

(12) UK Patent Application (19) GB (11) 2 361 431 (13) A

(43) Date of A Publication 24.10.2001

(21) Application No 0009901.0

(22) Date of Filing 20.04.2000

(71) Applicant(s)

Photo Therapeutics Limited
(Incorporated in the United Kingdom)
PO Box 88, The Fairbairn Building, UMIST,
MANCHESTER, M60 1QD, United Kingdom

(72) Inventor(s)

Colin Whitehurst

(74) Agent and/or Address for Service

R.G.C.Jenkins & Co
26 Caxton Street, LONDON, SW1H 0RJ,
United Kingdom

(51) INT CL⁷
A61N 5/06 , A41D 31/00

(52) UK CL (Edition S)
A5R REHR
A3V V5X

(56) Documents Cited
GB 2185188 A WO 97/04836 A1 US 5339223 A
US 4234907 A

(58) Field of Search
UK CL (Edition R) A5R REHR , G2J JGX
INT CL⁷ A61N 5/06
Online: EPODOC, WPI, JAPIO

(54) Abstract Title

Fibre optic fabric

(57) A fibre optic fabric 1 for phototherapy comprises optical fibres 2 connectable 9 to a light source and arranged so that light emitted A-C from the fibres is directed towards a patient. The fabric can comprise a diffusing portion 5 and reflecting portion 6 and at least one fibre optic portion 1 in between. The fabric may be interwoven with fill fibres 3 and formed into a garment to be worn. The light source is preferably incoherent. The optical fibres are preferably formed from polymethyl methacrylate, and may have cladding 4 or be chemically treated or have abrasions along their surface to cause light to be transmitted substantially continuously along their length.

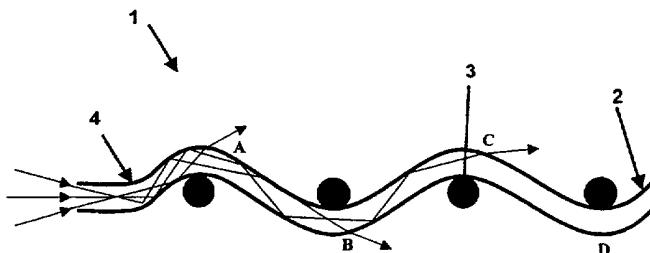


FIG. 1

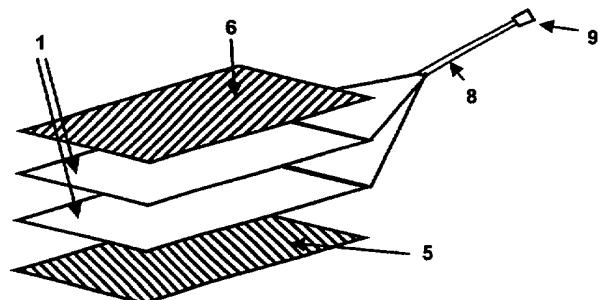


FIG. 2

GB 2 361 431 A

1/2

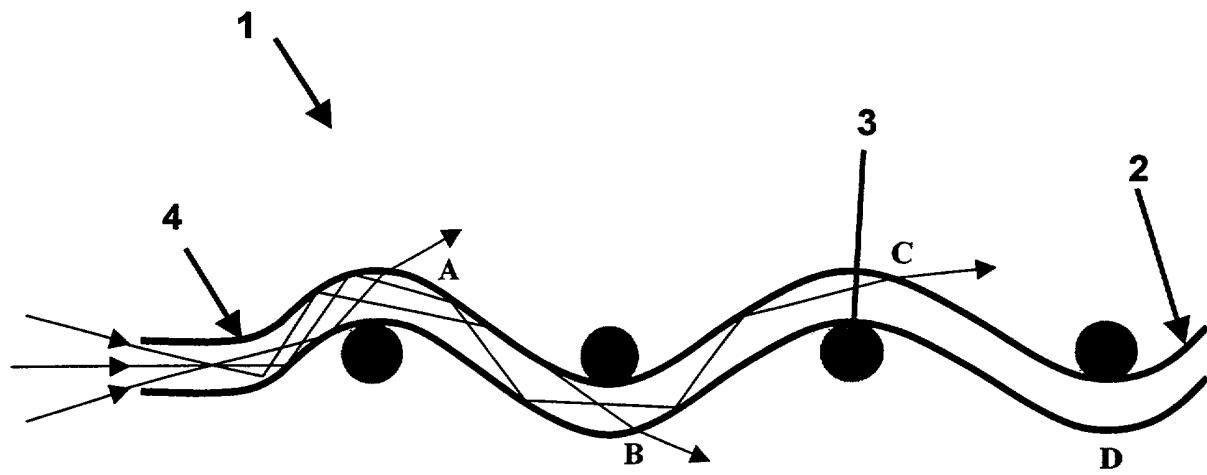


FIG. 1

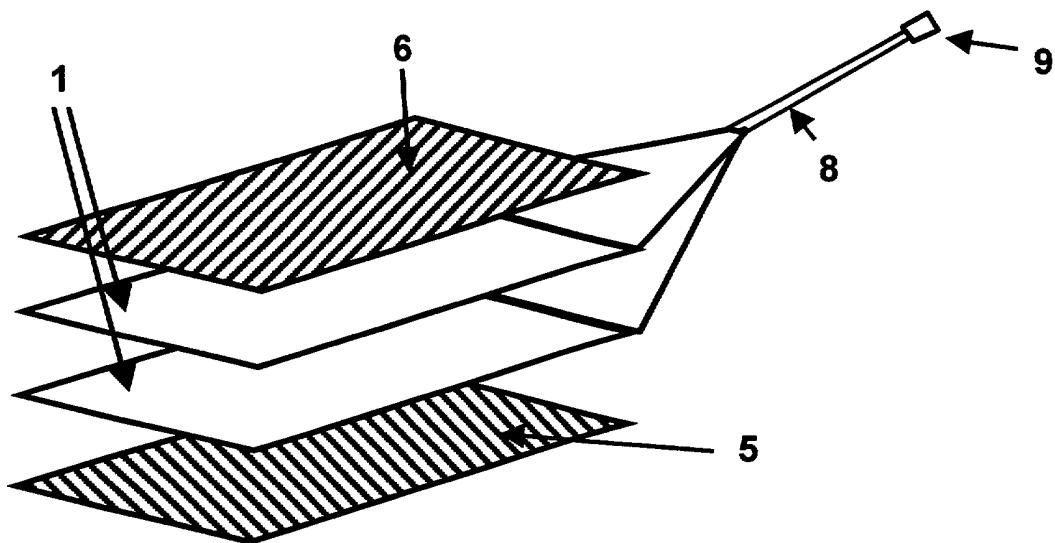
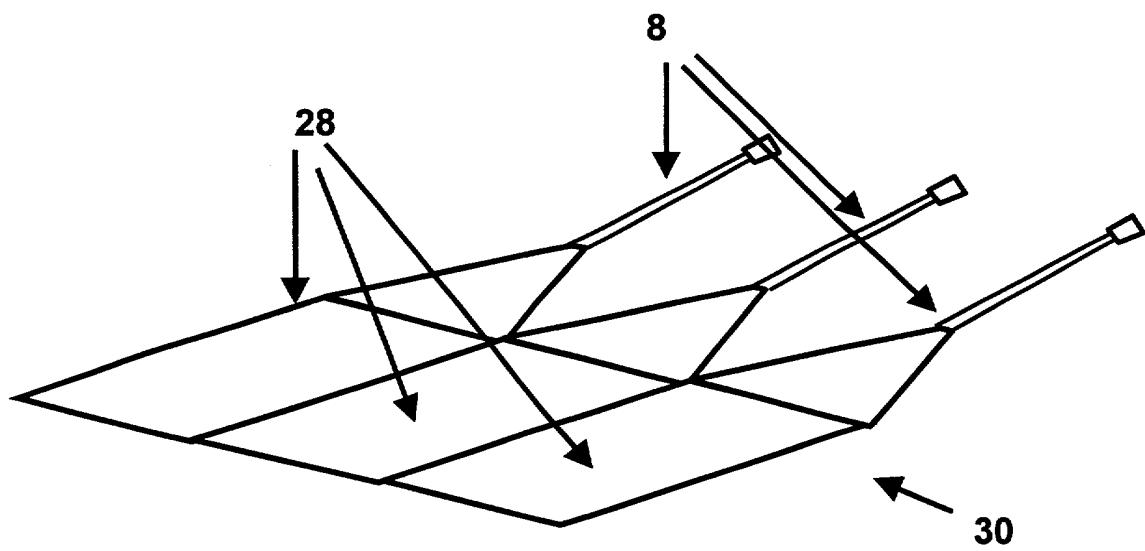
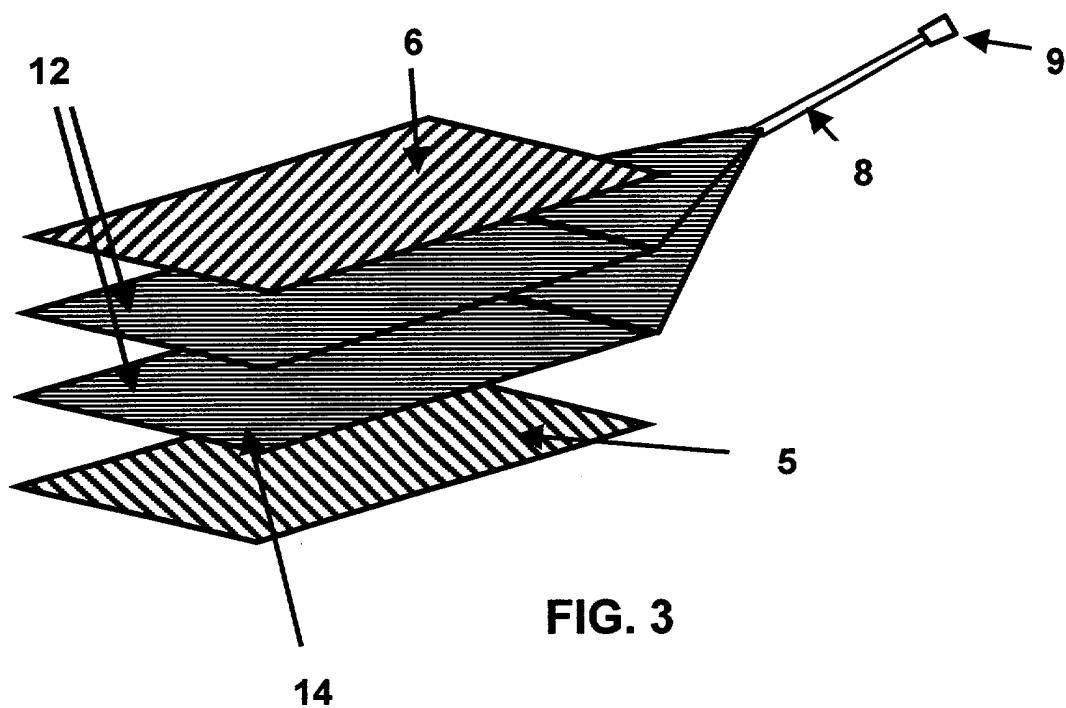


FIG. 2



Radiation Delivery Method and Apparatus

The present invention relates to a method and apparatus for delivering electromagnetic radiation to an affected area of a patient, particularly but not exclusively in the treatment of skin conditions, particularly but not 5 exclusively using photosensitising drugs.

In known high-intensity phototherapy techniques, the affected area is treated using a narrow beam so as to concentrate the radiation onto the affected part. Where the affected part extends over a larger area, the treatment becomes very lengthy. In addition, the geometry of the treated areas can create 10 serious problems in achieving uniform illumination.

Alternative devices have been proposed by which radiation may be applied at multiple points simultaneously. For example, US 5,000,752 (Hoskin) discloses apparatus for treating port wine stains using a pad supporting a plurality of diamond-tipped needles, to which laser radiation is delivered through optical fibres. However, such apparatus is difficult to 15 position correctly, requires the patient to be anaesthetised and is not suitable for treating large, non-planar areas.

One aim of the present invention is to allow treatment of large, non-planar areas of the skin.

20 An alternative or additional aim of the present invention is to allow treatment of large areas without causing undue discomfort to the patient.

An alternative or additional aim of the present invention is to provide apparatus suitable for treatment of large areas of the skin with incoherent or non-laser light.

According to one aspect of the present invention, there is provided a 5 garment incorporating optical fibres connectable to a light source, and arranged such that light emitted from the fibres is directed towards a wearer.

According to another aspect of the present invention, there is provided a fibre optic fabric comprising a reflecting portion, a fibre optic portion including optical fibres and a diffusing portion, said fibre optic portion being 10 positioned between said diffusing portion and said reflecting portion.

According to yet another aspect of the present invention, there is provided a fabric comprising a series of woven optical fibres, where the weaving causes any light transmitted through the optical fibres to escape from the fibre.

15 According to a further aspect of the invention there is provided, fabric comprising a series of optical fibres treated so as to cause light transmitted through the optical fibres to substantially continuously escape along the length of the fibre.

According to a further aspect of the invention, there is provided use of 20 a fabric or garment as described above for therapy or cosmetic treatment or photodynamic therapy.

Preferably, the garment or fabric includes a reflective layer positioned outside a layer of optical fibres, so as to reflect escaped light inwards.

Preferably, the garment or fabric includes a diffusing layer positioned inside the layer of optical fibres, so as to diffuse light emitted inwards.

5 Preferably, the garment or fabric includes means for coupling incoherent light from a light source into the optical fibres.

The garment or fabric may have a plurality of layers incorporating optical fibres.

The invention will now be described with reference to the following
10 drawings in which:

Figure 1 is a cross section through one form of fibre optic layer in accordance with the invention, showing the path of the light transmitted through an individual optical fibre;

15 Figure 2 is an exploded perspective view of one form of material in accordance with the invention, incorporating a layer as shown in Figure 1, showing connection of the optical fibres to a suitable light source;

Figure 3 is an exploded perspective view of a second embodiment of the invention, showing a further form of material including layers comprising side emitting optical fibres; and

20 Figure 4 is a schematic perspective view of a further embodiment of the invention, showing a plurality of fibre optic layers, as shown in Figure 1, attached together to form a larger blanket.

Light can be transmitted through optical fibres by total internal reflection; that is, any light rays travelling through the fibre and incident on the internal walls of the fibre at angles greater than a critical angle (where the critical angle = $\sin^{-1}(1/n)$ where n is the refractive index of the fibre medium) 5 are reflected back into the optical fibre.

Weaving such optical fibres together with suitable fill material forms a flexible fibre optic fabric layer 1 having advantageous properties in the field of PDT.

Figure 1 illustrates a cross-section through such a flexible fabric layer 10 1 showing a section through one optical fibre 2 interwoven with several fill fibres 3.

As, in this case, the optical fibre 2 is bent around fill fibres 3, certain of the light rays transmitted through the optical fibre 2 will not be incident on the internal walls of the optical fibre 2 at angles greater than the critical 15 angle, and as such will be refracted out of the optical fibre 2 and hence out of the layer of fabric 1.

As can be seen in Figure 1, at points A, B, C and D, the light travelling through the optical fibre 2 is emitted from the side of the fibre 2 through cladding 4 on the optical fibre 2. It will be appreciated that when a large 20 number of optical fibres 2 are woven in this way, the optical fibre fabric layer 1 formed will emit light in a generally uniform distribution across the fabric layer 1.

Referring to Figure 2, two fibre optic fabric layers 1, as described above and shown in Figure 1, are positioned between a diffusing layer 5 and a reflecting layer 6 to form a flexible multi-layered material suitable for use in PDT applications.

5 The diffusing layer 5 may be formed from a thin sheet of translucent plastic material that further diffuses the light emitted from the optical fibres 2. However, any suitable form of diffusing material may be used. The diffusing layer 5 will also act to protect the fibre optic fabric layer.

10 As the light emitted from the optical fibre fabric layers 1 is generally of a uniform distribution when the diffusing layer 5 is not present, it is not essential that a diffusing layer 5 be included.

15 A layer of transparent plastic material may be provided on the side of the optical fibre fabric layer 1 in place of the diffusing layer 5 to prevent damage on handling. The transparent plastic layer on the innermost surface of the optical fibre fabric layer 1 protects the optical fibres 2 in the fibre optical layer 1 when it is placed in contact with a patient undergoing PDT.

20 The reflecting layer 6 is a diffusely or specularly reflective layer provided on the surface of the optical fibre fabric layer 1 opposing the surface carrying the diffusing or protecting layer 5. The reflecting layer 6 acts to reflect light emitted towards the reflecting layer 6, from the fibre optic fabric layers 1, back towards the fibre optic fabric layers 1 and the diffusing layer 5.

The reflecting layer 6 may be formed from a Mylar (TM) diffuse

reflecting sheet, a self-adhesive metallic vinyl sheet, such as DMX300 supplied by X-Film UK, Luton, Bedfordshire, or a thin aluminised or metallised plastic sheet.

Although the fibre optic fabric material shown in Figure 2 includes 5 two fibre optic fabric layers 1, it will be appreciated that any number of fibre optic fabric layers 1 may be used. Indeed, a single fibre optic fabric layer 1 may suffice.

The ends of the optical fibres 2 of the fibre optic layers 1 are brought together and formed into fibre optic bundle 8. The ends are then terminated, 10 polished and fixed, for example by adhesive, into a connector 9 for connection to a suitable PDT light source (not shown) emitting, in this case, non-laser or incoherent light. One example of a suitable light source is disclosed in UK Patent No 2272278 and is hereby incorporated in its entirety. The light source may have had the ultra-violet, infra-red and non-active visible light removed, 15 however, any suitable light source may be used. Depending on the number of optical fibres 2 involved, the diameter of the face of the bundle 8 may be in the region of 5 to 20 mm. This makes the material 1 particularly suited to connection to a non-laser light source, as these sources have an inherently large focused beam diameter of at least 5mm.

20 Should a suitably small fibre optic bundle 8 be formed, it will be appreciated that the fibre optic fabric layers 1 described here may also be connected to a laser light source.

The optical fibres 2 are preferably formed from polymethyl methacrylate (PMMA) which has the appropriate transmission properties. However, it will be appreciated that any suitable glass material, such as E-glass, or plastic material having the appropriate light transmission properties 5 may be used. The optical fibres are preferably clad but it will be appreciated that cladding is not essential.

Preferably, the diffusing layer 5 (if in use), the fibre optic layers 1 and the reflecting layer 6 are connected together at the edges by adhesive. However, it is not always necessary to attach the layers together at all. 10 Furthermore, other suitable methods of attachment may be used such as stitching. Additionally, the layers need no be attached together at their edges but may be attached at any other suitable location.

In use, the material 1 is placed on a patient with the diffusing layer 5 closest to the patient and the light is transmitted from the PDT light source 15 into the optical fibres 2 of the fibre optic fabric layers 1. The light is transmitted along the axis of the optical fibres 2 and periodically escapes from the top and bottom surface of the fibre optic fabric layer 1.

As shown in Figure 1, the light escaping from the bottom surface, at points B and D, is transmitted toward the diffusing layer 5 and hence towards 20 the patient. The light escaping from the top surface, at points A and C, is transmitted toward the reflecting layer 6 where it is reflected back toward the fibre optic layer 1, the diffusing layer 5 and hence the patient.

It will be appreciated that the fabric as shown in Figure 2 is drawn in an exploded manner and that the diffusing layer 5, the optical fibre layers 1 and the reflecting layer 6 when in use appear as a single multi-layer flexible material. However, further layers of material may be positioned between the 5 reflecting layer 6, the fibre optic layers 1 and the diffusing layer 5.

As the flexible material 1 is woven from elastically deformable fibres 2, a flexible light source is provided that could be manufactured to fit a wearer. For example, the fabric could be formed into the shape of a glove, a sleeve, a collar, or jacket or a large blanket for uniformly illuminating large 10 non-planar areas of a wearer whilst at the same time maintaining wearer mobility and comfort.

Such a fabric or garment would provide a flexible PDT source for treatment of skin conditions or for use with photosensitising drugs easily and comfortably wearable by any person. Fabrics or garments manufactured for 15 such use would require the material to be arranged such that the diffusing layer 5 is positioned closest to the wearer, the fibre optic layer or layers 1 are positioned outwardly of the diffusing layer 5 relative to the wearer, and the reflecting layer 6 is positioned outwardly of the fibre optic layer or layers 1 relative to the wearer.

20 It will be appreciated that parameters such as flexibility, number of fibre optic layers and size of illuminating area need to be carefully chosen when the fabric is used for PDT. Different forms of treatment for different

areas of the body will require different forms of fibre optic material 1. The flexibility of the material 1 depends on the diameter of the individual optical fibres, the material used for the diffusing layer, the thickness and rigidity of the diffusing layer and the ply or number of woven fibre optic fabric layers 1
5 employed

For example, if a highly irregular or tightly curved area of the body is to be treated, a high degree of flexibility in the fibre optic material 1 is required. For these curved areas, the material 1 is formed using optical fibres 2 having a diameter of between 200 and 250 μ m and between one and three fibre optic fabric layers 1. No diffusing layer 5 is included. Such a material 1
10 is highly flexible. For more planar areas of the body, where the material 1 does not have to be as flexible, more fibre optic fabric layers may be used, for example between three and six layers 1. Alternatively or additionally, optical fibres 2 having a larger diameter of around 300 μ m may be used. A diffusing
15 layer 5 may be employed.

The output intensity of the material 1 can be increased by increasing the optical power launched into the fibre optic bundle 8, by increasing the number of fibre optic fabric layers 1 or by a combination of increased power and increased number of layers 1.

20 The use of plastic optical fibres 2 can limit the optical power in the material 1. Increasing the optical power launched into the fibre optic bundle 8 by too large an amount may cause damage to the optical fibres 2 and may

cause the connection between the fibre optic bundle 8 and the light source 10 to be damaged. For example melting of the fibres 2 may occur. The maximum power that can be used will depend on the ambient temperature, the degree of infra-red filtration and the wavelength of the light used. In any case, 5 the temperature of the fibre optic bundle 8 should not exceed 85 deg C.

Preferably, the light launched into the optical fibre has the ultra-violet and infra-red portions filtered out. The light may also have any other non-active light removed. In this way, wastage of light and glare are reduced. This also prevents the fibres, and hence the material and the patient, from 10 heating up substantially.

Furthermore, as the light is transmitted from the light source via light guides, the light source can be positioned remote from the patient and there is little electromagnetic (EM) radiation emitted transmitting the light via the fibre optic bundle 8 to the fibre optic fabric material in the vicinity of the patient. EM radiation can adversely affect heart pacemakers and other 15 electronic equipment in use in hospitals. The fibre optic fabric material provides a flexible long life PDT source that can be moulded to uneven contours, like an item of clothing.

In general, therefore, to produce a uniform output, between two and 20 four fibre optic fabric layers 1 should be used. Loss of flexibility and self absorption of emitted light yields an upper limit of about six fibre optic fabric layers 1.

The size of the fabric panel to be used will also depend on the treatment being carried out. For example, a panel for wrapping around and treating the whole or partial circumference of a leg would require a surface approximately 15cm by 60cm. However, the dimensions of the active, light emitting area of the material 1 will vary depending on the size and number of lesions to be treated and the size of the patient's leg. A Velcro (TM) attachment would be provided for securing the material to the patient's body. Similarly, for treatment of an arm, a scaled down version of the above would be required.

10 For treatment of a torso, a scaled up version would be required. However, the material 1 could be formed into a garment such as a waistcoat for treatment of the front and back of the torso. This would advantageously secure the material 1 to the patient during treatment. Furthermore, it will be appreciated that other garments such as gloves, jackets or collars could be 15 formed from the material 1 for treatment of appropriate parts of the body.

In a second embodiment of the invention, the fibre optic fabric layers 12 are formed from optical fibres 14 that are placed adjacent and in parallel to one another. These optical fibres 14 have surfaces that have been roughened, for example by chemical alteration such as etching or by rubbing their 20 surfaces with glass paper. This changes the transmission properties of the optical fibres 14 and causes them to emit light from their surfaces along their length within the fibre optic fabric layer 1 in a manner similar to that

described above with reference to the first embodiment of the invention. Fibres suitable for use in this way are supplied by Intelite, Inc., CA, U.S.A. However, it will be appreciated that any suitable optical fibres may be used.

The optical fibres 14 are again brought together into one bundle 8 and 5 connected to a suitable PDT light source for use in PDT as described above. Furthermore, the diffusing layer 5 and reflecting layer 6 may be included as described above.

In this way, a fibre optic layer for inclusion in a fibre optic fabric suitable for PDT may be formed without weaving optical fibres together with 10 fill fibres.

The fabric formed using the fibre optic layers described in relation to the second embodiment of the invention, is used in the same manner described above in relation to the first embodiment of the invention.

In a further embodiment of the invention, as shown in Figure 4, panels 15 28 including fibre optic layers 1, previously described above, are attached together to form a large blanket 30. Preferably, the layer or layers 1 of each panel 28 have their own fibre optic bundle 8 connected to a suitable PDT light source. In use, therefore, it is possible to activate only a portion of the whole blanket and treatment can be aimed only where required.

20 Similarly, fibre optic layers 1 or panel 28 could be incorporated into garments having non-active portions. For example, a waistcoat or jacket where the torso portion is formed from panels 28 or fibre optic layers 1 but the

shoulder and/or sleeve portions are formed from non-fibre optic material. In this manner, the garment is easily worn by the patient, whilst the panels 28 or fibre optic layers¹ are positioned correctly for treatment purposes.

A method of treatment for superficial cases of actinic/solar keratoses,
5 Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, psoriasis, eczema, nevus sebaceous, viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata or hirsutism, using a fibre optic
10 fabric material as detailed above, will now be described.

A cream or solution containing a photosensitising drug such as 5-ALA is applied topically under medical supervision to the affected area of the skin of the patient, or administered intravenously or orally. For large areas, the patient may be immersed in a bath of solution. The affected area may then be
15 covered for a period of 3 to 6 hours, or up to 24 hours if the treatment is to be continued the next day, to prevent removal of the drug and carrier, or activation by sunlight. The area is then uncovered and exposed to light from the light source, via the fibre optic fabric material, as described in any of the embodiments for a period of 15 to 30 minutes. The treatment may then be
20 repeated as necessary, for a total of 1 to 3 treatments or more, depending on the severity and type of the condition. This method is particularly suitable for

the treatment of patients with very large lesions or multiple lesions extending over a large area.

The light source may also be used for fluorescence detection (photodiagnosis).

5 The light source may also be used for cosmetic or partially cosmetic treatment with a photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

CLAIMS

1. A garment incorporating optical fibres connectable to a light source, and arranged such that light emitted from the fibres is directed towards a wearer.
- 5
2. A garment according to claim 1 in which said optical fibres form at least one layer of the garment.
- 10
3. A garment according to claim 2 further comprising a reflecting layer positioned outwardly of the fibre optic layer or layers relative to the wearer so as to reflect any outwardly emitted light back toward said wearer.
- 15
4. A garment according to claim 2 or 3 further comprising a diffusing layer positioned inwardly of the fibre optic layer or layers relative to the wearer so as to diffuse said light directed toward the wearer.
- 20
5. A fibre optic fabric comprising a reflecting portion, a fibre optic portion including optical fibres, and a diffusing portion, said fibre optic portion being positioned between said diffusing portion and said reflecting portion.

6. A fibre optic fabric according to claim 5 in which said fabric is formed in the shape of a garment wearable by a wearer.
7. A fibre optic fabric according to claim 6 in which said fabric, when formed as a garment, comprises said diffusing portion positioned inwardly of said fibre optic portion relative to the wearer.
5
8. A fibre optic fabric according to any one of claims 5 to 7, in which said fabric, when formed as a garment, comprises said reflecting portion positioned outwardly of said fibre optic portion relative to the wearer.
10
9. A fibre optic fabric according to any one of claims 5 to 8 in which said reflecting portion acts so as to reflect any outwardly transmitted light inwardly toward said wearer.
15
10. A fibre optic fabric according to any one of claims 5 to 9 in which said diffusing portion acts so as to diffuse any inwardly transmitted light directed toward said wearer.
- 20 11. A fabric or garment according to any preceding claim in which the optical fibres are connected to a light source.

12. A fabric garment according to claim 11 in which said light source comprises an incoherent or non-laser light source.

13. A fabric or garment according to any preceding claim in which said optical fibres are formed from PMMA.

14. A fabric or garment according to any preceding claim in which said optical fibres are interwoven with fill fibres.

10 15. A fabric or garment according to any of claims 3 to 12 and 13 and 14 when dependent thereon, in which said reflecting layer is formed from Mylar (TM).

15 16. A fabric comprising a series of woven optical fibres, where the weaving causes any light transmitted through the optical fibres to escape from the fibre.

20 17. A fabric comprising a series of optical fibres treated so as to cause light transmitted through the optical fibres to substantially continuously escape along the length of the fibre.

18. A fabric according to claim 17, in which the treatment comprises chemical treatment of the surface of the fibres or abrasion of the surface of the fibres.

5 19. Use of a fabric or garment according to any preceding claim, for therapy of a patient.

20. Use of a fabric or garment according to any one of claims 1 to 18 for cosmetic treatment of a patient.

10 21. Use of a fabric or garment as claimed in claim 19, for photodynamic therapy of said patient.

15 22. A fabric or garment as hereinbefore described with reference to the accompanying diagrammatic drawings.



Application No: GB 0009901.0
Claims searched: 1-18, 22

Examiner: Peter Trickey
Date of search: 5 October 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5R (REHR), G2J (JGX)

Int Cl (Ed.7): A61N 5/06

Other: Online: EPDOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 2185188 A	(Mori) see entire document	1-18
X	WO 97/04836 A1	(Dusa) Figures 2-3 and line 20 page 12 to line 11 column 13	5, 11-13
X	US 5339223 A	(Kremenchugsky) see entire document	5, 9-17
X	US 4234907 A	(Daniel) Figures 1-3 and lines 14-16 and 23-27 column 3, line 66 column 5 to line 19 column 6	1-18

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.