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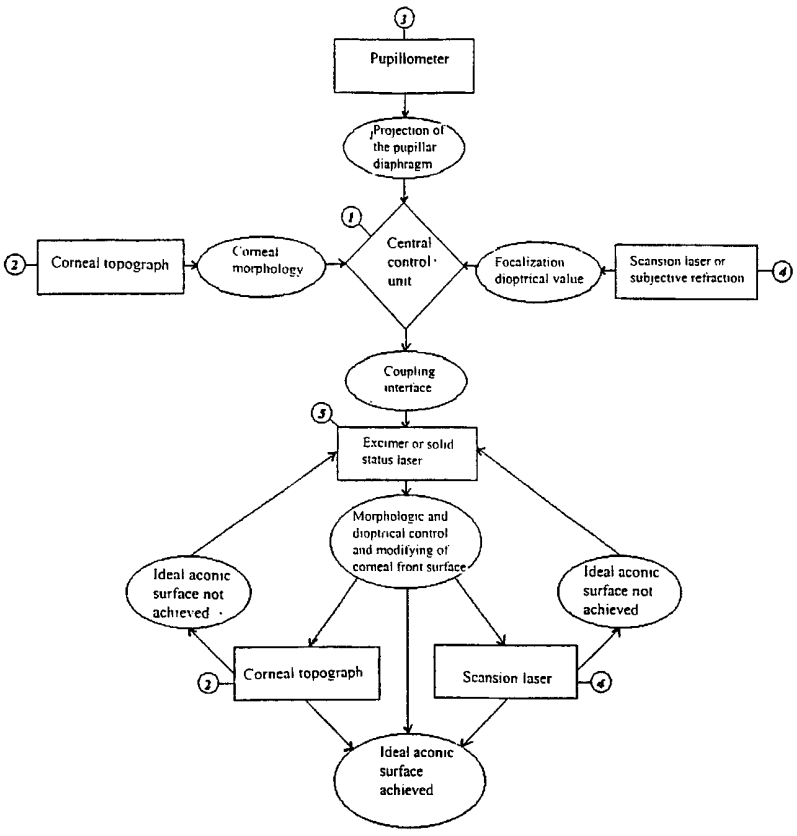
(54) Title: APPARATUS FOR DETERMINING AND ABLATING THE CORNEAL TISSUE VOLUME FOR CORRECTING VISUAL AMETROPIA



(57) Abstract: Apparatus for determining and ablating the corneal tissue volume for correcting visual ametropia, as optimized for each individual patient, whereby the apparatus comprises a central control unit (1) to which are operatively connected, either generally or partially, a corneal topograph (2), an infrared pupillometer (3), a scansion laser (4) and an excimer or solid-status laser (5).

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Published:
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— *With amended claims.*

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Description

APPARATUS FOR DETERMINING AND ABLATING THE CORNEAL TISSUE VOLUME FOR CORRECTING VISUAL AMETROPIA

BACKGROUND OF THE INVENTION

The present invention relates to an apparatus for determining and ablating the corneal tissue volume necessary for correcting visual ametropia, as optimized for each individual patient.

As is known, for correcting visual ametropia, it is necessary to perform a corneal tissue ablation, and optimize it depending on the clinic status of each individual patient.

SUMMARY OF THE INVENTION

The aim of the present invention is to provide an apparatus adapted to mutually coordinate a set of operating devices, so as to univocally define the position, area and volume of the corneal structure to be ablated, for consequently performing the related processing.

Within the scope of the above mentioned aim, a main object of the present invention is to provide such an apparatus which is very efficient from an operating standpoint and which is specifically designed for providing accurate values to properly perform the ablating operation.

Yet another object of the present invention is to provide such an apparatus which, owing to its constructional peculiar features, is very reliable and safe in operation.

Yet another object of the present invention

is to provide such an apparatus which can be easily made starting from easily available elements and materials and which, moreover, is very competitive from a mere economic standpoint.

According to one aspect of the present invention, the above mentioned aim and objects, as well as yet other objects, which will become more apparent hereinafter are achieved by an apparatus for determining and ablating a corneal tissue volume necessary for correcting visual ametropia, as optimized for each individual patient, characterized in that said apparatus comprises a central control unit, to which are operatively connected, either generally or partially, a corneal topograph, an infrared pupillometer, a scansion laser and an excimer or solid-status laser.

BRIEF DESCRIPTION OF THE DRAWINGS

Further characteristics and advantages of the present invention will become more apparent hereinafter from the following detailed disclosure of a preferred, though not exclusive, embodiment of an apparatus for determining and ablating an optimum corneal tissue volume necessary for correcting visual ametropia, and being illustrated, by way of an indicative, but not limitative example, in the accompanying drawings, where:

Figure 1 illustrates an operating flow diagram, associated with the apparatus according to the present invention; and

Figure 2 illustrates an operating block diagram of the apparatus according to the present

invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to the number references of Figure 1, the apparatus for determining and ablating the corneal tissue volume necessary for correcting visual ametropia, as optimized for each individual patient, comprises a central control unit, generally indicated by the reference number 1, to which is connected a corneal topograph 2, operating for morphologically determining the front surface of the cornea.

To said unit 1 is connected an infrared pupillometer 3, for determining the iris diaphragm projection under scotopic conditions, at the level of the front corneal surface.

To said central unit is moreover connected a scansion laser 4 operating to define the dioptrical corrective value to be applied, point by point, with a discrete type of function, to the front corneal surface.

This value is determined by searching the diopter value optimizing the focalization at foveal level of each single light beam impinging on the corneal region, as in turn generated by a light source arranged at an infinite distance.

To said control unit 1 is moreover connected an excimer or solid status laser, of a microspot type, 5, having a coupling interface, for reading-out the altimetric ablative datum as expressed in micrometers on a square matrix in the x, y plane.

The apparatus according to the present invention allows to determine the ablating volume obtained by a crossing of the front corneal surface and an ideal aconic surface, as determined at a level of the pupillar diaphragm projection, as detected in a scotopic condition.

The front corneal surface is given by the corneal topograph 2.

The ideal aconic surface is that surface determining the minimum of the sum function, as expressed in an absolute value, of the eccentricity, as measured in a radial direction, between the projection of the light beam impinging on the retina and the foveal center.

The light beam inciding on the retina is generated by a light source arranged at an infinite distance.

The sum or summation function analyzes, by discrete steps, all of the points where the impinging light beams cross the corneal front surface at an area delimited by the projection of the pupillar diaphragm as detected in a scotopic condition.

The connecting area between the ideal aconic surface and the residual corneal front surface is determined by assuring a constant curvature variation in a radial direction.

During the practical operation of the apparatus, an operator will detect, at the start, the corneal front surface by using said topograph 2.

Then, the operator will define the localization of said surface by locating the processing center as well as the reference axis.

The processing center, in particular, can be constituted by the corneal apex, the pupillar centroid projection, the fixation reflex or it can be selected at will by the operator.

The reference axis can comprise the optical axis, or the TV camera axis, or an axis perpendicular to the processing center.

The optical zone is delimited by the crossing perimeter of the corneal front surface, as determined by the topograph and localized as stated, and the preset ideal aconic surface.

The altimetric dislocation or offset between the two mentioned surfaces will be defined by determining the specific crossing perimeter which is circumscribed to the diameter referred to a projection on the corneal front surface of the pupillar diaphragm as detected in a scotopic condition and by the infrared pupillometer 3.

This function assures that the processing be performed through the overall corneal portion affected by the refractive process, by specifically limiting the overall volume to be ablated to a minimum necessary volume.

As the crossing perimeter exceeds the maximum diameter specified by the operator, it will be limited, for the exceeding portion, to the mentioned diameter.

Alternatively, said ideal aconic surface can be determined by a subjective refraction of the patient, as expressed in terms of correcting dioptrical values, either spherical and/or cylindrical, with the related asphericity axis and

index.

In such a case, it is necessary to define the reference corneal refraction by determining that aconical surface adapted to better approximate the patient corneal front surface the center, axis and optical zone thereof being specified as previously stated.

The curvature, either maximum or minimum, of the preset aconical surface, referred to the corneal front surface refraction index, will express the related refractive power, in the term of the maximum and minimum values thereof.

That same aconical surface will express, moreover, the reference asphericity index.

In this latter case, the ideal aconic surface will be obtained from a vectorial summation of the refraction related to the aconic surface better approximating the corneal front surface, as determined as previously stated, and of the subjective refraction, as expressed as previously stated.

In particular, the operator pre-selects the surgical mode of operation, by choosing between PRK or LASIK, in order to properly correlate the processing amount and size, as designed at the level of the corneal front surface, depending on the actual distance thereof from the focal plane.

In particular, the operator preselects the target minimum width for the transition zone and the optional maximum ablation additional thickness, to obtain a constant curvature variation in a radial direction through the transition area, connecting the

desired ideal aconic surface and residual corneal front surface.

Then, the operator will moreover define a maximum diameter for limiting therewithin the perimeter of the transition area.

The operator, in the case of a surgical PRK mode of operation, can possibly define, to obtain a laser corneal processing, the area thereon to add a constant thickness to be ablated, as defined with reference to the total processing perimeter, as well as the related value.

The above defined mode of operation, will establish univocally the processing mode both at a planimetric and at an altimetric level.

It has been graphically represented by different color areas, clearly showing the ideal aconic surface, the transition area between the ideal aconic surface and the residual corneal front surface, as well as the residual corneal front surface.

Moreover, by numeric data the operator will express or define the total ablation surface, the total ablation volume, the maximum ablation thickness and related planimetric dislocation as well as the ablation center planimetric dislocation with respect to the pupillar centroid.

The altimetric ablation datum, in particular, will be defined on a square matrix in the x, y plane, to allow the laser 5 to detect, through a suitable interface, the ablation profile or contour to be consequently performed.

As desired, the system, by intraoperatively

detecting the morphologic datum and dioptrical variation will verify that the processing be carried out in accordance with the programmed ablation schedule, by modifying the latter, if necessary, together with the number of pulses localized for surface unit.

The processing is ended after having obtained a proper fitting of the detected and desired data.

From the above disclosure it should be apparent that the invention fully achieves the intended aim and objects.

In particular, an apparatus according to the functional block diagram shown in Figure 2 has been provided, which apparatus is specifically adapted to provide very accurate and objective elements for controlling and performing the surgical operation.

The invention as disclosed is susceptible to several modifications and variations, all of which will come within the scope of the invention.

Moreover, all of the constructional details can be replaced by other technically equivalent elements.

In practicing the invention, the used materials, as well as the contingent size and shapes, can be any, depending on requirements.

CLAIMS

1. An apparatus for determining and ablating a corneal tissue volume necessary for correcting visual ametropia, as optimized for each individual patient, characterized in that said apparatus comprises a central control unit, to which are operatively connected, either generally or partially, a corneal topograph, an infrared pupillometer, a scansion laser and an excimer or solid-status laser.

2. An apparatus, according to the preceding claim, characterized in that said corneal topograph is adapted to morphologically define the corneal front surface.

3. An apparatus, according to the preceding claims, characterized in that said infrared pupillometer is adapted to define the iris diaphragm projection, under scotopic conditions, at a level of the corneal front surface.

4. An apparatus, according to one or more of the preceding claims, characterized in that said scansion laser is adapted to define a correcting dioptrical value to be applied to the corneal front surface to optimize a focalization, at foveal level, of a light projecting source arranged at an infinite distance, the impinging light beams of said light source crossing the corneal front surface, through the area of the pupillar diaphragm projection as detected under scotopic conditions.

5. An apparatus, according to one or more of the preceding claims, characterized in that said

excimer or solid status laser is of a microspot type.

6. An apparatus, according to one or more of the preceding claims, characterized in that said apparatus comprises an interface for coupling an excimer laser to said central control unit, and that said interface is adapted to read-out an altimetric ablation datum as expressed in micrometers on a square matrix in the x, y plane.

7. An apparatus for determining and ablating the corneal tissue volume necessary for correcting visual ametropia, as optimized for each individual patient, according to one or more of the preceding claims, and substantially as broadly disclosed and illustrated and for the intended aim and objects.

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OPERATING FLOW DIAGRAM

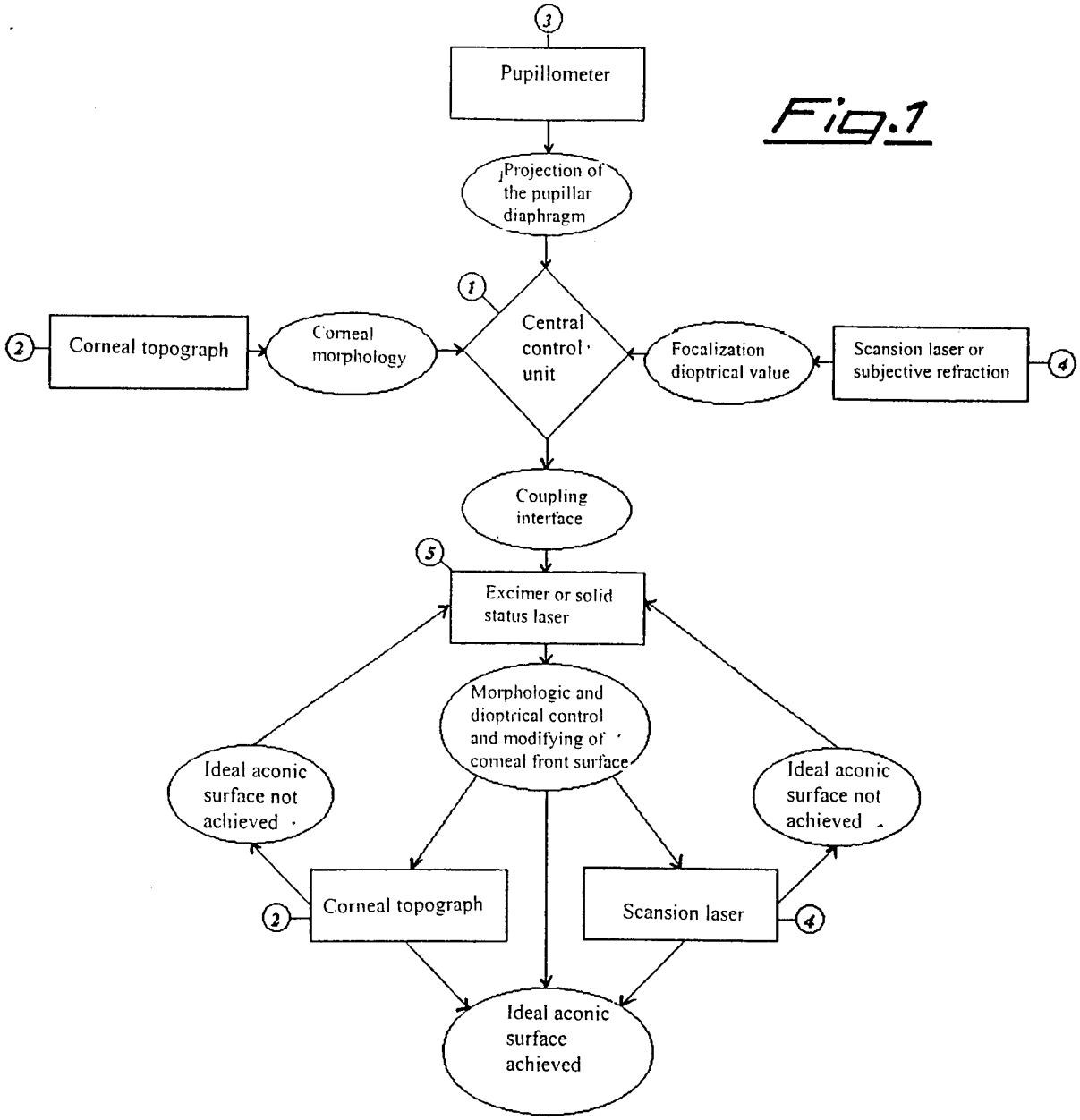

Fig.1

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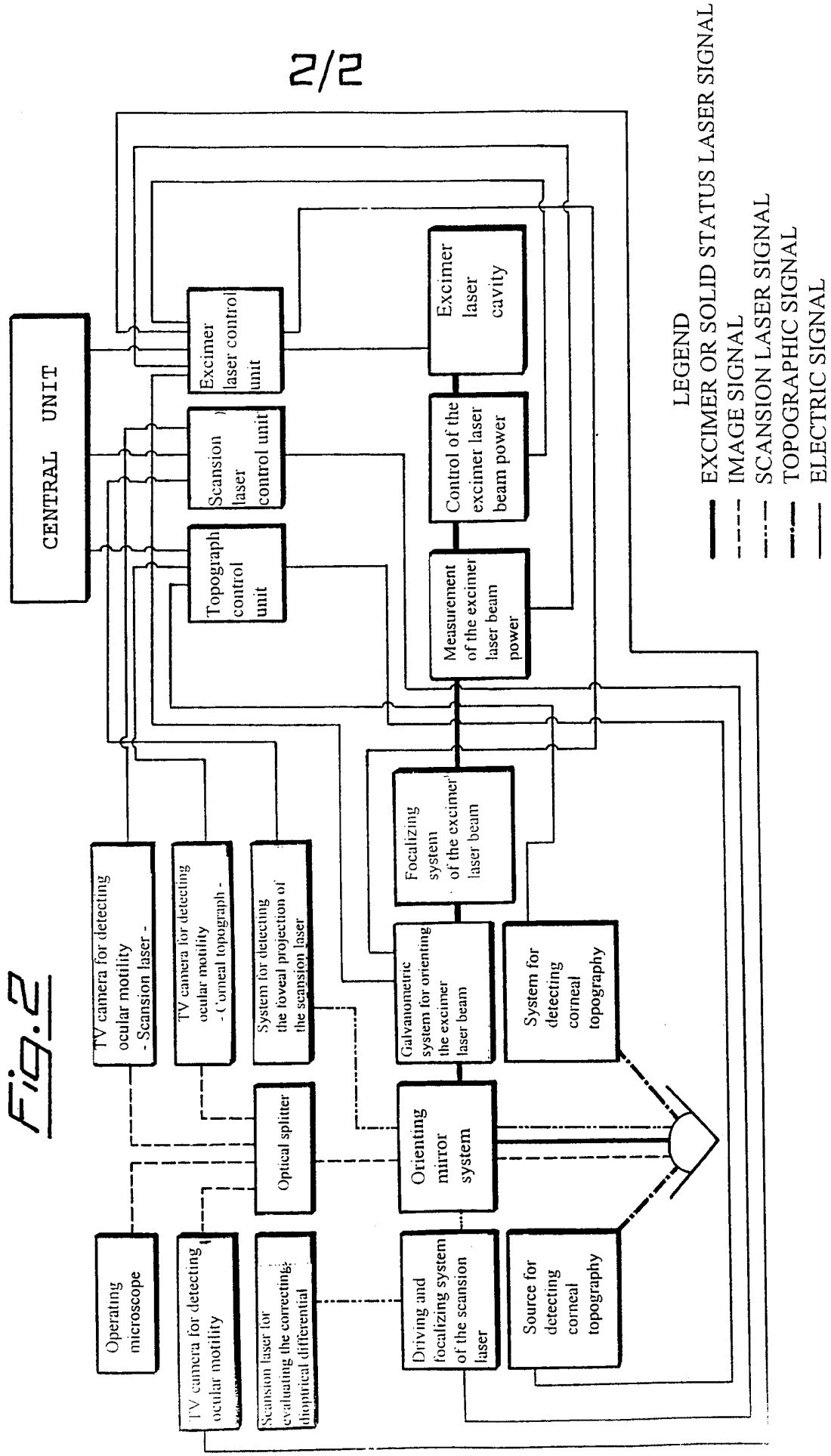
CENTRAL UNIT
Excimer laser control unit
Scansion laser control unit
Topograph control unit
Excimer laser cavity
Control of the excimer laser beam power
Measurement of the excimer laser beam power
Focalizing system of the excimer laser beam
Galvanometric system for orienting the excimer laser beam
System for detecting corneal topography
TV camera for detecting ocular motility - Scansion laser -
TV camera for detecting ocular motility - Corneal topograph -
System for detecting the foveal projection of the scansion laser
Optical splitter
Orienting mirror system
Operating microscope
TV camera for detecting ocular motility
Scansion laser for evaluating the correcting dioptrical differential
Driving and focalizing system of the scansion laser
Source for detecting corneal topography
LEGEND
EXCIMER OR SOLID STATUS LASER SIGNAL
IMAGE SIGNAL
SCANSION LASER SIGNAL
TOPOGRAPHIC SIGNAL
ELECTRIC SIGNAL

Fig.2

INTERNATIONAL SEARCH REPORT

Inter ›nal Application No
PCT/IT 99/00341

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 132 A (HOHLA KRISTIAN) 6 April 1999 (1999-04-06) claim 16	1,2,5,6
A	EP 0 568 081 A (RODENSTOCK INSTR) 3 November 1993 (1993-11-03) abstract	1
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A	WO 92 01430 A (EMMETROPIX INC) 6 February 1992 (1992-02-06) abstract; figure 2	1

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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 March 2000	24/03/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Korth, C-F

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/IT 99/00341

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 721 379 A (L ESPERANCE FRANCIS A) 26 January 1988 (1988-01-26) figure 1	1
A	US 5 490 098 A (KARDON RANDY H) 6 February 1996 (1996-02-06) abstract	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter ional Application No
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