogel layer or coating 20 may permit a current of up to 20mA at the electrode(s) to be applied to mucosal tissues, and up to 40mA to be applied to normal skin.

The stem 16, where present, provides a convenient handle for a practitioner to grasp in order to apply pressure to the electrode 10. The other electrode may be of the same configuration, or alternatively may comprise a patch 26, connected to the power supply by a lead 28, that is applied to the patient's skin at a suitable location.

An alternative form of the device is shown in Figure 2 where two electrodes 14 are plugged into a power supply 12. A patch 26 provides the other polarity as the two electrodes 14 are pressed against the area to be treated. The power supply 12 may

even be provided with three electrodes 14 in the form of a triangle, or eventually four in a line or a square (not shown).

For some applications where the pain or for improvement of function requires treatment over a larger area, an array or matrix of up to six or more electrodes 14 mounted on a stiff or semi-stiff backing 30 as shown in Figures 5 and 6 may be used. The electrodes 14 are each provided with a hydrogel layer and connection(s) 24 for connection to a power supply. The electrodes 14 may be of the same or alternating polarities, or a grounding patch may be provided. The diameter of the electrodes in such an array may conveniently be 5mm ±1mm for optimum effect. In some applications it may be convenient to form the hemisphere-shaped active surfaces on a single electrode, wherein whole electrode or the active surfaces are coated or covered by a layer of hydrogel.

The electronic power supply may advantageously be provided with a number of frequency and power ranges. The frequency ranges will preferably cover the range 1 to 100Hz and the range 1 to 10kHz so that the frequency can best be chosen to suit the patient and the type of pain they are suffering from. Other frequency ranges as suggested above may be chosen to better suit the treatment of specific pain or improvement of function.

Equally, the power ranges provided on the power supply may be up to 1mA, 1 to 10mA, 1 to 20mA and say 1 to 50mA. Again, the power ranges are chosen to suit the requirements of the condition(s) to be treated.

Most available power supplies 12 also offer a range of wave forms, and wave sequences. The practitioner will choose one that is suitable for the characteristics of the pain to be treated, and his experiences and preferences, and the response of the patient.

In order that the power supply 12 and the electrodes 14 that comprise a stimulating device may be taken home for prolonged use by a patient without supervision, once the power and frequency settings have been adjusted by a practitioner, the power supply 12 may be locked, or limited to only a small range of adjustment.

For use on normal skin it has been found that a single electrode where the diameter of the active surface is 10mm produces the good results.

However, for mucosal tissue, for example in the nose, the diameter of the active surface may be as small as 2 and 3mm, as shown in Figure 3. Where multiple electrodes are used, as in Figure 6, the diameter of the electrodes 10 is more usually 5 to 6mm. The thickness of the hydrogel layer may be more than the usual 1 to 2mm when intended for mucosal tissue, for example in the vagina. In such cases it may be from 3 to 4mm thick.

Where the electrode is at the tip of a rigid stem, the length of the stem is conveniently 5 to 10cm so that it can be held to provide the firm pressure as required. The even pressure applied by the coated tip 20 of an electrode 18 on the skin is illustrated in Figure 4.

The treatment to improve function using electrical stimulation is becoming increasingly relevant. The use of cuff with a matrix comprising a larger number of electrodes or active surfaces arranged to cover the abdomen for example may enable effective treatment of Crohn's disease or constipation or even some cancers. The invention particularly permits the use of higher stimulating currents necessary for deeper penetration, that would otherwise result in discomfort or even cause damage to the patient's skin.

The invention extends to a method for treating chronic or acute pain, and for the treatment to improve function comprising applying one or more electrodes as described above to an area affected by the pain, applying a firm pressure sufficient to cause indentation of the skin, and applying a stimulating signal as described.

The method includes choosing the stimulating current from one of the ranges up to 1mA, 1 to 10mA, 1 to 20mA or 1 to 50mA according to the sensitivity of the area to be treated.

Various wave forms and wave patterns may be used with the electrodes and are described both in my others' earlier patent applications and in the literature.

In summary, the use of electrodes coated with or having a layer of hydrogel substantially improves the effectiveness of the treatment and the comfort of the

patient. Namely, it permits higher stimulating currents to be used; reduces the electrical resistance between the electrodes and the patient's skin and improves penetration of the stimulating signal.

CLAIMS

1. An electrically-conducting electrode for connection to an electronic power supply arranged in use to deliver a stimulating signal for the management and/or treatment of neurological or muscular pain or improvement of function comprises one or more active surface(s) each shaped substantially as a hemisphere (as herein defined) and whose diameter is between 2 and 12 mm, and each active or stimulating surface of the electrode is covered by or coated with a layer of an electrically-conducting hydrogel or similar soft electrically-conducting gel-like material.

2. An electrode as claimed in Claim1, in which the layer of hydrogel is removable and replaceable.

3. An electrode as claimed in Claim1 or Claim 2, in which the layer of hydrogel is between half a millimetre and 5mm thick.

4. An electrode as claimed in Claim 1 or Claim 2, in which the hydrogel is between three quarters of a millimetre and 3mm thick.

5. An electrode as claimed in Claim 1 or Claim 2, in which the hydrogel is between 1 and 2mm thick.

6. An electrode as claimed in any preceding claim, in which the diameter of the active surface is between 5 and 10mm.

7. An electrode as claimed in any preceding claim, in which the diameter of the active surface of the or each electrode is between 2 and 3mm.

8. An electrode as claimed in any preceding claim, in which the active surface that is covered by the layer of hydrogel is formed at the end of a rigid stem.

9. An electrode as claimed in Claim 8, in which the length of the rigid stem is 5 to 10cm.

10. An electrode as claimed in either Claim 8 or Claim 9, in which the rigid stem is adapted to fit directly into an electronic power supply that can be adjusted to produce a stimulating signal at a frequency of up to 10kHz and at a current of up to 50mA.

11. A pair of electrodes as claimed in Claim 10, wherein the electrodes are of opposite polarity.

12. An electrode as claimed in any preceding claim, having a plurality of active surfaces on its surface.

13. An electrode as claimed in Claim 12 which is formed or shaped to fit or treat a specific part of the anatomy

14. A matrix or array comprising a plurality of electrodes as claimed in any one of Claims 1 to 7 mounted on a stiff or semi-stiff backing wherein the electrodes are provided with connection(s) for connection to an electronic power supply.

15. A matrix or array of electrodes as claimed in Claim 14, in which backing is electrically conducting with an insulating coating between the active surfaces of the electrodes.

16. A matrix or array of electrodes as claimed in Claim 14 or Claim 15, in which the active surfaces of the electrodes are in the form of separate buttons or inserts mounted on a thermo-formable or curable backing comprising a substrate or woven or non-woven material.

17. A matrix or array of electrodes as claimed in any one of Claims 14 to 16, in which the diameter of the electrodes is 5mm ±1mm.

18. A method for treating chronic or acute pain comprising applying one or more electrodes as claimed in any preceding claim to an area affected by the pain, applying a firm pressure sufficient to cause indentation of the skin, and applying a stimulating signal either in the range 1 to 100Hz or in the range 1 to 10kHz.

19. A method as claimed in Claim 18, in which the stimulating current is chosen from one of the ranges 1-10mA, 1 to 20mA or 1 to 40mA according to the sensitivity of the area to be treated.

20. A method as claimed in Claim 18, or in which a stimulating signal is applied either in the range 1 to 100Hz or in the range 1 to 10kHz.

21. A method for treating chronic or acute pain or for improving function comprising applying one or more electrodes mounted on a thermo-formable or curable backing to an area to be treated, applying a firm pressure sufficient to make the backing conform to the area to be treated whilst causing indentation of the skin, and curing the backing to retain the desired form prior to treatment.

Intellectual Property Office

Application No:	GB1803064.3	**Examiner:**	Colin Powys
Claims searched:	1-17	**Date of search:**	8 August 2018

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-12, 14 & 17.	US 2015/360027 A1 (DJO LLC) - see the abstract, figures 2-4, 16B, 18B, 21A, 22C and paragraphs [0074], [0077], [0078], [0082], [0085], [0112], [0115], [0118], [0121], [0122], [0129]-[0131].
X	1-13.	US 2014/316310 A1 (OCULEVE INC) - see the abstract, figures 1a, 1d, 14 and paragraphs [0026], [0050]-[0053], [0105], [0235].
A	-	US 2007/027515 A1 (MEDTRONIC) - see figure 12 and paragraph [0064].
A	-	US 2015/012079 A1 (GOROSZENIUK et al) - see the abstract, the figures and paragraphs [0096]-[0098], [claim 18].
A	-	GB 2417688 A (GOROSZENIUK) - see the abstract, the figures and [p.6, line 5, p.7, line 30].
A	-	US 2017/333706 A1 (AVENT INC) - see figures 2a-2e and paragraphs [0059], [0066]-[0072], [0098], [0117].
A	-	US 2016/346544 A1 (UNIV RUSH) - see the abstract, figure 3 and paragraphs [0027], [0028].

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61N

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI, Patent Fulltext

International Classification:

Subclass	Subgroup	Valid From
A61N	0001/04	01/01/2006
A61N	0001/18	01/01/2006