(54) **Title:** MULTIFOCAL INTRAOCULAR LENS

FIG. 1B

(57) **Abstract:** A multifocal IOL including at least one diffractive surface including a plurality of discrete, adjacent, diffractive, con¬ centric rings, having a radial phase profile cross-section with a near-symmetrical diffractive surface topography, and an odd number, greater than three, of diffractive orders and an asymmetrical distribution of energy flux over the diffractive orders.

WO 2020/053864 A1

MULTIFOCAL INTRAOCULAR LENS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001]   This application claims the benefit of priority to U.S. Provisional Patent Application No. 62/730,769 filed September 13, 2018, entitled "MULTIFOCAL INTRAOCULAR LENS" the contents of which are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

[0002]   The present invention, in some embodiments thereof, relates to multiple focus intraocular lenses in general and, more particularly, but not exclusively to multi-focal, diffractive, intraocular ophthalmic lenses.

BACKGROUND

[0003]   An intraocular lens (IOL) is a lens implanted in the eye as part of a treatment for cataracts or myopia. The multifocal intraocular lenses (IOLs) available are often able to restore visual function and allow eyeglasses independence after their implantation with great levels of patient satisfaction.

[0004]   Multifocal IOLs correct far-vision, near-sightedness and all mid-range distances. Multifocal IOLs improve near vision by dividing light in different focuses, which changes the vision physiology because of the light dispersion that happens when it enters into the eye. Modern multifocal IOLs provide a more physiological division of light and, in this way, optimize the eyeglasses independence and also provide better vision quality and less visual symptoms for the patient.

[0005]   The foregoing examples of the related art and limitations related therewith are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the figures.

SUMMARY

[0006]   The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope.

[0007]   There is provided, in accordance with some embodiments of the invention, a multifocal IOL including at least one diffractive surface including a plurality of discrete, adjacent, diffractive, concentric rings, having a radial phase profile cross-section with a near-symmetrical diffractive surface topography, and an odd number, greater than three, of diffractive orders. In some embodiments, the IOL includes an asymmetrical distribution of energy flux over the diffractive orders.

[0008]   In some embodiments, the IOL includes five diffractive orders. In some embodiments, the diffractive surface includes diffractive steps designed to maintain the diffractive profile unchanged in between the steps, and wherein the diffractive steps are partially inside and partially outside the base curvature of the IOL.
In some embodiments, the diffractive, concentric rings include a repetitive pattern of diffractive profiles. In some embodiments, the profiles are asymmetrical.

[0009]   In some embodiments, the diffractive rings include a repetitive pattern of a single diffractive profile. In some embodiments, the diffractive rings include a repetitive pattern of two different diffractive profiles, and wherein the diffractive rings include a single transition from a first zone having a repetitive pattern of one diffractive profile to a second peripheral zone having a repetitive pattern of a second diffractive profile.

[0010]   In some embodiments, height of the diffractive surface topography of the second peripheral zone is maintained constant when advancing radially outwards in respect to the center height of the IOL. In some embodiments, the radial phase profile cross-section has an asymmetrical double-peaked geometry.

[0011]   In some embodiments, thickness of the IOL is variable and the curvature is maintained. In some embodiments, thickness of the IOL is variable and the curvature is variable.

[0012]   In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the figures and by study of the following detailed description.

BRIEF DESCRIPTION OF THE FIGURES

[0013]   The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

[0014]   Exemplary embodiments are illustrated in referenced figures. Dimensions of components and features shown in the figures are generally chosen for convenience and clarity of presentation and are not necessarily shown to scale. The figures are listed below.

[0015]   Fig. 1A is a plan view simplified illustration of a multifocal IOL; and

[0016]   Fig. 1B is a cross-section view simplified illustration of a diffractive surface of a multifocal IOF according to some embodiments of the present invention;

[0017]   Fig. 2A is a radial, cross-section, simplified illustration of a diffractive surface topography of a portion of the IOF; and

[0018]   Fig. 2B is a graph of distribution of energy flux (power) levels over specific diffractive orders associated with the diffractive surface topography shown in Fig. 2A;

[0019]   Fig. 3A is a radial, cross-section, simplified illustration of a diffractive surface topography of a portion of the IOF; and

[0020]   Fig. 3B is a graph of distribution of energy flux (power) levels over specific diffractive orders associated with the diffractive surface topography shown in Fig. 3A;

[0021]   Fig. 4 is a graph superimposing two radial phase profiles in accordance with some examples of the invention;

[0022]   Fig. 5A is a radial, cross-section, simplified illustration of a diffractive surface topography of a portion of the IOF;

[0023]   Fig. 5B is a graph of distribution of energy flux (power) levels over specific diffractive orders associated with the diffractive surface topography shown in Fig. 5A;

[0024]   Fig. 6 is a graph of a simulation of a through-focus Modulation Transfer Function (MTF) of the IOF in accordance with some embodiments of the invention; and

[0025]   Fig. 7 is a simplified graph illustration depicting a profile of a diffractive portion of an exemplary lens in accordance with some embodiments of the current invention.

DETAILED DESCRIPTION

[0026]   For purposes of better understanding some embodiments of the present invention, as illustrated in Figures 1A to 6 of the drawings, reference is first made to the construction and operation of a multifocal intraocular lens (IOL).

[0027]   Multifocal Intraocular lenses (IOL) are designed such that to produce one, two, three or more diffractive orders or foci on the optical axis such that each image focal point is formed on the retina when an object associated with the image is located at a corresponding distance from the eye. Most of the intraocular lenses are designed to have a refractive (lens) focal point and energy flux (power) that corresponds to far vision i.e. the spherical/aspherical surfaces of the lens are designed to focus an image of an object on the retina when the object is located at the far-sighted distance from the eye (>5-6 meters). The diffractive surfaces in most bifocal and trifocal lenses create additional foci at the near (30-40cm) and intermediate distances (60-80cm).

[0028]   Most refractive-diffractive IOLs have the same general structure - a lens comprising multiple rings, each ring having a diffractive profile that is scaled to the ring width. The diffractive profiles are repeated along the radius for each Fresnel zone. In some cases, the rings are also scaled vertically (apodization).

[0029]   According to an aspect of the invention there is provided an IOL comprising diffractive steps which are partially inside and partially outside the base curvature of the IOL. In some embodiments, the thickness of the IOL is variable and the curvature is constant. In some embodiments, change in curvature is produced by optimization of the sphericity between steps.

[0030]   According to an aspect of some embodiments of the present invention there is provided an IOL that has a spherical surface and an aspherical surface. In some embodiments, the IOL comprises an asymmetrical number of active diffractive orders along the optical axis of the eye. In some embodiments, the IOL comprises more than three diffractive orders on the optical axis of the eye. In some embodiments, the IOL comprises five diffractive orders on the optical axis.

[0031]   In some embodiments, the IOL comprises a diffractive pattern on one or more surfaces of the lens. In some embodiments, the diffractive pattern comprises a repetitive pattern of diffractive profiles. In some embodiments, the profiles are asymmetrical.

[0032]   Reference is now made to Figs. 1A and 1B (not drawn to scale), in which Fig. 1A is a plan view simplified illustration of a multifocal IOL and Fig. 1B is a cross-section view simplified illustration of a diffractive surface of a multifocal IOL according to some embodiments of the present invention.

[0033]   As shown in the exemplary embodiment depicted in Fig. 1A, An IOL 100 comprises a diffractive surface having a plurality of discrete, adjacent, diffractive, concentric sections or rings 102.

[0034]   In some embodiments, the IOL diffractive surface comprises diffractive steps which are partially inside and partially outside the base curvature of the IOL. This induces changes in diffractive status between two steps. In some embodiments, the thickness of the IOL is variable but the curvature is maintained. In some embodiments, change in curvature is produced by optimization of the sphericity between steps.

[0035]   Potential advantages in the described design are in that:

      1. The designing of the diffractive steps does not change the diffractive profile in between the steps. This allows to have multifocal IOL of any added power and more efficiency for near focal lengths without losing contrast for distance.

      2. Design of diffractive steps allows rays of light to be parallel to the step which is the ideal condition for diffraction.

[0036]   In some embodiments, the rings are distributed along Fresnel zones (102-1/102-2). In some embodiments, and a shown in Fig. 1B, an IOL surface150 topography features repetitive triangular forms, squared forms or parabolic forms depending on the type of lens.

[0037]   Reference is now made to Fig. 2A which is a radial, cross-section, simplified illustration of a diffractive surface topography of a portion of the IOL and Fig. 2B, which is a graph of distribution of energy flux (power) levels over specific diffractive orders associated with the diffractive surface topography shown in Fig. 2A.

[0038]   Fig. 2A depicts a radial cross-section or radial phase profile 200 of a diffractive surface topography through a concentric ring. The specific cross-section of the radial phase profile is generated by using a Gerchberg-Saxton (GS) iterative algorithm. Fig. 2A depicts

an exemplary embodiment of a radial phase profile cross-section showing an asymmetrical double-peaked cross-section having a near-symmetric local diffractive surface topography. Radial phase profile 200 is converted to a height profile which is radially and parabolically integrated to each of the Fresnel zones (rings) of the diffractive lens with a specific focal length.

[0039]   The authors of this disclosure have come to learn that symmetric local diffractive surface topography function combined with an odd number of diffraction diffractive orders e.g., 1, 3, 5, 7 or 9 diffraction diffractive orders, and specifically a number of diffraction diffractive orders greater than three increase the overall light transmission efficiency of the IOL above 90% and in some cases up to at least 93%.

[0040]   In some embodiments, IOL 100 comprises five diffractive orders on the optical axis. In some embodiments, one of the diffractive orders e.g., the far vision focal length has a high energy flux level. In some embodiments, one of the diffractive orders is entirely suppressed. In some embodiments, the five diffractive orders or foci correspond to the following five diffractive orders: -2, -1, +1 and +2 which are diffracted diffractive orders produced by the diffractive pattern and a single order 0 which is the refractive power produced by the spherical / aspherical surfaces of the IOL. In some embodiments, the spherical / aspherical surfaces of the lens are designed such as to focus an image on the retina when the imaged object is located at an intermediate distance from the eye, between near vision (~30-40cm) and far vision (several meters).

[0041]   In some embodiments, and as depicted in Fig. 2B, of the five diffractive orders, the diffractive order -2, corresponds to far vision has the highest energy flux level. In some embodiments, of the remaining diffractive orders, the diffractive order +2, which corresponds to near vision has the highest energy flux level. In this embodiment, the diffractive order -1 is suppressed.

[0042]   Reference is now made to Fig. 3A which is a radial, cross-section, simplified illustration of a diffractive surface topography of a portion of the IOL and Fig. 3B, which is a graph of energy flux levels distribution over specific diffractive orders associated with the diffractive surface topography shown in Fig. 3A.

[0043]   Figures 3A and 3B show a design different than that illustrated in Figures 2A and 2B however both have been designed using the same method of profile generation by using

a Gerchberg-Saxton (GS) iterative algorithm and conversion of the phase profile to a height profile which is radially and parabolically integrated to each of the Fresnel zones (rings) of the diffractive lens with a specific focal length.

[0044]   Fig. 3A depicts an additional example of a radial cross-section or radial phase profile 300 of a diffractive surface topography through a concentric ring. Fig. 3A depicts an exemplary embodiment of a radial phase profile showing an asymmetrical double-peaked cross-section having a near-symmetric local diffractive surface topography. Radial phase profile 300 is converted to a height profile which is radially and parabolically integrated to each of the Fresnel zones (rings) of the diffractive lens with a specific focal length.

[0045]   In some embodiments, and as depicted in Fig. 3B, of the five diffractive orders, the diffractive order -2, corresponds to far vision has the highest energy flux level. In some embodiments, of the remaining diffractive orders, the diffractive order +2, which corresponds to near vision has the highest energy flux level and the energy flux level at order 0 is higher than the energy flux level at diffractive order +1. In this embodiment, the diffractive order -1 is suppressed.

[0046]   As shown in Fig. 4, which is a graph superimposing radial phase profile 300 over radial phase profile 200 demonstrates phase differences between the designs in accordance with some examples of the invention. When using this technique with more than 5 foci (for example 7), the diffractive focal length determines the location of the far focus (diffractive order -3) and near focus (diffractive order +3) and the refractive focal length (spherical surfaces) determines the location of one of the intermediate foci (order 0). In the exemplary embodiment depicted in Fig. 4, radial phase profile 200 comprises phases: 1, 0 ,0.333, 0.38 and 0.637, wherein radial phase profile 300 comprises phases: 1, 0, 0.6, 0.45 and 0.65.In some embodiments, the IOL comprises two zones - a central zone 102-1 (Figs. 1A and Fig. 1B) and a peripheral zone 102-2. In some embodiments, the diffractive pattern of central zone 102-1 is not apodized. In some environments, the diffractive pattern of the peripheral zone 102-2 is not apodized. The height of the diffractive surface topography of zone 102-2 is maintained constant and does not have a gradual step height reduction when advancing radially outwards in respect to the center height of the IOL. This arrangement and design are planned in diffractive order to vary the intensity distribution when increasing the

aperture and allow increased light flux, even if not optimally focused, with pupil dilation (low intensity environmental) light.

[0047]   A potential advantage in this design is in that the apodization design allows for diffraction efficiency near 100% thus minimizing loss of light.

[0048]   For modifying the intensity distribution according to the aperture size, the technique used here is to change the diffractive pattern at any radius of the intraocular lens or at one of the Fresnel Zone (or near one of them) for better performance. For this invention, the design transition occurred at radius ~1.228mm.

[0049]   As shown in Figs. 5A and 5B, in which Fig. 5A depicts an example of a radial cross-section or radial phase profile 500 of a diffractive surface topography through a concentric ring of the peripheral zone of the IOL in accordance with some embodiments of the invention. Fig. 5A depicts an exemplary embodiment of a radial phase profile cross-section at the IOL peripheral zone 102-2 showing an asymmetrical single-peaked cross-section having a near-symmetric local diffractive surface topography.

[0050]   In some embodiments, a radial phase profile cross-section at the IOL peripheral zone 102-2 comprises an asymmetrical double-peaked cross-section having a near-symmetric local diffractive surface topography. Radial phase profile 500 is converted to a height profile which is radially and parabolically integrated to each of the Fresnel zones (rings) of the diffractive lens with a specific focal length.

[0051]   In some embodiments, and as depicted in Fig. 5B, the flux energy level declines from the far diffractive order to the near diffractive order with two suppressed orders at -1 and +1.

[0052]   The phase obtained at the source plane and used in the design (at radius >1.228mm) depicted in Figs. 5A and 5B is obtained using normalized target intensity [1, 0, 0.5, 0, 0.34] in the Gerchberg-Saxton (GS) algorithm.

[0053]   However, in some embodiments, the other diffractive profile (after transition) can be a different diffractive design based on three or more foci and can be also a monofocal design with full energy at far vision or bifocal with energy at far vision and other foci at intermediate or near vision

[0054]   Also, for fine tuning of the intraocular lens, the entire diffractive height profile (before and after transition from IOL zone 102-1 to IOL zone 102-2) can be tunable. In the

exemplary embodiment depicted in Figs. 5A and 5B, the first diffractive profile before the transition has been increased by 5% and the second diffractive profile after the transition has been increased by 12%. Our multifocal IOL, based on zero order for intermediate vision, has a high efficiency- over 90% - in the used diffractive orders (-2, -1, 0, 1, 2).

[0055]   Reference is now made to Fig. 6, which is a graph of a simulation of a through-focus Modulation Transfer Function (MTF) of the IOL in accordance with some embodiments of the invention. As shown in the exemplary embodiment depicted in Fig. 5, three graphs are drawn for three levels of eye pupil diameter: graph 602 for a 2mm pupil diameter (i.e., intense light condition), graph 604 for a 4.5 mm pupil diameter (i.e., low light condition) and graph 606 for a 3 mm pupil diameter (i.e., normal light condition).

[0056]   The graphs depicted in Fig. 6 exhibit the biphasic nature of the IOL at all three shown levels of environmental light however, as the level of environmental light decreases changing the pupil diameter from 2mm to 4.5mm, the MTF value correspondingly increases on the far-sighted range of the IOL, even though it is limited from a diopter range between approximately 22 and 24.5 to a narrower diopter range between approximately 23 to 23.75 and allows for an improved low-light intensity vision.

[0057]   Fig. 7 which is a simplified graph illustration depicting a profile of a diffractive portion of an exemplary lens in accordance with some embodiments of the current invention. As shown in Fig. 7, the depicted cross-section profile comprises an asymmetrical single-peaked topography comprising a plurality of peaks having a height of between 1.5 and 2.5 uM dispersed along a portion of the lens radius between 0 and 3000 uM.

[0058]   Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

[0059]   Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases "ranging/ranges between" a first indicate number and a second indicate number and "ranging/ranges from" a first indicate number "to" a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

[0060]   In the description and claims of the application, each of the words "comprise" "include" and "have", and forms thereof, are not necessarily limited to members in a list with which the words may be associated. In addition, where there are inconsistencies between this application and any document incorporated by reference, it is hereby intended that the present application controls.

[0061]   The descriptions of the various embodiments of the present invention have been presented for purposes of illustration but are not intended to be exhaustive or limited to the embodiments disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art without departing from the scope and spirit of the described embodiments. The terminology used herein was chosen to best explain the principles of the embodiments, the practical application or technical improvement over technologies found in the marketplace, or to enable others of ordinary skill in the art to understand the embodiments disclosed herein.

WHAT IS CLAIMED IS:

1.   A multifocal IOL comprising

        at least one diffractive surface including a plurality of discrete, adjacent, diffractive, concentric rings, having

        a radial phase profile cross-section with a near-symmetrical diffractive surface topography; and

        an odd number, greater than three, of diffractive orders.

2.   The IOL according to claim 1, wherein said IOL comprises an asymmetrical distribution of energy flux over said diffractive orders.

3.   The IOL according to any one of claims 1 and 2, wherein said IOL comprises 5 diffractive orders.

4.   The IOL according to any one of claims 1-3, wherein said diffractive surface comprises diffractive steps designed to maintain the diffractive profile unchanged in between said steps.

5.   The IOL according to claim 4, wherein said diffractive steps are partially inside and partially outside the base curvature of the IOL.

6.   The IOL according to any one of claims 1-5, wherein said diffractive, concentric rings comprise a repetitive pattern of diffractive profiles.

7.   The IOL according to claim 6, wherein said profiles are asymmetrical.

8.   The IOL according to any one of claims 1-7, wherein said diffractive rings comprise a repetitive pattern of a single diffractive profile.

9.   The IOL according to any one of claims 1-7, wherein said diffractive rings comprise a repetitive pattern of two different diffractive profiles.

10.   The IOL according to claim 9, wherein said diffractive rings comprise a single transition from a first zone having a repetitive pattern of one diffractive profile to a second peripheral zone having a repetitive pattern of a second diffractive profile.

11.   The IOL according to any one of claims 9 and 10, wherein height of the diffractive surface topography of said second peripheral zone is maintained constant when advancing radially outwards in respect to the center height of the IOL.

12.   The IOL according to any one of claims 1-8, wherein said radial phase profile cross-section has an asymmetrical double-peaked geometry.

13.   The IOL according to any one of claims 1-12, wherein thickness of the IOL is variable and the curvature is maintained.

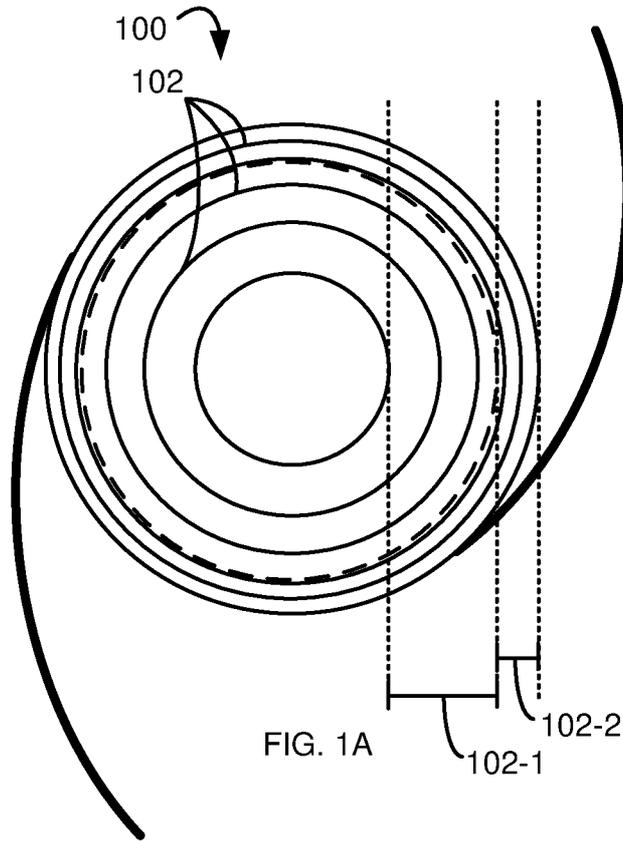14.   The IOL according to any one of claims 1-13, wherein thickness of the IOL is variable and the curvature is variable.
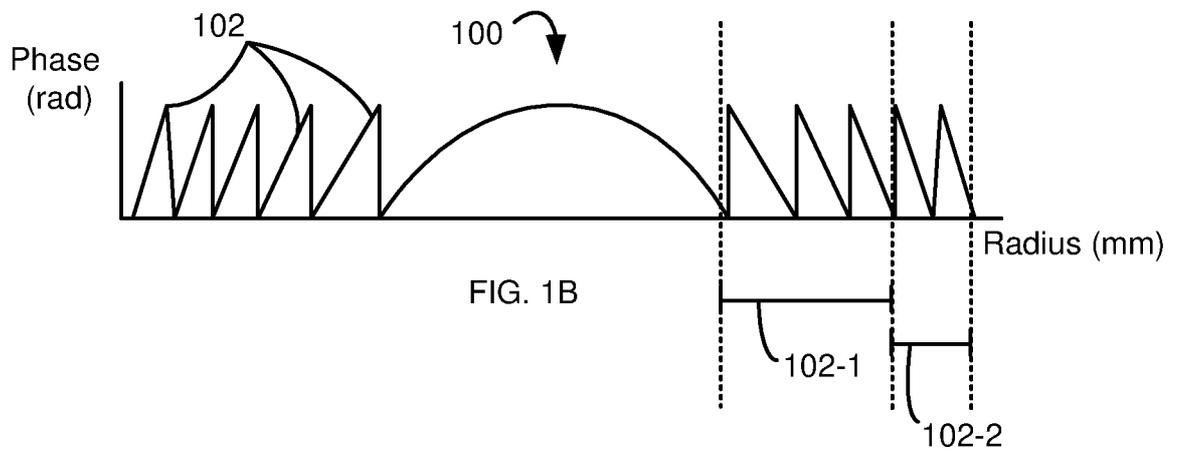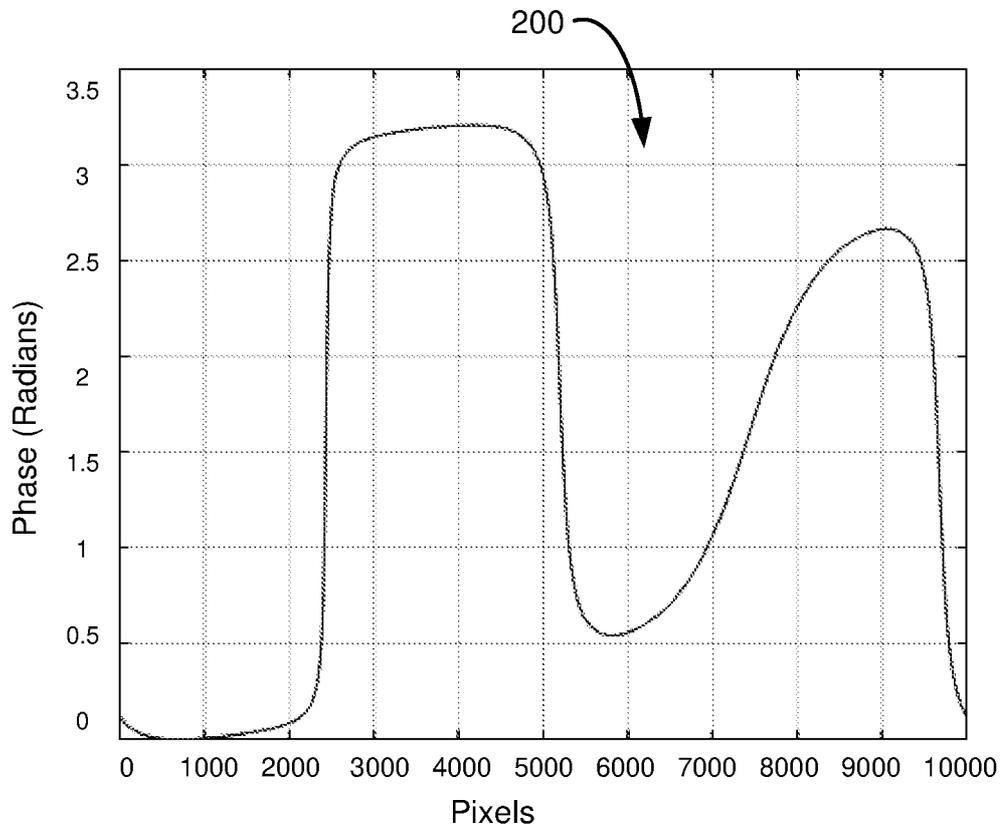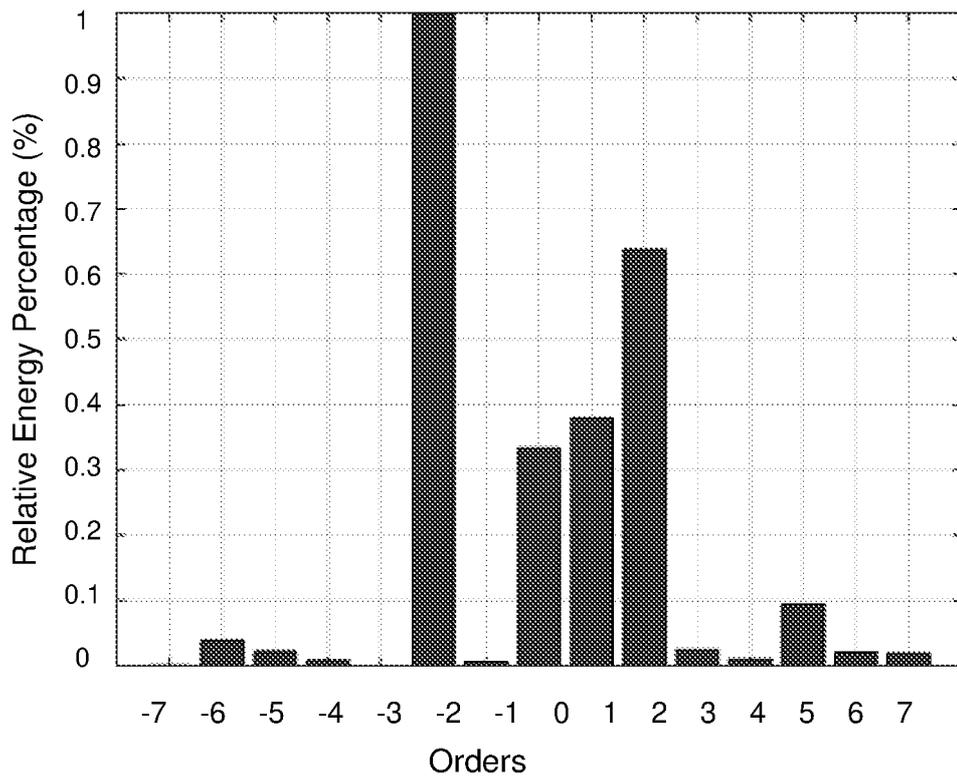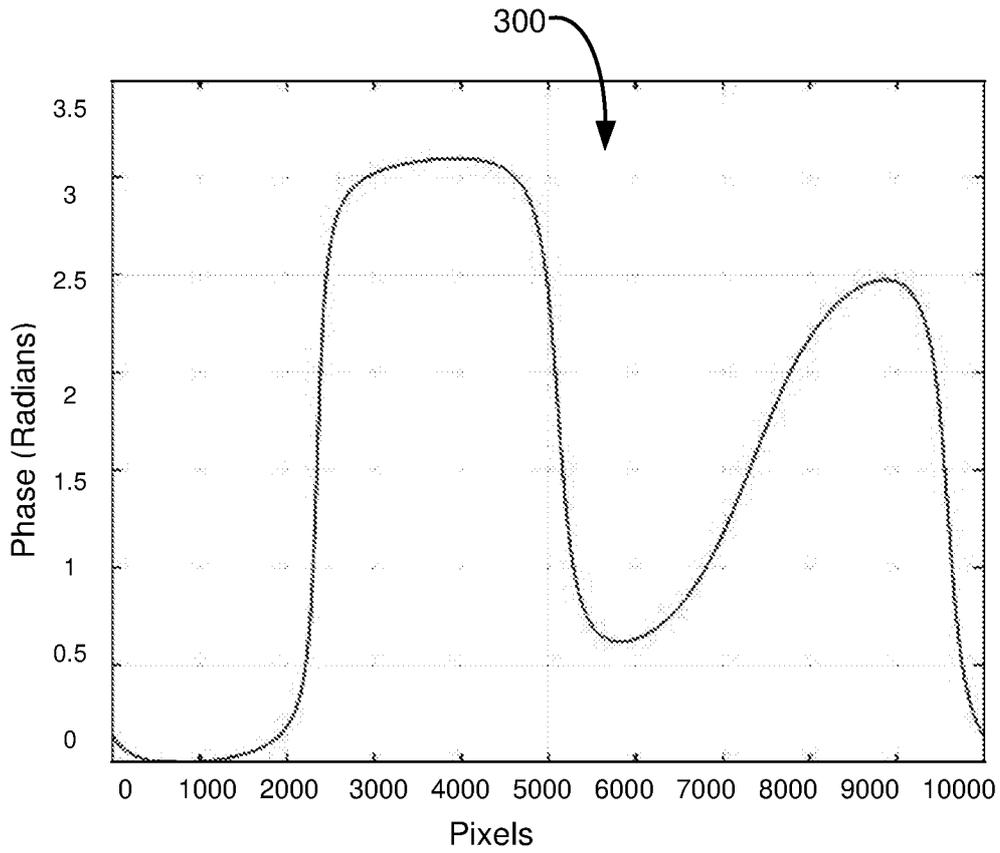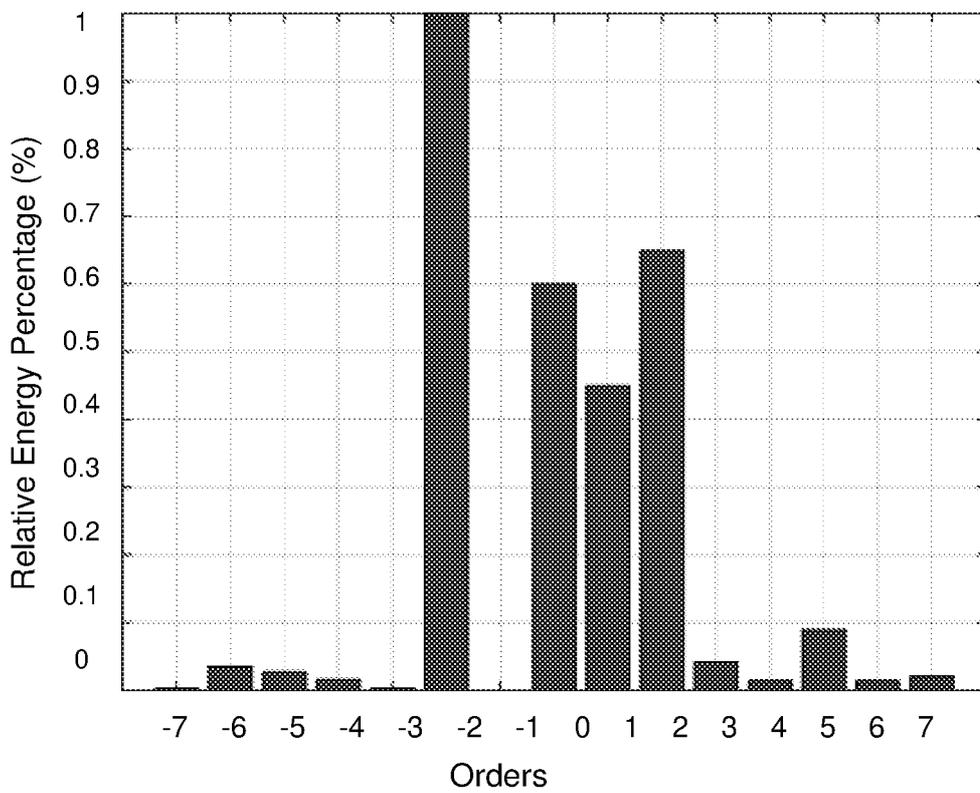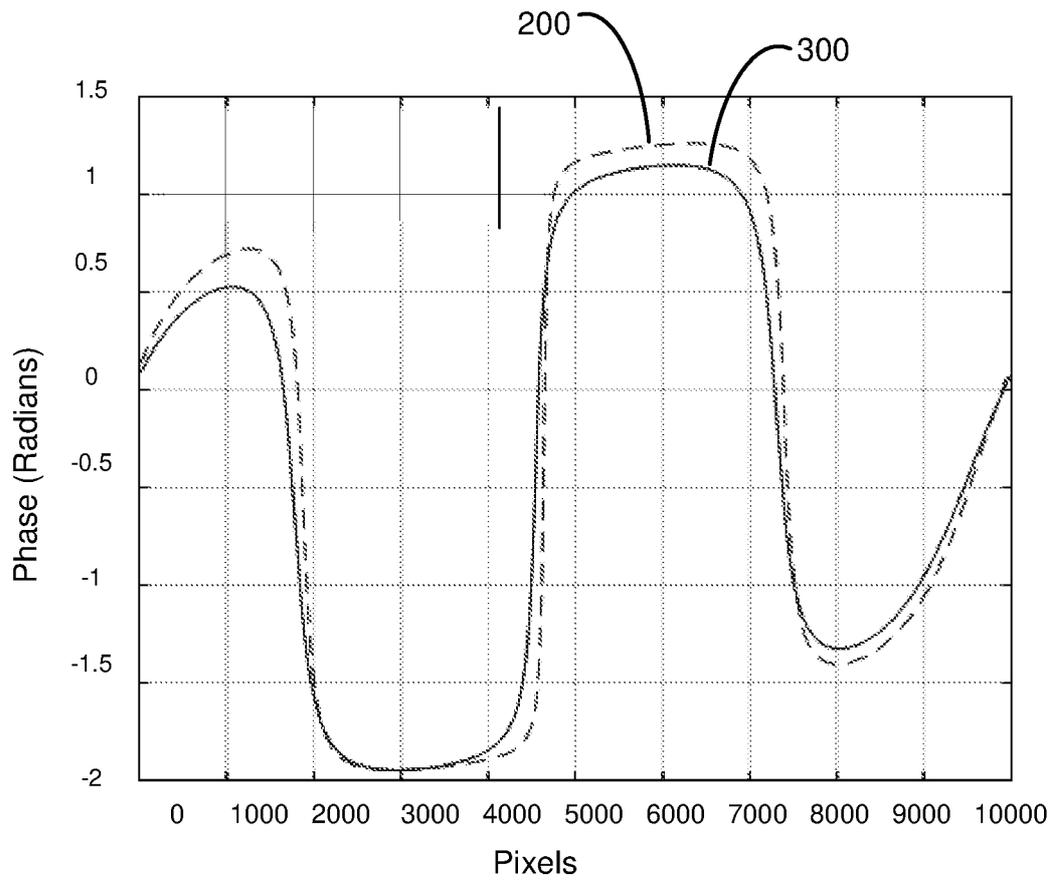
FIG. 1A

FIG. 1B

FIG. 2A

FIG. 2B

300

FIG. 3A

FIG. 3B

FIG. 4
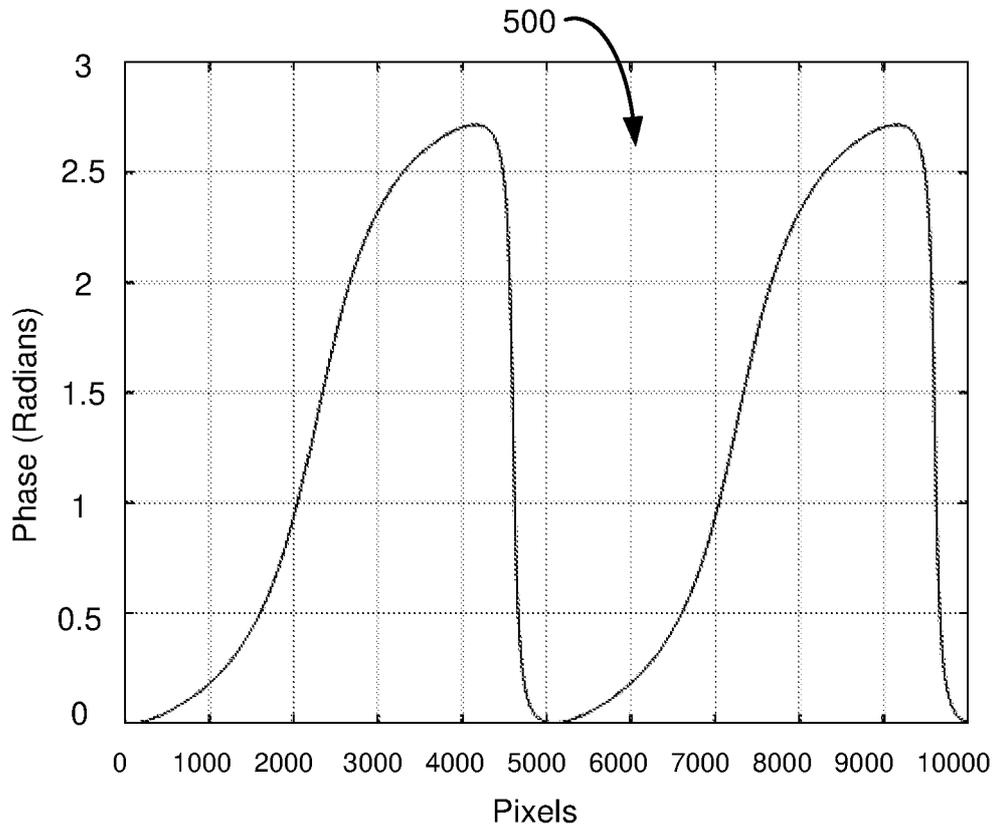
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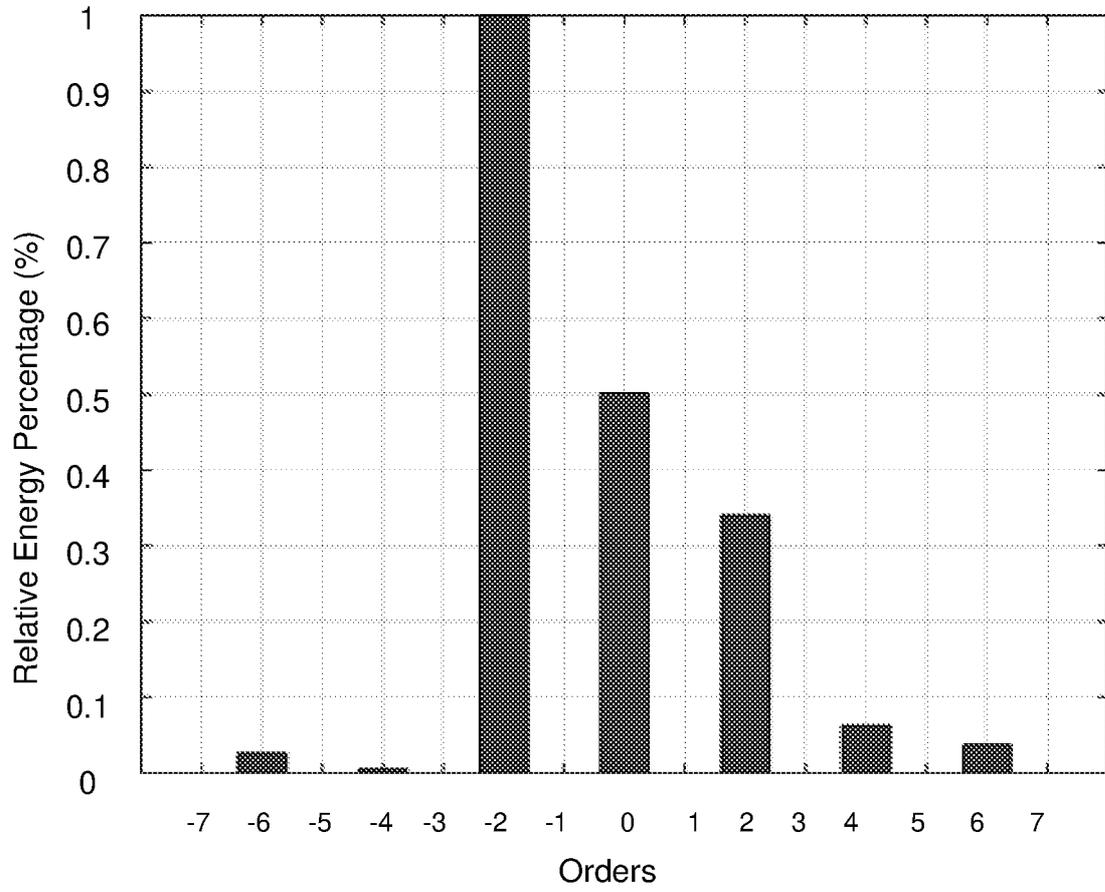
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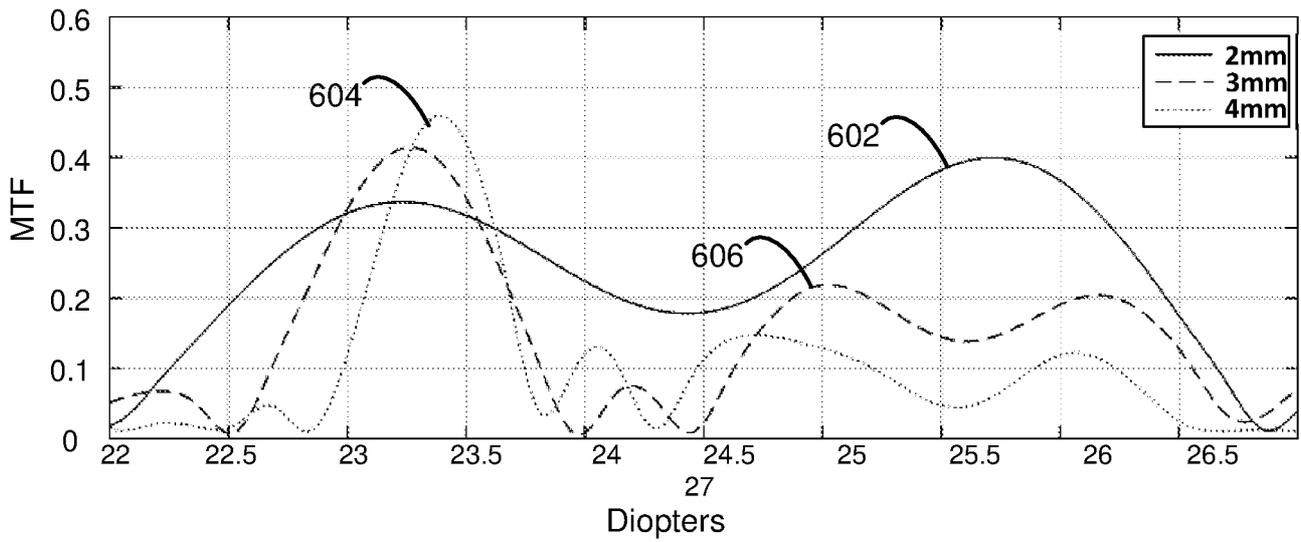
FIG. 6
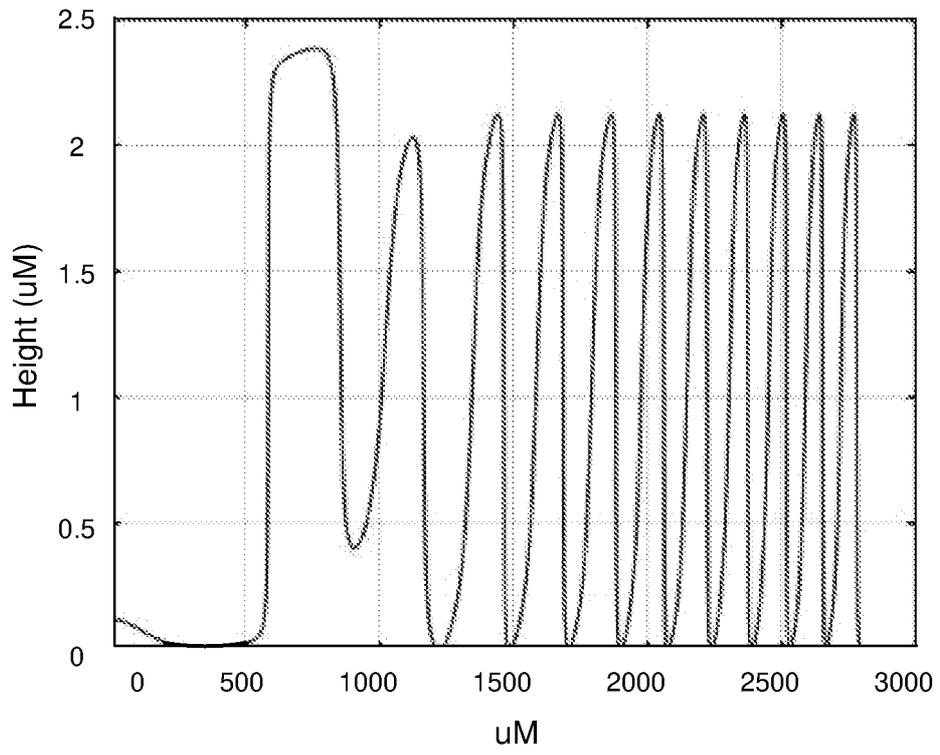
FIG. 7

	International application No.
	PCT/IL20 19/05 1025

A.   CLASSIFICATION OF SUBJECT MATTER
IPC (20200101) A61F 2/16, G02B 5/18
CPC (20150401) A61F 2/1613, A61F 2/1654, A61F 2/1618, G02B 5/1876
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 (20200101) A61F 2/16
CPC (20130101) A61F 2/1618, A61F 2/1613

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 practicable, search terms used)
Databases consulted: Google Patents, Orbit

C.   DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009027438 A2 AMO REGIONAL HOLDINGS 05 Mar 2009 (2009/03/05) The whole document	1-14
X	WO 2012078763 A1 ABBOTT MEDICAL OPTICS INC 14 Jun 2012 (2012/06/14) The whole document	1-14
X	US 2009240328 A1 ICON LAB GMBH 24 Sep 2009 (2009/09/24) The whole document	1-14
A	US 6536899 B1 BIFOCON OPTICS GMBH 25 Mar 2003 (2003/03/25) The whole document	1-14

☐ Further documents are listed in the continuation of Box C.   ☒   See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority
"A" document defining the general state of the art which is not considered	date and not in conflict with the application but cited to understand
to be of particular relevance	the principle or theory underlying the invention
"D" document cited by the applicant in the international application	"X" document of particular relevance; the claimed invention cannot be
"E" earlier application or patent but published on or after the	considered novel or cannot be considered to involve an inventive
international filing date	step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is	"Y" document of particular relevance; the claimed invention cannot be
cited to establish the publication date of another citation or other	considered to involve an inventive step when the document is
special reason (as specified)	combined with one or more other such documents, such combination
"O" document referring to an oral disclosure, use, exhibition or other	being obvious to a person skilled in the art
means	"&" document member of the same patent family
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than the priority date claimed	

Date of the actual completion of the international search	Date of mailing of the international search report
21 Jan 2020	21 Jan 2020

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Form PCT/ISA/210 (second sheet) (revised January 2019)

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