18-02307-E

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, February 02, 2018 6:21 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.35 to the 12/31/07 10-K, filed by Occulogix, Inc. (now called TearLab Corp.) on 3/17/2008. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

February 26, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02307-E

Dear Mr. Edwards:

This letter is in response to your request, dated February 02, 2018 and received in this office on February 05, 2018, for information regarding Exhibit 10.35 to the Form 10-K (dated December 31, 2007), filed by Occulogix, Inc. (now called TearLab Corp.) on March 17, 2008.

The search for responsive records has resulted in the retrieval of 96 pages that may be responsive to your request. They are being provided to you with this letter in their entirety at no cost.

If you have any questions, please contact me at Luetkenhausj@SEC.GOV or (202) 551-8352. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Aaron Taylor as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Jason Luetkenhaus

Jason Luetkenhaus
Lead FOIA Research Specialist

Enclosures

EXHIBIT 10.35

Deacons

Dated October 25, 2007

Manufacturing and development agreement

Parties

MiniFAB (Aust) Pty Ltd
ACN 100 768 474

OcuSense, Inc.

Contact

Bernard O'Shea
Partner
Level 15, RACV Tower, 485 Bourke Street, Melbourne, Victoria 3000
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Email: bernard.oshea@deacons.com.au
Website: www.deacons.com.au
Our ref: 2626784

Contents

Manufacturing and Development Agreement dated October 25, 2007

Parties

MiniFAB (Aust) Pty Ltd ACN 100 768 474
of 9 The Centreway, Mount Waverley, Victoria 3149,
Australia (**MiniFAB**)

OcuSense, Inc.
of 12707 High Bluff Dr., Suite 200, San Diego, CA 92130,
U.S.A. (**OcuSense**)

Introduction

A. MiniFAB is a micro-nano-bio company that offers customised manufacturing and advanced product development services.

B. OcuSense is an in-vitro diagnostics company that is developing and desires to commercialise a proprietary tear testing platform, TearLab™, capable of accurately and rapidly diagnosing various eye diseases at the point-of-care.

C. MiniFAB and OcuSense are parties to that certain development agreement for a tear collection interface ("**TCI**") device comprised of Terms of Business and the Project Proposal for Project Tear-Sense (Stage 0), each dated 17 November 2006 (collectively, the "**Development Agreement**").

D. OcuSense wishes to acquire the services of MiniFAB in the manufacture and supply of the TCI Device developed under the Development Agreement, as well as potential development and manufacture of other TCI Devices, and MiniFAB has agreed to provide such services, on the terms of this Agreement.

It is agreed

1. Definitions and interpretation

1.1 Definitions

In this Agreement:

(1) **Agreement** means this document, including any schedule or annexure to it;

(2) **Annual Production Capacity** means, in respect of each Product, the quantity of the Product that MiniFAB is reasonably capable of manufacturing each year, and as varied in accordance with clause 3.5. The Annual Production Capacity for the First Product is specified in Schedule 1 and the Annual Production Capacity for the New Products is to be agreed between the parties pursuant to clause 5.8;

(3) **Business Day** means a day that is not a Saturday, Sunday or any other day which is a public holiday or a bank holiday in Melbourne, Australia;

(4) **cGMP** means current Good Manufacturing Practices, as established by the FDA;

(5) **Commencement Date** means October 19, 2007;

(6) **Commercially Reasonable Efforts** means the exercise of such efforts and commitment of such resources by MiniFAB as would be expended on, or committed by MiniFAB for, a comparable development or manufacturing program of a similar scope and at a similar stage in development or product lifecycle, comparable profit margin and potential, competitive landscape, and risk profile, in each case with due regard to the nature of efforts and cost required for such development or manufacturing and taking into account payments made by OcuSense, or obligated to be made by OcuSense, under this Agreement;

(7) **Confidential Information** of a party means any Information (and all tangible and intangible embodiments thereof of any kind whatsoever) provided by that party or its Representatives to the other party or its Representatives whether provided orally or in any form and is marked, identified as or otherwise acknowledged to be confidential at the time of disclosure to the other party; provided, however, that information, data and results generated by MiniFAB under the Development Agreement, or in the course of performing activities under this Agreement, that relate to OcuSense's technology or to the development of Products or prototypes thereof shall be deemed the Confidential Information of OcuSense;

(8) **Default Rate** means 10% per annum;

(9) **Delivery Point** means the premises of MiniFAB located at 1 Dalmore Drive, Scoresby, Victoria, AUSTRALIA;

(10) **Development Expenses** means all costs and expenses incurred by MiniFAB for the development of a New Product as more particularly described in clause 5.5(1)(a), but does not include the capital expenditures referred to in clause 5.5(1)(b);

(11) **Development Order** means a document substantially in the form set out in Schedule 2 executed by or on behalf of MiniFAB and OcuSense which details a New Product to be developed by MiniFAB in accordance with clause 5;

(12) **Development Request** has the meaning given in clause 5.2;

(13) **EXW** means "ex works", according to the Incoterms 2000 published by the International Chamber of Commerce (ICC) as amended from time to time;

(14) **FDA** means the United States Food and Drug Administration;

(15) **First Product** means the TCI Device developed under the Development Agreement, together with the capsule and applicable packaging, all as further described in Schedule 1;

(16) **Force Majeure** means any cause which is not within the reasonable control of the party affected by it including, but not limited to, acts of God, war declared or undeclared, civil disturbance, acts or omissions of government or other competent authority, fire, lightning, explosion or flood, but excludes any cause due to lack of demand or market success for the Products;

(17) **Governmental Agency** means any court, administrative agency or commission or other governmental agency, body or instrumentality, domestic or foreign;

(18) **Information** means any information or know-how pertaining to, or in the possession or control of, a party including, but not limited to, information concerning its business, systems, technology and affairs, such as:

(a) financial, technological, strategic or business information, concepts, plans, strategies, directions or systems;

(b) research, development, operational, legal, marketing or accounting information, concepts, plans, strategies, directions or systems;

(c) technology, source and object codes for computer software, intellectual property rights and technical and historical information relating thereto;

(d) customer and supplier information; and

(e) information relating to the Products;

(19) **Insolvency Event** in the context of a person means:

(a) a receiver, receiver and manager, official manager, trustee, administrator, other controller (as defined in the *Corporations Act 2001* (Cth)) or similar official is appointed, or steps are taken for such appointment, over any of the equipment or undertaking of the person;

(b) the person is or becomes unable to pay its debts when they are due or is or becomes unable to pay its debts within the meaning of the *Corporations Act 2001* (Cth) or is presumed to be insolvent under the *Corporations Act 2001* (Cth);

(c) the person ceases or threatens to cease to carry on business; or

(d) an application or order is made for the liquidation of the person or a resolution is passed or any steps are taken to liquidate or pass a resolution for the liquidation of the person otherwise than for the purpose of an amalgamation or reconstruction;

(20) **Intellectual Property** means any copyright, design (whether registered or unregistered), trademark (whether registered or unregistered), patent or patent application or invention, circuit layout, know-how, confidential information (whether such information is in writing or recorded in any other form) and other proprietary or personal rights arising from intellectual activity in the business, industrial, scientific or artistic fields;

(21) **Supply Start Date** has the meaning given in clause 3.2(2);

(22) **Loss** means any loss, damage, cost, interest, expense, fee, penalty, fine, forfeiture, assessment, demand, liability or damages incurred by a person to the extent resulting from any action, suit, claim, proceeding or cause of action brought against such party by a third party.

(23) **Minimum Orders** means, in respect of each Product, the minimum quantity of Product that OcuSense must purchase from MiniFAB during a specified period. The Minimum Orders are specified in clause 3.3(7);

(24) **New Products** means any TCI Devices developed pursuant to this Agreement and any other goods that the parties agree are New Products. For the avoidance of doubt, New Products do not include the First Product;

(25) **OcuSense IP** has the meaning given in clause 6.1;

(26) **Price** means, in respect of each Product, the price payable by OcuSense to MiniFAB for the supply of that Product, inclusive of all packaging, labelling and all other handling charges (other than the freight costs);

(27) **Products** means the First Product and any New Products;

(28) **Prototype First Product** means a pre-production prototype of the First Product conforming to the First Product Requirement Definitions, and may

include prototype units of the First Product at different stages of development (such as, for example, alpha prototypes and beta prototypes).

(29) **Purchase Order** has the meaning given in clause 3.4;

(30) **Quarter** means a period of three months commencing on 1 January, 1 April, 1 July or 1 October;

(31) **R&D Services** means those development services for New Products as specified in clause 5.1;

(32) **Registrations** means all registrations or approvals required from the relevant Regulatory Authority or Authorities for the export, import, storage, promotion, supply, sale or other distribution in the of the Products;

(33) **Regulatory Authority** means any Governmental Agency having responsibility for the regulation of, oversight of or whose approval is required for the manufacture, marketing, sale or supply of the Products or the facilities in which it is manufactured;

(34) **Regulatory Requirements** means, collectively:

(a) all laws and regulations and any and all other requirements of the FDA or any other Regulatory Authority that are mandatory to the manufacture, packaging, labelling, storage, handling and shipment of the Products by MiniFAB and, subject to clause 2.1, includes cGMP; and

(b) all standards set by the International Organization for Standardization (ISO) that are mandatory to the manufacture, packaging, labelling, storage, handling and shipment of the Products by MiniFAB, including without limitation ISO 13485:2003 (Medical Devices Quality Management System), ISO 10993-1 (Biocompatibility), ISO 10993-5 (Biocompatibility: Cytotoxicity), and ISO 10993-10 (Biocompatibility: Sensitization and Irritation), but excludes

(c) any law, regulation, requirement or standards that apply to the design, trials, marketing, sales or supply of the Products (and which do not also apply to the manufacture of Products and/or to MiniFAB's supply to OcuSense hereunder);

(35) **Representative** of a party means the employees, directors, agents or advisors of that party;

(36) **Requirement Definitions** means, with respect to any Product, the written documentation guiding MiniFAB's development of such Product, including detailed requirement definitions for such Product, as agreed by the parties. The initial Requirement Definitions for the First Product have been agreed by the parties as of the Commencement Date. The Requirement Definitions may be modified from time to time by mutual agreement of OcuSense and MiniFAB in the course of development work for such Product, and MiniFAB agrees to use Commercially Reasonable Efforts to accommodate changes to the Requirement Definitions as OcuSense may from time to time request;

(37) **Second Product** means the first New Product developed pursuant to this Agreement, which the parties intend to be a TCI Device similar to the First Product, provided that such product would be designed to measure either (i) a marker other than osmolarity, or (ii) both osmolarity and one other additional marker;

(38) **Specifications** means, with respect to any Product, the definitive written documentation guiding MiniFAB's manufacture, packaging, labelling, storage and handling of such Product, prepared and agreed in accordance with clause 3.1; in each case, and as modified from time to time by mutual agreement of OcuSense and MiniFAB in accordance with clause 10;

(39) **Successful Completion** has the meaning provided in clause 5.10;

(40) **TCI Device** means any tear collection interface device or any microfluidic based device;

(41) **Technical Agreement** means the technical agreement entered into between MiniFAB and OcuSense with respect to each Product, as may be amended from time to time, which specifies their respective responsibilities for quality control and quality assurance and related activities and qualifications with respect to the applicable Product. The Technical Agreement for the First Product shall be entered into concurrently with this Agreement. Mutually agreed Technical Agreements for other Products shall be entered into prior to commercial manufacture and supply of such Products;

(42) **Term** means the term of this Agreement, including any extended term under clause 15.1; and

(43) **Wholesale Price** of a Product at a particular time means the highest wholesale price at which OcuSense has sold such Product to third parties during the previous 3 months period.

1.2 **Interpretation**

(1) Reference to:

(a) one gender includes the others;

(b) a person includes a body corporate;

(c) a party includes the party's executors, administrators, successors and permitted assigns;

(d) a statute, regulation, code or other law or a provision of any of them includes:

(i) any amendment or replacement of it; and

(ii) another regulation or other statutory instrument made under it, or made under it as amended or replaced; and

(e) dollars means Australian dollars unless otherwise stated.

(2) "Including" and similar expressions are not words of limitation.

(3) Where a capitalized word or expression is given a particular meaning, other parts of speech and grammatical forms of that capitalized word or expression have a corresponding meaning.

(4) Headings and any table of contents or index are for convenience only and do not form part of this Agreement or affect its interpretation.

(5) A provision of this Agreement must not be construed to the disadvantage of a party merely because that party was responsible for the preparation of the Agreement or the inclusion of the provision in the Agreement.

(6) If an act must be done on a specified day which is not a Business Day, it must be done instead on the next Business Day.

1.3 **Parties**

(1) If a party consists of more than 1 person, this Agreement binds each of them separately and any 2 or more of them jointly.

(2) An obligation, representation or warranty in favour of more than 1 person is for the benefit of them separately and jointly.

(3) A party which is a trustee is bound both personally and in its capacity as a trustee.

2. Development of the First Product

2.1 Regulatory approvals and exemptions

As between the parties, OcuSense shall be responsible, in its discretion, for activities in seeking Registrations and other regulatory approvals from applicable Regulatory Authorities with respect to Products (including any CLIA waiver from the FDA in respect of the FDA 510(k) application for the OcuSense system which uses the Products developed under this Agreement).

2.2 Design Development completed

The parties agree that the development of the design for the First Product has been completed, and the Requirement Definitions of the First Product are as annexed to Annexure A.

2.3 Prototype Acceptance Testing

(1) The parties agree that MiniFAB has manufactured and supplied to OcuSense sufficient units of the Alpha Prototype First Product for the purposes of testing on or about 26 July 2007, and that prior to the Commencement Date, OcuSense has tested such units to determine whether the Alpha Prototype First Product is as described in "Design Specification Stage 1 Work package 1.1 Final Report", and has generated and provided MiniFAB with feedback regarding areas of improvement with respect to the First Product, to be addressed by MiniFAB prior to manufacturing and supplying OcuSense with the Beta Prototype First Product.

(2) The parties acknowledge that, as of the Commencement Date, manufacture, supply and testing of units of the Beta Prototype First Product has not yet occurred, and further acknowledge that the terms and conditions of the Development Agreement continue to apply with respect to such activities.

(3) MiniFAB will, in accordance with its obligations under the Development Agreement, develop and optimise its manufacturing process such that MiniFAB can manufacture the First Product to meet the Minimum Orders of the First Product.

3. Supply of Products

3.1 Specifications

(1) The initial Specifications for the First Product have been agreed by the parties prior to execution of this Agreement. Promptly after OcuSense's Acceptance of a New Product as set forth in clause 5.9, MiniFAB shall prepare, on the basis of the most recent Requirement Definitions for such New Product, and provide to OcuSense for approval, the definitive Specifications for the applicable Product, for MiniFAB's use to manufacture, package, label, store and handle the applicable Product.

(2) OcuSense will review the Specifications submitted by MiniFAB under clause 3.1(1) and may request amendments or modifications to the Specifications if:

(a) the Specifications are inconsistent with the Requirement Definitions;

(b) the Specifications are inconsistent with the Regulatory Requirements;

(c) the requirements of the Specifications are unreasonable or uncommercial having regard to the Price or proposed Price of the relevant Product; or

(d) the requirements of the Specifications are unrelated to the Product.

(3) MiniFAB must act reasonably and accommodate any requests for amendment to the Specifications made by OcuSense under clause 3.1(2).

(4) OcuSense must accept the Specifications when it is satisfied that the Specifications are consistent with the Requirement Definitions and the Regulatory Requirements, and are reasonable and commercial having regard to the Price or proposed Price of the relevant Product.

(5) The parties agree that the definitive Specifications for the First Product are set forth in Annexure B.

(6) The Specifications for any Product may be modified or amended by mutual written agreement of the Parties. In the event that OcuSense requests changes to the Specifications for reasons other than those set forth in clause 3.1(2) above, MiniFAB agrees to use Commercially Reasonable Efforts to accommodate such requested changes.

3.2 **Capital investments and Supply Start Date**

(1) MiniFAB will:

(a) in respect of the First Product – from the Commencement Date; and

(b) in respect of each New Product – in accordance with the project plan specified in the Development Order for that New Product,

use Commercially Reasonable Efforts to acquire, construct or develop such plant, equipment, raw materials, labour, utilities and capital improvements as are necessary to manufacture the Product to meet the Minimum Orders of that Product. MiniFAB shall set up the manufacturing process, manufacture the Products, and assemble and package the Products, all in accordance with the Specifications and all Regulatory Requirements. MiniFAB shall label the Products with such labels, tradenames, and trademarks as directed by OcuSense.

(2) MiniFAB will notify OcuSense when MiniFAB reasonably believes that it has the necessary plant and equipment to manufacture a particular Product to meet the Minimum Orders of that Product. Promptly following such notification by MiniFAB, the parties shall mutually agree on and set the date (**Supply Start Date** for that Product) on which OcuSense may begin placing binding Purchase Orders for that Product pursuant to clause 3.4.

(3) It is the intention of the parties that the Supply Start Date for the First Product shall take place no later than March 15, 2008 (the initial "**Cut-Off Date**"). If the Supply Start Date for the First Product has not taken place on or prior to the Cut-Off Date, then, provided that MiniFAB has used Commercially Reasonable Efforts to meet the Cut-Off Date, the parties will:

(a) meet and discuss the reasons for the failure;

(b) negotiate a mutually agreed remedy plan to address the reasons for the failure; and

(c) acting reasonably, agree on a revised Cut-Off Date, subject to clause 3.2(4) .

MiniFAB must implement the remedy plan and use Commercially Reasonable Efforts to meet the revised Cut-Off Date.

(4) The procedures described in clause 3.2(3) will apply for at least two times, but the revised Cut-Off Date shall not be later than sixty (60) days following the initial Cut-Off Date specified in clause 3.2(3), above. If MiniFAB fails to meet the Cut-Off Date for the third time, then OcuSense may immediately terminate this Agreement, which shall be effective upon written notice to MiniFAB.

3.3 **Supply and Purchase Obligations**

(1) MiniFAB shall manufacture the Products exclusively for OcuSense; and MiniFAB shall sell the Products exclusively to OcuSense or its designee; and MiniFAB shall not otherwise manufacture, sell, or distribute the Products to any third party. MiniFAB acknowledges that OcuSense may manufacture Products itself and/or engage one or more third parties in addition to MiniFAB to supply the Products to OcuSense.

(2) OcuSense agrees to order from MiniFAB at least seventy percent (70%) of the units of First Product required by OcuSense (including those it may make itself), until such time as OcuSense has purchased Nine Hundred Thousand (900,000) units of the First Product from MiniFAB. Thereafter, OcuSense shall order at least fifty percent (50%) of the units of First Product required by OcuSense (including those it may make itself) until the date eight (8) years after the Supply Start Date. The foregoing purchase obligations shall apply solely if and when MiniFAB supplies such First Product, (a) if any units of First Product are supplied to OcuSense by a third party manufacturer, at a Price equal to or below the price charged by such other suppliers, and (b) if any units of First Product are manufactured by OcuSense, at a Price equal to or below OcuSense's fully allocated cost (calculated on the same basis as MiniFAB's fully allocated cost) for the First Product, multiplied by the applicable Agreed Margin, as determined in accordance with clause 3.3(3). The parties shall cooperate in good faith to share with each other such information and documentation as necessary to enable the parties to perform the foregoing cost comparison. In the event OcuSense claims being excused from its purchase obligations under this clause 3.3(2) due to the results of a Price comparison performed pursuant to clause (b) of this clause 3.3(2), MiniFAB shall have the right, at its sole cost, to designate an independent accounting firm reasonably acceptable to OcuSense to audit OcuSense's books and records to verify the calculations of the OcuSense's fully allocated costs to determine the rights of the parties as described above in this clause 3.3(2). For clarity, if OcuSense orders sufficient units of the First Product to satisfy the obligations set forth in this clause 3.3(2), but MiniFAB does not accept such orders and/or MiniFAB does not supply such ordered quantities in accordance with this Agreement, failure by OcuSense to purchase such quantities shall not be a breach of OcuSense's obligations hereunder. In the event that a third party manufacturer agrees to supply units of the First Product to OcuSense, or OcuSense itself manufactures units of the First Product, under specifications requiring tighter manufacturing or performance tolerances, or lower variability, than the Specifications, OcuSense's obligations under this clause 3.3(2) shall not apply unless and

until such time as MiniFAB agrees to revise the Specifications under this Agreement to reflect such tighter manufacturing and/or performance tolerances, or lower variability. This clause 3.3(2) shall not be construed to require OcuSense to place orders in excess of the Annual Production Capacity.

(3) For the purposes of clause 3.3(2), **Agreed Margin** means:

(a) 160% if the Wholesale Price of the First Product is higher than $13.50 at the time the Price comparison under clause 3.3(2) is performed;

(b) 150% if the Wholesale Price of the First Product is $13.50 or lower and higher than $12 at the time the Price comparison under clause 3.3(2) is performed; and

(c) 140% if the Wholesale Price of the First Product is $12 or lower at the time the Price comparison under clause 3.3(2) is performed.

(4) MiniFAB hereby acknowledges that OcuSense needs to obtain a reliable supply of the Products that meets certain quality, quantity and timing requirements, and agrees to comply with the following **Supply Requirements**:

(a) subject to clause 3.2(3), ensure that the Supply Start Date for the First Product occurs on or prior to the Cut-Off Date;

(b) ensure that the Supply Start Date for the Second Product occurs on or prior to the applicable cut-off date as specified in the Development Order for the Second Product;

(c) ensure that each batch of Product are in full compliance with the Specifications (including without limitation any failure rates specified therein), the Technical Agreement, and the Regulatory Requirements; and

(d) ensure that, for each 3 month period, at least 95% of shipments of Products are delivered by the delivery date required under clause 3.6.

(5) If MiniFAB fails to comply with the Supply Requirements then, subject to clause 3.3(6):

(a) MiniFAB must provide OcuSense with the reasons for the non-compliance;

(b) the parties must meet and discuss the reasons given by MiniFAB;

(c) the parties must, acting reasonably, negotiate a mutually agreed remedy plan to address the reasons for the non-compliance; and

(d) MiniFAB must implement the agreed remedy plan.

(6) If MiniFAB fails to comply with the same Supply Requirement again within a period of 3 months after the first non-compliance, then MiniFAB is deemed to have committed a material breach of this Agreement for the purposes of clause 15.2(1).

(7) OcuSense shall have the following obligations to order Products from MiniFAB (the "**Minimum Orders**"):

(a) Order from MiniFAB (and, to the extent such orders are accepted and filled in accordance with this Agreement, purchase from MiniFAB) at least Nine Hundred Thousand (900,000) units of the First Product during the first three (3) year period (comprising years 1, 2 and 3) after the Supply Start Date for the First Product; and

(b) Order from MiniFAB (and, to the extent such orders are accepted and filled in accordance with this Agreement, purchase from MiniFAB) at least a further Nine Hundred Thousand (900,000) units of the First Product during the next period of two (2) years (comprising years 4 and 5 after the Supply Start Date for the First Product).

In addition, in the event of a Successful Completion with respect to the Second Product, and provided that the Specifications and agreed upon price for such Second Product are, in OcuSense's reasonable determination, satisfactory to support commercialization of the Second Product under then-current market conditions:

(c) Order from MiniFAB (and, to the extent such orders are accepted and filled in accordance with this Agreement, purchase from MiniFAB) at least three Million Australian Dollars (A$3,000,000) worth of units of the Second Product during the three (3) year period after the Supply Start Date for the Second Product.

(8) If OcuSense fails to meet the Minimum Orders requirement set forth in clause 3.3(7) after the relevant period (other than as a result of the inability or failure of MiniFAB to timely supply conforming Products in quantities ordered by OcuSense), then OcuSense must pay to MiniFAB the following minimum order penalties (as applicable):

(a) For shortfalls under clause 3.3(7)(a), an amount equal to seventy five percent (75%) of the Price of the Product payable multiplied by the difference between the Minimum Orders requirement set forth therein and the actual quantity of the Product ordered by OcuSense from MiniFAB during the period set forth therein;

(b) For shortfalls under clause 3.3(7)(b), an amount equal to fifty percent (50%) of the Price of the Product payable multiplied by the difference between the Minimum Orders requirement set forth therein and the actual quantity of the Product ordered by OcuSense from MiniFAB during the period set forth therein; and

(c) For shortfalls under clause 3.3(7)(c), an amount equal to X percent (X%) of the Price of the Product payable multiplied by the difference between the Minimum Orders requirement set forth therein and the actual quantity of the Product ordered by OcuSense from MiniFAB during the period set forth therein; where the percentage represented by "X" shall be determined by the parties in accordance with clause 5.8.

(9) OcuSense shall have no purchase obligations under this Agreement, except as expressly set forth in this clause 3.3. For the avoidance of doubt, subject to clauses 3.3(2), 3.3(7) and 3.3(8), OcuSense shall have the right to engage any third party to manufacture and supply any Products.

3.4 Forecast and ordering

(1) Not less than 3 months prior to the Supply Start Date for a Product and on or before the 1st date of each calendar month thereafter, OcuSense must submit to MiniFAB a non-binding forecast of the quantity of each of the Products that OcuSense expects to purchase in each of the 3rd through the 6th month following the month for which the forecast is due (e.g., the forecast due on January 1, 2010 would contain a forecast for April through June of 2010).

(2) OcuSense must order the Products 45 days prior to their requested delivery dates (as determined in accordance with clause 3.6) by sending binding written purchase orders to MiniFAB stating the Product, unit quantities and any other information reasonably required by MiniFAB from time to time (**Purchase Orders**). OcuSense may begin placing Purchase Orders for any particular Product commencing with the Supply Start Date for that Product. OcuSense shall use reasonable endeavours to ensure that the quantities of Products set forth in its Purchase Orders are consistent with the then-current forecast.

(3) A Purchase Order constitutes an irrevocable offer made by OcuSense to MiniFAB for the supply of the Products specified in the Purchase Order on the terms and conditions of this Agreement. Once received by MiniFAB, the Purchase Order is firm and may not be cancelled or modified without MiniFAB's prior written consent.

(4) Subject to clauses 3.4(5) or 3.5, MiniFAB must accept a Purchase Order if the quantity of the Product the subject of the Purchase Order is between 80% and 150% of the most recent forecast. In addition, MiniFAB agrees to use Commercially Reasonable Efforts to accept and satisfy Purchase Orders exceeding 150% of the most recent forecast. In the event that OcuSense places a Purchase Order that exceeds 150% of the most recent forecast, MiniFAB shall (i) accept the Purchase Order with respect to quantities at least equal to 150% of the most recent Purchase Order, and (ii) notify OcuSense in writing of those quantities (if any) exceeding 150% of the most recent forecast with respect to which MiniFAB is rejecting the Purchase Order.

(5) If MiniFAB believes, on reasonable grounds, that a Purchaser Order is materially incorrect or, to the extent a Purchase Order exceeds 150% of forecast amounts, it is not capable of satisfying the Purchase Order with respect to excess amounts so ordered, then MiniFAB may reject the Purchase Order and must notify OcuSense as soon as possible. If MiniFAB does not reject to a Purchaser Order within 5 Business Days of receipt of the Purchase Order, then MiniFAB is deemed to have accepted the Purchaser Order. Any rejection by MiniFAB of a Purchase Order that is not provided for in this clause 3.4(5) or 3.5 is deemed to be a material breach of this Agreement for the purposes of clause 15.2(1).

3.5 **Annual Production Capacity**

(1) Despite clause 3.4(4), MiniFAB may, in its absolute discretion, refuse to accept any Purchase Order for a particular Product if the Purchase Order would require MiniFAB to exceed the Annual Production Capacity of that Product during that year.

(2) The parties may, from time to time, vary the Annual Production Capacity of a particular Product by agreement in writing. If OcuSense requests MiniFAB to increase the Annual Product Capacity, the parties shall promptly confer and discuss such matter in good faith, and MiniFAB shall endeavor to inform OcuSense within thirty (30) days whether MiniFAB will agree to the requested increase in the Annual Production Capacity.

3.6 **Delivery**

MiniFAB will manufacture and deliver the Products EXW (Incoterms 2000) the Delivery Point within 45 days after the date of Purchase Order, unless the Purchase Order specifies a later delivery date. MiniFAB shall pay pre-pay all freight, insurance charges, taxes, import and export duties, inspection fees and other charges applicable to the transport and delivery of the Products, and add all such charges to

invoices to OcuSense as a separate line item at pass-through cost. MiniFAB shall use such shipping method and carrier, and shall provide such carrier with such shipping instructions, as specified by OcuSense. In the even that any two or more consecutive shipments ordered by OcuSense in accordance with clause 3.4 are delivered more than five (5) business days after the delivery date indicated in the first sentence of this clause 3.6, then OcuSense shall be entitled to a thirty percent (30%) discount on the Price of the actual Products in such shipments which were not actually delivered by the required delivery date. The parties acknowledge and agree that such discount is independent of, and without prejudice to, other applicable remedies that may be available to OcuSense for failures of MiniFAB to supply Products in accordance with this Agreement.

3.7 **Inspection and Nonconforming Goods**

(1) OcuSense must inspect the Products within 14 days after delivery (or such longer time as provided in the Technical Agreement) and must accept the Products if they meet the Specifications, the requirements of the Technical Agreement, and the Regulatory Requirements. If OcuSense fails to object in writing within the applicable period, then OcuSense must accept the delivered Products. OcuSense may reject the delivered Products only if the Products fail to meet the Specifications, the requirements of the Technical Agreement, and/or the Regulatory Requirements. If OcuSense rejects the delivered Products, OcuSense must provide MiniFAB in writing the reasons for the rejection and the reasonably available evidence to substantiate those reasons.

(2) If OcuSense rejects the relevant Product, then MiniFAB shall promptly supply conforming replacement Products as soon as possible, whether or not MiniFAB agrees that OcuSense properly rejected such Products. MiniFAB agrees to notify OcuSense in writing if such replacement Products will not be shipped within five (5) business days.

(3) If OcuSense properly rejected the original Products, then OcuSense's payment for the rejected Products shall be deemed payment for the replacement Products. If OcuSense was not entitled to reject the original Products, then OcuSense shall pay for both the rejected Products and the replacement Products.

(4) If the parties disagree whether OcuSense properly rejected the original Products, then the parties shall refer such matter to a mutually acceptable, independent testing laboratory (the **Testing Lab)** to determine whether such Products were properly rejected. The fees and costs of the Testing Lab shall be borne by OcuSense if the Testing Lab determines that the Products were improperly rejected and by MiniFAB if the Testing Lab determines that the Products were properly rejected. If the Testing Lab is unable to determine whether the rejected Products met the Specifications, the requirements of the Technical Agreement or the Regulatory Requirements, then either party may submit the matter to the dispute resolution process in clause 19.

(5) OcuSense may withhold payment for any rejected Products (and only the rejected Products) until:

(a) MiniFAB re-delivers conforming Products, or

(b) the Testing Lab or dispute resolution process determines that the Products rejected by OcuSense met the Specifications, the requirements of the Technical Agreement and the Regulatory Requirements.

3.8 **Technical Agreements**

MiniFAB and OcuSense shall enter into a Technical Agreement with respect to the First Product promptly following (and no later than sixty (60) days after) the Commencement Date, and the manufacture, production and supply of the First Product shall be conducted in accordance with such Technical Agreement. The parties shall enter into a Technical Agreement with respect to each New Product promptly following agreement upon the applicable Requirement Definitions, and no later than ninety (90) days prior to the applicable Supply Start Date for such New Product. MiniFAB and OcuSense shall determine in good faith those subcontractors (if any) performing any manufacturing activities with respect to Products with whom OcuSense shall enter into separate written technical or quality agreements. Technical Agreement will address matters such as shelf life, storage, release requirements, facility registrations, recordkeeping, retention and review of documentation, annual product review, shipping products only upon release, and the like, which are not addressed in this Agreement.

3.9 **Quality Control**

MiniFAB shall conduct all quality control testing of the Products supplied hereunder prior to shipment in accordance with the Technical Agreements and applicable Laws. MiniFAB shall, and shall cause its subcontractors to, retain records and samples of Products relating to such testing, and samples (identified by batch number) of Products supplied to OcuSense, in each case in conditions and for times as required by applicable Law (collectively, "Shipment Samples"), and shall provide OcuSense with reasonable access to the Shipment Samples for testing and other purposes on OcuSense's request. If OcuSense conducts quality control testing of Products supplied hereunder after delivery thereof to OcuSense, OcuSense shall also use the same analytical methodology as used by MiniFAB. Upon written request from OcuSense, MiniFAB shall provide a reasonably detailed description of the analytical methodology used by MiniFAB for quality control testing of the Products.

4. Price

4.1 **Fixed components**

The Price the Products is:

(1) in relation to the First Product:

(a) for the first 900,000 units of the Product, the "Initial Price" of the Product as specified in Schedule 1; and

(b) for all subsequent units of the Products, the "Subsequent Price" as specified in Schedule 1;

(2) in relation to the Second Product:

(a) for the first units of the Product up to the amount necessary to fulfil OcuSense's Minimum Order obligation described in clause 3.3(7)(c), as determined by mutual written agreement of the parties using a cost model as similar as reasonably practicable to the cost model used with respect to the First Product; and

(b) for all subsequent units of the Product, the price as revised in accordance with clause 4.2; and

(3) in relation to any New Product subsequent to the Second Product, as would be determined by mutual written agreement of MiniFAB and OcuSense.

4.2 **Price revisions**

(1) When the Minimum Orders requirement for the Second Product has been satisfied, the parties will meet and discuss any revision to the Price of the Second Product, with the intent that the price will be adjusted as mutually agreed by the parties to reflect:

(a) the fact that the initial capital expenses incurred by MiniFAB have been amortised;

(b) any further capital expenses incurred by MiniFAB to meet expected demand; and

(c) any cost savings and efficiency improvements (which will be shared equally unless otherwise agreed between the parties).

(2) The parties agree to act reasonably when negotiating the revision to the Price of the Second Product.

5. Development of New Products

5.1 **R&D Services**

(1) R&D Services for New Products include:

(a) project management services relating to the development of the New Product;

(b) assisting OcuSense in the development, validation and finalisation of the Requirement Definitions for the New Product;

(c) assisting OcuSense in the development, validation and finalisation of the Specifications for the New Product;

(d) using Commercially Reasonable Efforts to develop processes, methodology and technology to manufacture the New Product;

(e) using Commercially Reasonable Efforts to evaluate and recommend appropriate technology necessary to manufacture the New Product;

(f) using Commercially Reasonable Efforts to develop and construct plant and equipment necessary to manufacture the New Product; and

(g) such other services as specified in a Development Order.

(2) R&D Services exclude:

(a) the initial formulation of and research on the Requirement Definitions for the New Product;

(b) carrying out experiments, clinical tests or other validation methodologies in relation to the New Product;

(c) preparations or filings relating to obtaining Registration for the New Product;

(d) sales, distribution, marketing or public release of the New Product;

(e) patent review; and

(f) legal or other professional advisory services.

5.2 **Request for development**

(1) OcuSense may, from time to time, request MiniFAB in writing to provide R&D Services to develop a New Product (**Development Request**).

(2) Subject to clause 5.2(4), if and when OcuSense elects, in its discretion, to develop a Second Product, OcuSense agrees that it will provide an opportunity for MiniFAB to provide the R&D Services with respect to the Second Product, as follows:

(a) OcuSense shall provide a written Development Request for the Second Product pursuant to clauses 5.2(1) and 5.2(3);

(b) the parties shall discuss in good faith the anticipated activities under the Development Request and capabilities required to perform such activities;

(c) if MiniFAB does not wish to undertake to perform the applicable R&D Services for the Second Product, MiniFAB agrees to promptly notify OcuSense in writing;

(d) if MiniFAB wishes to perform the applicable R&D Activities for the Second Product, MiniFAB shall propose the financial terms under which it is willing to undertake the R&D Services specified in the Development Request; and

(e) if MiniFAB has appropriate capability to perform such R&D Activities for the Second Product as set forth in the Development Request, and offers to perform such activities on financial terms that are at least as favorable to OcuSense as other bids for conducting such R&D Services OcuSense receives from third parties with capability of performing such R&D Services, then OcuSense shall engage MiniFAB for the conduct of such R&D Services for the Second Product. In such event, the parties shall prepare and sign a mutually agreed written Development Order, which shall set forth the activities to be conducted, timelines, deliverables, financial terms, and other mutually agreed terms and conditions regarding such R&D Services. Such Development Order shall be consistent with the intellectual property provisions and other applicable terms and conditions of this Agreement.

Subject to the foregoing, OcuSense may engage any other person to provide R&D Services and OcuSense shall have no obligation to offer to MiniFAB the opportunity, or to engage MiniFAB, to perform any R&D Services. For clarity, OcuSense shall not be obligated to engage MiniFAB to perform R&D Services for any New Product other than the Second Product.

(3) A Development Request must include:

(a) a detailed description of the New Product;

(b) draft Requirement Definitions for the New Product; and

(c) a draft project plan including a proposed timetable.

(4) MiniFAB will consider a Development Request and notify OcuSense in writing whether or not MiniFAB accepts the Development Request within 20 Business Days of receipt of the request. If MiniFAB fails to respond within that time period, then it is deemed to have rejected the Development Request. To avoid doubt, MiniFAB is not required to provide any reason for rejecting a Development Request. It is understood that the Development Request is intended as an opportunity for the parties to negotiate terms and conditions on which MiniFAB may conduct the applicable R&D Services for OcuSense. Accordingly, (i) MiniFAB shall not be obligated to accept any Development Request, and (ii) except as expressly set forth in clause 5.2(2)(e) with respect

to the Second Product, OcuSense shall not be obligated to engage MiniFAB to conduct R&D Services. Without limiting the foregoing, if MiniFAB rejects (or is deemed to have rejected) the Development Request for the Second Product, then despite clause 5.2(2), OcuSense may engage another service provider to provide R&D Services in respect of that Development Request. OcuSense shall have no obligation to offer to MiniFAB any further opportunity, or to engage MiniFAB, to perform any R&D Services except as expressly set forth under clause 5.2(2).

5.3 **Development Order**

(1) If MiniFAB accepts a Development Request, then:

(a) MiniFAB will provide OcuSense with a revised draft project plan including proposed milestones and payment milestones; and

(b) the parties must meet within 20 Business Days of the acceptance to meet and discuss the Development Request with the intent to finalise a Development Order.

(2) The parties will act reasonably in negotiating the terms of the Development Order.

(3) To avoid doubt, neither party is bound by a Development Request, a Development Order or any obligations to develop a New Product until the relevant Development Order is signed by both parties.

5.4 **Provision of R&D Services**

(1) MiniFAB will provide the R&D Services in accordance with the relevant Development Order in a diligent and ethical manner, with due care and skill and to a high professional standard, in accordance with this Agreement, and all applicable Regulatory Requirements.

(2) MiniFAB will use Commercially Reasonable Efforts to meet any milestones agreed in the relevant Development Order. Each Development Order may specify the agreed-upon remedies that shall apply for any failure by MiniFAB to meet such milestones, or otherwise fail to perform the R&D Services in accordance with clause 5.4(1).

5.5 **Responsibilities of each party**

(1) MiniFAB is responsible for and will bear the costs and expenses associated with:

(a) the provision of the R&D Services in accordance with the relevant Development Order (**Development Expenses**); and

(b) the construction and acquisition of any plant and equipment and other related capital expenditures relating to the R&D Services.

(2) OcuSense will develop, validate and finalise the Requirement Definitions and the Specifications of the New Product in consultation with MiniFAB. MiniFAB will assist OcuSense in accordance with the R&D Services.

(3) OcuSense is solely responsible for and will bear all costs and expenses associated with all activities relating to the research and development of the New Product that are not expressly included as part of R&D Services or that are expressly excluded from the R&D Services.

5.6 **Ownership of Requirement Definitions and Specifications**

The Requirement Definitions and the Specifications of any Product and all Intellectual Property rights relating to any Product, the Requirement Definitions and the Specifications therefor are and will remain to be owned solely by OcuSense. MiniFAB hereby assigns all Intellectual Property subsisting in the foregoing to OcuSense.

5.7 **Payment for R&D Services**

OcuSense will pay MiniFAB for the provision of the R&D Services in accordance with payment milestones specified in the relevant Development Order.

5.8 **Other matters relating to Development Order**

Prior to the Successful Completion of a New Product, the parties will meet and negotiate (acting reasonably) the following items relating to the New Product:

(1) the Price for the New Product (provided that the Price for the Second Product is set in accordance with clause 4.1(2));

(2) the percentage applicable to calculating the amount payable under clause 3.3(8)(c)

(3) the Minimum Orders requirement for the New Product, if any (provided that the Minimum Order for the Second Product is set in accordance with clause 3.3(7)(c)); and

(4) the Annual Production Capacity for the New Product.

5.9 **Prototype Acceptance Testing**

(1) If required under the relevant Development Order, the parties will conduct acceptance testing of the New Product in accordance with this clause 5.9.

(2) Promptly upon completion of the development of the New Product, MiniFAB shall manufacture and supply to OcuSense a reasonable number of prototype units for the purposes of OcuSense's testing and evaluation, together with such documentation (including without limitation the QA test report), materials and equipment reasonably necessary for OcuSense to perform testing and evaluation of the prototype. It is understood that the mutually agreed Development Order may provide for the supply and testing of multiple sets of prototype units for the New Product at different stages of development (such as, for example, alpha prototypes and beta prototypes).

(3) OcuSense may reject the prototype of the New Product only if it does not conform to the Requirement Definitions. OcuSense must accept the prototype of the New Product if it conforms to the Requirement Definitions.

(4) If OcuSense rejects the prototype then OcuSense must notify MiniFAB of the reasons for such rejection and MiniFAB will have thirty (30) days to cure such defect or non-conformance or dispute Ocusense's rejection pursuant to the dispute resolution process under clause 19. OcuSense may require MiniFAB to resubmit revised prototype units to OcuSense for testing and evaluation until the prototype fully conforms to the Requirement Definitions of the Product.

(5) Upon OcuSense's acceptance of the New Product ("**Acceptance**"), OcuSense shall promptly inform MiniFAB in writing.

5.10 **Successful Completion**

Successful Completion in relation to a New Product means:

(1) if the relevant Development Order provides a definition – the meaning ascribed to that term in the Development Order; or

(2) the Acceptance of a New Product by OcuSense, as such term is defined in clause 5.9.

5.11 **Discontinuance – Unable to finalise Requirement Definitions**

If the parties are unable to finalise the Requirement Definitions for the New Products by the deadline specified in the relevant Development Order (or after a reasonable time if no such deadline is specified), then either party may discontinue the relevant Development Order by notifying the other party in writing, in which case OcuSense will be solely responsible for all Development Expenses incurred up to that point in time and any other unavoidable costs reasonably incurred by MiniFAB in connection with the discontinuance.

5.12 **Discontinuance – OcuSense**

OcuSense may discontinue the development of any New Product at any time upon written notice, in which case MiniFAB will invoice, and OcuSense must pay, all outstanding amounts that are payable in accordance with the payment milestones specified in the Development Order for the R&D Services actually rendered by MiniFAB prior to the termination of the relevant Development Order. It is understood and agreed that any R&D Services with respect to the Second Product and any other New Product will be undertaken in reasonable stages in order to provide OcuSense an opportunity to evaluate the results of the R&D Services in each such stage and to determine whether OcuSense, in its discretion, wishes to cease development of the Second Product or other New Product. In the event that OcuSense unilaterally discontinues development of the Second Product and terminates the corresponding R&D Services (other than as a result of MiniFAB's inability or unwillingness to conduct such R&D Services, or as set forth in clause 15.2) prior to MiniFAB's shipment of beta prototypes, then OcuSense agrees that it will provide an opportunity for MiniFAB to provide the R&D Services with respect to development of its next subsequent New Product (excluding any New Products then already under contract for development by third parties) as set forth in clause 5.2(2), subject to the terms of clause 5.2(4).

6. OcuSense Licence

6.1 **Limited licence**

(1) Subject to the terms and conditions of this Agreement, OcuSense grants to MiniFAB during the Term a limited, royalty free, non-exclusive licence (without the right to sublicense) under any Intellectual Property, know-how and technical information owned (or licensed with the right to sublicense) by OcuSense relating to the development or manufacture of the Products (**OcuSense IP**) to use OcuSense IP to perform MiniFAB's obligations under this Agreement (**OcuSense Licence**).

(2) MiniFAB may only use OcuSense IP to the extent necessary or desirable to develop and manufacture the Products and New Products or otherwise necessary for the purposes of this Agreement.

6.2 **Provision of OcuSense IP materials**

OcuSense will provide or otherwise make available all information and materials relating to the OcuSense IP known to or possessed by OcuSense that are reasonably necessary to enable MiniFAB to perform its obligations under this Agreement.

6.3 **Ownership of OcuSense IP and Improvements to OcuSense IP**

All OcuSense IP, and all improvements to OcuSense IP, including any modifications and developments made thereto by MiniFAB shall be the sole property of OcuSense and MiniFAB hereby assigns to OcuSense its entire right, title and interest therein. Such improvements, modifications and developments will be included in OcuSense IP and covered by the OcuSense Licence. All injection moulds directed to the Products, and all rights in and to such injection moulds, shall be owned by OcuSense and part of the OcuSense IP. MiniFAB will cooperate with OcuSense in good faith to assist OcuSense in such manner as OcuSense may reasonably request if such moulds are required to be duplicated, but may otherwise retain them whilst MiniFAB has an obligation to continue to manufacture the relevant Product. All OcuSense IP shall be treated by MiniFAB as Confidential Information of OcuSense. MiniFAB shall promptly disclose to OcuSense all improvements, modifications and developments to OcuSense IP made or conceived by or on behalf of MiniFAB, and provide OcuSense with copies of all information available to MiniFAB regarding such improvements, modifications and developments. To the extent any of the rights that the parties intend to be assigned by MiniFAB to OcuSense (as set forth in clause 5.6 and this clause 6.3) cannot be assigned by MiniFAB to OcuSense, MiniFAB hereby grants to OcuSense an exclusive, royalty-free, transferable, irrevocable, worldwide license (with rights to sublicense through multiple tiers of sub-licensees) to practice such non-assignable rights, title and interest. To the extent any of such rights can be neither assigned nor licensed by MiniFAB to OcuSense, MiniFAB hereby irrevocably waives and agrees never to assert such non-assignable and non-licensable rights, title and interest against OcuSense or any of OcuSense's licensees or successors in interest to such non-assignable and non-licensable rights.

6.4 **IP Warranties and indemnity**

(1) OcuSense warrants that OcuSense has the right and authority to grant MiniFAB the OcuSense Licence.

(2) OcuSense shall indemnify and at all times holds harmless MiniFAB against any Losses resulting from a third person's claim against MiniFAB alleging that the use of OcuSense IP by MiniFAB constitutes an infringement of any Intellectual Property of that third person; provided, however, that OcuSense shall not be obligated to indemnify MiniFAB, and MiniFAB shall indemnify and at all times hold harmless OcuSense against any such Losses (i.e., Loses arising from third party claims of infringement), to the extent the alleged infringement results from any modifications and developments made to OcuSense IP by MiniFAB other than in accordance with instructions contained in any Specifications.

6.5 **Termination of licence**

The OcuSense Licence terminates automatically upon the termination or expiry of this Agreement for any reason.

6.6 **Infringement and protection of OcuSense IP**

OcuSense is solely responsible for the protection, defence and maintenance of the OcuSense IP. However, MiniFAB will promptly notify OcuSense if MiniFAB is aware of any infringement of the OcuSense IP by any third person.

7. Obligations of MiniFAB

7.1 Cooperation with OcuSense

MiniFAB will (a) provide OcuSense with analytical and manufacturing documentation, internal progress reports, regulatory compliance files and quality assurance files, and other relevant information as requested by OcuSense regarding quality control for the Products supplied under this Agreement, (b) reasonably cooperate with OcuSense in responding to all requests for information from customers and the relevant Regulatory Authorities having jurisdiction to make such requests, and (c) on a quarterly basis, prepare and submit to OcuSense a production capacity development plan addressing MiniFAB's efforts to increase production capacity to meet OcuSense's forecasts, and participate in a review thereof with OcuSense. OcuSense must bear any reasonable pre-approved out-of-pocket costs incurred by MiniFAB pursuant to this clause 7.1. If OcuSense refuses to pre-approve any such reasonable costs described in the preceding sentence on request by MiniFAB, then MiniFAB is released from its obligations under this clause 7.1 in respect of the obligations that are subject of, and to the extent subject of, those costs that OcuSense refused to pre-approve.

7.2 Regulatory licences

MiniFAB must at its own cost obtain and comply with all necessary licences, consents, permits and regulations which may from time to time be required by the relevant Regulatory Authorities in Australia to carry out its development and manufacturing services under this Agreement. Without limiting the generality of the foregoing, prior to commencing the manufacture of the First Product, MiniFAB shall be certified to meet ISO 13485 for manufacturing. OcuSense is responsible for obtaining all Registrations and approvals for the export of the Products from Australia or supply of the Products anywhere in the world.

7.3 Batch records

Without limiting the generality of clause 7.1, on a monthly basis, MiniFAB must retain and furnish to OcuSense for analysis by OcuSense's Quality Department:

(1) samples of each batch of Products manufactured under this Agreement; and

(2) batch production and quality control records,

to the extent required by the Specifications and all applicable Regulatory Requirements.

7.4 Facility Audits

OcuSense shall have the right, during normal business hours and upon reasonable notice, to audit MiniFAB's facility at which the Products are manufactured for compliance with the Specifications, the Regulatory Requirements, and the terms and conditions of this Agreement. MiniFAB shall give OcuSense prior written notice (whenever reasonably feasible) of any Governmental Agency inspection of the MiniFAB facility, and MiniFAB shall permit a representative of OcuSense to be present at such inspection. MiniFAB shall promptly provide to OcuSense copies of all notices, correspondence and other materials delivered to or received from the Governmental Agency regarding such MiniFAB facility or the Products.

8. Meeting

8.1 During the Term, the parties will endeavour to meet at least every 6 months to discuss and review the state of the relationship between them. Each party must ensure that at least one of its senior representatives attend each meeting. Any such meeting may be teleconferenced.

8.2 Each party will alternate to organise the meeting. The party responsible for organising the meeting must prepare a formal agenda prior to the meeting and organise formal minutes to be taken and distributed to all attendees after the meeting takes place. Each party may provide its suggest agenda items. The compulsory topics for the agenda are as follows:

(1) review of previous minutes; and

(2) progress of any development and registration.

9. Payment and invoicing

9.1 Invoice

(1) In relation to the supply of Products, MiniFAB will invoice OcuSense on a monthly in arrears basis.

(2) In relation to the provision of R&D Services, MiniFAB will invoice OcuSense in accordance with the Development Agreement for the First Product and the payment milestone specified in the relevant Development Order for New Products.

9.2 Payment

OcuSense must pay all undisputed invoices within 40 days after receipt of the invoice or, if later, within 40 days after delivery of the relevant Products to the Delivery Point.

9.3 Interest

If OcuSense fails to pay an amount on the due date for any undisputed payment, OcuSense must pay MiniFAB interest at the Default Rate on that amount, calculated and payable monthly, computed from the due date until the amount is paid in full.

10. Amendments to Specifications

10.1 Compliance with Regulatory Requirements

In the event that OcuSense or MiniFAB becomes aware of any changes or any pending changes in any applicable Regulatory Requirements which could affect the manufacture of a Product, OcuSense or MiniFAB, as applicable must promptly notify the other party in writing of any such change or proposed change and the Specifications of that Product must then, if necessary be amended by mutual written agreement of the parties. Such change will become effective and binding on MiniFAB from a date agreed by the parties. Costs and expenses reasonably incurred by MiniFAB to implement the amendments to the Specifications required under this clause 10.1 may be reflected in the Price of Products as set forth in clause 10.3.

10.2 Voluntary changes

Either party may suggest changes in the Specifications of any of the Products by notifying the other party in writing in reasonable detail of such suggested changes. The parties must negotiate in good faith with a view to agreeing to the same and who will bear the cost of the same. If the parties agree in writing upon the suggested changes, including the lead-time for implementing such changes, the Specifications must be amended accordingly, and any such change will become effective and binding on MiniFAB from a date agreed by the parties. Notwithstanding the foregoing, OcuSense shall not be obligated to agree to any change to Specifications proposed by MiniFAB.

10.3 Cost of amendments to Specifications or changes in Regulatory Requirements

Unless otherwise agreed by the parties, it is understood that the Price of applicable Products will be adjusted up or down by an amount equal to the increase or decrease

in MiniFAB's costs (as determined by the parties' mutually agreed cost model, which shall not include amounts allocable to other products or to facilities or equipment not utilized for Products) as a result of changes in Regulatory Requirements and/or changes in the Specifications. Subject to clauses 10.1 and 10.2, OcuSense is responsible for all pre-approved reasonable out-of-pocket costs and expenses incurred by MiniFAB to implement any changes to the Specifications under this clause 10. It is understood and agreed that if OcuSense pays for the purchase of capital equipment under this clause 10.3, then (i) OcuSense shall be the owner of such equipment, (ii) such equipment shall not be used in the manufacture or testing of any products other than Products, and (iii) and the parties shall reasonably cooperate to execute and file such documents as are reasonably required to evidence and protect OcuSense's ownership interest in such equipment. In the event MiniFAB proposes an upward adjustment in the Price of any Product under this clause 10.3, OcuSense shall have the right, at its sole cost, to designate an independent accounting firm reasonably acceptable to MiniFAB to audit MiniFAB's books and records to verify the amount of the cost increase claimed by MiniFAB to determine the rights of the parties as described above in this clause 10.3.

11. Registrations, safety and Product liability

11.1 Registrations of Products

OcuSense is responsible for the sales, marketing and distribution of the Products, and is also responsible for:

(1) obtaining all necessary Registrations for the Products; and

(2) maintaining records of all sales of Product sufficient to adequately administer a recall, market withdrawal or correction for such period as is required under applicable regulations.

MiniFAB agrees to maintain all applicable records relating to the manufacture of the Products supplied hereunder for a period of 5 years after the Product is supplied hereunder, as more particularly set forth in the Technical Agreement. Thereafter, MiniFAB shall notify OcuSense in writing before destroying any such records and, if requested by OcuSense, agrees to transfer all such records to OcuSense or its designee at OcuSense's expense.

11.2 Adverse events

OcuSense must promptly disclose to MiniFAB during the Term any information it acquires which relates to the safety of the Product, including, inter alia, all side effects, injury, toxicity or sensitivity reactions including unexpected or increased incidence and severity thereof. All such information will be treated as Confidential Information of OcuSense.

11.3 Notification of defects

In the event that MiniFAB becomes aware of any defect in the Product it will immediately notify OcuSense in writing and provide it with a full disclosure of the defect or non-compliance.

11.4 Recalls

(1) The parties each must notify the other promptly and in writing if any Product is requested or required to be the subject of a recall, market withdrawal or correction (**Recall**).

(2) OcuSense is solely responsible for the handling and disposition of any Recall and will assume all regulatory responsibility for such matters, including responsibility for all communications with the relevant Governmental

Agencies. MiniFAB shall diligently cooperate with OcuSense in the administration of any recall.

(3) If a Recall is due to a non compliance with the Specifications or the Regulatory Requirements of the Product that is caused by the fault MiniFAB then MiniFAB will bear the reasonable cost of the Recall. In all other cases OcuSense is solely responsible for the cost of the Recall.

12. Insurance

12.1 Required Insurance from MiniFAB

MiniFAB must take out prior to the Cut-Off Date, and thereafter maintain during the Term:

(1) all insurances required by law, including workers compensation insurance in accordance with relevant law; and

(2) public liability insurance for an amount of not less than A$5 Million per claim and in the aggregate.

12.2 Required Insurance from OcuSense

OcuSense must take out prior to the Cut-Off Date, and thereafter maintain during the Term:

(1) all insurances required by law, including workers compensation insurance in accordance with relevant law; and

(2) product liability insurance for an amount of not less than US$5 Milion per claim in the aggregate.

12.3 Evidence of insurance

Each party must, if reasonably requested by the other party, provide the other party with evidence that the each insurance required to be taken out by the party pursuant to this clause 12 exists and is current.

13. Warranties

13.1 Product warrantles

MiniFAB warrants that (a) the Products manufactured by MiniFAB under this Agreement will comply with the Specifications of the Products and shall be free from defects in material and workmanship, and (b) MiniFAB's facility for manufacture of Products shall be maintained and operated in compliance with all applicable Regulatory Requirements, and all Products shall be manufactured, packaged, labelled, stored, handled, and shipped by MiniFAB in compliance with all applicable Regulatory Requirements and the applicable Technical Agreement.

14. Third party licensors and contractors; Technology Transfer

14.1 Sub-Contractors

Except with respect to laser ablation and etching and injection molding activities, which activities shall be conducted at MiniFAB's facilities unless otherwise agreed by the parties, MiniFAB may engage sub-contractors to perform MiniFAB's obligations under this Agreement upon express prior written consent of OcuSense, which consent shall not be unreasonably withheld. Without limitation, it is agreed that if OcuSense is not comfortable that a proposed sub-contractor has the requisite capabilities and that such proposed sub-contractor will protect OcuSense's intellectual property rights and that such proposed sub-contractor will comply with the terms and conditions set forth in this Agreement (including assignment of intellectual

property), or if such proposed sub-contractor is involved in the manufacture, development or commercialization of products competing with the Products, then it shall be reasonable for OcuSense to withhold approval of such proposed sub-contractor. The appointment of sub-contractors shall not affect or diminish MiniFAB's responsibilities and obligations under this Agreement, and MiniFAB shall ensure the compliance of each such subcontractor with the confidentiality obligations and other obligations of MiniFAB set forth in this Agreement. If OcuSense engages a third party to manufacture the Products, it will impose similar restrictions to the foregoing on that third party.

14.2 **Cooperation with Sensortec**

MiniFAB acknowledges that OcuSense has entered into that certain development and option agreement with Sensortec Limited ("**Sensortec**"), pursuant to which Sensortec may provide certain services and a license with respect to certain of its technology, in each case pertaining to the manufacture of the Products. MiniFAB agrees that upon request of OcuSense, MiniFAB shall coordinate its activities under this Agreement with Sensortec, as may be necessary or useful for MiniFAB's and Sensortec's performance of their respective obligations to OcuSense regarding the Product. Upon request of MiniFAB, OcuSense shall act as a liaison between MiniFAB and Sensortec to facilitate productive cooperation between them.

14.3 **Non exclusive arrangement**

Nothing in clause 14.2 prevents either party from contracting with Sensortec independently for purposes unrelated to this Agreement.

14.4 **Evaluation and licensing of other third party technology**

If the parties agree or MiniFAB recommends (pursuant to the provision of R&D Services) that a particular technology is necessary to manufacture any New Product, then OcuSense will evaluate such recommendation, and if OcuSense determines in its sole discretion that licensing of such technology is desirable, OcuSense will be solely responsible for procuring (at its own cost and expenses) the requisite licences from the owner of that technology for the purposes of including the relevant technology in the New Product.

14.5 **Technology Ownership and Licensing; Technology Transfer**

(1) OcuSense shall retain ownership of any pre-existing intellectual property rights in materials and information provided by OcuSense to MiniFAB for use by MiniFAB for the purposes of undertaking activities under this Agreement. MiniFAB shall retain ownership of any pre-existing intellectual property rights in materials, information, tools and methodologies provided by MiniFAB for the purposes of undertaking activities under this Agreement (and any improvements to them, except to the extent that those improvements comprise patented or unpatented intellectual property owned or controlled by OcuSense or that have application in the field of measuring osmolarity or osmolality of, or other characteristic of or any biomarker in, human tear fluid) (collectively, "**MiniFAB Background IP**") and MiniFAB hereby grants OcuSense a worldwide, non-exclusive, royalty-free license (with the right to grant and authorize sublicenses) to make, have made, use, offer for sale, sell and otherwise exploit MiniFAB Background IP as may be required to make, have made, use, offer for sale, sell and otherwise exploit Licensed Products or incorporated into processes or procedures for manufacturing or testing Licensed Products. As used herein, "**Licensed Product**" means any article, item, product, equipment, process, data, report or other deliverable designed or developed in whole or part for OcuSense by MiniFAB under the Development Agreement or this Agreement, whether or not such development

or design is completed or successfully meets intended criteria, including without limitation the First Product, Second Product and any other New Products developed in whole or part under the Development Agreement or in R&D Services performed by MiniFAB under this Agreement.

(2) Subject to clause 14.5(1) and the requirement for OcuSense to pay MiniFAB all outstanding fees and charges due to MiniFAB, MiniFAB agrees to assign and hereby assigns to OcuSense all right, title and interest in and to any trade dress, trademarks and design registrations or design patents, and any inventions, whether patentable or not, and any other discoveries, trade secrets or know-how which:

(a) are embodied in a Licensed Product; and

(b) were made, developed, conceived or first reduced to practice by or for MiniFAB as a direct result of MiniFAB undertaking activities under the Development Agreement or this Agreement

along with all patents, copyrights, and any other intellectual property rights therein, including the right to apply for and maintain the rights described in this clause 14.5(2) in all countries worldwide (such rights comprising the '**Project IP**') and MiniFAB will (at the OcuSense's request and cost) do those things that may be reasonably necessary to effect the registration of such intellectual property. OcuSense must provide to MiniFAB full details (including copies of all relevant documentation) of any application for registration (whether as a registered patent, a registered design or otherwise) of the Project IP or any part of it.

(3) At any time during the term of this Agreement, or in the event of any termination of this Agreement, OcuSense shall have the right to require MiniFAB:

(a) to provide all reasonable assistance as requested by OcuSense, including without limitation transfer of technology, materials, information and documentation, to enable OcuSense to manufacture the Products internally or to secure the production and supply of the Products by a third party contractor (whether or not all or part of such technology, materials, information and documentation falls within the MiniFAB Background IP owned by MiniFAB); and

(b) to provide OcuSense with the consultancy services of all key engineering personnel of MiniFAB to effect or support such transfer of technology and/or the license to MiniFAB Background IP.

OcuSense shall pay MiniFAB for the time spent by MiniFAB's key personnel in conducting such technology transfer activities as may be requested by OcuSense, at MiniFAB's reasonable and customary rates for similar consultancy, and shall reimburse MiniFAB's out-of-pocket expenses incurred in conducting such technology transfer.

(4) All MiniFAB Background IP shall be treated by OcuSense and its sublicensees and their third party manufacturers as Confidential Information of MiniFAB; provided, however, that (i) OcuSense may disclose the MiniFAB Background IP to actual and potential investors, sublicensees, advisors and/or contract manufacturers of Licensed Products, in each case under reasonable and customary terms of confidentiality; and (ii) OcuSense and its sublicensees and contract manufacturers may disclose such information as is reasonably necessary in seeking regulatory approvals in connection with the manufacture, clinical development, use or commercialization of Licensed Products. For

clarity, this clause 14.5(4) shall not be construed to prevent the use of MiniFAB Background IP in under authority of the license set forth in clause 14.5(1) above.

(5) This clause 14.5 will survive termination of this Agreement.

15. Term, breach and termination

15.1 Term

(1) This Agreement commences on the Commencement Date and continues for an initial period of ten (10) years after the Commencement Date.

(2) This Agreement shall automatically renew for additional terms of three (3) years each, unless either party provides the other party with a written notice of non-renewal at least 180 days prior to the scheduled expiration of the then-current term.

15.2 Termination for cause

Notwithstanding clause 15.1, either party may terminate this Agreement effective immediately upon the giving of written notice to the other party (**Defaulting Party**) if:

(1) the Defaulting Party commits a material breach of this Agreement and fails to correct the breach within 30 days after written notice to do so;

(2) the Defaulting Party fails to carry out any material provision of this Agreement and the failure is not capable of remedy; and/or

(3) an Insolvency Event occurs in relation to the Defaulting Party.

In the event that OcuSense is entitled to terminate this Agreement under clause 15.2(1) or 15.2(2) above and the applicable default or breach relates to the R&D Services under one or more Development Orders, OcuSense may, in its discretion, elect to terminate such Development Orders without terminating this Agreement with respect to manufacture and supply of Products.

15.3 Effect of termination

(1) Upon termination or expiry of this Agreement for any reason other than for material breach by MiniFAB or due to an Insolvency Event in relation to OcuSense, MiniFAB will complete the delivery of all outstanding Purchase Orders.

(2) Upon termination of this Agreement for material breach by MiniFAB, OcuSense may elect to cause MiniFAB to complete the delivery of all outstanding Purchase Orders or to cancel any or all outstanding Purchase Orders (in whole or in part).

(3) Upon termination or expiry of this Agreement for any reason

(a) OcuSense must pay all outstanding undisputed invoices for all completed Purchase Orders;

(b) all Development Orders are deemed to be discontinued and:

(i) if this Agreement is terminated under clause 15.2 and MiniFAB is the Defaulting Party, then MiniFAB will be responsible for all Development Expenses incurred; and

(ii) if this Agreement is terminated for any other reason, then OcuSense must pay MiniFAB all Development Expenses incurred and any other unavoidable costs incurred by MiniFAB

in connection with the termination, as set forth in clause 5.12; and

(c) each party must immediately return the Confidential Information of the other party to the other party.

(4) Except as provided in clause 15.4, termination is without prejudice to the rights of either party for any prior breach.

15.4 **Termination Fee**

(1) If this Agreement is terminated for any reason, other than where MiniFAB is the Defaulting Party, and the Minimum Orders requirements set forth in clause 3.3(7) have not been satisfied on or before the effective date of termination (other than as a result of the inability or failure of MiniFAB to timely supply conforming Products in quantities ordered by OcuSense), then OcuSense shall be deemed to have failed to meet the Minimum Orders requirement, and shall pay MiniFAB the amounts specified in clause 3.3(8).(**Termination Fee**); provided, however, the Termination Fee shall not include any amounts with respect to Minimum Orders requirements for Second Products as set forth in clause 3.3(7)(c) and 3.3(8)(c) unless such termination is effective after the date MiniFAB notifies OcuSense pursuant to clause 3.2(2) that MiniFAB has put in place the necessary plant and equipment to manufacture the Second Product to meet the Minimum Orders of that Product.

(2) The parties acknowledge and agree that (i) the Termination Fee is a genuine pre-estimate of the anticipated loss or damage which would be suffered by MiniFAB as a result of the early termination of this Agreement, (ii) the agreed upon Termination Fee shall be in lieu of any actual or alleged damages, losses or harm to MiniFAB resulting from such Termination and/or from any failure of OcuSense to order or purchase Products from MiniFAB under this Agreement (**Termination Losses**), and (iii) MiniFAB waives its right to seek recovery or reimbursement of all Termination Losses other than the Termination Fee.

15.5 **Survival**

All clauses that by their nature survive expiration or termination of this Agreement will remain in force. For the avoidance of doubt, clauses 1, 5.6, 6.3, 6.4(2), 11.1, 11.4, 13, 14.5, 15, 16, 17, 18, 19, 21 and 22 survive termination.

16. Liability and indemnity

16.1 **Indemnity by OcuSense**

OcuSense shall indemnify MiniFAB and its Representatives against all Losses incurred by them as result of claims by third persons against MiniFAB arising directly or indirectly as a result of:

(1) any grossly negligent, unlawful, fraudulent or wilful misconduct committed by OcuSense or its Representatives in the performance of this Agreement;

(2) the marketing, promotion, sale or supply of the Product by OcuSense; or

(3) OcuSense's failure to obtain, maintain or comply in any respect with any Registrations,

except, in each case, to the extent Losses result from any event described in clause 16.2.

16.2 **Indemnity by MiniFAB**

MiniFAB shall indemnify OcuSense and its Representatives against all Losses incurred by them as a result of claims by third persons against OcuSense arising directly or indirectly, to the extent resulting from:

(1) any grossly negligent, unlawful, fraudulent or wilful misconduct committed by MiniFAB or its Representatives in the performance of this Agreement;

(2) any manufacturing defect in any Product supplied by MiniFAB to OcuSense, or any failure of any such Product to conform to the Specifications or the Regulatory Requirements therefor; or

(3) MiniFAB's failure to obtain and maintain all necessary governmental permits for the development and manufacture of Products hereunder.

16.3 **General provisions applicable to indemnities**

A party (the "Indemnitee") that intends to claim indemnification under this clause 16 shall promptly notify the other party (the "Indemnitor") of any claim, demand, action or other proceeding for which the Indemnitee intends to claim such indemnification. The Indemnitor shall have the right to assume and control the defense thereof with counsel selected by the Indemnitor; provided, however, that the Indemnitee shall have the right to retain its own counsel to participate in the defense, subject to Indemnitor's right to control the defense. The indemnity obligations under this clause 16 shall not apply to amounts paid in settlement of any Loss if such settlement is effected without the prior express written consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver notice to the Indemnitor within a reasonable time after notice of any relevant claim, or the commencement of any such action or other proceeding shall not relieve such Indemnitor of all liability to the Indemnitee under this clause 16 with respect thereto, but if such failure is prejudicial to the Indemnitor's ability to defend such claim, and if such prejudice results in Losses that otherwise would likely have been avoided or reduced if timely notice had been given, then the Indemnitor shall be relieved of said part of the Losses. The Indemnitor may not settle or otherwise consent to an adverse judgment in any such claim, that diminishes the rights or interests of the Indemnitee without the prior express written consent of the Indemnitee, which consent shall not be unreasonably withheld or delayed (it being understood that no consent by the Indemnitee is required for the Indemnitor to obtain a full release of all claims by a third person against an Indemnitee in exchange solely for the payment of a settlement amount by Indemnitor). The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any claim covered by this clause 16. The indemnities contained in this clause 16 do not negate the obligation of the party having the benefit of such indemnity to mitigate its losses; and are continuing obligations on each party, separate and independent of any other obligation.

16.4 **No consequential damages**

Except for any liability under clause 18 or the indemnity provided under clauses 16.1 or 16.2, to the extent permitted by law, neither party will be liable to the other party in any circumstances for any special, incidental, punitive, exemplary, consequential or any other indirect loss or damage, or in any event for any loss of revenue, loss of production, loss of profit or loss of data.

17. Goods and services tax

17.1 In this clause 17:

(1) **GST** means GST as defined in *A New Tax System (Goods and Services Tax) Act 1999* as amended (**GST Act**) or any replacement or other relevant legislation and regulations;

(2) words or expressions used in this clause which have a particular meaning in the **GST law** (as defined in the GST Act, and also including any applicable legislative determinations and Australian Taxation Office public rulings) have the same meaning, unless the context otherwise requires;

(3) any reference to GST payable by a party includes any corresponding GST payable by the representative member of any GST group of which that party is a member;

(4) any reference to an input tax credit entitlement by a party includes any corresponding input tax credit entitlement by the representative member of any GST group of which that party is a member; and

(5) if the GST law treats part of a supply as a separate supply for the purpose of determining whether GST is payable on that part of the supply or for the purpose of determining the tax period to which that part of the supply is attributable, such part of the supply is to be treated as a separate supply.

17.2 Unless GST is expressly included, the consideration to be paid or provided under any other clause of this Agreement for any supply made under or in connection with this Agreement does not include GST.

17.3 To the extent that any supply made under or in connection with this Agreement is a taxable supply, the GST exclusive consideration otherwise to be paid or provided for that taxable supply is increased by the amount of any GST payable in respect of that taxable supply and that amount must be paid at the same time and in the same manner as the GST exclusive consideration is otherwise to be paid or provided. A party's right to payment under this clause is subject to a valid tax invoice being delivered to the recipient of the taxable supply.

17.4 To the extent that one party is required to reimburse or indemnify another party for a loss, cost or expense incurred by that other party, that loss, cost or expense does not include any amount in respect of GST for which that other party is entitled to claim an input tax credit.

18. Confidentiality

18.1 Prohibited acts

Neither party may, without the other party's prior written consent, copy or disclose or cause to be copied or disclosed any Confidential Information of the other party other than to the extent that such Confidential Information must be disclosed:

(1) to the party's sub-contractors, employees, legal advisers, auditors, investors or other consultants in order for this Agreement to be performed, provided that the recipients of the information undertake in writing to the party to keep that information strictly confidential; or

(2) to Regulatory Authorities as required to obtain or maintain any regulatory approvals.

18.2 **Permitted uses**

Each party may only make use of Confidential Information of the other party to the extent necessary to enable the party to perform its obligations or exercise its rights under this Agreement.

18.3 **Excluded information**

For the purposes of this clause, Confidential Information does not include any information which the receiving party can establish:

(1) was in the public domain when it was disclosed to the receiving party;

(2) becomes, after being disclosed to the receiving party, part of the public domain, except through disclosure contrary to this Agreement;

(3) was already in the receiving party's possession when it was disclosed to the receiving party and was not otherwise acquired from the other party directly or indirectly; or

(4) was lawfully disclosed to the receiving party by a third party having the unrestricted legal right to disclose that information without requiring the maintenance of confidentiality.

Prior to making a disclosure of information which the receiving party alleges is no longer or never was Confidential Information by virtue of falling within one of the above exceptions, the receiving party must give to the other party 10 Business Days notice of the proposed disclosure and the reasons for the exception applying.

18.4 **Compulsory disclosures**

The obligations of confidentiality in this clause do not apply to a receiving party where the receiving party is required under the lawful compulsion of any court, tribunal, authority or regulatory body to disclose any Confidential Information of the other party. Provided that before a party discloses any Confidential Information pursuant to the foregoing it must provide the other party with reasonable notice to enable it to seek a protective court order or other remedy in respect of the Confidential Information, and it must provide the other party with all assistance and co operation which the other party considers necessary to obtain such protective court order or other remedy.

18.5 **Protection of information**

Each party must notify the other party in writing immediately upon the discovery of any apparent unauthorised use or disclosure of any Confidential Information and take all reasonable steps to enforce the confidentiality obligations imposed or required to be imposed by this clause 18 including diligently prosecuting at its cost any breach or threatened breach of any such confidentiality obligations by any person to whom it has disclosed or allowed access to the Confidential Information or at the other party's option making all reasonable efforts to assist the other party to help regain possession of the Confidential Information and prevent any further unauthorised disclosure or use.

18.6 **Confidentiality of agreement**

The parties must maintain absolute confidentiality concerning the existence and subject matter of this Agreement and no public announcement or communication relating to the negotiations of the parties or the existence, subject matter or terms of this Agreement may be made or authorised by a party without the prior written approval of the other party except that the following disclosures may be made in relation to this Agreement:

(1) by either party to its sub-contractors, employees, auditors, consultants, professional advisers, bankers, financial advisers, financiers, investors and potential investors upon those persons undertaking to keep confidential any information so disclosed; or

(2) to comply with any applicable law or requirement of any Governmental Agency or of any public stock exchange on which shares of the disclosing party are listed.

18.7 **Return of Confidential Information**

Each party agrees that on termination or expiration of this Agreement it will deliver to that other party any and all materials containing or embodying that other party's Confidential Information and any copies thereof; provided that each party shall be entitled to retain one (1) copy of the other party's Confidential Information, to be kept at such party's legal files for use solely for the purpose of ensuring continued compliance with the terms of this Agreement.

19. Disputes

19.1 **Attempt to Settle**

If a dispute arises between the parties in connection with this Agreement then the parties must use all reasonable endeavours acting in good faith to settle the dispute as soon as practicable.

19.2 **Limitations on Court Proceedings**

A party must not commence court proceedings in relation to a dispute arising in connection with this Agreement until it has exhausted the procedures in this clause 19, unless the party seeks urgent interlocutory relief.

19.3 **Disputes relating to Product**

If the dispute relates to whether or not a particular Product meets the Specifications and the Regulatory Requirements, then the parties must submit the dispute to an independent laboratory, which will act as an expert in determining whether or not the Product meets the Specifications and the Regulatory Requirements; provided, however, that if it is not technically feasible to make such independent laboratory determination in connection with a particular dispute (e.g., if insufficient number of samples of a relevant batch of Products is available), then such dispute shall be determined by arbitration under clause 19.5

19.4 **Other disputes**

If a dispute does not relate to whether or not a particular Product meets the Specifications and the Regulatory Requirements and the parties are unable in good faith to settle the dispute within 20 Business Days after the dispute arose, then either party may submit the matter to arbitration under clause 19.5.

19.5 **Arbitration**

(1) If any dispute arises under, or in connection with, this Agreement and/or any Development Order, or in connection with any breach or alleged breach of this Agreement or any Development Order, and such matter is not resolved pursuant to clause 19.1 or 19.3 or by other agreement of the parties, such matter shall be finally resolved through binding arbitration as set forth in this clause 19.5. Either party may initiate arbitration of such a matter, and the party initiating arbitration of such dispute must give to the other party or parties to the dispute notice specifying the dispute and requiring its resolution

under this clause 19.5 (**Notice of Dispute**). Such Notice of Dispute shall be given in accordance with the arbitration rules specified under this clause 19.5.

(2) Each such dispute is by this clause 19.5 referred to binding arbitration for final resolution. The arbitration must be conducted in:

(a) Melbourne, Australia if the Notice of Dispute is given by OcuSense; and

(b) San Diego California, USA, if the Notice of Dispute is given by MiniFAB.

(3) If the parties have not agreed upon the arbitrator within 7 days after the Notice of Dispute is given, the arbitrator is the person appointed by the Chair of the Victorian Chapter of the Institute of Arbitrators and Mediators Australia (**Principal Appointor**) or the Principal Appointor's nominee, acting on the request of any party to the dispute.

(4) The arbitrator must not be a present or former member, officer, employee or agent of a party to the dispute or a person who has acted as a mediator or advised any party in connection with the dispute.

(5) The arbitration shall be conducted in accordance with the then-current rules of the International Centre for Dispute Resolution by one (1) arbitrator appointed in accordance with such rules. The arbitrator shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the parties must expend for discovery; provided the arbitrator shall permit such discovery as the arbitrator deems necessary to permit an equitable resolution of the dispute. The arbitrator shall not order or require discovery against either party of a type or scope that is not permitted against the other party. The costs of the arbitration, including administrative and arbitrators' fees, shall be shared equally by the parties, and each party shall bear its own costs and attorneys' and witness' fees incurred in connection with the arbitration. Any arbitration subject to this Article shall be completed within one (1) year from the filing of notice of a request for such arbitration. No punitive damages may be granted by the arbitrator. The arbitration proceedings and the decision shall not be made public without the joint consent of the parties, and each party shall maintain the confidentiality of such proceedings and decision unless otherwise permitted by the other party, except to the extent (and solely to the extent) either party is required to disclose such information by applicable securities or other laws. The parties agree that the decision shall be the sole, exclusive and binding remedy between them regarding any and all disputes, controversies, claims and counterclaims presented to the arbitrator. Any award may be entered in a court of competent jurisdiction for a judicial recognition of the decision and applicable orders of enforcement, and either party may apply to any court of competent jurisdiction for appropriate temporary injunctive relief pending resolution of any arbitration proceeding. The arbitrator shall provide a written arbitration award setting forth the arbitrator's findings on material questions of law and of fact, including references to the evidence on which the findings of fact were based. Each party may be represented by a qualified legal practitioner or other representative.

(6) This clause 19.5 applies even where the Agreement is otherwise void or voidable.

19.6 **Continuing Obligations**

19.7 Except as specifically provided in this Agreement, the parties must continue to perform their obligations under this Agreement despite the existence of a dispute or any steps being taken under this clause 19.

20. Force Majeure

20.1 **Party not liable**

Where a party is required under this Agreement to perform an obligation or do any act or thing by a designated time or date (**Obligation**), the party is not liable for any delay in performing or for failure to perform an Obligation where the delay or failure arises from Force Majeure and that party has complied with this clause.

20.2 **Notice of Force Majeure**

A party who claims Force Majeure must:

(1) give the other party prompt notice of the Force Majeure with reasonably full particulars and an estimate of the extent and duration of its delay in performance, or inability to perform; and

(2) use all possible diligence to resume normal performance of the delayed obligations as quickly as possible.

20.3 **Termination in case of Force Majeure**

If the delay continues beyond 30 days after the notice given under clause 20.2, the parties must meet to discuss in good faith a mutually satisfactory resolution of the problem and, if unable to achieve such a resolution within a further 60 days, either party may elect to terminate this Agreement by 30 days prior written notice to the other.

21. Notices

21.1 A notice or other communication connected with this Agreement (**Notice**) has no legal effect unless it is in writing.

21.2 In addition to any other method of service provided by law, the Notice may be:

(1) sent by prepaid post to the address of the addressee set out in this Agreement or subsequently notified;

(2) sent by facsimile to the facsimile number of the addressee;

(3) sent via email to the email address of the addressee; or

(4) delivered at the address of the addressee set out in this Agreement or subsequently notified.

21.3 If the Notice is sent or delivered in a manner provided by clause 21.2, it must be treated as given to and received by the party to which it is addressed:

(1) if sent by facsimile or email, on the next Business Day at the place of receipt, unless a transmission failure notice is received by the sender; or

(2) if sent by post or otherwise, upon receipt by the addressee.

21.4 Despite clause 21.3(1):

(1) a facsimile is not treated as given or received unless at the end of the transmission the sender's facsimile machine issues a report confirming the transmission of the number of pages in the Notice;

(2) a facsimile is not treated as given or received if it is not received in full and in legible form and the addressee notifies the sender of that fact by the close of the Business Day on which it would otherwise be treated as given and received.

22. General

22.1 Further assurance

Each party must promptly at its own cost do all things (including executing and if necessary delivering all documents) necessary or desirable to give full effect to this Agreement, to the extent commercially reasonable to do so.

22.2 Entire understanding

This Agreement is the entire agreement and understanding between the parties on everything connected with the subject matter of this Agreement and supersedes any prior agreement or understanding on anything connected with that subject matter. Notwithstanding the foregoing, the Development Agreement continues to govern the development of the First Product; provided, however, that in the event of a conflict between any provision of the Development Agreement and any provision of this Agreement, the relevant provision of this Agreement shall govern.

22.3 Variation

An amendment or variation to this Agreement is not effective unless it is in writing and signed by the parties.

22.4 Waiver

A party's failure or delay to exercise a power or right does not operate as a waiver of that power or right. The exercise of a power or right does not preclude either its exercise in the future or the exercise of any other power or right. A waiver is not effective unless it is in writing. Waiver of a power or right is effective only in respect of the specific instance to which it relates and for the specific purpose for which it is given.

22.5 Costs and outlays

Each party must pay its own costs and outlays connected with the negotiation, preparation and execution of this Agreement.

22.6 Governing law and jurisdiction

This Agreement shall be governed and construed in accordance with the laws of England, United Kingdom.

[Signature page follows]

Executed as an agreement.

Executed by **MiniFAB (Aust) Pty Ltd** ACN 100 768 474 in accordance with section 127 of the *Corporations Act 2001*:

Director/company secretary

MICHAEL WILKINSON

Name of director/company secretary (BLOCK LETTERS)

Director

Name of director (BLOCK LETTERS)

Signed for and on behalf of **OcuSense, Inc.** by its authorised representative in the presence of:

Signature of witness

STEPHEN ZMINDA

Name of witness (BLOCK LETTERS)

13707 High Bluff Dr. #200

Address of witness

San Diego, CA 92130

U.S.A.

Signature of authorised representative

ERIC DONSKY, CEO

Name of authorised representative (BLOCK LETTERS)

Schedule 1
First Product

1. **Name**

   Osmolarity TCI cards

2. **Description**

   A TCI Device for measuring osmolarity, as more particularly described in the applicable Requirements Definitions and Specifications

3. **Initial Price**

   Price payable for the first 900,000 units of the First Product supplied during the first three-year period after the Supply Start Date for the First Product: A$2.90 per unit

4. **Subsequent Price**

   The Price for units of the First Product beyond the first 900,000 units purchased (**Subsequent Price**) shall be determined using a cost model mutually agreed by the parties. The parties will negotiate in good faith to determine the cost model to be used to determine Subsequent Price of the First Product, having regard to the factors specified in clause 4.2(1), and shall diligently endeavor to agree upon a mutually acceptable cost model no later than sixty (60) days after the Cut-Off Date.

   The parties anticipate they will begin discussions to determine the Subsequent Price at such time as Purchase Orders have been placed for 700,000 units of the First Product, but if order volumes have increased quickly, the parties may begin discussions at an earlier time in order to permit discussion and determination of the Subsequent Price in a timely manner.

   If the parties fail to reach an agreement as to the Subsequent Price or the cost model for determining Subsequent Price, then the Subsequent Price will be A$2.40 per unit until the parties reach an agreement.

5. **Annual Production Capacity**

   700,000 units

Schedule 2
Form of Development Order

Development Order made between MiniFAB and OcuSense pursuant to the Manufacturing and Development Agreement dated ###

Date of Development Order _____

1. **Description of New Product**

   ###

2. **Draft New Product Development Requirements**

   #Insert draft#

3. **Estimated Development Expenses**

   ###

4. **Project Plan**

   #Please insert a project plan for carrying out the development.#

5. **Development Milestones and Payments (if not included in the Project Plan)**

   #Each payment milestone should specify the amount payable and when it is payable. Other payment terms (if any) should be specified.#

6. **Successful Completion**

   #Please insert criteria for Successful Completion. If this is left blank, then the default provisions in clause 5.10 will apply.#

7. **Other terms**

   #Insert any other applicable terms relevant to the development of the new product.#

MiniFAB and OcuSense agree that MiniFAB will provide the R&D Services pursuant to the Manufacturing and Development Agreement between the parties to develop the New Product as detailed in this Development Order.

Signed for and on behalf of MiniFAB

_____

Signed for and on behalf of OcuSense

_____

Annexure A
Requirement Definitions of First Product

[#To be inserted]

Annexure B
Specifications for First Product

[#To be inserted]

OcuSense
Tear Testing Made Simple™

Title: Osmolarity System Product Requirement Document

Document Approvals*					
REQUIRED	NOT REQUIRED	PRINT NAME	DEPARTMENT	SIGNATURE	DATE
☒	☐	Steve Zmina	Engineering/Man.		
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DOCUMENT REVISION HISTORY

Revision No.	Revision(s)	Author	Revision Effective Date
0.1	Pre-Initial Release	Steve Zmina	15-Dec-2006
0.2	Pre-Initial Release Updates from Marketing Requirements, input from Invetech, and internal reviews	Steve Zmina	22-Dec-2006
1.0	Initial Release	Steve Zmina	20-Feb-2007
A	New document format and revision control Updates to verification table. Removed Shonin	Steve Zmina	15-May-200
B	Updates to Regulatory Requirements, Packaging Requirements, System Description, Verification Table	Steve Zmina	10-Jul-2007
C	Updates to Packaging Requirements, Interface Requirements, and Workflow	Steve Zmina	17-Sep-2007
D	Update workflow, add sheath and TCI Card packaging requirements	Steve Zmina	8-Jan-2008
E	Updated Workflow to reflect temperature algorithm	Ben Sullivan	7-Feb-2008

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Figures

1. Purpose

1.1 This document defines the Product Requirements and Design Input for product development of the Osmolarity System.

2. Scope

2.1 This document outlines the description of the Osmolarity System (OS) and the development strategy that will be used to develop the elements of the system. This document will provide general requirements for the Osmolarity System and detailed requirements for the OS Instrument and OS Pen. Detailed requirements for the TCI Card will be provided in the Tear Collection Interface Card Product Requirements Document.

2.2 This document will be modified as required and on an ongoing basis, based on written review by the OcuSense management team.

3. References/Related Documents

3.1 Osmolarity System Marketing Requirements Document (MRD00001)
3.2 Osmolarity System Product Development Plan (PDP00001)
3.3 Tear Collection Interface Card Product Requirements Document (PRD00001)
3.4 Invetech Instrument Requirements Specification
3.5 Osmolarity System Risk Analysis

4. Acronyms/Definitions

4.1 Assay – A procedure where a property of a system or object is measured.

4.2 Osmolarity – The concentration of osmotically active particles in solution, which may be quantitatively expressed in osmoles of solute per liter of solution, or milliosmoles per kilogram.

4.3 CLIA – Clinical Laboratory Improvement Amendment.

4.4 Osms – Osmoles – Measure of Osmolarity of the tear fluid.

4.5 PoC – Point of Care

4.6 TCI Chip – Glass, plastic or other suitable substrate material mounted or integral to the TCI Card disposable that is used for collection of the tear sample by passive capillary action, transport and holding of the tear sample for electrical measurement using electrodes.

4.7 Capsule – Disposable plastic housing containing the TCI Chip, facilitating the collection of tear fluid by the TCI Card by insuring a stable platform for the TCI Chip. It also provides a secure connection to the OS Pen.

4.8 TCI Card – Microfluidic device for collecting tears for the measurement of tear fluid. It consists of the TCI Chip and the Capsule.

4.9 IgE – Immunoglobulin E (IgE)

4.10 Osmolarity System (OS) – A system comprised of the OS Instrument, OS Pen and TCI Card that in combination measure and display Osmolarity of tear fluid.

4.11 Accuracy - Spread of means between independent distributions.

4.12 Precision – Closeness of agreement between independent test/measurement results obtained under stipulated conditions, reported as a coefficient of variation = standard deviation / mean

4.13 Controls – Contrived fluid samples representative of tear fluid at known osmolarity levels traceable to a reference standard

4.14 Normal Control – A control with osmolarity levels representing normal tear osmolarity 270-316 mOsmols/L

4.15 High Control – A control with osmolarity levels representing abnormally high tear osmolarity 317-400 mOsmols/L

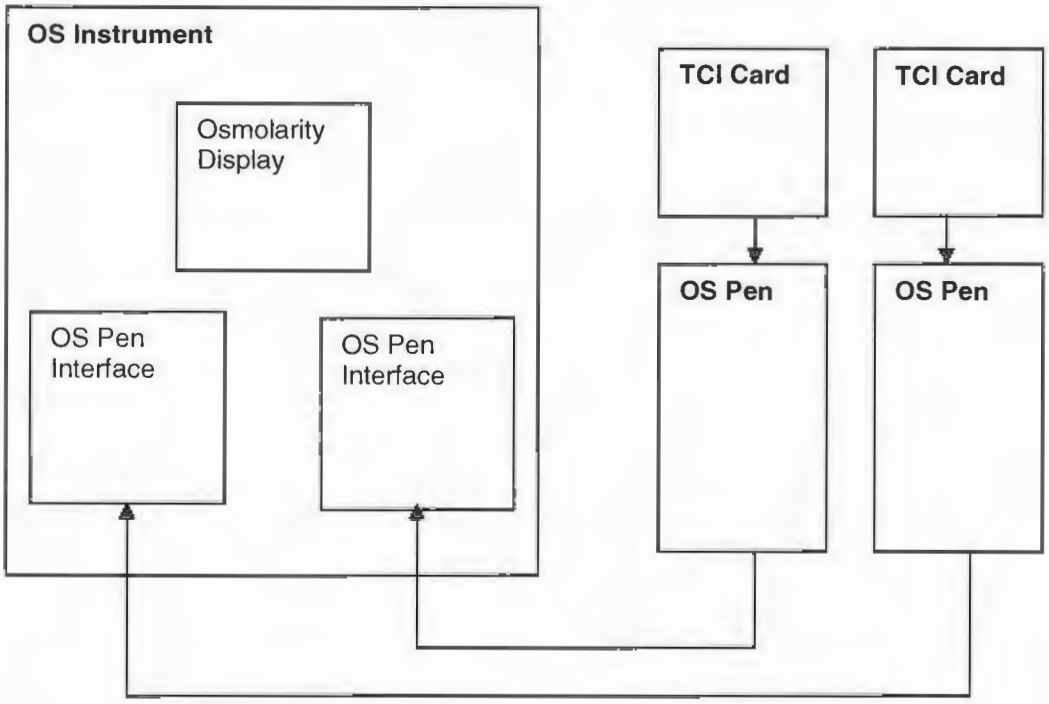
5. Responsibilities

5.1 It is the responsibility of Engineering, Manufacturing, Quality, R & D and Marketing to insure that the product requirements are incorporated in the development of this system.

6. General Product Description

6.1 The Osmolarity System (OS) will consist of a single use, disposable Tear Collection Interface Card (TCI Card), on which the tear film capture and osmolarity assay will operate, two hand held holders or pens (OS Pen) for mounting the disposable, and an instrument (OS Instrument), for measuring and displaying the osmolarity assay result. Refer to Figure 1 for a Block Diagram of the OS. The OS will have the capability of measuring the Osmolarity of a single eye (using one OS Pen and TCI Card) or two eyes (using two pens and two TCI Cards)

6.2 The Osmolarity System (OS)Block Diagram (Figure 1)



6.3 The Osmolarity System Components

6.3.1 TCI Card

The TCI Card is a disposable, microfluidic enabled component of the OS that contains all of the necessary fluidic features to collect a tear sample by passive capillary action and on card components that support the tear film osmolarity assay

when used in conjunction with the OS Instrument and OS Pen. It is comprised of the TCI Chip and the Capsule.

6.3.2 OS Instrument

The OS Instrument will provide an electromechanical platform for supporting the OS Pen in conjunction with the TCI Card and the measurement of tear film osmolarity by making an electrical impedance measurement of the tear sample.

6.3.3 OS Pen

The OS Pen is a hand held holder for the TCI Card used during tear collection and transport to the OS Instrument. The OS Pen will have all the necessary mechanical and electrical provisions to insure proper operation of the TCI Card during tear collection, transport, and measurement with the OS Instrument. The OS Pen will operate from rechargeable batteries that are recharged when placing in the OS Instrument.

6.4 OS System General Design Features

6.4.1 The TCI Card, OS Pen, and OS Instrument will work as an integrated system to automate the osmolarity measurement of the tear film sample. The assay will be performed on the TCI Card.

6.4.2 The test (tear film) sample will be introduced into the TCI Card by passive capillary action by directly placing the tip of the TCI Card onto the patient's inferior "tear lake" (a thin meniscus of tears along the lower eyelid).

6.4.3 The TCI Card will mount on the hand held OS Pen prior to tear film collection. After the collection of the tear film, the TCI card will be transported on the OS Pen to the OS Instrument for the osmolarity measurement.

6.4.4 The Osmolarity System is intended to be operated by a single user such as a doctor, or ancillary staff such as a technician, nurse, nurse practitioner, or physician's assistant in a doctor's office, optometrist's office, hospital clinic, wellness clinic or pharmacy setting.

6.5 Performance Requirements of the Osmolarity System

6.5.1 The necessary sample volume per assay shall be a maximum of 50 nL. This volume shall be passively drawn using capillary action into the card and the electrode area.

6.5.2 Osmolarity measurement accuracy of the OcuSense System shall be less than 1.0 % of a osmolarity solution traceable (measured or calculated) to a reference standard representing 290 mOsms/L.

6.5.3 Osmolarity measurement precision of the OcuSense System shall be less than 2.5% CV.

6.5.4 The TCI Card shall mount and dismount from the OS Pen in less than 5 seconds.

6.5.5 The OS Pen, with the mounted TCI Card shall insert into the OS instrument in less than 5 seconds.

6.5.6 The time required for the measurement processing of the tear film sample for each eye is preferred to be 60 seconds or less. This is preferred to minimize the overall time for User to acquire the measurement and complete the Osmolarity test. This is defined from introduction (connection) of the tear film filled TCI Card into the OS Instrument, to the display of the osmolarity reading on the OS Instrument. The reader must therefore display a result in less than 60 seconds from docking the pen.

6.5.7 The OS Pen shall have a minimum of 10,000 partial or full charging cycles.

6.6 Osmolarity System General Features and Requirements

6.6.1 All elements of the system shall meet and be consistent with the General Features and Requirements.

6.6.2 Ergonomics

6.6.2.1 The combined elements of the system shall operate together in a simple and intuitive manner that will allow the OS to be CLIA waived. The ergonomic design shall consider human factors such that the collection of the tears can be easily and consistently performed. Once the tear sample is collected on the TCI Card using the OS Pen(s) , the tear sample will be transferred to the OS instrument by placing the pen, containing the TCI Card with tear fluid, into the OS Instrument. The ergonomics should allow the User to easily transport and place the OS pen(s) into the instrument.

6.6.2.2 Graphics, physical features (alignment keys, etc.) and labeling should be used wherever possible to aid in the overall ease of use for all the elements of the system. Universal symbols or icons should be used wherever possible. The requirements of EN980 will be used when applicable.

6.6.3 Measurement Range

6.6.3.1 The OS shall be able to measure and display readings of representative osmolarity values in the range 270 to 400 mOsms/L.

6.6.4 Measurement Display

6.6.4.1 The osmolarity measurement result shall be displayed on an inbuilt screen in the OS Instrument after conversion of the impedance measurement into an Osmolarity value using a calibration curve.

6.6.5 Osmolarity System Performance Check

6.6.5.1 The OS shall use a fixed resistance Electronic Control TCI Card to verify OS performance at the User location.

6.6.5.2 The OS shall use a liquid Control to verify OS performance at the User location.

6.6.6 Interfaces

6.6.6.1 User Interface

6.6.6.1.1 OS User Switches/Buttons

6.6.6.1.1.1 User buttons shall be located near the LCD display and be readily visible to the User.

6.6.6.1.2 System Outputs

6.6.6.1.2.1 OS Display

6.6.6.1.2.1.1 The OS Instrument will display all measurements and error conditions for the OS Pen and Instrument. The display shall have options for multiple languages.

6.6.6.1.2.1.2 The OS Instrument shall indicate when an OS Pen is inserted in the OS Instrument, with a TCI Card that has a tear collected..

6.6.6.1.2.1.3 The OS Pen will indicate when a tear sample has been collected.

6.6.6.1.2.1.4 The architecture of the system shall allow for the future capability of sending an osmolarity measurement result to a host PC via a wireless or wired interface that is yet to be determined..

6.6.6.2 Electrical Interface

6.6.6.2.1 TCI Card to OS Pen Interface

6.6.6.2.1.1 This interface shall use electrically conductive contacts.

6.6.6.2.2 OS Pen to OS Instrument Interface

6.6.6.2.2.1 This interface shall use electrically conductive contacts..

6.6.6.2.3 OS Instrument to Power Module

6.6.6.2.3.1 This interface shall use an industry standard connector.

6.6.6.2.3.2 A unique power supply adaptor or plug will be required for the OS use in various geographic locations including Europe, Japan, and North America. The power supply shall be able to operate with an input voltage ranging from 90 to 264 VAC, at 49-60 Hz and will have the appropriate contact configuration and size. This adaptor shall meet the requirements of UL 60601.

6.6.7 Information and Error Reporting.

6.6.7.1 The following conditions shall be detected and reported.

Description	Signal Type	Pen		Reader		Error Code
		Light	Tone	Display	Tone	
Remove Pen from Reader						
Remove sufficiently charged Pen from Reader	Informational			Ready		
Remove Pen from Reader, Pen battery low	Informational			"Bat Low"	Yes	
Return Pen (without data) to Reader, Pen battery low	Informational			"Bat Low" + Batt Icon "Charging"	No	
Return Pen (with data) to Reader, Pen battery low	Informational			Measuring Bar Icon, then NUMERICAL RESULT + BATTERY Icon "Charging"	No	
Remove Pen from Reader, Pen battery won't hold charge	Informational			"Bat Fail"	Yes	
Return Pen from Reader, Pen battery won't hold charge	Informational			"Bat Fail"	No	
Insert Test Card In Pen						
Unused Test Card inserted on sufficiently charged Pen	Informational	Green LED On	Yes			
Collect Tear Fluid						
Pen powers down before tear collection	Informational	Green LED Off	No			
Tear Sample Collected, Full Channel	Informational	Green LED Off	Yes			
Tear Sample Collected, 30 seconds elapse	Informational	Green LED Off	Beeps every 2 sec			
Place Pen into Reader						
Pen is docked in Reader	Informational			Ready		

without a Test Card						
Low battery Pen with test card with no sample collected is docked in Reader	Informational			Ready		
Charged Pen with test card with no sample collected is docked in Reader	Informational			Ready		
A used test card with fluid is inserted into Pen	Alarm			Used TC		
Pen w/valid test card containing valid sample is docked in Reader	Informational			Measuring Bar Icon, then NUMERICAL RESULT		
Pen w/valid test card containing sample above measurement range is docked in Reader	Informational			Measuring Bar Icon, then ABOVE RANGE		
Pen w/valid test card containing below measurement range is docked in Reader	Informational			Measuring Bar Icon, then BELOW RANGE		
Pen w/test card containing sample is docked in Reader later than 40 seconds	Informational			Pen T/O		
Background Charging Status						
Pen w/ fully charged battery docked in Reader	Informational			Solid Battery Icon		
Pen w/ low battery docked in Reader	Informational			Growing Battery Icon		
No Pen docked in Reader	Informational			No Battery Icon		
Pen/Reader Communication Error	Informational					E51
Reader sent command to Pen but received no response	Informational					E52
Communication protocol between Pen and Reader failure	Informational					E53
Reader and Pen software do not match – size error	Informational					E54
Reader and Pen firmware incompatible – version error	Informational					E55
Pen fails pre-measurement relay check	Informational					E56

6.6.7.2 The following errors should be prevented by using mechanical features designed into the various elements of the system

6.6.7.2.1 TCI Card inserted incorrectly in the OS Pen

6.6.7.2.2 The OS Pen inserted incorrectly in the OS Instrument.

6.6.8 Test Requirements

6.6.8.1 The OS Instrument and OS Pen will have self test capability during initial power up.

6.6.9 Environmental

6.6.9.1 OS Operating Conditions:

6.6.9.1.1 Temperature range: 15 - 35 Degrees C

6.6.9.1.2 Relative Humidity: 10 – 85 % - Non condensing

6.6.9.1.3 Altitude: 0 - 2000 meters

6.6.9.2 OS Storage Conditions

6.6.9.2.1 Temperature Range – 2 – 50 Degree C

6.6.9.2.2 Relative Humidity 10 – 85 %

6.6.9.2.3 The OS Pen and OS instrument shall not be designed with any components that have a specified shelf life of less than 5 years. The Minimum shelf life for the TCI Card is 2 years.

6.6.10 OS Transportation

6.6.10.1 The packaged OS system shall be able to operate after worldwide shipping on transportation vehicles. Vibration requirements are based on ASTM D4169.in addition to the requirements of the IVD Directive..

6.6.10.2 The packaged OS shall be able to operate after a drop of 1 meter onto a concrete surface and should not show visible physical damage to the OS, such as denting, scratches or misalignment of components.

6.6.11 Regulatory

6.6.11.1 For the United States Market, the OS is to be labeled and Marketed under US Food and Drug Administration 510(k) guidelines. It will be marketed as a FDA Class 1,, non exempt medical device as per FDA 21 CFR 809.10

6.6.11.2 The OS shall be CLIA waivered under the U. S. Clinical Laboratory Improvement Act of 1988 (CLIA '88).

6.6.11.3 The Osmolarity System shall be designed and manufactured under FDA, QSR guidelines.

6.6.11.4 The OS shall comply with EN60601-1:2006.

6.6.11.5 The OS power supply (external adaptor) shall have UL/CSA and CE approval required for the North American, European and Japanese markets.

6.6.11.6 The OS shall meet all applicable requirements of the In Vitro Diagnostic Directive (IVD) 98/79/EC.

All elements of the OS shall meet the applicable Directive 2002/95/EC Restriction of Hazardous Substances (RoHS) and Directive 2002/96/EC Waste Electrical and Electronic Equipment (WEEE) requirements,. The OS packaging shall be labeled appropriately. to meet these requirements.

6.6.11.7 The OS shall comply with the following IEC Requirements

6.6.11.7.1 IEC 60601-1-6:2006 for usability.

6.6.11.7.2 IEC 60601-1-8:2006 for alarms

6.6.11.8 EMC

6.6.11.8.1 The OS shall conform to emission standard FCC Code of Federal Regulations, Title 47, Part 15, Subpart B, Class A.

6.6.11.8.2 The OS shall conform to IEC 60601-1-2:2007

6.6.12 Labeling

6.6.12.1 The labeling shall meet the applicable requirements of the IVD Directive.

6.6.12.2 The labeling shall comply with FDA 21 CFR 809.10.

6.6.13 Manufacturing

6.6.13.1 It is preferred that the OS system be designed such that the components are available globally and the system could be manufactured at multiple geographic locations without increase in cost form the original manufacturing site. It is preferred that the manufacturing equipment and processes established in one manufacturing location could be transported or duplicated at an alternate manufacturing site.

6.6.13.2 The Osmolarity System shall be manufactured in an FDA registered, QSR compliant manufacturing facility.

6.6.13.3 The Osmolarity System shall be manufactured in a facility that is certified to ISO 13485.

6.6.14 Reliability

6.6.14.1 The combined OS shall be designed to have an Operating Life of 10,000 disposable measurement cycles.

6.6.15 Service and Warranty

6.6.15.1 The system shall be designed to not require service during the product life.

6.6.15.2 The OS Instrument and OS Pen shall have a Warranty of 1 year.

6.6.16 Maintainability

6.6.16.1 The OS shall be designed so that the Instrument can be serviced or upgraded by an authorized Service Center.

6.6.16.2 There will be no special maintenance required for any of the OS elements during the specified operating life of the system.

6.6.16.3 The OS Instrument and Pen shall be suitable for light cleaning using specified fluids (disinfectant solutions eg alcohol, consistent with AAO Information Statement – Minimizing Transmission of Blood Borne Pathogens and Surface Infectious Agents in Ophthalmic Offices and Operating Rooms) applied to a soft cloth or paper towel.

6.6.17 Size and Shape

6.6.17.1 All elements of OS shall be easily transportable inside the office environment without the use of external tools or movement aids.

6.6.17.2 It is preferred that the OS Instrument and OS Pens can be moved with the OS Pen(s) mounted in the instrument.

6.6.17.3 All elements of the OS have no sharp edges that could cause injury to the User or the Patient during normal use.

6.7 Performance Requirements of the TCI Card

6.7.1 Sample volume per assay shall require a maximum of 50 nL to perform an Osmolarity Measurement . This volume shall be passively drawn into the TCI card and the electrode area.

6.8 TCI Card General Features and Requirements

6.8.1 The detailed Product Requirements for the TCI Card can be found in the TCI Card Product Requirements Document, PRD00001

6.8.2 The TCI Card will be a single use, disposable microfluidics based card. The osmolarity measurement requires measuring the electrical impedance of the tear fluid sample using non-oxidizing, corrosion resistant microelectrodes in contact with the tear fluid.

6.8.3 The TCI Card will be manufactured under the necessary controlled environments and conditions associated with a medical product that has non-sterile application requirements The use of additional post processing may be used to insure the required level of cleanliness.

6.8.4 The TCI Card shall have no rough or sharp edges on the disposable particularly on the tear collection interface.

6.8.5 The TCI Card shall be biocompatible and comply with ISO 10993.

6.8.6 The processed TCI Card will be suitable for disposal in a standard Biohazard container.

6.8.7 TCI Card Interface Requirements

6.8.7.1 The TCI Card shall have alignment features for accurate and positive alignment in the OS Pen and the OS Instrument for reliable electrical connections. The design shall insure that the User cannot insert the TCI Card into the OS Pen incorrectly.

6.8.7.2 The TCI Card shall have the necessary vertical retention features to facilitate firm and reliable pressure for the TCI Card contacts with the OS Pen and the OS Instrument contacts.

6.8.8 TCI Card Environmental Requirements

6.8.8.1.1 Same as OS.

6.8.9 TCI Card Transportation Requirements

6.8.9.1 Consistent with OS. There are no unique requirements for the TCI Card. The packaged TCI Card shall be able to withstand the combined temperature, humidity and atmospheric pressure prevalent in a commercial aircraft cargo hold, ocean bound shipping vessel, or land-based vehicle.

6.8.10 TCI Card Regulatory Requirements

6.8.10.1 Consistent with OS. There are no unique requirements for the TCI Card

6.8.11 TCI Card Manufacturing Requirements

6.8.11.1 The TCI card shall meet the biocompatibility requirements of ISO 10993 for limited mucosal contact.

6.8.11.2 The TCI Card shall be manufactured in an FDA registered, QSR compliant manufacturing facility.

6.8.11.3 The manufacturing process and final processing of the disposable shall be consistent with a non sterile medical product.

6.8.11.4 The TCI Card shall be free of contaminants that could affect the osmolarity measurement. The osmolarity measurement is an electrical impedance measurement, therefore the impedance between electrodes should be a high impedance greater than 1M Ohm, when using a signal excitation frequency of 10 kHz to 100kHz .

6.8.12 TCI Card Reliability

6.8.12.1 The TCI Card will work reliably with the OS Pen. It shall be designed for a single insertion and removal from the pen.

6.8.13 TCI Card Maintainability

6.8.13.1 The TCI Card is a single use device and requires no maintenance.

6.8.14 TCI Card Packaging and Labeling Requirements

6.8.14.1 The TCI card will be packaged individually or in pairs.

6.8.14.2 The tip of the TCI Card must be kept free from contamination during packaging, transportation and handling by the User. Any method used should allow for reliable protection. A sheath shall be used as a protection mechanism for the tip of the TCI Card. It must be easy to remove when the User desires to use the TCI Card.

6.8.14.3 The sealed individual pack age for the TCI Cards shall be easy to open to minimize the risk of dropping the TCI Card.

6.8.14.4 TCI card shall be designed to achieve a minimum shelf life of 2 years

6.8.14.5 Individually packaged TCI Cards will be packaged for sale in a box or container in quantities of consistent with the expected usage.

6.8.14.6 The TCI Card Package shall comply with the ISTA Standard for transit and shipping requirements.

6.8.14.7 The package shall be design to minimize the contact by the User to the tip of the TCI Card.

6.8.14.8 The individual card package size should not exceed 80mm x 85mm x 25mm.

6.8.14.9 The box that contains the individual cards should not exceed 10" x 10" x 8".

6.8.14.10 The box that contains the individual cards shall include 42 individually packed cards, Directions for Use and with an option to contain a clear poly bag containing 2 controls in individual sealed containers

6.8.14.11 TCI Card Package Labeling

6.8.14.11.1 Refer to TCI Card Product Requirements Document PRD00001.

6.8.14.12 TCI Card Use Instructions

6.8.14.12.1 Refer to TCI Card Product Requirements Document PRD00001

6.8.15 TCI Card Size and Shape

6.8.15.1 Size and shape shall be suitable for collecting the tear from the patient's eye with minimized discomfort to the patient.

6.8.15.2 Size and shape shall be suitable to facilitate easy handling by the end user and ease of application to the tear lake on the patient by the User.

6.9 Performance Requirements of the OS Instrument and OS Pen

6.9.1 Osmolarity measurement inaccuracy due to the performance of the OS Instrument in conjunction with the OS Pen shall be less than 0.5 % of a reference standard representing 290 mOsms/L.

6.9.2 Osmolarity measurement precision error due to the performance of the OS Instrument in conjunction with the OS Pen is less than 0.5 % CV with a reference standard representing 290 mOsms/L.

6.10 OS Instrument and Pen General Features and Requirements

6.10.1 The OS Instrument in conjunction with the OS Pen shall be a measurement platform for tear film Osmolarity utilizing the disposable TCI Card as the tear collection interface and mechanism for utilizing electrodes to measure conductivity of the tear fluid.

6.10.2 The OS Pen will be a rechargeable battery operated holder and interface to the TCI Card that facilitates the collection of the tear sample and insures that the correct amount of tear fluid for measurement has been collected on the TCI Card. In conjunction with the OS instrument, the OS Pen facilitates the measurement of the tear sample,

6.10.3 The OS Pen will power on when the TCI Card is mounted to the pen.

6.10.4 The OS Pen shall allow for easy insertion of the TCI Card, while minimizing the possibility that the User will contact the capillary end of the TCI Card.

6.10.5 The OS Pen and TCI Card design shall be such to insure that the TCI Card cannot be inserted incorrectly.

6.10.6 It is preferred that the OS Pen will minimize shock and vibration to the TCI Card during normal handling and OS Pen insertion into the OS Instrument.

6.10.7 Platform Extensions and Future Models

6.10.7.1 It is preferred that the platform is extendable to allow for PC based patient data and treatment management software including population study applications.

6.10.7.2 The architecture of the system shall allow for the future capability of sending an osmolarity measurement result to a host PC via a wireless or wired interface that is yet to be determined.

6.10.8 OS Instrument and Pen Interface Requirements

6.10.8.1 The OS Pen shall have alignment features for accurate and positive alignment of the TCI Card to provide for reliable electrical connections.

6.10.8.2 The OS Pen and TCI Card design shall be such to insure that the OS Pen cannot be inserted incorrectly into the OS Instrument.

6.10.8.3 The OS Instrument and OS Pen shall have the necessary mating features to insure reliable electrical connections.

6.10.8.4 The OS Instrument shall have the ability to have firmware upgraded at an Authorized Service Center.

6.10.8.5 The OS Instrument shall have the capability to set the time and date and to display the time and date with the measurement. The instrument set-up shall have the capability to provide for the display of multiple languages to include:

6.10.8.5.1 Italian
6.10.8.5.2 German
6.10.8.5.3 French
6.10.8.5.4 Spanish
6.10.8.5.5 English (United Kingdom)
6.10.8.5.6 English (US)
6.10.8.5.7 Japanese

6.10.8.6 User Interface

6.10.8.6.1 OS Instrument Switches/Buttons

6.10.8.6.1.1 There will be a minimal set of switches/buttons on the OS Instrument.

6.10.8.6.1.1.1 Buttons used for initial OS Instrument set-up and for selecting screens on the LCD screen.

6.10.8.6.2 OS Pen Controls

6.10.8.6.2.1 The OS Pen will preferably have no controls or buttons.

6.10.8.6.3 OS Instrument Outputs

6.10.8.6.3.1 OS Instrument Display

6.10.8.6.3.1.1 The OS Instrument will display all measurements and error conditions on a backlit LCD Display.

6.10.8.6.3.1.2 The LCD display shall provide:

6.10.8.6.3.1.2.1 Icons wherever possible to represent instructions or responses

6.10.8.6.3.1.2.2 Alphanumeric characters for the menu, measurement and other information displayed on the screen.

6.10.8.6.3.1.2.3 The display shall have the capability of displaying information in multi-languages to include:

6.10.8.6.3.1.2.3.1 Italian
6.10.8.6.3.1.2.3.2 German
6.10.8.6.3.1.2.3.3 French
6.10.8.6.3.1.2.3.4 Spanish
6.10.8.6.3.1.2.3.5 English (United Kingdom)
6.10.8.6.3.1.2.3.6 English (US)
6.10.8.6.3.1.2.3.7 Japanese

6.10.8.6.3.2 The architecture of the system shall allow for the future capability of sending an osmolarity measurement result to a host PC via a wireless or wired interface that is yet to be determined..

6.10.8.6.4 OS Pen Outputs

6.10.8.6.4.1.1 The OS Pen will indicate when a tear sample has been collected with a visible and audible indication.

6.10.8.6.4.1.2 The OS Pen and OS Instrument will indicate when there is a low battery condition. The OS Instrument will indicate when there is a full battery condition. The OS Instrument will indicate when there is a faulty battery condition.

6.10.8.6.4.1.3 The OS will indicate when an OS Pen has been docked in the OS Instrument.

6.10.8.6.5 OS Instrument Switches

6.10.8.6.5.1 There shall be a power on/off switch.

6.10.8.6.6 OS Pen Switches

6.10.8.6.6.1 There shall be no switches on the OS Pen

6.10.8.7 Electrical Requirements

6.10.8.7.1 OS Instrument Measurement Signal

6.10.8.7.1.1 The instrument shall apply a signal to the tear sample in the TCI card to facilitate the measurement of impedance that will be converted to Osmolarity.

6.10.8.7.2 Electrical Interface

6.10.8.7.2.1 There shall be sufficient number of electrically conductive contacts for connection of the OS Pen to the TCI Card.

6.10.8.7.2.2 There shall be a cap for the OS Pen to cover the electrically conductive contacts when not in use.

6.10.9 OS Instrument and OS Pen Environmental Requirements

6.10.9.1 Same as OS.

6.10.10 OS Instrument and OS Pen Transportation Requirements

6.10.10.1 Same as OS

6.10.11 OS Instrument and OS Pen Regulatory Requirements

6.10.11.1 Consistent with OS.

6.10.11.2 The OS Pen will have no unique requirements.

6.10.11.3 The OS Instrument Safety Requirements

6.10.11.3.1 The OS Instrument shall conform to the applicable requirements of EN 60601-1:2006

6.10.11.3.2 The OS Instrument shall conform to the applicable requirements of CAN/CSA 22.2 No.601.1-M90

6.10.11.3.3 The OS Instrument shall be certified to conform with the requirements of UL 60601:2003

6.10.12 OS Instrument and Pen Manufacturing Requirements

6.10.12.1 Same as OS.

6.10.13 OS Instrument Reliability

6.10.13.1.1 The OS Instrument shall be designed to have a minimum Operating Life of 10,000 disposable (via the OS Pen) measurement cycles.

6.10.14 OS Pen Reliability

6.10.14.1.1 The OS Pen shall be designed to have a minimum Operating Life of 10,000 TCI Card measurement cycles. This includes the ability to insert at least 10,000 single use TCI Cards into the OS Pen and to insert the OS Pen into the OS Instrument 10,000 times.

6.10.15 OS Instrument and OS Pen TCI Card Maintainability

6.10.15.1 Same as OS.

6.10.16 OS Instrument and OS Pen Packaging and Labeling Requirements

6.10.16.1 The OS Package will contain one OS Instrument, two OS Pens, one Power Supply (with plug adaptors as applicable), two Electronic TCI Cards, Instructions for Use including an Owner's Manual and Quick Instruction Guide.

6.10.16.1.1 Packaging dimensions and appearance TBD.

6.10.16.1.2 The OS Instrument and OS Pen shall comply with the ISTA Standard for transit and shipping requirements and the applicable requirements of the IVD Directive.

6.10.16.1.3 The OS system packaging shall include all required instructions for use and including an Operation Manual and Quick Instruction Guide.

6.10.16.1.3.1 The Operation and Quick Instruction Guide shall use multi-languages as required.

6.10.16.2 OS Instrument Graphics and Labeling

6.10.16.2.1 It is preferred that the OS Instrument will have graphics or labels that will aid in the normal use of the system

6.10.16.2.1.1 The OS Instrument shall have labeling or graphics that conform to the requirements of the IVD Directive and the FDA 21 CFR 809.10

6.10.16.3 OS Pen Graphics and Labeling

6.10.16.3.1 It is preferred that the OS Pen will have graphics or labels that will aid in the normal use of the OS Pen with the OS Instrument and TCI Card

6.10.16.3.1.1 The OS Pen shall have labeling that conforms to the requirements of the IVD Directive and the FDA 21 CFR 809.10.

6.10.17 OS Instrument and OS Pen Size and Shape

6.10.17.1.1 The OS Pen will be a handheld device with maximum dimensions of 8" inches by 2".

6.10.17.1.2 The OS Instrument will be a table top unit with dimensions not to exceed 12" wide by 12" deep by 12" high.

7. Product Cost

7.1 The total manufacturing cost of the OS Instrument shall not exceed $1000 US in quantities of 1000 units per year, produced in minimum lots sizes of 250 units.

7.2 The total manufacturing cost of the OS Pen shall not exceed $80 US. In quantities of 4000 units per year, produced in minimum lot sizes of 500 units.

7.3 The total manufacturing cost of the disposable TCI Card, packaging, controls and Instruction sheet shall not exceed $2.50 in quantities of 300,000 units per year, produced in minimum lot sizes of 5000 units.

8. Osmolarity System Intended Use and Operation

8.1 The intended use of the production Osmolarity System is for collecting and measuring tear film osmolarity. The TCI Card, OS Pen and OS Instrument will work as a system together to automate the osmolarity measurement of the tear film sample. The assay will be performed on the TCI Card. The Osmolarity System (OS) is intended to be operated by a single user such as a doctor, or ancillary staff such as a technician, nurse, nurse practitioner, or physician's assistant in a doctor's office, optometrist's office, hospital clinic, wellness clinic or pharmacy setting.

The OS Instrument is powered on and initialized for processing. This includes setting the time when the Instrument is powered up.

The next step during initial set-up is to set the language preference.

The normal workflow assumes that the starting point is with two OS Pens mounted in the OS Instrument. It will not matter if a TCI Card is mounted on either or both of the OS Pens. The OS Pens can also function in either side of the instrument, although it is recommended that during the workflow the pen is returned to the side that it was removed.

There will be only one mode of operation. It is assumed but not required that two eyes of the patient will be measured.

Each side of the OS Instrument will operate and measure independently from the other. Two measurement channels will be required that will facilitate the ability for two measurements to be processed simultaneously. Interaction between the two sides will occur if the second OS Pen has been removed after first measurement has been displayed. In that case, the first measurement will be cleared from the display and will be able to be recalled from the "last measurement memory." This will eliminate the possibility of ever having two different patient's measurements displayed on the OS Instrument at the same time. The only way this could occur in this workflow is if a User knowingly, and simultaneously takes tear samples from two patients with two pens.

A) A new TCI Card is removed from the package and held in the User's hand. The TCI Card has a protective sheath on its tip which also indicates that the TCI Card is new and unused

B) Either OS Pen is removed from the dock in the instrument. The display will clear measurements for both eyes on the LCD and indicate "READY" on the LCD for both sides of the instrument (corresponding to each OS Pen). There shall be separate "READY" indicators on the LCD for each OS Pen. This will indicate that the OS Instrument is waiting for the pen to be docked again for taking a measurement after the tear sample has been collected.

C) If a TCI Card has been left on the OS Pen from a previous measurement, it will be removed from the OS Pen by the User. If not, the User will move to the next step.

D) TCI Card is inserted into to OS Pen and the pen turns ON. The pen takes a few seconds to initialize and the LED indicator light turns ON and an information tone is provided, indicating that the TCI Card has been connected and it is ready to take a tear sample. The OS Pen "power off" timer starts in the pen. The operator removes the protective sheath from the tip of the TCI Card and disposes of it.

E) The tear film sample is collected. The (tear film) sample fluid will be introduced into the TCI Card by passive capillary action by directly placing the tip of the TCI Card onto the patient's inferior "tear lake" (an accumulation of tears along the lower eyelid margin).

F) After the sample is collected, the Pen will indicate that the tear sample is sufficient by turning OFF the LED and providing an information tone..

i. The OS Pen applies an electrical sine wave to two of the electrodes in the TCI Card and the OS Pen measures the impedance (voltage/current) between two of the other electrodes also located in the TCI Card. The impedance data of the tear sample is then stored into memory in the OS Pen for later transfer to the OS Instrument.

ii. If after 30 seconds following tear collection the User has not placed the OS Pen into the OS Instrument, the OS Pen will emit a series of informational tones (once every 2 seconds) to remind the User to dock the OS Pen. The User has a total of 40 seconds following tear collection to place the OS Pen in the OS Instrument. If the User has not placed the OS Pen in the OS Instrument within 40 seconds of tear collection, the OS Pen will timeout and disallow the reading to be loaded to the OS Instrument.

G) The OS Pen (with tear sample in disposable) is placed into the OS Instrument. The OS will provide an information message on the OS Instrument display to indicate that the OS Pen has been connected to the OS Instrument.

H) The "READY" indication on the OS Instrument display for that side will turn off and the "MEASURING Icon" indication will turn on. The OS Instrument will access the impedance data in the OS Pen memory for the osmolarity calculation.

i. The osmolarity is calculated from a temperature compensated impedance.

I) The OS Instrument will signal that the measurement is complete by removing the "MEASURING Icon" from the LCD screen and display the osmolarity reading and the time of day on the side of the instrument's LCD screen that the pen was inserted.. The OS Pen will turn off when it's "power off" timer has expired. The timer will clear (if not expired) anytime a new TCI Card is inserted and then restart. The OS Pen impedance data memory will also clear anytime a new TCI Card is inserted.

J) [The TCI Card can then be removed from the OS Pen(s) and discarded in the appropriate waste container and the OS Pen returned to the dock. The instrument will indicate "Ready" informational message.

K) If the User desires to take a measurement for the second eye for that patient, the TCI Card for the next eye is removed from the package and held in the User's hand.

L) The opposite OS Pen is removed from the dock in the instrument. The display will clear measurements for both eyes on the LCD and indicate "READY" on the LCD to indicate that it is waiting for the pen to be docked again for the side that the pen was removed. If

the opposite side is in "MEASURING" or "READY" mode, the OS instrument will continue to operate in that state for that side and the display will not change on that side.

M) During the time that the second Pen is collecting the second tear, it is likely that the first measurement will be complete. The OS Instrument will display the measurement and the time for the first eye that was tested.

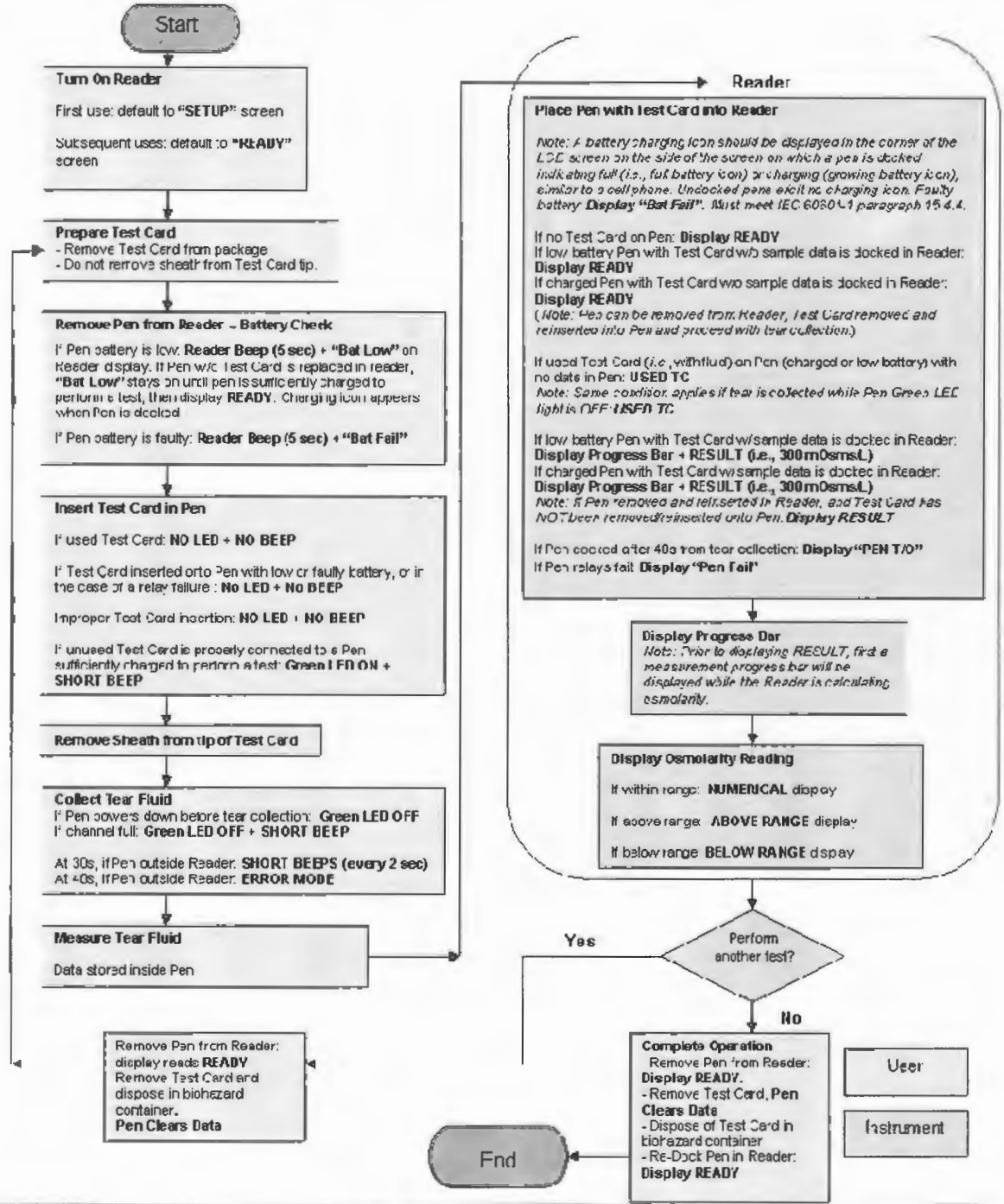
N) Repeat Steps C) through J) and Step O) for the second pen.

IMPORTANT

If the second OS Pen was removed while the first OS Pen had been docked and was in the process of measuring a tear sample in the OS Instrument, the first OS Pen reading will be displayed when it's measurement is complete. When the second OS Pen is docked with a tear sample, the second measurement will be displayed.. The first OS Pen measurement will remain on the display (both measurements will be displayed).

If the second OS Pen has been removed after the first measurement has been displayed. the first measurement will be cleared from the display and will be able to be recalled from the "last measurement memory" by pressing the button corresponding to that side of the display. Pressing the recall button will present the last displayed Osmolality test result and time, it will not display the last informational or error message. Upon completion of the second OS Pen's measurement, only the reading for that OS Pen will be displayed on the LCD.

The only case where a tear sample should be collected from a patient is when the green LED is illuminated on the OS Pen.



9. Product Development Strategy

9.1 The product development plan will be developed under FDA GMP and QSR and ISO design controls and shall be consistent with these Product Requirements.

9.2 Alpha Osmolarity System

9.2.1 An integrated system that fully demonstrates the operation of the following requirements:

9.2.1.1 Reliable and consistent tear collection

9.2.1.2 Mechanical and electrical interfaces representative of final system in appearance and functionality. The TCI Card must be able to be reliably connect to the OS Pen.

9.2.1.3 Includes all functional components and electrical circuits of the production Osmolarity Systems

9.2.1.4 Mechanical and electrical reliability of connections between TCI Card, OS Pen and OCS Instrument.

9.2.1.5 Mechanical and electrical tolerances to achieve overall OS System measurement accuracy of less than 2.0 % and precision of 2.5%.

9.2.1.6 Built using components and assembly techniques that are sufficiently repeatable to produce a minimum of 5 Alpha OS systems that have representative appearance and operate in a similar manner (workflow and User interface) of the final product.

9.2.1.7 Housing and mechanical components shall have similar appearance and similar materials to the final product. Durability of the units shall be such that a minimum of 500 osmolarity measurements can be made per instrument and still meet accuracy and repeatability requirements for this stage.

9.2.1.8 Built using suitable techniques to allow for Pre-clinical trials on patients. This includes a hygienically clean interface for tear collection.

9.3 Beta Osmolarity System

9.3.1 An integrated system that meets the following requirements:

9.3.1.1 Shall meet or improve on all requirements of the Alpha units.

9.3.1.2 Manufactured using final production tooling and processes suitable for high volume manufacturing.

9.3.1.3 Mechanical and electrical tolerances to achieve overall OS measurement accuracy of 1.0 % to a standard osmolarity reference and precision of 2.5% at 290 mOsms/L.

9.3.1.4 Housing and mechanical components shall have same appearance and materials as the final product. Durability of the units shall be such that a minimum of 5000 osmolarity measurements can be made per instrument and still meet accuracy and repeatability requirements for this stage.

9.3.1.5 Built with all commercial factors considered.

9.3.1.6 The OS shall meet cost targets or have process and tooling changes identified to achieve cost targets.

9.3.1.7 Representative packaging for the OS, suitable for transportation and drop testing.

9.3.1.8 OS System shall be suitable for verification testing and (validation testing where applicable) regulatory testing including 510(k), IVD Directive UL, EMC, and EMI..

9.4 Pre-production Osmolarity System

9.4.1 An integrated OS that meets the following requirements:

9.4.1.1 Shall meet or improve upon all of the requirements of the Beta units.

9.4.1.2 Shall be manufactured at the production Manufacturing location.

9.4.1.3 Shall be able to manufacture near production volumes of systems.

9.4.1.4 Shall be suitable for final Validation testing.

9.5 Production Osmolarity System

9.5.1 An integrated OS that meets the following requirements:

9.5.1.1 Must meet or improve upon all of the requirements of the Pre-production units

9.5.1.2 Built using final process and tooling for manufacture.

9.5.1.3 Produced in an FDA registered, QSR manufacturing facility.

	Requirement	Verification	Source/Notes
9. 1 Critical			
9.1.1 Accuracy (PRD 6.5.2)	+/-1.0 %	Confirm during verification testing with a osmolarity solution traceable to a reference standard of 290 mOsms/L	Measurement
9.1.2 Precision (PRD 6.5.3)	2.5% CV	Confirm during verification testing with samples of known osmolarity	Measurement
9.1.3 Measurement Input Range (PRD 6.6.3.1)	6K ohms to 40K ohms Corresponds to Measurement Range	Use reference TCI Cards for evaluation of measurement range	Measurement
9.2 Performance			
9.2.1 Measurement and Display Time (PRD 6.5.6)	The OS Instrument will display and osmolarity reading in less than 60 seconds from the time the OS Pen is inserted in the OS Instrument	Confirm during verification testing with samples of known osmolarity	Measurement
9.2.2 Tear Sample Volume	< 50 nL for measurement – OK to overfill to maximum TCI Card can accommodate	Confirm during verification testing with samples of known volume	Measurement
9.2.3 TCI Card Load Time (PRD 6.5.4)	Mount or dismount TCI Card from OS Pen in less than 5 seconds	Confirm during verification testing with overall OS System	Measurement
9.2.4 OS Pen Load Time (PRD 6.5.5)	Mount or dismount OS Pen from OS Instrument in less than 5 seconds	Confirm during verification testing with overall OS System	Measurement
9.3 General			
9.3.1 Display Range (PRD 6.6.3.1)	The OS Instrument will display osmolarity measurements in the range of 270 - 400 mOsms/L and will indicate if the measurement is higher or lower than the measurement range.	Use reference TCI Cards for evaluation of measurement range	Measurement
9.3.2 Biocompatible (PRD 6.8.5)	The TCI Card shall meet requirement	Perform verification test to specification	
9.3.3 User Safety (PRD 6.8.15.1)	TCI Card minimizes discomfort to patient	Verify during clinical trials by getting patient's response	
9.3.4 OS Pen Battery Life (PRD 6.5.7)	The OS Pen rechargeable batteies shall have a minimum of xx charging cycles	Confirm during verification testing Using alkaline battery	Measurement

	Requirement	Verification	Source/Notes
9.4 Manufacturing			
9.4.1 Meet biocompatibility requirements of ISO 10993. (PRD 6.8.11.1)	TCI Card shall meet requirement	Confirm specifications and acquire Certificates of Conformance from suppliers	
9.4.2 Process consistent with requirements of a non sterile medical product (PRD 6.8.3)	TCI Card shall meet requirement	Approve Manufacturing Quality Plan	
9.4.3 The impedance between electrodes should approximate an open circuit when using a signal frequency of 10kHz to 100kHz (PRD 6.8.11.4)	TCI Cards minimum impedance is greater that 1M	Measure during verification testing	Measure
9.5 Environmental			
9.5.1 Temperature Range (Operating) (PRD 6.6.9.1.1)	15 – 35 Degrees C	Confirm during verification testing of OS System	Measure critical and performance parameters
9.5.2 Relative Humidity (Operating) (PRD 6.6.9.1.2)	10 – 85 % Non - condensing	Confirm during verification testing of OS System	Measure critical and performance parameters
9.5.3 Altitude (Operating) (PRD 6.6.9.1.3)	0 – 2000 Meters	Confirm during verification testing of OS System	Measure critical and performance parameters
9.5.4 Temperature Range (Storage) (PRD 6.6.9.2.1)	2 – 50 Degrees C	Confirm during verification testing of OS System	Measure critical and performance parameters
9.5.5 Relative Humidity (Storage) (PRD 6.6.9.2.3)	10 – 85 % Non - condensing	Confirm during verification testing of OS System	Measure critical and performance parameters
9.5.6 TCI Card Minimum Shelf Life (PRD 6.8.14.2)	2 years under recommended storage conditions	Automated accelerated temperature and humidity storage conditions	Measure critical and performance parameters

	Requirement	Verification	Source/Notes
9.6 Regulatory			
9.6.1CE Mark (PRD 6.6.11.5)	Develop in accordance with IVD Directive CE requirements	CE Self Certification	Invetech/OcuSense
9.6.2 CLIA Waiver (PRD 6.6.11.2)	Develop in accordance with CLIA requirements	FDA Categorized	Invetech/OcuSense
9.6.3 UL 60601:2003/CAN/CSA 22.2 No 601.1-M90 (PRD 6.10.11.3.2 and 6.10.11.3.2)	Develop in accordance with UL/CSA requirements	UL Approval	Invetech/OcuSense
9.6.4 In Vitro Diag. Directive (IVD) - 98/79/EC (PRD 6.6.11.6)	Develop in accordance with requirements	Certification	Invetech/OcuSense
9.6.5 FDA 510(k) (PRD 6.6.11.3)	Develop in accordance with requirements	Marketing Clearance Letter	OcuSense
9.6.6 EN60601-1:2006 (PRD 6.6.11.4)	Develop in accordance with requirements	Certification	OcuSense
9.6.7 FCC Title 47, Part 15, Subpart B, Class A (PRD 6.6.11.8.1)	The OS shall conform	Certification	Invetech/OcuSense
9.6.8 IEC 60601-1-2:2007 (PRD 6.6.11.8.2)	The OS shall conform (including amendments A1 and A2), Class A (CISPR11)	Certification	Invetech/OcuSense
9.6.9 IEC 60601-1-6:2006 (PRD 6.6.11.7.1)	The OS Shall Conform	Certification	OcuSense
9.6.10 IEC 60601-1-8:2008 (6PRD 6.6.11.7.2)	The OS Shall Conform	Certification	OcuSense
9.7 Packaging and Labeling			
9.7.1 Package (PRD 16.10.16)	Package to include all graphics labeling and printing as specified	Visual Inspection	

9.7.2 Operation Manual and Quick Instruction Guide PRD 6.10.16.2)	Operation and Quick Instruction Guide to include all graphics and printing as specified	Visual Inspection	
9.7.3 510(k) and CLIA Waiver	Labeled according to guidelines	Visual Inspection	
9.7.4 FDA 21 CFR 809.10 requirements (PRD 6.6.12.2)	OS shall conform	Visual Inspection	
	Requirement	**Verification**	**Source/Notes**
9.7.5 IVD Requirements for labeling (PRD 6.6.12.1)	OS shall conform	Visual Inspection	
9.8 Durability			
9.8.1 Transportation (PRD 6.6.10.1)	Survive and Operate. Vibration requirements based on ASTM D4169	Certification to specified levels.	Measure critical and performance parameters
9.8.2 Package Drop (PRD 6.6.10.2)	Survive and Operate after 1 meter drop	Confirm during verification testing with overall OS System	Measure critical and performance parameters
9.9 Reliability			
9.9.1 Operating Cycles (PRD 6.10.13)	The OS Instrument shall allow for 10,000 insertions of OS Pen	Accelerated Life Test	Measure critical and performance parameters
9.9.2 Operating Cycles (PRD 6.10.13)	The OS Pen shall allow for 10,000 insertions of the TCI Card	Accelerated Life Test	Measure critical and performance parameters
9.10 Error/Exceptions			
9.10.1 Osmolarity Measurement Out of Range (PRD 6.6.7.1.2)	OS Instrument shall alert User. No result will be displayed. Either above or below out of range message will be displayed	Confirm during verification testing with overall OS System	
9.10.2 Insufficient Tear Fluid Sample Volume (PRD 6.6.7.1.1)	OS Pen will not change state to indicate fluid has been collected	Confirm during verification testing with overall OS System	
9.10.3 Used TCI Card (PRD 6.6.7.1.4)	OS Pen will provide an indication if the TCI Card has previously collected fluid	Confirm during verification testing with overall OS System	

9.11 Operational Indicators			
Tear Fluid Collected (PRD 8 (F)	OS Pen shall provide an information tone when sufficient fluid has been collected in TCI Card.	Confirm during verification testing with overall OS System	

Document Template			
Prepared by:	Reviewed by:	Approved by:	Review Period
Date:	Date:	Date:	24 Months

1 DOCUMENT REVISION HISTORY

Version No.	Reason for Revision	Author	Revision Effective Date
1.1	Initial Release. Written to meet the OcuSense Product Requirements (Document No. PRD0001, Revision B, 10 Sept. 2007).	Carl G. Chen	31-Oct-07

2 DOCUMENT APPROVAL

Title	Name	Signature	Date
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OcuSense, Inc.			
VP Manuf. & Eng.	Steve Zmina		
COO	Mike Berg		
CSO	Benjamin Sullivan		
Quality Management Representative	Eddie Olivas		

3 RELATED DOCUMENTS

Document No.	Document Title	Revision & Date	Owner
PRD0001	Osmolarity System Product Requirements Document	Revision A, 15 May 2007	OcuSense
PRD0002	Tear Collection Interface Card Product Requirements Document	Revision B, 10 Sept. 2007	OcuSense

TABLE OF CONTENTS

4 INTRODUCTION

This document shall define in detail the Design Specifications and Design Output required in order to meet the approved OcuSense Product Requirements and Design Input for the Tear Collection Interface Card (TCI Card).

This document shall be reviewed, modified and approved as required and on an ongoing basis, based on formal Design Reviews held jointly between MiniFAB and OcuSense.

4.1 Scope

This Design Specification Document (DSD) shall detail all aspects of the design, construction and production verification criteria relating to the TCI Chip, a low cost microfluidic disposable component designed and manufactured by MiniFAB for the OcuSense Osmolarity System (OS). This document shall also address all aspects of the assembly of the TCI Chip into the Capsule, the packaging and the labeling of the resulting assembly called the TCI Card for volume production.

This document shall not address the design, construction or verification criteria of the Capsule, nor shall it address any aspect of the Osmolarity System Pen (OS Pen) or the Osmolarity System Instrument (OS Instrument). Design Specifications for the Capsule, the OS Pen and the OS Instrument shall be produced by their respective manufacturers.

4.2 System Overview

This section shall provide an overview of the OcuSense Osmolarity System (Figure 1), designed for point-of-care testing of tear film osmolarity.

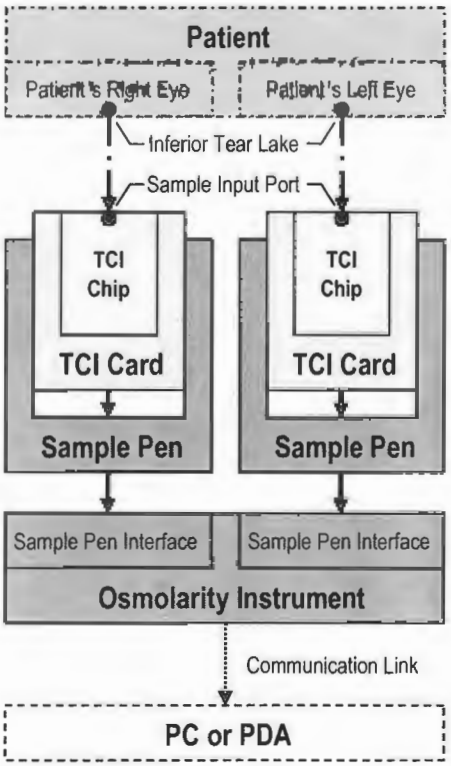

Figure 1. Schematic of the Osmolarity System.

Conventional tear testing systems are not suitable for clinical use due to their high cost and complexity, the need for large sample volumes, and the length of time required for testing. The OcuSense Osmolarity System requires only nanoliters of tears for testing, reducing collection time and simplifying the tear collection process. Tear osmolarity measurements can be done within minutes of the tear collection. The System is ideally suited for point-of-care usage.

The Osmolarity System will consist of a single use, disposable Tear Collection Interface Card, on which a tear film capture and osmolarity assay will be performed, two hand held holders or sample pens for mounting the disposable, and an instrument for measuring and displaying the osmolarity assay result. The Osmolarity Instrument in conjunction with the Osmolarity Pen will form the platform for measuring the tear film osmolarity.

The disposable TCI Card is made of two components: a microstructured plastic consumable called the TCI Chip and a disposable plastic housing holding the TCI Chip called the Capsule. When used in the Osmolarity System, the TCI Chip serves as the interface to tear collection and the site of the osmolarity assay, as well as the electrical sensor connection to the assay for measuring tear fluid osmolarity. The Capsule ensures a stable housing for the TCI Chip during tear collection, and it also provides the critical mechanical linkage to the Osmolarity Pen to ensure a secure electrical contact between the Chip and the Pen.

Tear film sample will be collected when the input port of the TCI Chip is put in direct contact with a patient's inferior tear lake (a thin meniscus of tears along the lower eyelid). Through strong capillary action, a sufficient amount of tear fluid will be passively wicked into a microfluidic channel patterned with a set of interdigitated microelectrodes. By interrogating these electrodes, tear conductivity and ultimately calibrated osmolarity measurements can be conducted.

The Osmolarity Pen will be a battery-operated holder for the TCI Card. It serves the following functions: Facilitates the collection of the tear sample; insures that the correct amount of tear fluid for measurement has been collected by the TCI Chip; provides an electrical connection between the TCI Chip and the Osmolarity Instrument; and measures and stores tear impedance as well as ambient temperature data while the Pen is in the process of being docked to the Instrument.

The Osmolarity Instrument serves the following functions: Acts as the docking station to the Pens; measures and downloads tear impedance data in conjunction with the Pen; signals the end of a measurement and calculates and displays the tear film osmolarity figure.

4.3 System Use Case

The intended use of OcuSenese Osmolarity System is to collect tear fluid from a patient and measure the tear film Osmolarity to determine if the patient suffers from Dry Eye Disease. The TCI Card, the Osmolarity Pen and the Osmolarity Instrument will work together as a system to automate the osmolarity measurement of the tear film sample. The System is intended to be operated by a user such as a doctor, or ancillary staff such as a technician, a nurse, a nurse practitioner, or a physician's assistant in a doctor's office, optometrist's office, clinic or pharmacy.

In a simplified way, the intended use and operation of the TCI Card within the framework of the Osmolarity System can be described by the following process steps:

1. A new disposable TCI Card, which contains a TCI Chip, is removed from its package.
2. Osmolarity Pen for either the left eye or the right eye is removed from its dock on the Osmolarity Instrument. (If a used TCI Card has been left on the Pen from a previous measurement, it needs to be removed by the user).
3. The new TCI Card is clipped into the Pen.
4. The tear film sample is collected when the input port of the TCI Chip is placed in direct contact with the patient's inferior tear lake. Tear fluid in the lake is wicked into the microfluidic channel on the Chip by passive capillary flow.

5. The Osmolarity Pen indicates whether a sufficient volume of tear fluid has been collected (fluid fill detection electrodes are an integral part of the electrode layout on the TCI Chip). The Pen starts measuring and recording the tear fluid impedance immediately following a successful fill. Ambient temperature data is also collected and recorded by the Pen for later use.

6. The Osmolarity Pen (including the disposable TCI Card containing the collected tear sample) is docked into the Osmolarity Instrument.

7. The Osmolarity Instrument downloads the already recorded impedance data from the Pen while continuing to perform an alternating current four-pole impedance measurement at a preset signal amplitude and frequency (via electrical connections from the Instrument to the Pen, and from the Pen to the TCI Chip).

8. Tear osmolarity is calculated and displayed by the Instrument from measured impedance data, compensated for temperature, channel geometry, and/or time related effects.

9. The instrument signals that the measurement is complete and further processes, stores and/or transmits the obtained data as per OcuSense Osmolarity System Product Requirements (cf. OcuSense Document No. PRD0002).

10. The TCI card is then removed from the Pen and discarded in an appropriate waste container, and the Pen is returned to the dock.

For complete descriptions of intended use and operation of the OcuSense Osmolarity System, please refer to the OcuSense Osmolarity System Product Requirements (cf. OcuSense Document No. PRD0002).

4.4 Product Description

This section shall describe the TCI Chip (Figure 2).

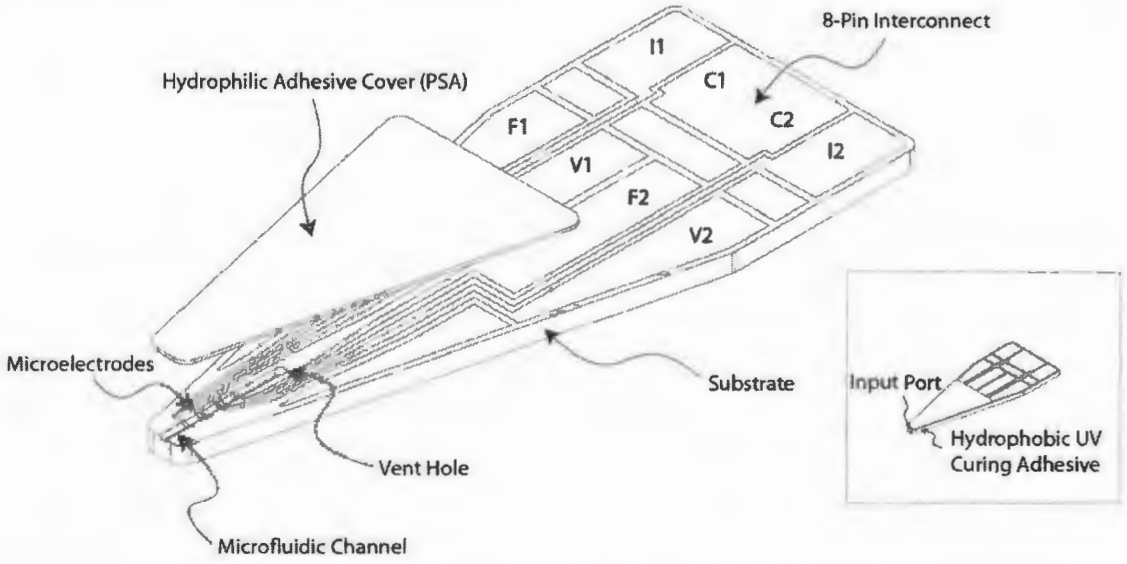

Figure 2. Schematic of the Tear Collection Interface Chip

The TCI Chip is a low cost microfluidic disposable component made of plastic. It is designed and manufactured to be an integral part of the OcuSense Osmolarity System (OS). The TCI Chip serves as the interface to tear fluid collection and the site of the osmolarity assay, as well as the electrical sensor connection to the assay for measuring tear fluid osmolarity.

The TCI Chip is made of two components: an injection molded plastic substrate and a hydrophilic adhesive cover. The substrate contains a microfluidic channel and a vent hole situated at the end of the channel. A set

of six microelectrodes is patterned across the channel by laser mask-projection machining. All six are routed to their respective pins on a 8-pin Smart Card interconnect, which provides the necessary electrical interface between the TCI Chip and the Osmolarity Pen. The outer two microelectrodes are for detecting fluid fill (F1 and F2). When sufficient tear fluid is inside the channel, the fill electrodes will produce an electrical short, detectable by the Pen. The inner four microelectrodes are the sensor electrodes required for the four-pole impedance measurement. Among the four, the two outer electrodes are for passing electrical current (I1 and I2), and the inner two are for sensing voltage (V1 and V2). Tear fluid impedance can be calculated from these current and voltage measurements. Two pins (C1 and C2) on the 8-pin interconnect have been purposely bridged. When the TCI Chip is seated properly into the Pen, C1 and C2 will form an electrical short, indicating that a card is present in the Pen and is ready for use.

The channel must be covered for the TCI Chip to be functional fluidically. The cover in use is a die-punched plastic sheet coated with a commercially available hydrophilic adhesive. The hydrophilic surface is in direct contact with the substrate. Both heat and pressure are applied to the cover to ensure a secure irreversible seal over the channel and the vent hole. In the context of this document, the term Pressure Sensitive Adhesive (PSA) is used exclusively to refer to the hydrophilic adhesive cover. The hydrophilic adhesive and the vent hole together enable rapid passive capillary flow of the tear fluid inside the sealed channel, as soon as the input port (Inset, Figure 2) comes into contact with the tear lake.

The hydrophilic adhesive exposed at the tapered edges of the die-punched cover needs to be sealed with a thin layer of hydrophobic UV curing adhesive (Inset, Figure 2). Left unsealed, tear fluid will wick along both tapered edges as well as the microfluidic channel, severely impacting the accuracy of the osmolarity measurement.

The TCI Chip is held in a disposable plastic housing called the Capsule (Figure 3). The Chip and the Capsule together form a disposable assembly called the TCI Card. The Capsule ensures a stable housing for the TCI Chip during tear collection, and it also provides the critical mechanical linkage to the Osmolarity Pen to ensure a secure electrical contact between the Chip and the Pen. MiniFAB is neither the designer nor the manufacturer of the Capsule. Capsule specifications will not be covered by this Design Specification Document.

Figure 3. 3D illustration of the Capsule.

The TCI Card is designed as a disposable component of the OcuSense Osmolarity System and is intended to be used in conjunction with the Osmolarity Pen and Instrument. It is intended to be operated by a user

such as a doctor, or ancillary staff such as a technician, a nurse, a nurse practitioner, or a physician's assistant in a doctor's office, optometrist's office, clinic or pharmacy.

4.5 Process Description

This section shall describe the process flow for volume manufacturing the TCI Card. Volume manufacture of the TCI Card is broadly divided into three stages: fabrication of the TCI Chip, assembly of the TCI Card, and packaging and labeling of the TCI Card. The three stages are broken down into ten major process steps; each step is further broken down into sub-steps, as listed below.

1. Material storage. Material storage and part handling capacity is required for the following process steps: 2, 3, 4, 5, 6, 9 and 10.

2. Injection molding. Injection molding is used to fabricate the TCI Chip substrate. Under high temperature and pressure, molten polycarbonate is injected into a steel mold which has been machined to assume the overall shape of the TCI Chip, including the microfluidic channel and the vent hole. The injection molding process is further defined by the following steps:

    2a. Loading polycarbonate resin into resin dryer;

    2b. Run drying process;

    2c. Run molding process;

    2d. Part handling after molding process;

    2e. Part breaking from runners; and

    2f. Tray loading.

3. Gold sputtering. Sputtering is used to deposit thin blank layers of chromium (Cr) and gold (Au) films on the substrate. The films will be subsequently defined into electrodes. During sputtering, Cr and Au atoms from solid target materials are ejected due to bombardment of the materials by energetic Argon ions. They coat the surface of the substrate facing the targets, with Cr coating the substrate first in order to promote the adhesion of the Au film layer. The sputtering process is further defined by the following steps:

    3a. Transport tray from injection molding room to production room;

    3b. Temporary storage of trays in production room;

    3c. Cleaning parts (optional, may be included in sputtering process);

    3d. Drying parts prior to sputtering;

    3e. Run sputtering process; and

    3f. Handling and storage of trays after sputtering.

4. Gold ablation. Krypton fluoride excimer laser is used to ablate the sputtered Cr/Au metal films and pattern the required sensor and contact electrodes. Laser irradiation (λ=248 nm) is projected through a chrome-on-quartz mask which has been patterned with the electrode layout. The projected mask image is focused onto the substrate to ablate the thin layers of metal, thus creating the pattern of electrodes. The ablation process is further defined by the following steps:

    4a. Transport tray from production room to microfabrication room;

    4b. Temporary storage of trays in microfabrication room;

4c. Loading parts onto the excimer laser machining tray;

4d. Loading tray into the excimer laser station;

4e. Run excimer laser machining process; and

4f. Handling and storage of trays after excimer ablation.

5. PSA application. In the context of this document, the term Pressure Sensitive Adhesive (PSA) is used exclusively to refer to the hydrophilic adhesive cover (Figure 2). PSA application refers to the process of aligning the PSA to the TCI Chip, applying heat and pressure to seal the PSA to the Chip to form a well defined microfluidic channel. The PSA application process is further defined by the following steps:

    5a. Transport tray from microfabrication room to production room;

    5b. Temporary storage of trays in production room;

    5c. Loading parts in the PSA alignment jig;

    5d. Loading PSA in the PSA alignment jig;

    5e. Run PSA alignment process;

    5f. Loading parts in temporary storage tray;

    5g. Move tray to sealing station;

    5h. Run sealing process; and

    5i. Handling and storage of trays after PSA application.

6. UV curing adhesive application. A thin layer of hydrophobic UV cured adhesive must be applied to the tapered edges of the TCI Chip near the tip to prevent wicking of the tear fluid along the edges. The process is further defined by the following steps:

    6a. Transport tray from production room to microfabrication room;

    6b. Loading adhesive in applicator;

    6c. Loading parts in applicatior;

    6d. Run adhesive application process;

    6e. Retrieve parts from applicator;

    6f. Load parts in tray; and

    6g. Handling and storage of trays after UV curing adhesive application.

7. Serial numbering. Serial numbering is the process where a laser is used to scribe on the back of each TCI Chip a pre-defined serial number. The process is further defined by the following steps:

    7a. Transport tray to microfabrication room;

    7b. Temporary storage of trays in microfabrication room;

    7c. Loading of trays in the laser;

7d. Run serial numbering process; and

7e. Handling and storage of trays after serial numbering.

8. Final card quality control. Final card quality control is the process where TCI Chips are inspected for manufacturing defects. The process is further defined by the following steps:

    8a. Transport tray from microfabrication room to production room;

    8b. Temporary storage of trays in production room;

    8c. Loading parts into inspection tool;

    8d. Run inspection process;

    8e. Loading parts into tray; and

    8e. Handling and storage of trays after final inspection.

9. Card assembly. Card assembly is the process where TCI Chips are inserted into their respective Capsules, and appropriate labels applied to the resulting assemblies called TCI Cards. A sheath is applied to the Card tip to protect it from accidental damages which may occur during transportation and storage, as well as from mishandling. The process is further defined by the following steps:

    9a. Temporary storage of trays in production room;

    9b. Load TCI Chip into the assembly process;

    9c. Load Capsule into assembly process;

    9d. Load tip protector sheath into the assembly process;

    9e. Load label into assembly process;

    9f. Run assembly process;

    9g. Load finished assemblies in storage container; and

    9h. Handling and storage of containers after assembly.

10. Packaging. The packaging process is further defined by the following steps:

    9a. Temporary storage of TCI Card assemblies in production room;

    9b. Load Card assemblies into packaging process;

    9c. Load packaging material into packaging process;

    9d. Load carton into packaging process;

    9e. Load label into packaging process;

    9f. Run packaging process; and

    9h. Handling and storage of packaged TCI Cards and cartons after packaging.

5 DESIGN SPECIFICATIONS

This section shall state the Design Specifications for the TCI Chip, the assembly, packaging and labeling of the TCI Card.

For readability and ease of reference, seven different categories of Design Specifications shall be described in table formats, in direct correspondence to those used in the OcuSense Product Requirements Document. They are Critical Specifications, Performance Specifications, General Specifications, Manufacturing Specifications, Environmental Specifications, Packaging and Labeling Specifications, and Durability Specifications.

Each table is made up of six columns: Design Specification Identification (DSID), OcuSense Product Requirement ID, Product Requirement Description, Specifications, Verification and References. Each specification is assigned a unique DSID and is traced to an OcuSense Product Requirement ID in the latest version of the OcuSense Product Requirements Document (PRD). Product Requirement Description explains the requirement in business and functional terms. The Specifications column lists explicitly any related design output. Verification states how the particular design specification can be validated during design and production. The References column provides reference codes to existing documents on design and production specifications. The reference codes are indexed in a Documentations Table at the end of the section.

Additionally, a Regulatory Specifications Table lists ALL of the regulatory requirements that the manufactured TCI Card must comply with, as specified by OcuSense.

5.1 Critical Specifications

The following performance specifications have been deemed critical. Unless otherwise stated, plus-minus type error notations are used throughout this Design Specification Document. All errors are implicitly in one-sigma form, assuming normal distributions.

DSID	OcuSense Product Requirement ID	Product Requirement Description	Specifications	Verification	References
DS1.1	PRD 6.6.2 (Table 9.1.1)	Accuracy: ±1.0%; defined as the error contribution from the TCI Card alone to the overall Osmolarity System error budget.	REV E TCI Chip design. Note: Sensor electrode width control: < ±1.5 µm. Channel width control @ sensor electrodes: < ±3 µm. Channel depth control @ sensor electrodes: < ±3 µm.	Design review & confirm during verification testing with liquid controls of known osmolarity.	R9.1 R9.2 R9.4
DS1.2	PRD 6.6.3 (Table 9.1.2)	Precision: ±1.5%; defined as the error contribution from the TCI Card alone to the overall Osmolarity System error budget.			

5.2 Performance Specifications

The following specifications relate to the TCI Card performance.

DSID	OcuSense Product Requirement ID	Product Requirement Description	Specifications	Verification	References
DS2.1	PRD 6.4.1 (Table 9.2.1)	Tear sample volume required to perform an osmolarity measurement shall be 50 nL maximum.	REV E TCI Chip design. Note: Minimum tear volume for fill detection is 46 nL by design.		R9.1
DS2.2	PRD 6.4.4 (Table 9.2.2)	Time to mount/dismount a TCI Card shall be less than 5 seconds.		Confirm during verification testing with the Osmolarity System.	

5.3 General Specifications

The following specifications relate to user safety and comfort.

DSID	OcuSense Product Requirement ID	Product Requirement Description	Specifications	Verification	References
DS3.1	PRD 6.5.5	The TCI Card shall have no rough or sharp edges on the disposable particularly on the tear collection interface.	REV E TCI Chip design. Note: Tapered form factor. Corner radii designed in. No flashing at the tear collection interface from injection molding process. PSA overhang at the interface controlled to < 20 μm.	Design review & confirmation during manufacturing process validation.	R9.1 R9.3
DS3.2	PRD 6.5.10.1 (Table 9.3.2)	The TCI Card shall cause minimal discomfort to the patient.		Verify during clinical trial by getting patients' feedback.	

5.4 Manufacturing Specifications

The following specifications relate to the TCI Card manufacturing.

DSID	OcuSense Product Requirement ID	Product Requirement Description	Specifications	Verification	References
DS4.1	PRD 6.5.11.5 (Table 9.4.3)	The TCI Card shall have a channel dry impedance of 1 MOhms minimum when used at a signal frequency between10 kHz and 100 kHz.	REV E TCI Chip design.	Design review & confirm during verification testing.	R9.1 R9.2

5.5 Environmental Specifications

The following specifications relate to the TCI Card operating and storage conditions.

DSID	OcuSense Product Requirement ID	Product Requirement Description	Specifications	Verification	References
DS5.1	PRD 6.5.12.1.1 (Table 9.5.1)	TCI Card operating temperature range shall be: 15 to 35°C.	REV E TCI Chip design.	Design review & confirm during verification testing of the Osmolarity System.	R9.1
DS5.2	PRD 6.5.12.1.2 (Table 9.5.2)	TCI Card operating humidity range shall be: 10 to 85%RH.			
DS5.3	PRD 6.5.12.1.3 (Table 9.5.3)	TCI Card operating altitude shall be: 0 to 2000 meters.			
DS5.4	PRD 6.5.12.2.1 (Table 9.5.4)	TCI Card storage temperature range shall be: 2 to 50°C.			
DS5.5	PRD 6.5.12.2.2 (Table 9.5.5)	TCI Card storage humidity range shall be: 10 to 85%RH.			
DS5.6	PRD 6.5.12.2.3 (Table 9.5.6)	TCI Card storage shelf life shall be two years under recommended storage conditions.		Accelerated shelf life testing.	

5.6 Packaging and Labeling Specifications

The following specifications relate to the TCI Card packaging and labeling.

DSID	OcuSense Product Requirement ID	Product Requirement Description	Specifications	Verification	References
DS6.1	PRD 6.7.8.1 to 6.7.8.8 (Table 9.7.1)	TCI Card shall be packaged as specified.	OcuSense to provide.	Visual inspection.	R9.5
DS6.2	PRD 6.7.8.10 (Table 9.7.2)	TCI Card Directions for Use shall be printed as specified.			
DS6.3	PRD 6.7.8.9 (Table 9.7.3)	TCI Card shall be labelled as specified.			

5.7 Durability Specifications

The following specifications relate to the durability of the TCI Card.

DSID	OcuSense Product Requirement ID	Product Requirement Description	Specifications	Verification	References
DS7.1	PRD 6.7.2.3 (Table 9.8.2)	TCI Card shall be able to survive and operate as per normal after a 1 meter drop.	Packaging design and specifications.	Confirm during verification testing of the Osmolarity System.	
DS7.2	PRD 6.7.6.2 (Table 9.8.3)	TCI Card shall withstand the combined temperature, humidity and atmospheric pressure prevalent in a commercial aircraft cargo hold, ocean bound shipping vessel, or land-based vehicle and operate as per normal afterwards.		Design review & confirm during verification testing.	

5.8 Regulatory Specifications

The design and construction of the TCI Chip, the assembly, packaging and labeling of the TCI Card shall comply with the regulatory requirements specified by OcuSense.

The following Regulatory Specifications Table is made up of five columns: Regulatory Specification Identification (RSID), OcuSense Product Requirement ID, Product Requirement Description, Verification and Implementation.

The RSID is a regulatory specification number unique to this Design Specification Document, which provides basis for validation traceability. The OcuSense Product Requirement ID links the regulatory specification to its Requirement ID in the latest version of the OcuSense Product Requirements Document (PRD). Product Requirement Description explains the requirement in business and functional terms. Verification states how a particular regulatory specification can be validated during design and production. Implementation specifies the party responsible for implementing the verification criterion and obtaining any relevant regulatory approval and certification.

RSID	OcuSense Product Requirement ID	Product Requirement Description	Verification	Implementation
RS1.1	PRD 9.1	The product shall be developed under FDA GMP and QSR and ISO design controls.	Design review to FDA 21 CFR 820 and ISO 13485	OcuSense and MiniFAB
RS2.1	PRD 6.7.7.3 (Table 9.6.2)	The TCI Card shall be compatible with the Osmolarity System; shall be capable of obtaining a Waiver under the U.S. Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).	FDA certification (42 CFR 493)	OcuSense
RS3.1	PRD 6.7.7.2 (Table 9.7.3)	The TCI Card shall be compatible with the Osmolarity System; shall be labeled and marketed under FDA 510(k) guidelines.	FDA 510(k) approval	OcuSense
RS4.1	PRD 6.7.7.4 (Table 9.6.3)	The TCI Card shall meet the In-Vitro Diagnostic (IVD) Directive 98/79/EC	Certification	OcuSense
RS5.1	PRD 6.5.11.3 PRD 6.5.11.4 PRD 9.5.1.3 PRD 6.5.11.2 (Table 9.4.2)	The TCI Card shall be designed and manufactured under FDA and QSR guidelines.	Design review	OcuSense and MiniFAB
RS5.2		The TCI Card shall be manufactured under ISO 9001 and ISO 13485 certification.	Certification & perform FMEA analysis	MiniFAB
RS5.3		The TCI Card shall be manufactured under ISO 14971 Risk Management.		
RS5.4		The TCI Card shall be manufactured in compliance with a non-sterile medical product.		
RS6.1	PRD 6.5.11.1 (Table 9.4.1) PRD 6.5.7	The TCI Card shall meet the biocompatibility requirements of ISO 10993 for limited mucosal contact.	Perform verification tests; obtain certificate of conformance	Certified independent test lab
RS6.2		The TCI Card shall be fabricated of materials that meet FDA		

	(Table 9.3.1)	biocompatibility guidelines.	from supplier	
RS7.1	PRD 6.7.7.6	The TCI Card shall be RoHS and WEEE compliant and the packaging labeled appropriately.	Design review & visual inspection	OcuSense and MiniFAB
RS8.1	PRD 6.7.7.5 Table (9.6.1)	The TCI Card shall be developed in accordance with CE requirements.	CE Self certification	OcuSense
RS9.1	PRD 6.7.8.9.1 Table (9.6.3)	The TCI Card labeling shall meet the applicable requirements from the IVD Directive.	Design review & visual inspection	OcuSense and MiniFAB
RS9.2	PRD 6.7.8.9.2 Table (9.6.4)	The TCI Card labeling shall comply with FDA 21 CFR 809.10 requirements.		
RS10.1	PRD 6.7.6.1 Table (9.8.1)	During transportation, the TCI Card shall conform to ASTM D4169 vibration requirements as well as those of the IVD Directive	Certification	OcuSense

5.9 Documentations

Reference Code	Document Description	Document File Name / Additional Notes
R9.1	Revision E TCI Chip design drawing, including material table and tolerances	070926_578_TCI_Card_REV_E_Design_Approval.pdf
R9.2	Coefficient of variation analysis	070723_578_04_CV_Analysis_V1.1.pdf
R9.3	TCI Card process FMEA analysis	070817_578-006_08_ProcessFMEA_V0.3.pdf
R9.4	TCI Card volume production process flow	070817_578-006_ProcessFlow_v1.3.ppt
R9.5	TCI Card packaging options	070815_578-006_Packaging Options.doc

Appendix 1 Acronyms and Definitions

- TCI Chip: Tear Collection Interface Chip is a low cost microfluidic disposable component designed and manufactured by MiniFAB for the OcuSense Osmolarity System (OS). The TCI Chip serves as the interface to tear fluid collection and the site of the osmolarity assay, as well as the electrical sensor connection to the assay for measuring tear fluid osmolarity.
- Capsule: A disposable plastic housing for holding a TCI Chip.
- TCI Card: The TCI Chip and the Capsule together form a disposable assembly called the TCI Card.
- Osmolarity Pen: Multiple use hand-held instrument designed for holding the TCI Card during tear collection, transport, and measurement; also designed as an electrical interface between the TCI Card and the Osmolarity Instrument.
- Osmolarity Instrument: Multiple use table-top instrument incorporating a computerized control system, sensor electronics and signal processing hardware and software for electrical impedance measurement, data logging and communication facilities, and two interfaces designed for connecting to and controlling the Osmolarity Pens.
- Osmolarity System: Tear fluid testing platform incorporating the Osmolarity Instrument, the Osmolarity Pen and the TCI Card.
- PSA: Acronym for Pressure Sensitive Adhesive. In the context of this Design Specification Document, the term is used exclusively to refer to the hydrophilic adhesive cover used to seal the microfluidic channel on a TCI Chip.

Appendix 2 List of Applicable Regulatory Standards and Legal Documents

Standard	Standard Name	US	EU	RoW
U.S. 21 CFR 820	Medical Device Quality System Regulation	X		
U.S. 42 CFR 493	Laboratory Requirements	X		
U.S. 21 CFR 809	In Vitro Diagnostic Products for Human Use	X		
U.S. CLIA '88	U. S. Clinical Laboratory Improvement Amendments of 1988	X		
ISO 10993-1:2003	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing	X	X	X
ISO 10993-13:1998	Biological Evaluation of Medical Devices – Part 13: Identification and Quantification of Degradation Products from Polymers	X	X	X
ISO 14971:2007	Medical devices – Application of risk management to medical devices	X	X	X
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems	X	X	X
ISO 13485-2003	Medical devices - Quality Management Systems - Requirements for Regulatory Purposes		X	X
1998/79/EC	In Vitro Diagnostic Directive (IVD)		X	
2002/95/EC	Restriction of Hazardous Substances Directive (RoHS)		X	