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(54) **Title:** CUSTOMIZED VARIABLE DENSITY 3D PRINTED ORTHOTIC DEVICE

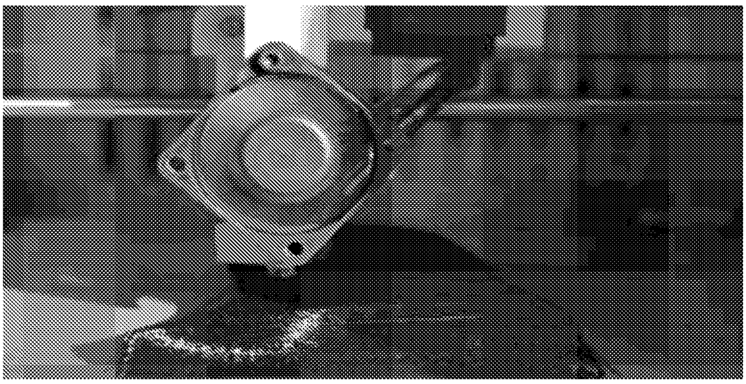

Fig.4: 3D printer adapted to manufacture the variable density custom orthotic from the 3D model by varying infill percentage of material in a selected infill pattern.

(57) **Abstract:** Disclosed is a method of manufacturing a variable density orthotic device for an individual comprising further region of varying Density, compressibility, hardness and softness. The method comprising Imaging feet from side, bottom and back followed by extracting data from these images to make a software generated 3D model of the insole. The regions of the insole in need of softening or hardening are selected and demarcated on to the 3D model based on the foot profile. This customized 3D model of the insole is now imported to a 3D printer. The 3D printer carries out the printing of the insole in a single piece by varying density of material at the selected or required regions.

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TITLE:

Customized variable density 3D printed orthotic device.

FIELD OF INVENTION:

The present invention relates to external orthotic devices, in particular, methods and systems for constructing variable density custom foot orthotic models and devices used in relieving and alleviating undesirable conditions of feet.

BACKGROUND:

Foot related problems are becoming a common issue all over the world. Structural deformities in the foot can have serious implications on daily activities and lifestyle. About 50% of the adult population worldwide experience restrictions in activities such as exercising, working, and walking due to foot pain. Foot related issues include bunion, corn, calluses, gout, plantar warts, peeling, redness, itching, burning, blisters and sores, Flatfoot (Pes Planus), athlete's foot, plantar fasciitis, verrucas caused by a viral infection found on the soles of the feet or between toes, fallen arches a common complaint in which the arch of the foot collapses and becomes flat such condition cause lot of discomfort to the patients.

Among diabetes mellitus related complications, foot ulceration is the most common, affecting approximately 15% of diabetic patients during their lifetime. India has the highest number of people with diabetes in the world. Diabetic foot care is one of the most ignored aspects of diabetes care in India. India had an estimated 31,705,000 diabetics in the millennium year which is estimated to grow by over 100% to 79,441,000 by 2030. Diabetics have a 25% risk of developing foot ulcers from repeated loading of high pressure points that result from structural deformities in the foot. Foot ulcers progress over time with loading, and failure to treat these pathologies can lead to adverse complications. With about 80% of diabetic ulcers leading to amputation, it is important to address the structural and biomechanical changes in pathological feet to both stop the progression and prevent the occurrence of the pathology.

Orthotics are common treatments used to offer pain relief and stabilize foot deformities, restrict unnecessary motion of the foot and ankle, and relieve areas of excessive pressure. The proper fitting of orthotics is essential because ill-fitting footwear can further introduce deformities in the foot.

Apart from clinical conditions insoles (orthotics) are used for many other purposes like running, walking, playing cricket and other sports. Foot related problems are found in all age groups and gender. Foot related issues are more prevalent in individuals whose work demand long hours of standing or walking. Women are more vulnerable to foot problems than men, because of sustained use of narrow-fitting shoes that squeeze the toes and from high-heels that cramp the forefoot and pose risks for arch and ankle. Pain in a child's foot or ankle is also becoming common this should never be ignored. It could be due to abnormal gait and should be evaluated by a foot and ankle clinician and corrected immediately through an external orthotic device.

Feet problems in individuals associated with sports is again very common. Due to excessive strain over the feet due to repeated thumping on hard surface and varied motion the feet and ankle is more likely to be damaged and needs correction and support by an external orthoic device. Therefore, there is need of a device which should have both a region of support and or relief. The region of support may be a profiled region designed to support the foot and provide correct positioning of the foot. The region of relief may be a soft/cushioned region aimed to reduce a force applied to a specific region of a patient's foot so as to relieve pain. A foot orthosis may be used to support a foot post surgery, to improve gait of a user, and/or to provide relief from conditions such as pressure ulcers. Support is also required in different degrees and similarly relief or cushioning is also required in different degrees. It is highly desirable to have an orthotic device which could provide different levels of softening of insole at one portion and hardening at other Moreover, The current method of manufacturing orthoses does not take in to account the hardening and softening of the insole and is labour intensive and time consuming.

SUMMARY:

A first aspect of the invention provides a method of manufacturing an orthosis comprising: providing electronic 3D data defining dimensions and shape of an orthosis. The 3D data also demarcates region in need of softening/cushioning or hardening for support according to user or clinicians input. The 3D data includes both a region of support and or relief. The region of support may be a profiled region designed to support the foot to different levels and provide correct positioning of the foot. The region of relief may be a soft/cushioned region aimed to reduce a force applied to a specific region of a patient's foot so as to relieve pain. This 3D data is uploaded onto a 3D printer to get the finished product.

Another aspect of the invention involves the blending of 3D printing technology with knowledge of skilled clinician and orthosis designer. The inventors have realised that 3D printing can be used to form an orthosis. Thereby reducing the time, cost and labour intensiveness of the manufacture of the orthosis compared to conventional manufacturing methods. 3D printing also negates the need for finishing operations such as grinding. Further, utilising 3Dprinting enables greater design freedom and customisation enabling features to be added to the orthosis that would be difficult or impossible to achieve using conventional machining methods.

DETAILED DESCRIPTION OF THE DRAWINGS:

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings

Figure 1 illustrates the side view of an insole depicting if any person is having heel pain, that portion is filled with either a soft material or density of insole material is reduced to make it more soft and extra cushioning is added to it.

Figure 2 illustrates the isometric view of an insole depicting, either harder material is used or density of insole material is increased to make the arch support region hard and firm making it proper for arch support.

Figure 3 illustrates the cut section of insole at which sheets of glass fibers can be placed and then again printing with the insole material can be started, making it a part of insole and creating a hard and firm insole.

Figure 4 illustrates the 3D printing mechanism where infill percentage can be varied over a particular region and density can be varied.

DETAILED DESCRIPTION:

In accordance with the present invention there is provided a new and improved process and system for manufacturing a variable density orthotic device for an individual. The invention is particularly useful for patients having diabetes, such individuals are affected by feet neuropathy. Reducing density at soft or sensitive points of their feet along with cushioning can keep their feet more safe. Similarly, individuals having corns/calluses in their feet, can be benefited by selectively altering the compressibility of a portion of the insole with a layer of cushioning, it can protect that region from external forces and also from getting worse. For a sports person the insole can be hardened from the arch support area as shown in Figure 2 at point b and the heel area can be softened as shown in Figure 1 at point a and forefoot region and add extra layer of cushioning for better running experience. For individuals suffering from plantar fasciitis, the insole can be softened at the metatarsal and mid region.

Different locations of the insole serve to cushion and support different regions of the foot. By adjusting the material properties and material thickness along the length of the insole, the insole can be designed to provide additional support for the ball of the foot, the arch of the foot, and/or the heel of the foot.

Varying density of 3D printed material along with adding cushioning layers can enhance the purpose of orthotics. Said printing method can substantially reduce cost of adding extra layers of cushioning. Further, in case of pain affected areas very low thickness of cushioning material can be used. A variable density 3D printed the sole is thin but it is still wearable providing all the comforts which a general insole provides like arch support, heel and forefoot cushioning, pressure distribution and biomechanics correction.

Clinical Issues

There are many anatomic biomechanical deficiencies of a foot that can be identified by a foot specialist: Such issues with the foot can be corrected or the clinical severity can be substantially reduced using the external variable density orthotic device and system of the invention.

Foot related issues include bunion, corn, calluses, gout, plantar warts, peeling, redness, itching, burning, blisters and sores, Flatfoot (Pes Planus), athlete's foot, plantar fasciitis, verrucas caused by a viral infection found on the soles of the feet or between toes, fallen arches a common complaint in which the arch of the foot collapses and becomes flat such condition cause lot of discomfort to the patients. Few more issues with the foot include; raised arch, Morton's neuroma, foot inversion, foot eversion, hammer toes, heel pain, heel spur syndrome, etc. Some of these deficiencies may be interrelated. For example, a raised arch may cause other problems such as corns, calluses or heel pains inasmuch as walking pressure is not properly distributed as compared to a normal foot. Other problems such as hammer toes may be caused by the type of footwear that is used, such as high heels or very tight shoes.

Furthermore, foot deficiencies may also cause problems or deficiencies in other parts of the body, particularly in the legs and the back of a person.

In one of the embodiments of the invention foot Orthoses can be used in multiple applications, including but not limited to: * Optirnisation of function -Either for sports or to compensate for congenital or acquired abnormality. For example. to improve gait in a child with Down's syndrome. Prevention of pathology -Orthoses are sometimes used to prevent either a structural change or a specific pathology. For example, to reduce the internal compression in the big toe joint to reduce the risk of degeneration. Treatment of specific active pathology -Orthoses can be used to treat Musculoskeletal pathologies both in the feet and higher up, for example to treat compressive knee osteoarthritis. Treatment of local manifestations of systemic conditions -Orthoses can be used to limit the impact of global conditions such as Rheumatoid Arthritis.

Foot orthoses may be used to treat numerous conditions. The type of treatment required dictates the form of the foot orthosis required. Conditions and potential treatments include but are not limited to: Compressive Medial Knee Osteoarthritis. May be treated using an orthotic with a fairly low arch and a full length lateral wedge. Plantar Fasciitis. May be treated using an orthotic with a higher arch and a medial rearfoot wedge. Mortons neuroma. May be treated using a softer orthotic with a dome under the ball of the foot. Child with Down's syndrome and hypermobility. May be treated using a ngid orthotic with a high heel cup and medial and lateral flanges. Adult with rheumatoid arthritis. May be treated with an orthotic formed to the shape of a foot but made as a relatively soft device.

In a preferred embodiment, the invention provides a variable density 3D printed insole is fully customized, built according to a profile of feet of a person and also according to its use case whether it is required for a physical activities or for a particular medical condition like corns/calluses, feet pain, plantar fasciitis or feet neuropathy. Dimensions of feet are extracted from three images of the person's feet and then an electronic 3D model is generated from the images. After that according to the person's need, density of 3D printed material is varied over the complete insole reducing the need of extra cushioning. Each shape and feature in the cushioning structure is determined deliberately either by the user or the computer system. Shapes and features in the cushioning structure can be seamlessly adjusted as needed by the computer system or the user.

In the most preferred embodiment the process of making customized 3D printed insoles is as follows: three images of person's feet are taken from three different sides: side, bottom and back. Data is extracted from all these images like arch length, arch height, arch contours is extracted from side image, from bottom image- heel diameter, feet width, feet outline and feet contours while from back image of the feet, Achilles tendon deviation is checked from normal. From all this data, an electronic 3D model is generated in the form of hexagonal basic structures similar to a Honey bee cell. In the next step of the method the areas for increased support or compressibility/cushioning are identified and the model of the orthosis is divided into regions according to the level of support or compressibility required using a CAD package.

Glass fibres are sometimes used to make the structure firm in case of flexible material.

The 3D orthosis model is then exported to a software from which a 3D printer can operate. This will often be software supplied with the relevant 3D printer. The software is then used to add data related to the region of hardness required in the insole based on the user's needs or as per the clinicians prescription. Now the data is exported to fdm based 3D printer where density can be varied over specific regions depending upon the purpose for which insole is needed whether for sports activities or any clinical /medical condition Figure 4.

In a yet another embodiment of the invention thermoplastic elastomers are used for hardening/softening the insole. Common materials that are used in insoles to improve cushioning energy include thermoplastic rubbers, which are actually a class of copolymers or a physical mix of polymers (usually a plastic and a rubber). It may be foam rubbers such as latex and cellular polymers such as polyethylene (PE), ethylene vinyl acetate (EVA), polyurethane (PU), and polyvinyl chloride (PVC). Synthetic polymers or rubber when used alone have certain disadvantages e.g Ethylene vinyl acetate (EVA) offers good cushioning and shock absorption, but tends to suffer high compression set, meaning that these properties deteriorate rapidly during wear. Polyethylene (PE) and polyvinyl chloride (PVC) can provide reasonable cushioning and shock absorption but polyethylene (PE), like ethylene vinyl acetate (EVA), suffers high permanent compression set. Latex rubber foams tend to be too soft and “bottom out” under low loads—they offer little cushioning or shock absorption and they primarily serve to protect the foot. Polyurethane (PU) foam and viscoelastic polyurethane's (PUs) offer good cushioning and shock absorption properties. However, polyurethane's (PUs) can be bulky, lose their properties when wet and are susceptible to creep and fatigue degradation which involves the increase in deformation with time under constant stress, thereby rendering them ineffective.

Density at a specific region of the insole is generally changed by changing the infill percentage of the material while it gets condensed layer by layer forming the 3D structure. By changing the amount of material to be condensed at a particular region, density of the material can be changed at that point as shown in Figure 4 where density is varied over arch support region. To change the properties of the material of foot orthotics sometimes sheet of glass fiber or carbon fiber is used as shown in Figure 3 at plane C to make the structure more firm and strong.

Although this description contains many specifics, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments thereof, as well as the best mode contemplated by the inventors of carrying out the invention. The invention, as described herein, is susceptible to various modifications and adaptation as would be appreciated by those having ordinary skill in the art to which the invention relates.

What is claimed is:

1. Disclosed is a method of manufacturing a variable density orthotic device for a individual comprising:

   (a) Imaging feet from side, bottom and back;

   (b) extracting data from these images to make a electronic 3D model of the insole;

   (c) selecting regions of insole in need of softening or hardening based on the foot profile;

   (d) importing the electronic 3D model of the insole in to a 3D printer;

   (e) printing the insole layer by varying density of the infill material at the selected region of step (c) in a single printing process.

2. The method of claim 1, comprising a 3D printer adapted to manufacture the variable density custom orthotic from the 3D model by varying infill percentage of material in a selected infill pattern.

3. The method of claim 2, wherein the selected infill pattern is a honeycomb.

4. The method of claim 1, step (e) wherein the infill material is a copolymer of plastic and rubber.

5. The orthotic device of claim 1, comprising further regions having a different density, compressibility, softness and hardness formed through differential filling of the infill material or adding layer of glass fibre or carbon fibre into the insole.

6. The orthotic device of claim 1, wherein the device can be used to treat one or more of the following foot conditions; bunion, corn, calluses, gout, plantar warts, peeling, redness, itching, burning, blisters, sores, flatfoot (pes planus), athlete's foot, plantar fasciitis, verrucas, fallen arches, raised arch, morton's neuroma, foot inversion, foot eversion, hammer toes, heel pain, heel spur syndrome or any other undesirable foot condition..

7. The orthotic device of claim 1, wherein further, the device can be used for; optimisation of foot function for sports personnel, to improve gait in a child, Prevention of pathology, to reduce the internal compression in the big toe joint, to reduce the risk of degeneration, to treat musculoskeletal pathologies, to treat compressive knee osteoarthritis, to limit the impact of rheumatoid Arthritis, to treat compressive medial knee osteoarthritis.

8. The orthotic device of claim 1, wherein the foot profile in step (c) describes any of the conditions or uses mentioned in claim 6 and 7.

9. A method of generating a electronic 3D model of an insole through computational device comprising:

   (a) processing of image data of the side image of feet to work out arch height, length and metatarsal point length from heel end;

   (b) processing the bottom image of the feet to carve out feet profile , heel and mid foot diameter ;

   (c) processing the back image of feet to check the deviation in achilles tendon from the normal;.

10. The method according to any one of the previous claims comprising a step of building a CAD model from which region of hardness and softness can be selected and printed.

FIGURES:

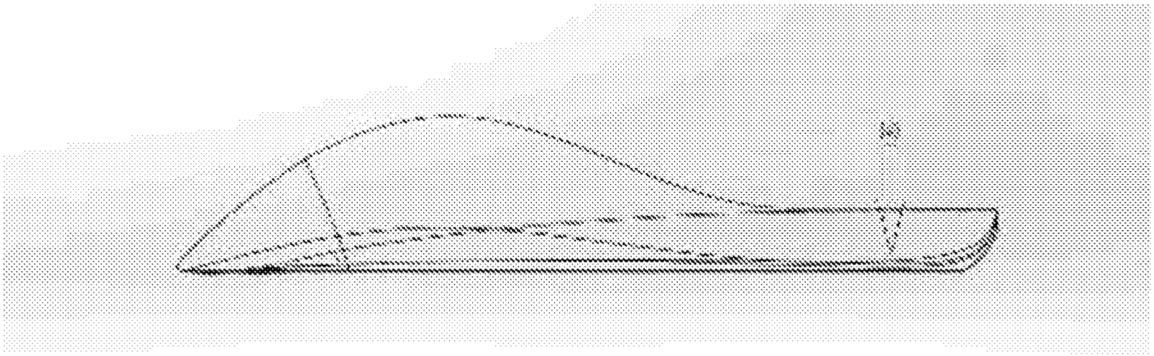

Fig.1: Insole where density of material is reduced at heel point or another soft material is used at the heel point (a).

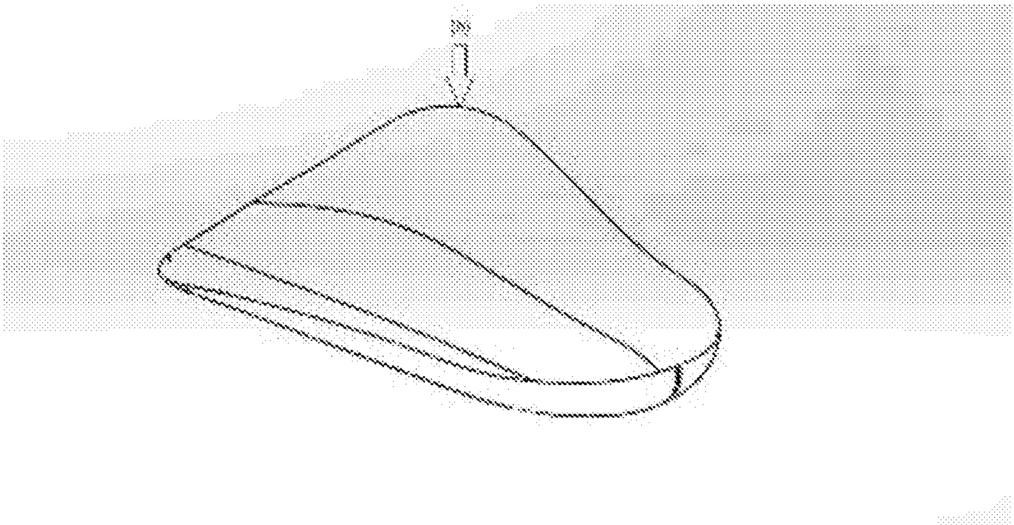

Fig.2: To provide strength and support infill percentage is increased at the arch support to make it firm and supportive.

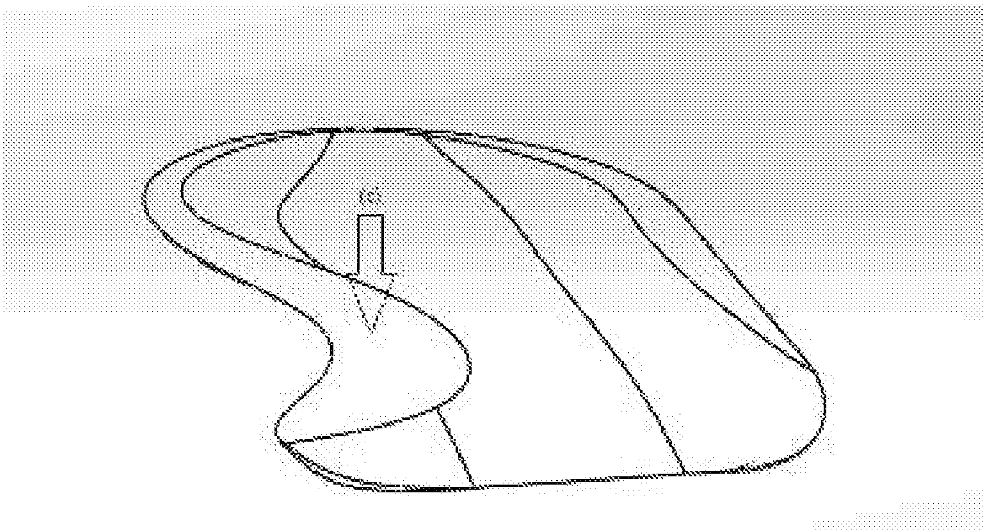

Fig.3: Orthotic device where glass fibres are used at (c) to make the structure firm in case of flexible material.

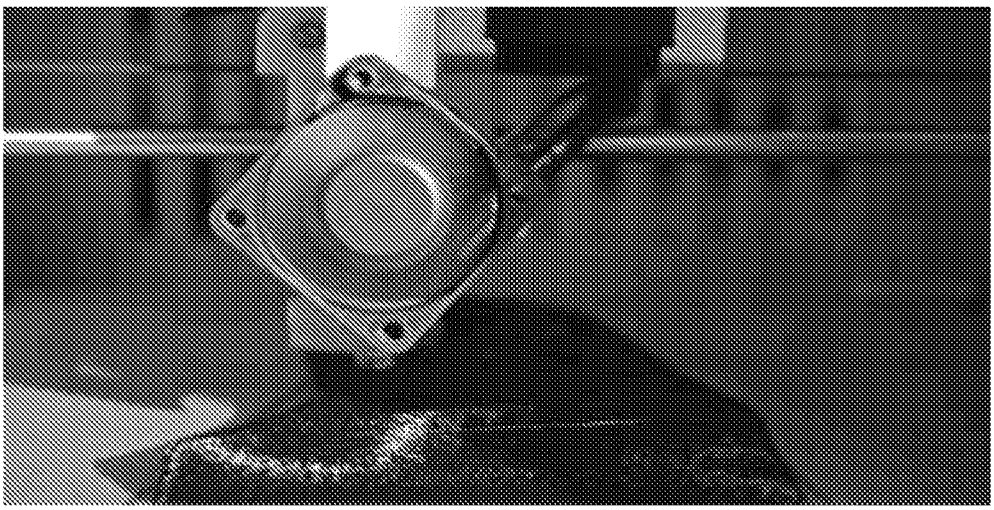

Fig.4: 3D printer adapted to manufacture the variable density custom orthotic from the 3D model by varying infill percentage of material in a selected infill pattern.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2017/050207

A. CLASSIFICATION OF SUBJECT MATTER
A43B7/28,G06T17/00,G06F17/50,B29C67/00,B33Y80/00 Version=2017.01

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)

A43B7, G06T,G06F,B29C,B33Y

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: Patseer, IPO Internal Database
Keywords: insole,3d printer,anisotropy,density,schema

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO2014014977A2 (TOW ADAM P) 23 January 2014 (23-01-2014) Paragraphs [0052],[0075],[0078],[0079],[0082],[0088],[0089],figures 1-9	1-10
Y	WO2016066750A1(RSPRINT N V (BE))06 May 2016(06-05-2016) Paragraphs [0035]-[0039],[0063],[0067], [0068],figures 1-3	1-10
Y	WO2015169942A1 (MATERIALISE NV) 12 November 2015 (12-11-2015) Paragraphs[0047],[0049],[0052],[0079],[088],Figures 1,2,3	1-10

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07-08-2017	07-08-2017

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT
Information on patent family members

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PCT/IN2017/050207

Citation	Pub.Date	Family	Pub.Date
WO 2014014977 A2	23-01-2014	EP 2874809 A2	27-05-2015
		US 2015165690 A1	18-06-2015
WO 2015169942 A1	12-11-2015	EP 3139785 A1	15-03-2017
		KR 20170015324 A	08-02-2017