U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER:	(ixg)
FOLDER:	K110301 - 693 pages (FOI:12000815)
COMPANY:	HOME SKINOVATIONS LTD. (HOMESKIN)
PRODUCT:	LIGHT BASED OVER THE COUNTER WRINKLE REDUCTION (OHS)
SUMMARY:	Product: SILK'N FX
DATE REQUESTED:	Mar 6, 2013
DATE PRINTED:	Mar 6, 2013
Note:	Releasable Version

K110301

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Home Skinovations Ltd.

Silk'n FX

AUG 19 2011

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Tavor building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Silk'n FX
Common/Usual name:	Light Emitting Diode (LED) device
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21CRF §878.4810)
Product code:	OHS

Predicate device

- Omnilux New-U, (K072459), By Photo Therapeutics Inc.

Intended use:

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Device Description:

Silk'n FX is a hand held device battery operated that uses low power light spectrum at red and infrared LED, at wavelength of 633 ±5nm, 830 ±5nm emitting optical power in a uniform distribution with no hot spots.

Performance data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CRF § 1040.10 & 1040.11.

Substantial Equivalence:

The Silk'n FX is substantial equivalent to its predicate device. The data in this 510(k) submission demonstrate that the Silk'n FX device has identical output and intended use as other predicate device. Therefore is substantial equivalent to its predicate devices.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the Silk'n FX should raise no new issues of safety or effectiveness.

January 27, 2011

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skinovations Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Home Skinovations Ltd.
% Amir Waldman, Ph.D.
Tavor Building, P.O.Box 533
Yokneam 20692, Israel

AUG 19 2011

Re: K110301
Trade/Device Name: Silk'n FX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: August 14, 2011
Received: August 17, 2011

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K110301.

Device Name Silk'n FX

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Neil R. Ogden for MKA
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110301

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Home Skinovations Ltd.
% Amir Waldman, Ph.D.
Tavor Building, P.O.Box 533
Yokneam 20692, Israel

AUG 19 2011

Re: K110301
Trade/Device Name: Silk'n FX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
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Product Code: OHS
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Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K110301

Device Name Silk'n FX

Indications For Use:

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Prescription Use_____ OR Over The Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Neil R. Ogden for MRN
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110301

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 05, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301
Product: SILK'N FX

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 22, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301
Product: SILK'N FX

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

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If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 27, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301

Product: SILK'N FX

Extended Until: 06/30/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

373

HomeSkinovations

Apolo building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

May 25, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAY 27 2011
Received K44

Re: Letter dated May, 3, 2011 K110301

Dear Mr. Bandukwala

Thank you for your letter dated May, 3, 2011 in response to our 510K submission for the Silk'n FX (K110301).

We would like to ask for extension in order to supply the additional information requested in your letter.

Regards,
Amir Waldman Ph.D.
VP regulation Amir Waldman
Home Skinovations Ltd.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 06, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301
Product: SILK'N FX

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Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 09, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301
Product: SILK'N FX

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Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 02, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301
Received: 2/2/2011
Product: SILK'N FX

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at
http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

HomeSkinovations

Apolo building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K-1

510(k) Submission for Silk'n FX

Home Skinovations Ltd.

January 27, 2011

474

Silk'n FX
510(k) Notification

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6.	Premarket Notification Truthful and Accuracy Statement	
7.	Class III Summary and Certification	NA
8.	Financial Certification or Disclosure Statement	NA
9.	Declaration of Conformity and Summary Reports	NA
10.	Executive Summary	
11.	Device Description	
12.	Substantial Equivalent Discussion	
13.	Proposed labeling	
14.	Sterilization and Shelf Life	NA
15.	Biocompatibility	
16.	Risk Analysis and Software Documents	
17.	Electromagnetic Compatibility and Electrical Safety	
18.	Performance Testing - Bench	
19.	Performance Testing - Animal	NA
20.	Performance Testing – Clinical-usability	

Chapter 1

Medical device user fee cover sheet (form FDA 3601)

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: Write the Payment Identification number o[redacted]

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
Home Skinovations Ltd. Apolo Buld POB 533 Yokneam 20692 IL	Yoram Sadeh 2.1 E-MAIL ADDRESS yorams@silkn.com 2.2 TELEPHONE NUMBER (include Area code) 972-49097476 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

[redacted] 24-Jan-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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Chapter 2

CDRH Premarketing Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
January 27, 2011	[redacted]	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Home Skinovations Ltd.	Establishment Registration Number *(if known)*: 3006948334		
Division Name *(if applicable)*:	Phone Number *(including area code)*: +972-547404616		
Street Address: Tavor building POB 533	FAX Number *(including area code)*: +972-49097471		
City: Yokneam Illit	State / Province:	ZIP/Postal Code: 20692	Country: ISRAEL
Contact Name: Amir Waldman Ph.D.			
Contact Title: VP regulatory affairs	Contact E-mail Address: amirw@silkn.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Graphics (301) 443-1090 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Response to FDA correspondence:

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OHS	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072459	1	Omnilux New-U	1	Photo Therapeutics Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Laser Instruments, Surgical powered- general and Plastic Surgery - Class II, 79 GEX

	Trade or Proprietary or Model Name for This Device		Model Number
1	Silk'n FX	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: OHS

C.F.R. Section *(if applicable)*:

Classification Panel:

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Home Skinovations Ltd.		Establishment Registration Number: 3006948334	
Division Name *(if applicable)*		Phone Number *(including area code)*: +972-547404616	
Street Address: Tavor Buld. POB 533		FAX Number *(including area code)*: +972-49097471	
City: Yokneam Illit		State / Province	ZIP Code: 20692 / Country: Israel
Contact Name: Amir Waldman Ph.D.	Contact Title: VP Regulatory affairs	Contact E-mail Address: amirw@silkn.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC 60601-1	International Electrotechnical Commission	Medical Electrical Equipment" Part 1:"General requirements for safety"	2 edition	01/01/1988
2	IEC 60601-1-2	International Electrotechnical Commission	Medical Electrical Equipment part 1-2 collateral standard electromagnetic compatibility - requirement and tests	2.1 edition	01/01/2004
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Chapter 3

510(k) Cover Letter

K110301

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

January 27, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
FEB 02 2011
Received

K-1

Subject: Traditional 510(k) Submission for Silk'n FX

Dear Sir/Madam,

Home Skinovations Ltd. is submitting this premarket notification for the purpose of obtaining FDA marketing clearance for its product. A table of contents for this 510(k) application is presented immediately after this cover letter. The following is information required under 21 CFR 807.87:

This is to notify you of the intention of Home Sknovations Ltd. to manufacture and market the following device:

Please send all correspondence by fax (+972-4-9097471), and e-mail amirw@silkn.com, in addition to mail

Trade/Proprietary name:	Silk'n FX
Common name:	Light Emitting Diode (LED)device
Classification name:	The subject of this application is a Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product codes:	OHS
Class of device:	The device should be considered a class II device, as are the predicate devices.
Reason for Application:	New device.

Name and address of Manufacturer:	Home Skinovations Ltd. Home Skinovations Ltd. Tavor building POB 533 Yokneam 20692 ISRAEL Tel: +972(4)9097440 Fax: +972(4)9097471
Contact person:	Dr. Amir Waldman VP regulatory affairs Tel. +972-547-404616, +972-4-9097440 Fax +972-4-9097471 E-mail - amirw@silkn.com
Applicable standards:	Action taken by the person required to register to comply with the requirements of the Act under section 514 for performance standards or section 513 for special controls: There are no mandatory performance standards applicable to this device. There are voluntary performance standards that the Silk'n FX complies with as discussed in chapter 17.
Labeling/Promotional material:	The labeling and promotional materials for the Silk'n FX, and for the substantially equivalent predicate devices, are presented in later sections of this application.
Substantial equivalence predicate devices:	Silk'n FX is substantially equivalent to the following devices: • Omnilux New-U, Indication for use: "The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles". Manufactured by Photo Therapeutics Inc.

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

	and subject of K072459.
Confidentiality:	The material in this application is considered confidential and is not meant for public release.
Truth and Accuracy Statement:	A truthful and accurate statement, according to 21CFR 807.87(k), is presented after a separate page with the indications for use.
SMDA Safety and Effectiveness Summary:	Summary of Safety and is presented following the table of contents.

We trust that the information included in this application will be adequate to allow for its prompt review. Please contact me if there are any questions.

Sincerely yours,

Dr. Amir Waldman

VP regulatory affairs

Home Skinovations Ltd.

Chapter 4

Indication For Use Statement

510(k) Number (if known) K110301.

Device Name Silk'n FX

Indications For Use:

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use_X___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Chapter 5

510(k) Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Home Skinovations Ltd.
Silk'n FX

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Tavor building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Silk'n FX
Common/Usual name:	Light Emitting Diode (LED) device
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21CRF §878.4810)
Product code:	OHS

Predicate device

- Omnilux New-U, (K072459), By Photo Therapeutics Inc.

Intended use:

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Device Description:

Silk'n FX is a hand held device battery operated that uses low power light spectrum at red and infrared LED, at wavelength of 633 ±5nm, 830 ±5nm emitting optical power in a uniform distribution with no hot spots.

Performance data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CRF § 1040.10 & 1040.11.

Substantial Equivalence:

The Silk'n FX is substantial equivalent to its predicate device. The data in this 510(k) submission demonstrate that the Silk'n FX device has identical output and intended use as other predicate device. Therefore is substantial equivalent to its predicate devices.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the Silk'n FX should raise no new issues of safety or effectiveness.

January 27, 2011

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skinovations Ltd.

Chapter 6

Premarket Notification Truthful and Accuracy Statement

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PREMARKET NOTIFICATION TRUTHFUL AND ACCURACY STATMENT

(As required by 21 CFR 807.87(j))

I certify that in my capacity as VP of Regulatory Affairs of Home Skinovations Ltd., I believe, to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Amir Waldman

Dr. Amir Waldman

January 27, 2011

Chapter 10
Executive Summary

Executive summary

Device description

Silk'n FX is a hand held device battery operated that uses low power light spectrum at red and infrared LED. B [redacted]

Indication for use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Substantial equivalent

The Silk'n FX is substantially equivalent (SE) to Omnilux New-U, Indication for use: "The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles". Manufactured by Photo Therapeutics Inc. and subject of K072459.

Intended use comparison: Silkn FX and Omnilux New-U have the same intended use.

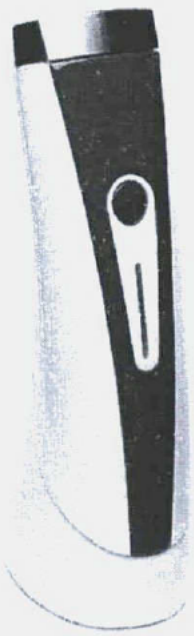
Technical and Output comparison: B [redacted]

Chapter 11
Device Description

Device Description

Silk'n FX is a hand held device battery operated that uses low power light spectrum B [redacted]

General View – Silk'n FX



Device specifications:

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Control

The control of the system is carried out through a combination of hardware controls and a real-time controller that monitors the status and parameters of the device subsystems. The micro controller generates electrical signals that deliver the proper energy out of the Applicator.

The interface of the real-time controller with the operator is carried out through a control panel that shows the status of the system.

The control functions and the structure of the hardware element of the control system are shown in ***Figure 1.***

[redacted]

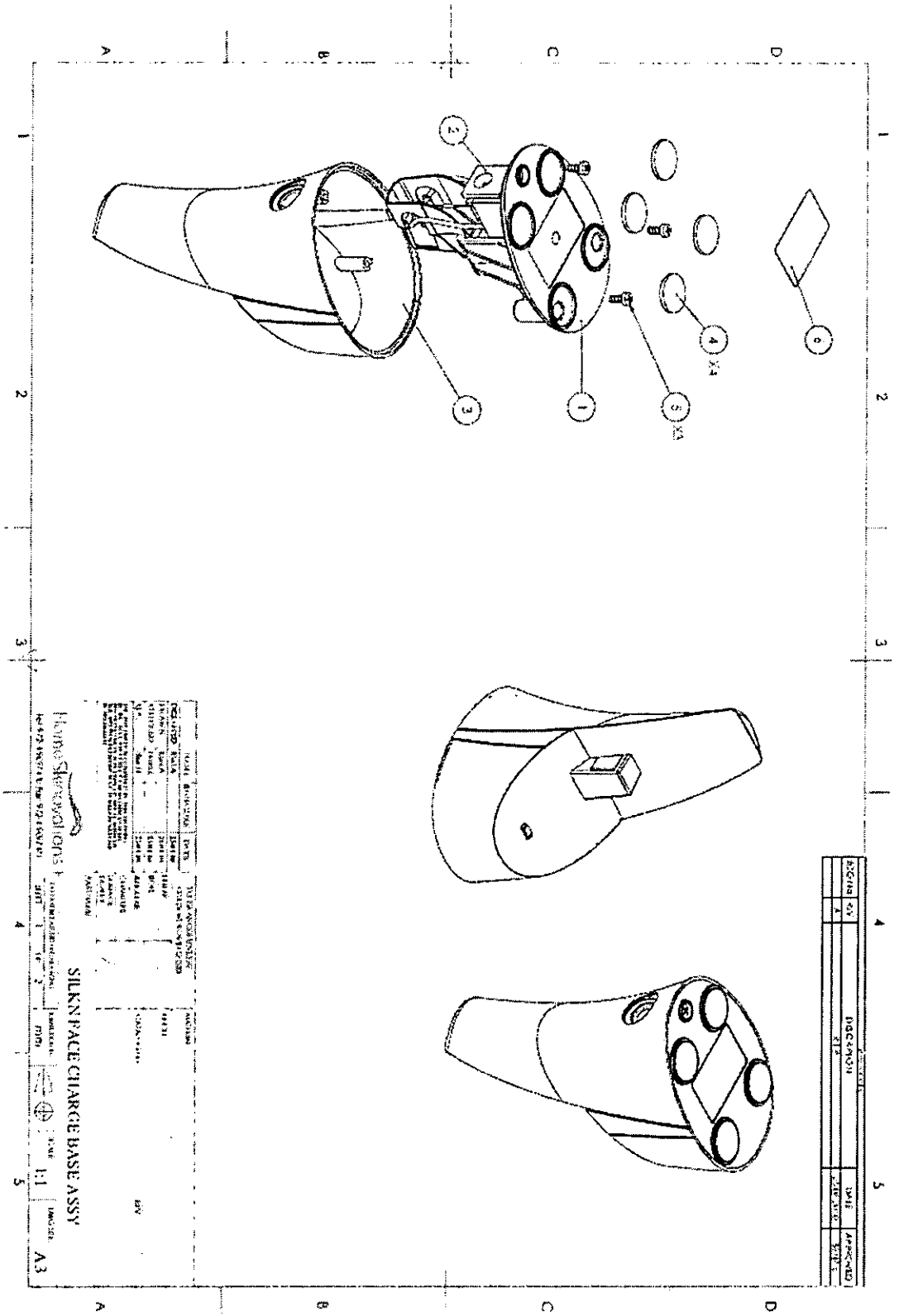
hFigure 1- Silkn FX - block diagram

AC Adaptor

AC-DC isolated power supply

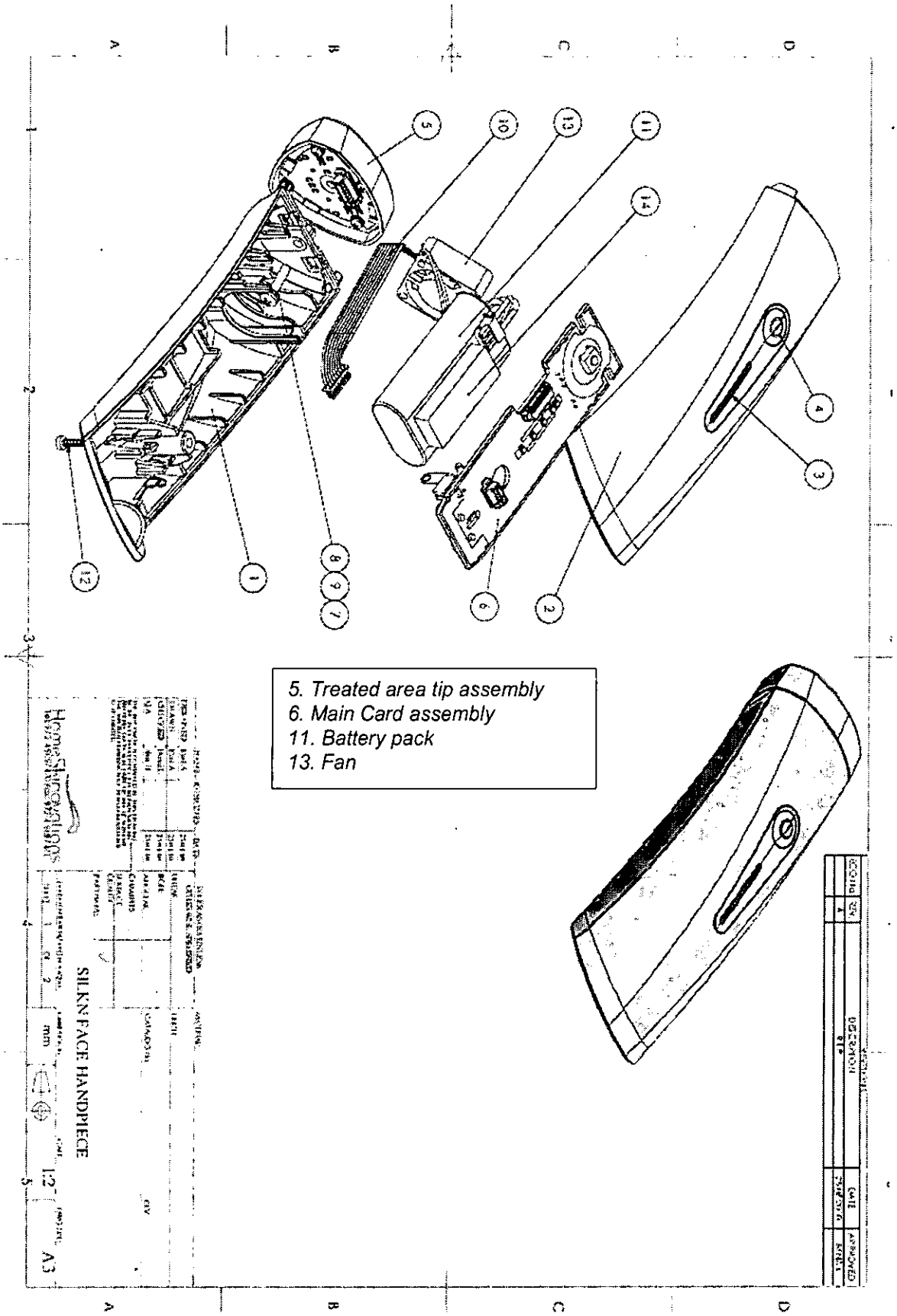
Base

The base is the charger cradle of the Applicator.



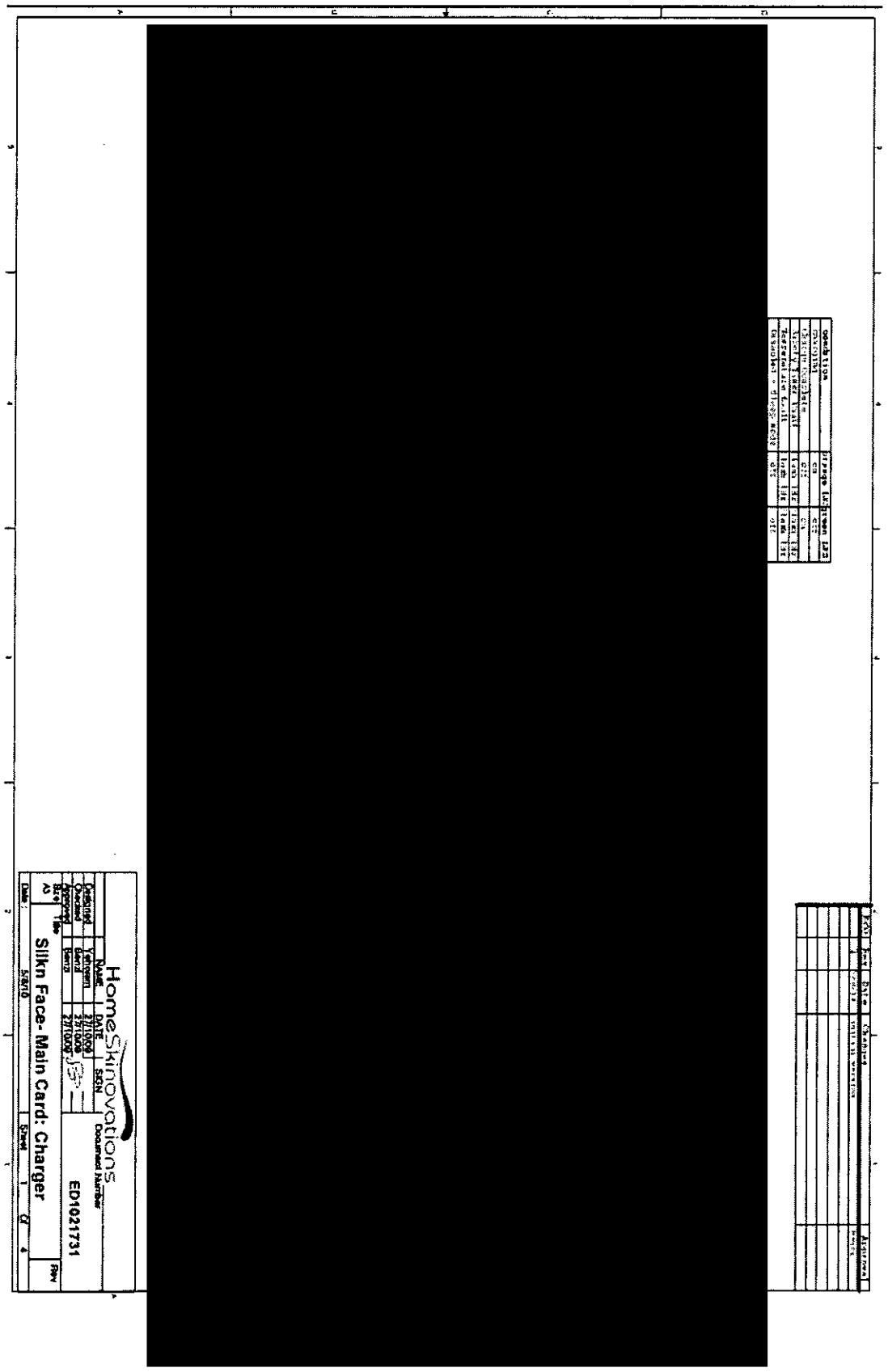
Applicator

The applicator contains Li-ion rechargeable battery pack, Lamp card, main card and FAN.



Main Card

The main card controls the device, it based on microcontroller that controls the device on off, battery charge, Fan speed, LED indications, treated LED and monitoring the treated area temperature.



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	DATE	SIGN
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	27/10/09	

Document Number

ED1021731

A3

Silkn Face- Main Card: Controller

Rev

Date : 5/8/10

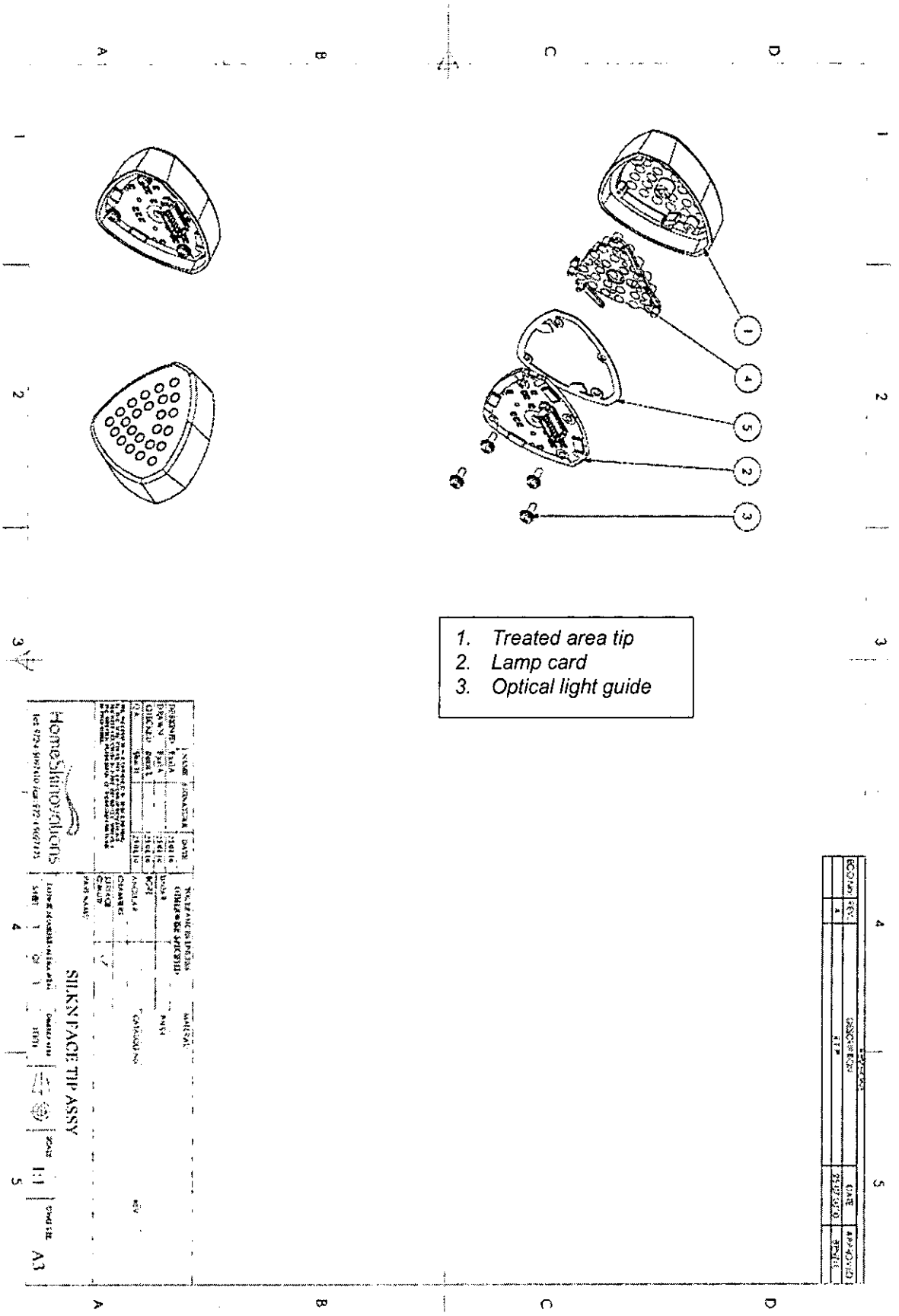
Sheet 4 Of 4

503

B4, Technical Drawings

B4, Technical Drawings

Treated area assembly:



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Fax: +972(4)9097471

Silk'n FX
SYSTEM REQUIREMENTS SPECIFICATION

B4 [redacted]

Project:	Silk'n FX
Date:	July, 2009
Written by:	Yehoram Bar
Approval:	Ben Zion Levi

Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	All	Initial	Ben Zion Levi	07 Nov 2009

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1. Introduction

1.1. Document Purpose and Scope

This document describes the inputs and outputs of the system, and the relationships between those inputs and outputs.
The recommended uses of this document are:

- To communicate the necessary information for implementation of the system to suppliers of FX System and the customers who may use the system. Suppliers are those entities that may wish to design and produce the system; customers are those entities who may wish to use the system.
- During systems design, to allocate requirements to subsystems, hardware, software, operations, and other major components of the system.
- Construction guidance of a FX System.
- During systems development, providing a baseline for verification of deliverables.
- Providing a baseline for validation of the completed system.

This specification does not:

- Recommend a specific hardware or software components of the desired system.
- Presume a supplier of the system, such as an independent systems supplier.

1.2. Document Overview

This document defines the characteristics Silkn FX is an over the counter device indicated to B4 [redacted]

1.3. References

The following table lists all documents which supply inputs to this FX System:

1. FX Marketing Requirements Specification - DO101581A.
2. IEC 1233-1996, Guide for Developing of System Requirements Specifications
3. DO1017063 FX AC adaptor specification

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1.4. Definitions, acronyms and abbreviations

The following table defines terms and definitions used in this FX submission:

Term	Definition
SRS	System Requirements Specification
V&V	Verification and Validation
µC	Micro Controller
I/O	Input/ Output
PS	Power Supply
I^2C communication	I2C communications standard
RFID	Radio Frequency Identification
HV	High Voltage
LED	Light Emitting Diode
HP	Hand piece
RH	Relative Humidity
MMI	Man Machine Interface
SWRS	Software Requirement Specification
MTBCC	mean time between customer calls
MTBF	mean time between failure
MDD	Medical Device Directive
LVD	Low Voltage Directive
FCC	Federal Communications Commission (USA)
EEC	European Electromagnetic Compatibility
CSA	Canadian Standards, Association
CE	CE marking

Table 1: acronyms and abbreviations

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2. Background

2.1. Function and purpose

B4 [redacted]

2.2. Environmental considerations

2.2.1. Physical Dimensions

The machine should have the following physical characteristics:
Size: in order to ensure easy transportation the system should have small dimensions for user convenient and storage in a regular bedroom drawer. Therefore, the package should be limited to be around 20x20x12 [cm].
Weight: for the above reason, the system + packaging should weigh no more than 1Kg while the hand piece should weigh less than 500gr, to ensure ease of use.

2.2.2. Operational Specification

Operating temperature:	15°C to 35°C
Humidity:	0-80% RH

2.2.3. Non Operational Specification

Storage temperature:	-20°C to 55°C
Humidity:	0-90% RH

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2.2.4. Electrical Specification

A universal AC wall Adaptor (90-264Vac 50-60Hz) is connected to the rear side of the Cradle part. The AC wall Adaptor power connector is interchangeable pin (EU, UK, US, SAA) defined in Table 2 according to the distribution market:

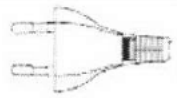
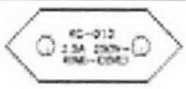
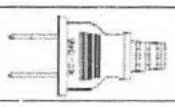
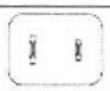
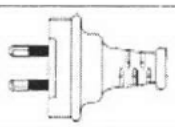
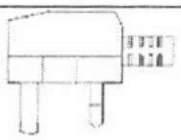
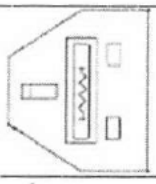
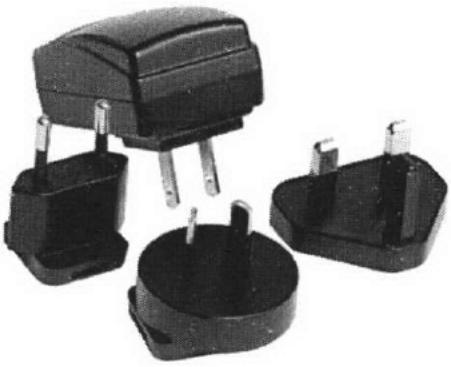
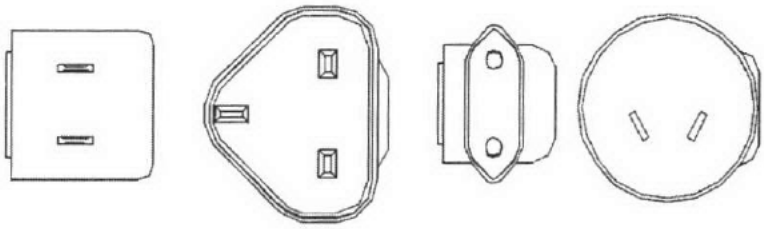
#	Destination	Plug type		
1	Europe	KC-013		
2	N. America	KC-048		
3	N. America- polarized			
4	Japan	YSI-03		
5	Australia	KC-033		
6	UK	Y006A (YSD-02)		

Table 2: AC power cords according to distribution markets.





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2.2.5. Customer

Who is the target customer?

The primary customers are adult users using the device for personal treatment of peri-orbital wrinkles.

Does the product have sterilization requirements?

No

2.3. System compatibility (Relation to other systems)

2.3.1. Other Equipment

The system contains the following parts:

- AC power wall adaptor
- Cradle
- Hand piece

In normal operation the hand piece is stand alone device.
Along the battery charging, the hand piece is inserted into the cradle which connected to the AC wall power adaptor.
Device is not required to interface with any other equipment.

2.3.2. Additional Option

N/A

2.4. Model

This section provides a functional description for each of the key system modules.
Figure 1 shows the system block diagram.

B4 [redacted]

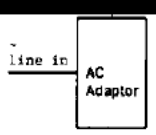

Figure 1 - System block diagram.

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The following table outlines the main system components and their functionality.

AC Adaptor	**Functional Description**
	Supplies 10V DC regulated voltage for battery charger.
Cradle	**Functional Description**
	Mechanical cradle for Hand Piece batteries charging and bridging connection between AC adaptor plug and charging contacts in Hand piece.
Hand Piece	**Functional Description**
Main card	Battery charger, the micro controller IC, FAN driver, toggle switch detector, voltage regulator and indications LEDs.
Lamp Card	Contains Temperature Stabilizer, LED array touch pad for touch sensor.
FAN	Fast heat removal for fast temperature reduction.

Table 3: Main system components and functionality.

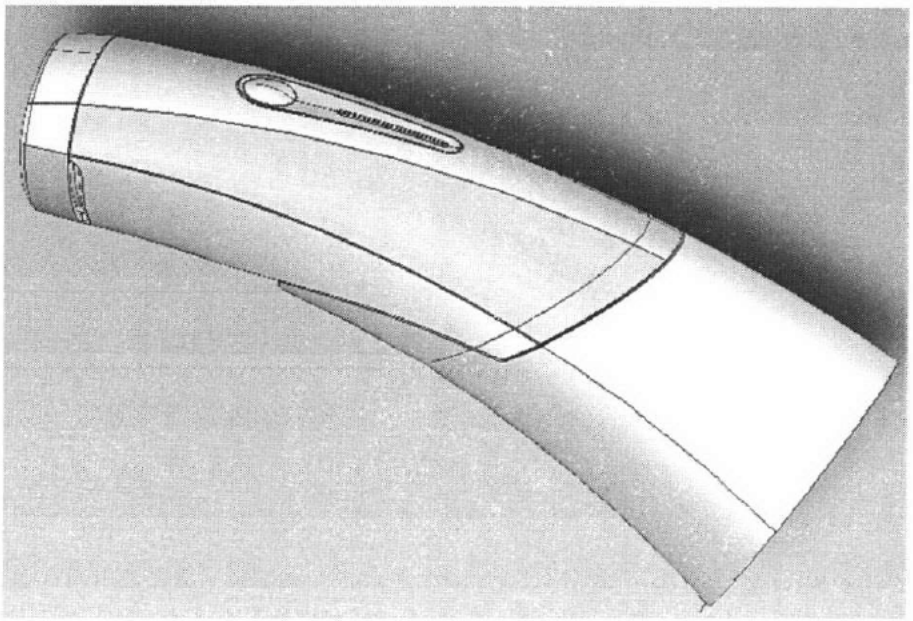

Figure 2 – Hand Piece attached to the cradle.

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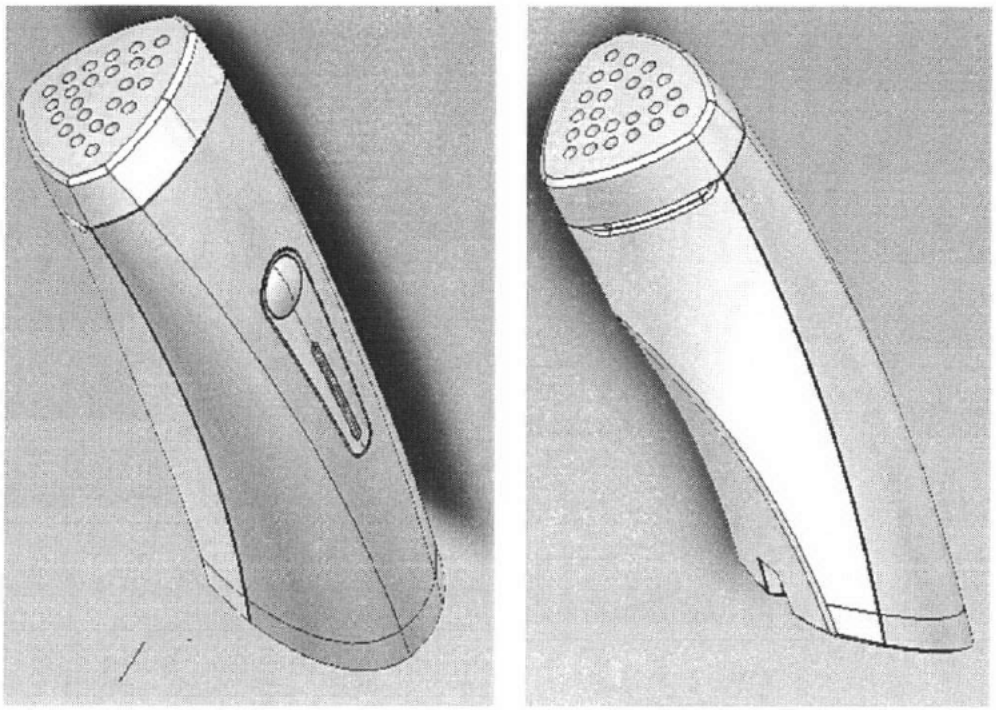

Figure 3 – different views of the Hand Piece.

2.5. Relation to another projects

N/A

2.6. General constraints

2.6.1. Standards

The Home Skinovations device will meet the requirements of the following standards:

LVD Directive 2006/95/EC

EMC Directive 2004/108/EC

MDD: 93/42/EEC

Safety standard, EN60601-1

EMC standard, EN60601-1-2

CSA International

2.6.2. Regulatory Approvals

The following regulatory approvals are required for the FX project:

CE Mark

- Requires design control according to MMD, EMC and LVD directives.

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- Safety and EMC testing will be prepared.
- FDA: Either 510k approval will be required
- Other regulatory approvals and requirements will be met as they arise.

2.6.3. Intended use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

2.6.4. Indication / Contra-Indication

2.6.4.1. Indication

The System is used for personal facial wrinkle and skin treatment

2.6.4.2. Contra Indication

- If you have dark brown or black spots, such as large freckles, birth marks, moles or warts on the area to be treated.
- If you have eczema, psoriasis, lesions, open wounds or active infections, such as cold sore in the area to be treated. Wait for the affected area to heal before using FX.
- If you have abnormal skin conditions caused by diabetes or other systemic or metabolic diseases
- If you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.
- If you have been treated with Accutane® (isotretinoin) within the past 6 months.
- If you have been on a steroid regimen within the past 3 months.
- If you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using FX.

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3. Specific Requirements

3.1. Overview

This document incorporates many sections that were found to be relevant from IEEE 1233 System requirement document. Few were altered to meet the device specifications.

3.2. FX system characteristics

The FX device will include the following characteristics:

3.2.1. Treatment characteristics

In order to maintain ease of use, the FX device should have the simplest possible human interface, with buttons and light indicators.
The Hand-Piece should be as light as possible, and in any case weigh no more than 0.5kg, to ensure the user can carry on treatments without tiring. Also, the Hand-Piece part should be ergonomically designed, so the user can hold it in the most natural and comfortable position while using the device.

3.2.2. Energy output characteristics

3.2.2.1. Light Energy

B4 [redacted]

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4. Hardware Requirements

4.1. AC Adaptor

B4 [redacted]

4.2. Cradle

The cradle is only a cradle which placing in the FX hand piece. Electrically it connects the AC wall adaptor output voltage to fast release spring contacts.

- Input/output voltage 10.5V±0.5V
- current 400mA

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4.3. Hand piece

4.3.1. General requirements

- The hand piece should weigh less than 500gr
- Hand-Piece part should be ergonomically designed.
- Low cost

The Hand Piece contains the following accessories:

4.3.2. Main Card

B4 [redacted]

[redacted]

4.3.2.2. Micro controller

The µC is responsible for the below tasks:

- MMI - monitor the device operating and control the LED indicators.
- Operating buttons:
  On/Off Toggle the system between 3 different On states for 3 different treatments and a Off state. While at off state - maximum leakage current ~ 2µA.

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- B4 [redacted]

4.3.2.4. *Toggle switch circuit*

The toggle switch circuit is responsible for turning on and off the Hand piece and changing the operational modes of the treatment using one momentary metal dome switch.

The circuit should meet the following requests:

- Switch on/off all the voltages in the system according to a toggle switch.
- Very low current consumption when system is off ~1μA
- Optional of Power off by the μC (such as for low battery voltage).
- Disconnect all the voltages in the system along battery charging.
- Reliable toggle operation at short and long switch pressing.
- Low power and voltage drop on the switching transistor
- Safety Shut down the system voltage on abnormal temperature operation
- Low cost < 1$

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4.3.2.5. 5V voltage regulator

The 5V voltage regulator is using for voltage regulation to the micro controller and Fan. It should meet the following requests:

- Output voltage 5V
- Output current > 200mA
- Low dropout voltage <0.3V
- Low consumption current <10mA
- Short Circuit Protection
- Low cost < 0.3$
- Small case size

4.3.3. B4 [redacted]

4.3.4. FAN

The FAN should have the following features:

- Nominal voltage 5V
- Current consumption <200mA
- Max. Airflow 2.4 CFM
- Speed ~8500 RPM

4.4. Box frame and covers

- Robust design of Plastic frame
- Low cost materials

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5. Communication services

- Optional RS232 communication to micro-controller via test point (internal only!).
- Optional I^2C communication to micro-controller via test point (internal only!).

6. System Capability

6.1. Functional

6.1.1. Self-Test

Self-Test preformed after Power switch is turned on.

If the self test is passed, the system start stabilizing the tip and the green indicator LEDs are flashing until the Temperature Stabilizer reach Treq-5°C. From this temperature and on, the relevant green indicator LED are turned on and the machine is ready for treatment (tip LED illuminations and tip temperature stabilizing).

In case of failure in the self test, the system is disabled for user operation and the yellow LED indicator will blink.

6.1.2. B4 [redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]		[redacted]
	[redacted]		[redacted]
	[redacted]		[redacted]

[redacted]

[redacted]

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6.1.4. B4 [redacted]

[redacted]

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B4 [redacted]

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A summary of the above states is shown below:

B4	ystem		B4 Indications					on

6.1.5. Sound Indicator

- None.

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6.2. Interfaces

6.2.1. Software

Refer to SWRS.

6.2.2. Hardware

- On/Off momentary switch
- Indication LEDs as following:

Index	indication	LED color
1	On state	2 Green LEDs
2	Error	Yellow
3	Battery charging	Orange - along charging Green - End Of Charging

6.2.3. Communications

Optional I^2C and Rs232 – Please refer to SWRS.

6.2.4. External interface

N/A

6.3. Operational

6.3.1. B4 [redacted]

[redacted] initiation process

- The user removes the hand piece from the cradle (or from the box) otherwise the hand-piece will not turn on.
- The user presses the "On/off switch" and turn on the system.
- The 5V regulated power supply is activated and the µC is turned on.

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- The software runs a self test. If any problem detected the system goes to Error mode.
- B4 [redacted]

6.3.6. User interface layouts

The layout of the user interface is shown in *Figure 4*. For detailed user interface please refer to SWRS.

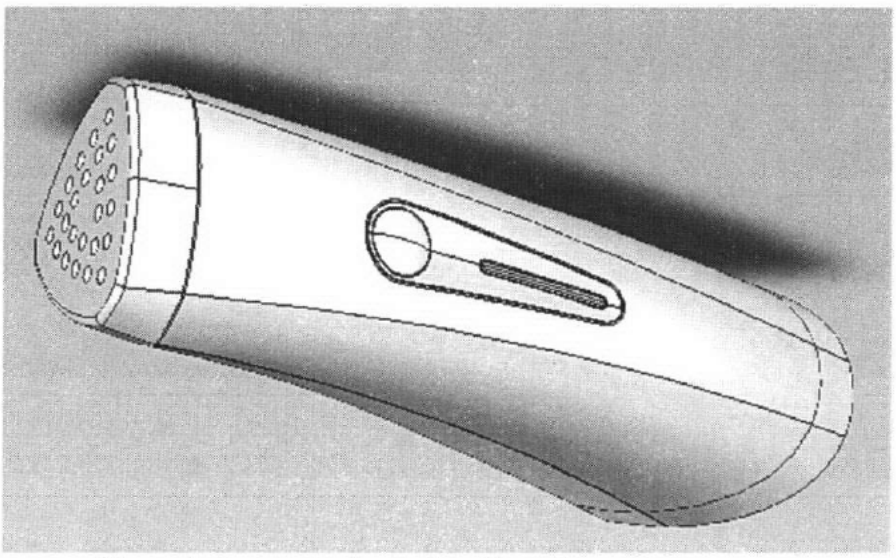

Figure 5 - user interface of the Hand Piece part.

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6.3.7. Handling of Error messages and Warnings

6.3.7.1. Errors

Refer to SWRS

6.3.7.2. Warnings Symbols

Refer to User Manual

6.4. Security and Integrity

N/A

6.5. Safety

6.5.1. Electrical, Mechanical and Fire Hazards

The FX device shall conform to applicable construction and performance requirements of, IEC 60601-1 for more details refer to Appendix A

6.5.2. Radiation Exposure and measurements

N/A

6.5.3. Electromagnetic Compatibility (EMC)

The FX device shall conform to the applicable EMC emissions and immunity requirements of IEC 60601-1-2;

For more details refer to Appendix A.

6.5.4. Patient Contact Material Biocompatibility and sterilization

N/A

6.6. Quality

- Complied with MDD:93/42/EEC (Annex II)
- FDA 21 CFR
- For more details refer to Appendix A

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7. System Management

7.1. Installation Support

N/A

7.2. Diagnostics tools

N/A

7.3. Configuration, release control

Refer to Quality Manual

7.4. Instrumentation

N/A

7.5. Tuning

N/A

7.6. Backup and recovery

N/A

7.7. Operational control (system administration)

N/A

7.8. Others

N/A

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Fax: +972(4)9097471

8. Operational characteristics

B4 [redacted]

[redacted]

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8.3. Availability

8.3.1. Failure Definition

- A failure has occurred whenever the user responds to the system behavior by calling for Service support. System reliability is measured using the mean time between customer calls (MTBCC).
- Because some of the calls can be related to user mistake it is important to trace mean time between failures (MTBF) which is indicated when system coming to service center is tested and real failure is found.

8.3.1.1. B4 [redacted]

8.4. Reliability

8.4.1. System required MTBF

System mean time between failures shall be no less than 12 months during first year of production and at least 24 months later.

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9. System Architecture

9.1. Maintainability

9.1.1. Installation and Warranty Failures

Since that the device cost is quite low (~30$), replacement of the product with new one will be done in warranty failures, unless different decision will be accepted.

9.2. Portability

By definition.

9.3. Software constitution and structure

Refer to FX software requirements specification

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10. Documentation

10.1. Operational Support

This product shall conform to the common standard of documentation which is required of all HSN products. The FX device shall conform to this definition and will follow the format described in Direction of HomeSkinovations Company.
Translations of all user documentation shall be provided on an as needed basis.
The user interface (U/I) shall only be available in English.
The FX shall have the following documentation in accordance with FX Policies English-Language Policy for FX products and English Language Policy for Service:

- Documentation:
- User's Manual
- Warranty
- Packaging information

10.2. Warranties

1 year for the customers
Different periods according to distributor's contracts.

10.3. Maintainability

User shall maintain system in clean conditions according to User Manual.
All testing and repairing are performed by company authorized personal only.

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11. Other Services

11.1. Training

- Sales, Marketing personal will be trained on product features, technology and ordering process.
- Service personnel must be trained on the product design and testing.

11.2. Installation Process

N/A

11.3. Environmental Requirements

B4 [redacted]

11.4. Service / Maintenance

- The FX device is intended for multiple uses and therefore, it requires cleaning the tip using a dry rag after each use.
- Installation - The Device should operate out of packaging, requiring minor assembly for batteries charging.

11.5. Packaging and Labeling

- The FX package will include the following items:
  1. FX Base Unit and Applicator.
  2. Adaptor.
  3. User's Manual.
  4. An Instructional DVD
- The Device will be labeled with the product logo.
- Labeling will be supplied in the language as relevant. Labeling will conform to EN 980:2008.

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12. Developmental requirements

12.1. Roles and Responsibilities

Refer to Project Plan

12.2. Phases

Refer to Project Plan

12.3. Verification

12.3.1. Safety Analysis and Documentation

In accordance with FX Quality Procedures, Risk Management according to ISO14971, FMEA, and design reviews shall be completed as appropriate to identify and control hazards and to assure regulatory compliance.

12.3.2. Software Design, Development and Validation

B4 [redacted]

12.3.3. Quality Management and Quality Systems

In accordance with FX policy on Good Manufacturing Practice, the design/development, production, installation and servicing of the FX device shall conform to the applicable requirements of EN (IEC)60601-1, EN (IEC)60601-2-2, EN (IEC)60601-1-2, EN (IEC)60601-1-1, EN14971, FCC part 18, Quality Devices, and FDA 21CFR Part 820, "Quality Systems Regulation"

12.4. Certification, Reporting, and Record Keeping

12.4.1. Pre-market Notification 510 (k)

- In accordance with 21CFR Part 807.81, the FX device must obtain FDA clearance of a 510K before orders are taken or the product is offered for sale.
- Clinical studies
- Clinical study should be conducted according to Investigational plan approved by IRB in the US

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12.4.2. Clinical Investigation Records

B4 [redacted]

12.4.3. Certification

B4 [redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	

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Appendix A

I. EC Directives (medical device)

This appliance complies with the requirements of Directives 93/42/EEC (Medical Device).

II. Harmonized Standards

III. EMC

The equipment should comply with

a. IEC 60601-1-2, 3 Ed. 2007

Medical electrical equipment, Part 1: General requirements for safety, 2. Collateral Standard: Electromagnetic compatibility – Requirements and test.

IV. Under CFR 47 Class B

a. FCC PART 18

Medical equipment (ISM) that emits electromagnetic energy on frequencies within the radio frequency spectrum in order to prevent harmful interference to authorized radio communication services.

V. Electrical Safety

The equipment should comply with.

a. IEC 60601-1: 3 Ed; 2009

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Amendment A1:1993 to EN 60601-1:1990
Amendment A2:1995 to EN 60601-1:1990

VI. Biocompatibility

a. ISO 10993-1:2003

Biological evaluation of medical devices -- Part 1: Evaluation and testing

VII. General

a. EN 980:2008

Graphical symbols for use in the labeling of medical devices.

b. EN 1041:2008

Information supplied by the manufacturer with medical devices.

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c. EN ISO 13485:2003

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003).

d. EN ISO 14969:2004

Medical devices - Quality management systems - Guidance on the application of ISO 13485: 2003.

e. EN ISO 14971:2007

Medical devices - Application of risk management to medical devices (ISO 14971:2007).

f. IEC 62304:2006

Medical device software - Software life-cycle processes.

g. EN 60812:2006

Analysis techniques for system reliability. Procedure for failure mode and effects analysis (FMEA).

h. IEC 60601-1-6:2006

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance- Collateral standard: Usability.

Chapter 12
Substantial Equivalent Discussion

Substantial equivalence Discussion

The Silk'n FX is substantially equivalent (SE) to the following device:

Omnilux New-U, Indication for use: "The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles". Manufactured by Photo Therapeutics Inc. and subject of K072459.

Labeling and promotional material of the substantially equivalent device are presented in Appendices 1 of this chapter.

Substantial equivalence is demonstrated according to the criteria outlined in the 510(k) "Substantial Equivalence" Decision Making Process, as published in the FDA 510(k) Guidance (FDA 90-4158).

A comparison table of the subject and predicate devices is included in this discussion.

1. B4 [redacted]

[redacted]

2. B4 [redacted]

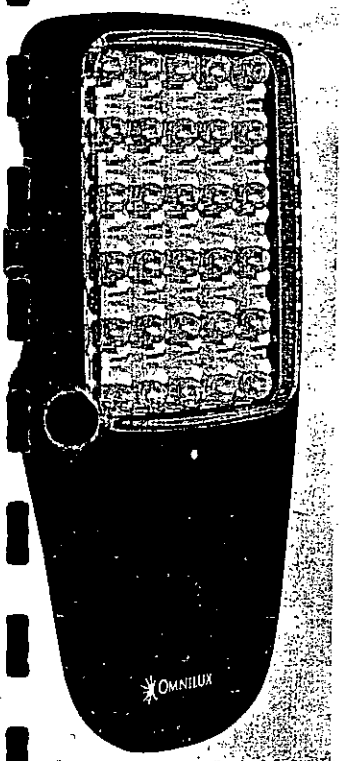
[redacted]

B4

[redacted]

The #1 LED hand-held device on the market

OMNILUX new-U™



$299 on spalook.com

ACTUAL SIZE:
5"H x 2.5"Wx 1.5"D, 2.9oz.

why it's different

FDA CLEARED

- **FDA cleared**
- Dermatologist Recommended
- Omnilux new-U is a miniature version of the medical in-office doctor-administered device, Omnilux Medical
- 60+ clinical studies over the last 12 years by well-known doctors
- It's parent device, Omnilux Medical, is clinically proven to treat a wide array of skin ailments
- **7 out of 10** subjects reported improvement in fine lines and wrinkles*

Twelve weeks post treatment after four weeks of two treatments a week, alternating between red and near-infrared settings.

*Results based on an independent clinical study by Dr. Sadick using Omnilux technology

rder online at www.spalook.com or call 800.709.1865

PHOTO THERAPEUTIC
world leader in light thera
email: handheld@phototherapeutics.cc

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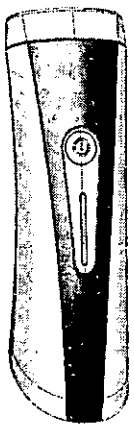
Chapter 13

Proposed labeling

Silk'n FX



Instructions for use

DO101950A

HomeSkinovations

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Home Skinovations Ltd.
Tavor Building, Shaar Yokneam
POB 533
Yokneam 20692
ISRAEL

Website: **www.silkn.com**

e-mail: **info@silkn.com**

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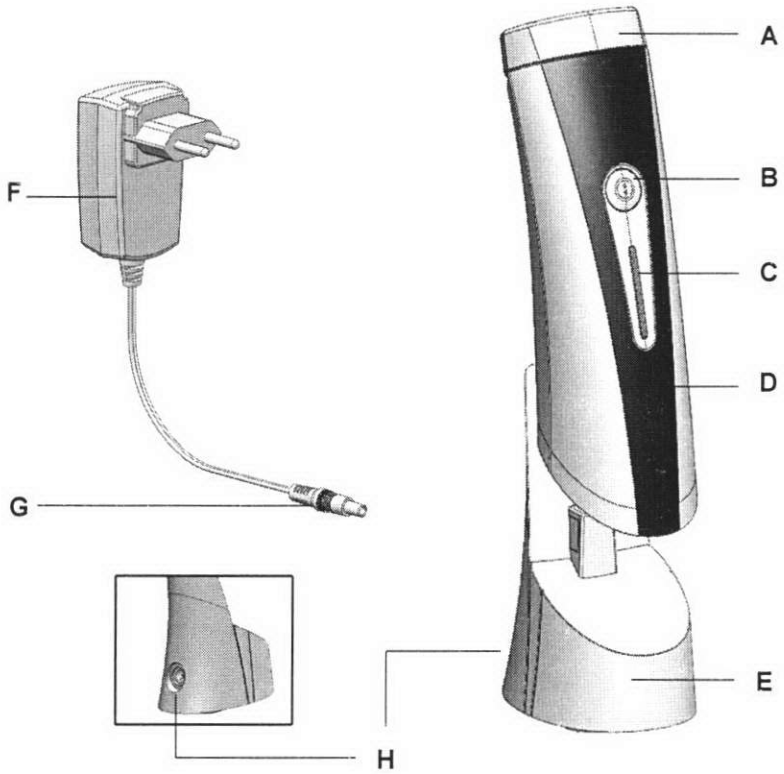
Silk'n FX device description

Your Silk'n FX device consists of a ***Base Unit*** an ***Applicator*** and an ***Adaptor.***

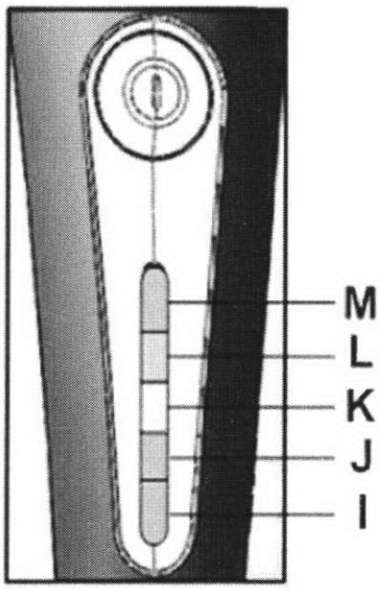
The Silk'n FX ***Applicator*** is a hand held unit used for treatment, as the ***Treatment surface*** at the *Applicator* tip is in contact with the skin. On the *Applicator* you can find the *Mode* ***switch*** and the ***Indicators Panel***.

The FX ***Base Unit*** is used to place the *applicator* while resting, and to charge the *applicator* batteries.

The ***Adaptor*** connects the ***Base Unit*** to the electrical outlet for battery recharging, using its ***Plug*** and the ***Base Unit socket.***



A	*Treatment surface*
B	*Mode Switch*
C	*Indicators Panel*
D	*Applicator*
E	*Base Unit*
F	*Adaptor*
G	*Plug*
H	*Base Unit socket*



J ***READY/TREATMENT*** - *INDICATOR LIGHT*
K ***SYSTEM ERROR*** - *INDICATOR LIGHT*
L ***BATTERY – CHARGING*** - *INDICATOR LIGHT*
M ***BATTERY – FULL*** - *INDICATOR LIGHT*

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(I)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to Red.

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(J)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to IR.

The orange ***BATTERY – CHARGING - INDICATOR LIGHT*** **(L)** illuminates while the *APPLICATOR* is placed in the *BASE & CHARGING UNIT* and charging.

The green ***BATTERY – FULL - INDICATOR LIGHT*** **(M)** illuminates when the batteries are fully charged.

The yellow ***SYSTEM ERROR - INDICATOR LIGHT*** **(K)** illuminates when a system error/malfunction occurs.

Package contents

Upon opening the Silk'n FX package, you will find the following parts:

- FX *BASE UNIT* and *APPLICATOR*
- Adaptor
- User's Manual

Silk'n FX - Indications For Use

Silk'n FX intended use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

As we grow older, the amount of collagen, the major supporting protein of the skin, diminishes and our skin becomes less flexible. Id addition, our skin becomes drier and thinner, and as the body's natural regeneration process slows down, the skin slowly loses its ability to retain moisture and loses the "teenage" glow. The harmful rays in sunlight further damage the skin's supportive structure and prevent the creation of new collagen. This leads to the development of fine lines and wrinkles, especially in the area around the eye (periorbital wrinkles – crows feet). HF™ technology in Silk'n FX works with the body's natural processes to reduce the appearance of periorbital wrinkles.

If you have noticed development of fine lines and wrinkles, especially in the area around your eyes, Silk'n FX may help reducing them.

Contraindications

- Do not use Silk'n FX except for its indications for use to treat periorbital wrinkles.

When to avoid using Silk'n FX?

Certain conditions may prevent the use of Silk'n FX temporarily. **DO NOT USE Silk'n FX** if any of the following conditions apply to you:

- If you have dark brown or black spots, such as large freckles, birth marks, moles or warts on the area to be treated.
- If you have eczema, psoriasis, lesions, open wounds or active infections, such as cold sore in the area to be treated. Wait for the effected area to heal before using Silk'n FX™.
- If you have abnormal skin conditions caused by diabetes or other systemic or metabolic diseases
- If you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.
- If you have been treated with Accutane® (isotretinoin) within the past 6 months.
- If you have been on a steroid regimen within the past 3 months.
- If you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using Silk'n FX.

Precautions and Warnings

- Keep Silk'n FX out of the reach of children.
- Keep Silk'n FX out of the reach of persons with reduced physical, sensory or mental capabilities.
- Do not use the Silkn FX unless you are between the ages of 35-57. The treatment of this device outside this age range has not been tested in trails.
- CONTACT your healthcare professional as soon as possible if you suspect that you have had an adverse reaction from use of the Silkn FX. If you do not obtain medical advice your reaction may get worse.
- DO NOT use the Silkn FX if you are pregnant. The safety of the treatment for pregnant women has NOT been tested in clinical trials.
- NEVER use the Silkn FX or the Wall Power Supply when bathing or standing in water.
- NEVER use the Silkn FX or the Wall Power Supply if you think they may have been immersed in water, may have become wet, or if you have spilt any liquids on them.
- NEVER remove any covers from the Silkn FX or the Wall Power Supply. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect reassembly could cause an electric shock when the Silkn FX is subsequently used.
- DO NOT try and force the plug of the Power Supply into an outlet. If the plug does not connect easily with the outlet there may be a mismatch.
- DO NOT attempt to operate the Silkn FX with any Wall Power Supply other than the one provided.
- DO NOT use the Silkn FX if it is damaged in any way.
- DO NOT use the Wall Power Supply if it is damaged in any way or if its cord or plug is damaged.
- ALWAYS clean the Silkn FX before each treatment. See the Care and Maintenance section for details on how to clean your Silkn FX.
- DO NOT treat the affected area for longer than the recommended time at each session. If you treat the affected area for longer than the recommended time the effectiveness of the treatments may be reduced.
- DO NOT treat the affected area more often than recommended. If you treat the affected area more often than recommended the effectiveness of the treatments may be reduced.
- NEVER cover the air vents in the Silkn FX they are provided for ventilation. Be aware of objects, items of clothing or material that may accidentally block the air vents.
- ALWAYS keep the Silkn FX, its Wall Power Supply, and cord away from heated surfaces. High temperatures may damage the plastic cases or the internal pads.
- ALWAYS unplug the Wall Power Supply from the AC electrical outlet and refer to a authorized representatives if the Silkn FX does not work normally by following the operating instructions or if it exhibits a distinct change in performance.
- AVOID scratching the lens cover as scratches may reduce the efficiency of the treatment.
- AVOID placing the Silkn FX unit in a dusty or dirty environment. Dirt or dust may restrict the airflow through the Silkn FX causing it to switch off before the end of the treatment time.

- Keep Silk'n FX away from water!
  Do not use or store Silk'n FX in a wet environment (e.g. near a shower or a bathtub)!
  Keep the device and its adaptor dry!
- Do not use Silk'n FX if the *ADAPTOR* or the *APPLICATOR* is damaged!
- If the *ADAPTOR* is damaged, make sure it is replaced with an original part from Home Skinovations!

- The *ADAPTOR* contains a dedicated transformer. Never replace the *ADAPTOR* with another plug!

Risks - Possible Side Effects of using FX

When used according to the instructions, side effects and complications associated with use of Silk'n FX are rare. However every cosmetic procedure, including those designed for home use, involve some degree of risk. Therefore it is important that you understand and accept the risks and complications that can occur with Light Emitting Diodes for home use.

Silk'n FX treatments are generally very well-tolerated. Most users sense the moderate heat applied by the device during use, with no further discomfort.

- **Minor Skin Discomfort**

  Your skin may become slightly irritated after using Silk'n FX. This is a typical and transient phenomenon. If the irritation does not disappear within three days, please consult a physician or a dermatologist.

- **Skin Redness**

  Your skin may become slightly red right after using FX. This should disappear a few hours after treatment.

  Following the treatment it is recommended to apply a small quantity of moisturizer. This will help eliminating any minor skin discomfort or redness.

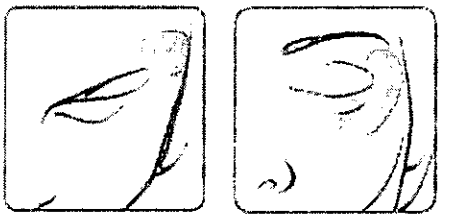
The benefits of Silk'n FX

The outcome of using Silk'n FX according to the instructions will be the reduction of fine lines and wrinkles in the perorbital area.

Best results can be expected 3-7 weeks after completing the recommended course of treatment.

Silk'n FX facial treatment areas

Typical areas for Silk'n FX treatment are the cheeks, the forehead around the eyes.



Before Using Silk'n FX

1. *Plan your Silk'n FX treatment for best results*

The efficiency of the results varies from person to person and according to the frequency of use. Some may see results sooner than others.

A full Silk'n FX treatment course:

1	**Forearm test***	20 minutes **RED** Light
2	**Forearm test***	20 minutes **IR** Light
3	**2. Week 1, first day (Day 1)**	20 minutes **IR** Light on EACH AREA
4	**3. Two days later (Day 3)**	20 minutes **RED** Light on EACH AREA
5	**4. Week 2, first day (Day 8)**	20 minutes **IR** Light on EACH AREA
6	**5. Two days later (Day 10)**	20 minutes **RED** Light on EACH AREA
7	**6. Week 3, first day (Day 15)**	20 minutes **IR** Light on EACH AREA
8	**7. Two days later (Day 17)**	20 minutes **RED** Light on EACH AREA
9	**8. Week 4, first day (Day 22)**	20 minutes **IR** Light on EACH AREA
10	**9. Two days later (Day 24)**	20 minutes **RED** Light on EACH AREA

* Some people may be sensitive to light. If you are sensitive to light Silkn FX may not be suitable for you. To determine if you are sensitive to light, we recommend you carry out a skin test on your forearm. If no adverse reaction appears within 24 hours, continue with step 2.

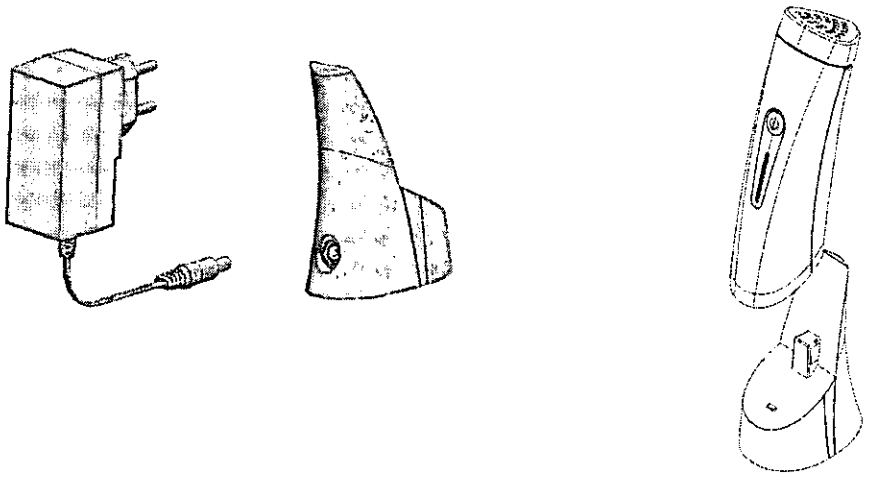
2. *Silk'n FX Setup*

1. Remove Silk'n FX *BASE UNIT, APPLICATOR, ADAPTOR* and other components from box.
2. Before using the Silk'n FX for the first time, fully charge its batteries. This may take up to 6 hours.

3. *Silk'n FX Battery Charging*

- Insert the *APPLICATOR* into its cradle in the FX *BASE UNIT*.
- Plug the *ADAPTOR PLUG* into the Base Unit socket.

- Plug the *ADAPTOR* into an electrical outlet. An orange *BATTERY – CHARGING - INDICATOR LIGHT* (L) will illuminate to indicate that your Silk'n FX is in the process of charging.



Caution! Never cover Silk'n FX and its adaptor while recharging!

Note! Silk'n FX can not be used while recharging

- When *BATTERY – CHARGING - INDICATOR LIGHT* (L) turns off and *BATTERY – FULL - INDICATOR LIGHT* (M) illuminates, **your Silk'n FX is fully charged and ready to start.**
  (Recharging will be needed when *BATTERY – CHARGING - INDICATOR LIGHT* (L) illuminates again.)

Treating with Silk'n FX

Prepare your skin for treatment

Make sure your skin is **clean**, **dry** and **free** of any powder, gel or cream.

Prepare your Silk'n FX device for treatment

- Remove the charged Silk'n FX *APPLICATOR* from its cradle in the *BASE UNIT.*
- Turn Silk'n FX on selecting the desired light mode:
  - For **RED** Light treatment
    - Press the *MODE SWITCH*. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (I) will start blinking, and shortly afterwards will be lit steadily.
      Your Silk'n FX device is ready for **RED** Light treatment.

- For **IR** Light treatment
  - Press the *MODE SWITCH* twice. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (J) will start blinking, and shortly afterwards will be lit steadily.
    Your FX is ready for **IR** Light treatment.

Perform the treatment

- Attach the *TREATMENT SURFACE* to your skin. The LED light will automatically activate.

- Perform the treatment for 20 minutes on each area.
- **Note:** After 20 minutes the device is automatically shut off. To reactivate the device push the Mode switch.

What to Expect when Treating with Silk'n FX?

During a Silk'n FX session it is **normal** to experience and feel:

- **A Sensation of Warmth** – During the Silk'n FX session you may feel slight warmth. This is normal and should disappear up to an hour after the session.
- **Some Mild Red Color** – After each Silk'n FX session you may notice a slight reddening of the skin (mild erythema) over the treated area. This is normal and should fade within an hour or two.

Best results can be expected 3-7 weeks after completing the recommended course of treatment, as the light stimulates process that continue the improvement after the completion of the treatment.

End the Silk'n FX treatment

- When Silk'n FX session has been completed turn the device off by pressing the *MODE SWITCH*. All indicator lights will be turned off.
- Finally place the applicator in its Base Unit cradle to recharge the batteries (See Section: "Silk'n FX Battery Charging").

After the Silk'n FX treatment

- Following a Silk'n FX treatment it is recommended to apply a small amount of a moisturizing cream on the treated skin areas and to massage it gently in circular motions.
- After each session it is recommended that you clean your Silk'n FX device, especially the *APPLICATOR TIP* (See Section: "Cleaning Silk'n FX").
- Store Silk'n FX according to the instructions (See Section: "Storage").

Alternative procedures and treatments?

Contact your dermatologist for treatment of periorbital wrinkles.

Silk'n FX Treatment Troubleshooting

What can go wrong?

Please see section: Risks - Possible Side Effects of using FX

When to call a doctor?

In case you experience one or more of the detailed possible side effects, please contact your physician or dermatologist.

Clinical Studies

In clinical studies using similar products, 7 out of 10 subjects reported a visible reduction in fine lines and wrinkles, and 7 out of 10 reported an improvement in skin clarity.

Care and Manitenance

1. Protect your Silk'n FX

- Do not cover the ventilation slots during use.
- Remove any obstruction to air flow through the ventilation slots.
- Never shake or drop Silk'n FX or subject it to severe shocks.
- Silk'n FX is sensitive to environmental temperature during use.
  Do not expose the FX to environmental temperatures lower than 15°C / 59°F or higher than 35°C / 95°F during use.
- Silk'n FX cannot tolerate extreme change of environment temperature.
  When moved from a cold environment (under 10°C / 50°F) to a warm environment, avoid use for approximately 3 hours.
- Do not expose Silk'n FX to a lengthy direct sunlight or UV light.
- Silk'n FX is designed for occasional home use (as opposed to an exhaustive commercial or professional use). Avoid such exhaustive use.
- Avoid covering Silk'n FX and its adaptor during recharge.

2. Cleaning Silk'n FX

After each session, it is recommended to clean your Silk'n FX device, and especially its *TREATMENT SURFACE.*

- Turn Silk'n FX off by pressing the *MODE SWITCH.*
- Unplug Silk'n FX from the electrical outlet
- Allow cooling down of its *TREATMENT SURFACE.*
- The exterior of the Silkn FX unit may be cleaned by wiping it with a damp (not wet) cloth or isopropyl alcohol wipe. Please refrain from using any other cleaning products as these may damage the plastic parts.

- Never immerse Silk'n FX or any of its parts in water!
- Never clean the FX or any of its parts under the tap or in the dishwasher.

3. Silk'n FX Storage

- Clean Silk'n FX according to the instructions (See "Cleaning Silk'n FX")
- Store the clean device and all its parts in a dry clean place free of dust, at a temperature of between -10°C to 60°C / 14°F to 140°F

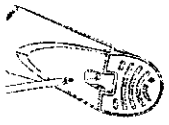
4. To protect the Environment

At the end of its life, do not discard Silk'n FX with the normal household waste. Hand it at an official recycling collection point.

Always remove the batteries before discarding or handing at a recycling collection point (See section: "Removing the rechargeable batteries"). Dispose of the batteries at an official collection point for batteries. If you have trouble removing the batteries, you can take the device to a Home Skinovations service centre.

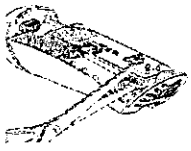
Removing the rechargeable batteries

Remove the rechargeable batteries only if they are completely empty and cannot be recharged.

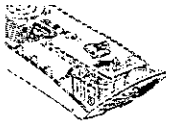


- Undo the screw at the bottom panel of the *APPLICATOR*.

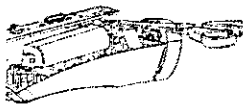
- Lift and remove the top panel of the *APPLICATOR*.



- Cut the tow wires that connect the electronics card to the lower panel of the *APPLICATOR*.



- Push the three snaps and pull out the electronics card.



- Cut the tow wires that connect the rechargeable batteries pack to the *APPLICATOR*.

5. Silk'n FX Troubleshooting

This chapter summarizes the most common problems you could encounter. If you are unable to solve the problem with the information below, contact your local Silk'n customer Service center for further support.

Problem	Possible cause	Solution
Silk'n FX does not work	The rechargeable batteries are empty	Charge the *APPLICATOR*
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
Silk'n FX suddenly switches off	The rechargeable batteries are empty	Charge the *APPLICATOR*
Device temperature rises during recharge	This is normal	No action is required
BATTERY – CHARGING - INDICATOR LIGHT (L) **does not turn on when connecting the *PLUG* into the *BASE UNIT SOCKET*.**	The *ADAPTOR* is not plugged in the electrical outlet	Insert the *PLUG* into the *BASE UNIT SOCKET*,
		Connect another appliance the wall socket to check if the electrical outlet is live.
		If the *APPLICATOR* still does not charge, Contact your local Silk'n customer Service center
	The *ADAPTOR* is not inserted properly into the electrical outlet and/or the *PLUG* is not inserted properly into the *BASE UNIT SOCKET*	Make sure the *ADAPTOR* is inserted properly into the electrical outlet and/or *PLUG* is inserted properly into the *BASE UNIT SOCKET*.
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
***APPLICATOR* temperature rises during use.**	This is normal	No action is required
READY/TREATMENT MODE - INDICATOR LIGHT (I) **does not illuminate when pressing the *MODE SWITCH***	The *APPLICATOR* needs to be reset	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *READY/TREATMENT MODE - INDICATOR LIGHT* (I) does not illuminate again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is lit.**	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *SYSTEM ERROR - INDICATOR LIGHT* (K) illuminates again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is blinking**	The rechargeable batteries are empty	Charge the *APPLICATOR*
The Green *BATTERY – CHARGING* and Orange *BATTERY – FULL - INDICATOR LIGHTS* are	Malfunction of the *ADAPTOR*	Disconnect the *ADAPTOR* from the electrical outlet, press the *MODE SWITCH* twice to switch the *APPLICATOR* on and off again. Connect the Adaptor to the wall socket, If the problem persists,

illuminated alternately		contact your local Silk'n customer Service center
	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If the problem persists, contact your local Silk'n customer Service center

User Assistance and Customer Service

1. For USA and Canada customers:

For more information about Silk'n™ products please enter www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact Silk'n™ Customer Service: **1-877-DO-SILKN / 1-877-367-4556**, contact@silkn.com

2. For customers in other countries:

For more information about Silk'n™ products please enter your local Silk'n™ website, www.silkn.eu or www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact your local Silk'n™ Customer Service or write to: info@silkn.com.

Warranty information

1. What does the Silk'n FX Warranty Cover?

Subject to the terms and conditions of this warranty, Home Skinovations Inc. warrants that it will repair or replace the FX device that accompanies this warranty (the "Device") to the extent that the Device exhibits material defects in materials or workmanship caused by Home Skinovations Inc.

2. Who Is Entitled To The Protections Of the Silk'n FX Warranty?

Only you, the original purchaser of the Device are entitled to the protections of this warranty. Home Skinovations Inc. may require original proof of purchase of the Device by having you provide your invoice or receipt from the purchase of the Device.

3. How Long Does The Coverage Last?

This warranty covers claims filed with Home Skinovations Inc. within one (1) year from the date of the original purchase of the Device. Claims filed after one (1) year from the date of purchase of the Device by you are not covered. Home Skinovations Inc. may require that you prove the date you purchased the Device by providing an invoice or receipt that specifically lists the date of purchase of the Device. Claims in respect of a repaired or replaced device must be filed with Home Skinovations Inc. within the later of (a) one (1) year from the date of purchase of the original Device by you or (b) ninety (90) days from the date that the Home Skinovations Inc.

service center ships the repaired or replaced Device back to you.

4. How Do You Get Warranty Service?

In order to obtain warranty service on the Device, go to the customer service section of www.silkn.com or call the then-current customer service telephone number (currently 877-367-4556) for assistance. You must obtain a Return Goods Authorization (RGA) number and an RGA form which will be sent to you before shipping the Device to Home Skinovations Inc. You must also comply with Home Skinovations Inc.'s instructions concerning shipment and the materials that must accompany the Device (such as a copy of the invoice that proves your status as the original purchaser and the date of purchase and the completed RGA form). It is suggested for your protection that you insure your shipment to Home Skinovations Inc. Damage during shipment to Home Skinovations Inc. is not covered by this warranty. It is also suggested that you ship the Device using a tracked method so that you can ensure that Home Skinovations Inc. has received the Device.

5. Shipping Charges

You are required to pay for packaging and shipping of the Device to the applicable Home Skinovations Inc. service center. Home Skinovations Inc. will pay for packaging and shipping of the Device back to you; provided that if upon receipt, inspection and testing of the Device by Home Skinovations Inc., Home Skinovations Inc. determines that the Device does not exhibit material defects in materials or workmanship, then you will be required to pay for return packaging and shipping back to you.

6. What Does the Silk'n FX Warranty Not Cover?

This warranty does not cover damage resulting from accident, misuse (including use not described in the user manual or instructions accompanying the Device), abuse, lack of reasonable care, the affixing of any attachment not provided with the device, loss of parts, use of unauthorized replacement parts or subjecting the device to any but the specified voltage.* This warranty is void if the Device is repaired by anyone other than an authorized Home Skinovations Inc. service center, and Home Skinovations Inc. will not have any liability for damage resulting from service performed by anyone other than an authorized Home Skinovations Inc. service center.

Travel with device

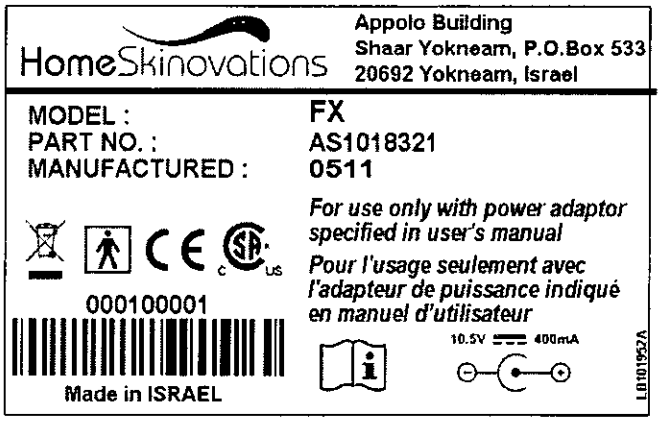
Silk'n FX is designed for your personal use wherever you are, at home or traveling.

- When fully charged, the device will provide continuous operation enough for a full treatment of the face.
- If you intend to use Silk'n FX more then once during your trip, be sure to carry all parts including applicator, charging base unit and cord with you.
- For recharge a 100V - 240V electrical outlet is required.

Specifications

Rated voltage (Adaptor)	100V - 240V
	Model: UE08WCP-105040SPA
Rated frequency (Adaptor)	50Hz – 60Hz
Rated currant (Adaptor)	400 mA
Applied part	Type BF
Protecting rating	IP20 (EN60529)
Storage condition	Temperature: -10°C to 60°C / 14°F to 140°F
	Relative humidity: 5% to 95%
Operating condition	Temperature: 15°C to 35°C / 59°F to 95°F
	Relative humidity: 10% to 80%
	Atmospheric pressure: 700 to 1060 hPa
Light source	Light Emitting Diodes
	Wavelengths peak emission wavelength: 633, 830nm
	Intensity power: 70,55mW/cm^2 ±10%
Lithium ion battery	2 x 3.7V, 750±50mAh
Max. charging time	180 minutes
Product life time	5 years

Labeling



Degree of protection against electric shock: type BF applied part

WEEE - Waste Electrical and Electronic Equipment

CSA Mark

CE Mark

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

The symbol on the label affixed to this device means "Attention, consult accompanying documents".

Silk'n
FX™
Discover Your
True Beauty!
● Successfully Treats Periorbital wrinkles
● Safe and Effective
● Recommended By Dermatologists

Silk'n FX™ - Discover your true beauty!

Silk'n FX™

Suitable and effective for men and women

For all facial sites and the neck

"Our work with the Silk'n FX™ device has shown marked clinical results. Patients can easily and safely self-treat, reporting improvement of periorbital wrinkles after a treatment course of only 8 weeks."

Tina S. Alster, M.D.
Director, Washington Institute of Dermatologic Laser Surgery Clinical Professor of Dermatology, Georgetown University Medical Center

Chapter 15
Biocompatibility

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

Silk'n FX Bio compatibility statement

Material that comes into contact with the user skin during the use of the device is made out of Stainless steels, the most commonly used alloys in medical application with 17-4PH.
This material is known for his bio computability compliance.

Amir Waldman Ph.D.
VP regulatory affairs
Home Skinovations Ltd.
January 27, 2011

Chapter 16
Risk Analysis and Software Documents

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n FX Risk Management File

DO101971A

Project	FX
Date	June ,2010
Written by	S.Francis-Najjar
Approval	Ben Zion Levi

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Description	Updated by	Date
A	Risk Identification and Assessment	Ben Zion Levi	06/2010

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

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Yokneam 20692, ISRAEL
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Fax: +972(4)9097471

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
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1 Introduction

1.1 Purpose

This document is used to evaluate the risk associated with the Silk'n FX device.

1.2 Scope

This document identifies and describes the potential hazards and risks of Silk'n FX. It also includes extensive risk analysis and describes the measures taken to ensure that FX meets the appropriate safety requirements.

1.3 Overview

This document describes the safety hazards associated with the Silk'n FX It also describes the possible consequences of these hazards, their probability of occurrence, the Risk Level, how they will be mitigated and how and where that mitigation will be implemented.

1.4 Applicable Standards

- IEC 62304:2006 Medical device software – Software life-cycle processes.
- IEC 60601-1-4: edition 1.1 2004, General requirements for safety-collateral standard: Programmable electrical medical systems
- ANSI/AAMI/ISO 14971:2007, Medical devices - Application of risk management to medical devices.
- IEC 60601-1: "Medical Electrical Equipment" Part 1:"General requirements for safety"1988, including amendments #1(1991),#2(1995).

1.5 Core team

Ben Zion Levy	VP R&D and Engineering
Dr. Amir Waldman	VP Regulatory and clinical affairs
Suhair Francis-Najjar	V&V and Quality Manager

HomeSkinovations

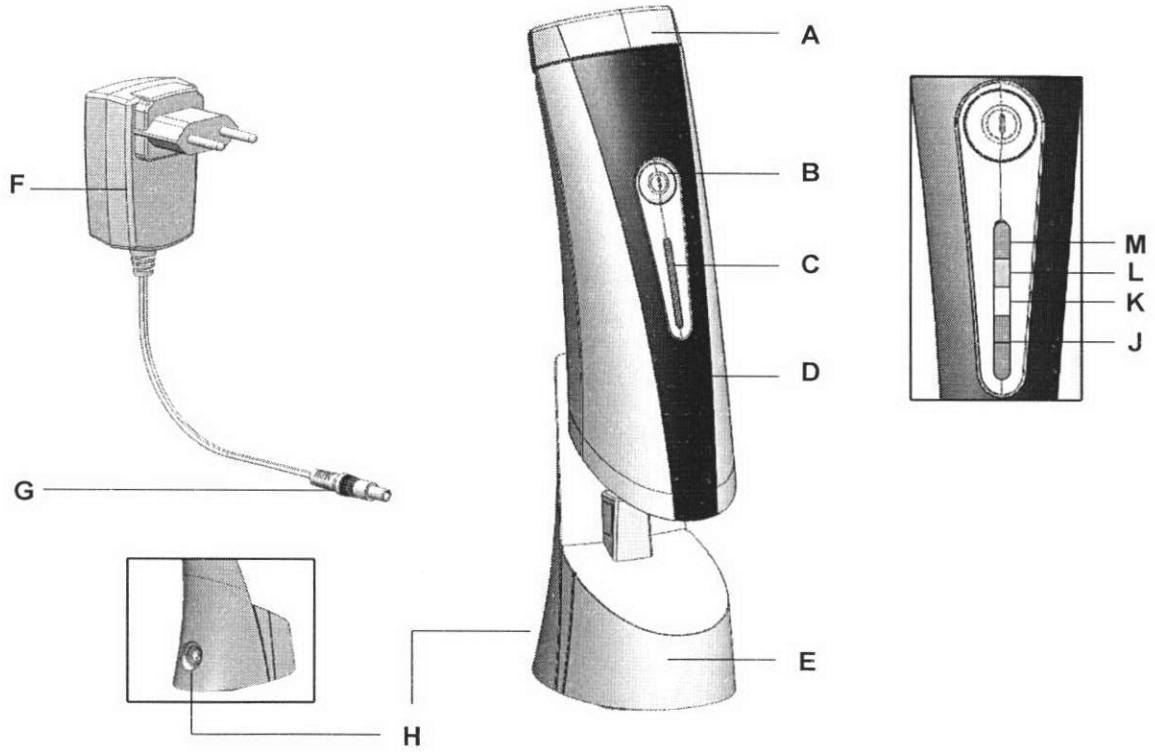
Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Daniel Wainer — Software Engineering Manager
Yohram Bar — System Engineer

1.6 Device Description

The device is used for personal facial skin treatment. It is comprised of two main components: the Base unit and the Applicator.

The Base Unit use to charge the batteries of the applicator. On the Silk'n FX Applicator you can find the on off switch as well as light indicators. The system contains the following parts:



- **A** *Treatment surface.*
- **B** *On/Off Switch*
- **C** *Indicator Panel*
- **D** *Applicator*
- **E** *Base Unit*
- **F** *Adaptor*
- **G** *Plug*
- **H** *Base Unit socket*
- **J** *Treatment - indicator light*
- **K** *System Error - indicator light*
- **L** *Battery – charging - indicator light*
- **M** *Battery – full - indicator light*

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In normal operation the Applicator is stand alone device.

Along the battery charging, the Applicator is inserted into the cradle which connected to the AC wall power adaptor.

Device is not required to interface with any other equipment.

The following table outlines the main system components and their functionality.

Module	Description
AC Adaptor	Switched-mode power supply that is built into the top of a plug. Supplies 10.5V DC regulated voltage for battery charger.
Base	Charging cradle for Applicator batteries charging and bridging connection between AC adaptor plug and charging contacts in Applicator
Applicator	Treatment appliance
Main Card	Battery charger, the micro controller IC, FAN driver, toggle switch detector, voltage regulator and indications LEDs. Responsible for: the man machine interface, control the machine stage software and control the light and temperature stabilizer functionality.
Lamp Card	Contains heater, LED array touch pad for touch sensor. Responsible for Light and heat sources circuit

Main system components and functionality.

1.7 Intended use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles

1.8 Contraindications

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- Dark brown or black spots, such as large freckles, birth marks, moles or warts.
- Eczema, psoriasis, lesions, opens wounds.
- Active infections such as cold sore.
- Abnormal skin conditions caused by diabetes or other systemic or metabolic diseases.
- Photosensitizing disease, patient taking photosensitizing drugs

1.9 Possible Side Effects

- Minor skin discomfort, most feel slight heat that the device deploys into skin.
- Skin redness: skin may become a little red and irritated

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2 Finding possible hazards

2.1 Identification of Qualitative Characteristics Related to the Silk'n FX device

1) **What is the intended use and how is the medical device to be used**

   Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles

2) **Is the medical device intended to be implemented?**

   No.

3) **Is the medical device intended to contact the patient or other persons?**

   The Applicator of the device comes into contact with the user skin surface during the treatment. Period and Frequency of contact: Transient normally intended for continuous use for less than 60 minutes (MDD 93/42/EEC Annex IX).

4) **What Materials and/or components are utilized in the medical device or are used with, or are in contact with, the medical device?**

   The material comes in contact with human body are biocompatible

Part	Description	Type of contact
Treatment surface	Medical grade stainless steel 17-4PH	Applied to the skin surface

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5) **Is energy delivered to and/or extracted from the patient?**

During the procedure the device delivers: Red peak emission wavelength: 633 nm; intensity power: 70 mW/cm^2 +/- 10%, 830 nm 55 $mWcm^2$ +/- 10%. Spot size is 7 cm^2.

Distance: In contact with user's skin eliminating distance deficiencies entirely.

6) **Are substances delivered to and/or extracted from the patient?**

No.

7) **Are biological materials processed by medical device for subsequent re-use?**

No

8) **Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?**

No

9) **Is the medical device intended to be routinely cleaned and disinfected by the user?**

Yes, after each session, it is recommended to clean your FX device, and especially the APPLICATOR TIP.

- Unplug Silk'n FX before cleaning.
- Use a dry, clean cloth and a specially formulated cleaner for electronic equipment to gently wipe Silk'n Fx surface, and especially the APPLICATOR Tip.
- Never immerse Silk'n FX or any of its parts in water!
- Never clean the Silk'n Fx or any of its parts under the tap or in the dishwasher.

10) **Is the medical device intended to modify the patient environment?**

No

11) **Are measurement taken?**

The Silk'n FX device does not provide vital sign monitoring. The Silk'n FX measures some variables for functional purpose: temperature sensing of the treated skin surface.

12) **Is the medical device interpretative?**

No, the Silk'n FX device is a home use device, and does not provide diagnostic.

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13) Is the medical device intended for use in conjunction with medications or other medical technologies?

No

14) Are there unwanted outputs of energy or substances?

Radiation

Optical radiation: The Silk'n FX device emitting CW optical radiation and shall be assigned to the exempt risk group as its accessible emission does not exceed emission limits in any of the hazard spectral regions of table 201.101 (page 11 of standard IEC 60601-2-57) when assessed for the angle of acceptance γ specified in Table 201.103 (page 13 of standard IEC 60601-2-57)

Ionizing radiation.-FX does not radiate ionizing radiation.

Electromagnetic Compatibility- is compliant with regard to the harmonized standard EN60601-1-2

15) Is the medical device susceptible to environmental influences?

Transport environment:

Vibrations during transportation and normal use.

Normal use vibrations: According to EN60601-1 there is no general requirement for vibrations, although the systems were designed to be transported on smooth surfaces.

Electromagnetic Environment

The device complies with the requirements of the EMC standard for medical equipment EN 60601-1-2.

Spillage

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

16) Does the Medical device influence the environment?

Do not throw away the Silk'n FX with the normal household waste at the end of its life, hand it at an official collection point for recycling.

17) Are the essentials consumables or accessories associated with medical device?

No.

18) Is maintenance and/or calibration necessary

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No.

19) Does the medical device contained software?

The Silk'n FX is operated and controlled by software. The software is fully verified and validated according to all relevant standards and installed by the manufacture.

20) Does the medical device have a restricted shelf time?

Yes. – the batteries has 6 month shelf time .

21) Are there any delayed and/ or long term use effects

No.

22) To what mechanical forces will medical device be subjected?

The Applicator of the device is held against the face skin by hand during the treatment.

23) What determines life time of the device?

The batteries determine the device Life time.

24) Is the medical device intended for single use?

No

25) Is safe decommissioning or disposal of the medical device necessary?

Yes – according to the user manual the batteries must be removed out of the device at the end of the batteries shelf life.

26) Does installation for use of the medical device require special training?

No

27) How will information for safe use provided?

By Instruction for Use (IFU).

28) Will new manufacturing processes need to be established or introduced?

No

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29) Is successful application of the medical device critically dependent on human factors such as the user interface?

Yes

I. Can the user interface design features contribute to use error?

Yes. But the controls and indicators, symbols used, Buttons, visibility of warnings, and standardization of color coding are designed according to IEC60601-1-6.

II. Is the medical device used in an environment where distractions can cause use error

No

III. Does the medical device have connecting parts or accessories?

Yes. External adapter

IV. Does the medical device have a control interface?

Yes. On/Off button.

V. Does the medical device display information

The device has LEDs indicator.

VI. Is the medical device controlled by a menu

No.

VII. Will the medical device be used by persons with special needs?

No.

VIII. Can the user interface be used to initiate user actions

No.

30) Does the medical device use an alarm system?

No.

31) In what way(s) might the medical device be deliberately misused?

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Fax: +972(4)9097471

Factors that should be considered are:

1) Treatment of other area - the device is only for facial treatment area for more detailed refer to User manual page 8
2) Treatment time recommendation is 20 minutes the device shut down automatically after 20 minutes of operation.
   To avoid misused conditions refer to user manual pages 5-7.

32) Does the medical device hold data critical to patient care?

No

33) Is the medical device intended to mobile or portable?

Yes.

34) Does the use of the medical device depend on essential performance?

Yes. Refer to section 4

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Fax: +972(4)9097471

3 Risk Method

3.1 Risk estimation

Various methods can be used to estimate risk. While the international standard does not require that a particular method be used, it does require that risk estimation be carried out. And accordingly we follow in the Silk'n FX project the qualitative methods.

Risk level = *probability of failure x severity category*

3.1.1 Qualitative analysis

Several approaches can be used for qualitative analysis. A typical approach is to use an N-by-M matrix to describe the propabilites and severities of the risk associated with each hazardous situation.

Qualitative **Severity** level

Rating	Description
Negligible	Nuisance only / Cosmetic in nature / User Inconvenience / Will not cause personal injury or harm
Minor	Loss of efficacy but patient safety not compromised / Will not cause personal injury or harm
Moderate	Non-functional or poor functional performance of device requiring additional medical intervention to compensate /Injury to patient or user requiring no or minor medical intervention to compensate
Major	Incapacitating / Serious injury or death

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Qualitative **Probability** levels

Rating	Description
High	Likely to occur frequently
Medium	Likely to occur sometime in the life of an item
Low	So unlikely that occurrence may not be experienced

Qualitative 3x4 **risk matrix**:

Qualitative probability Levels	Qualitative severity levels			
	Negligible	Minor	Moderate	Major
High	Minor	Moderate	Major	Major
Medium	Negligible	Minor	Moderate	Major
Low	Negligible	Negligible	Minor	Moderate

Risk acceptability

Assessment Risk Index	Necessary Actions
Major	Unacceptable under existing circumstances requires immediate action
Moderate	Corrective actions are needed and a plan must be developed to incorporate these actions within a reasonable period of time
Minor	The core team must determine whether corrective actions are still required or decide to accept the risk
Negligible	Corrective actions are not required or decide to accept the risk

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3.2 *Risk Control method*

An as low as reasonably achievable approach is used:

Level	Methods of control	Description
1	Inherent safe design	This strategy includes system functionality and features that have been especially incorporated to alleviate safety hazards.
2	Manufacturing control	This includes protective measures in the device itself/ in the manufacturing process, and testing
3	Adequate USER information	This includes the provision of adequate user information, training, and labeling

Risk mitigation measure

	Negligible(1)	Minor(2)	Moderate(3)	Major (4)
Adequate USER information (3)	IV	III	II	I
Manufacturing control (2)	IV	III	III	II
Inherent safe design (1)	IV	IV	IV	III

RISK IV: Acceptable Risk
RISK III: Medium risk
RISK II: High Risk.
RISK I: Very High Risk, Intolerable risk

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4 Risk Analysis

4.1 Chemical and biological Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Residual Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.1.1	Bio Compatibility	Improper Materials	Moderate	Low	Minor	The parts in contact with the patient is medical grade stainless steel 17-4PH	(1)	IV	
4.1.2	Bio-burden/ contamination /Inability to maintain hygienic	Improper hygienic and contaminatio n	Moderate	Medium	Moderate	Applicator supplied clean and Instructions for use in Operator Manual include maintain hygienic instruction.	(1)(3)	IV	Inspection of the operator manual
		toxicity	Moderate	Medium	Moderate	The parts in contact with the patient is medical grade stainless steel 17-4PH	(1)(3)	IV	
		allergenicity	Moderate	Medium	Moderate	No metal allergen parts are in contact with the user.	(1)(3)	IV	
4.1.3	Liquids	Hazard due to the presence of dangerous liquids.	Moderate	Medium	Moderate	The only liquid is sealed in approved electrolytic capacitors	(3)(2)	III	IEC 60601-1 test report clause

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Residual Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.1.4	Hazards of Implosion and Explosion (Electrolytic Capacitors)	Implosion and Explosion (Electrolytic Capacitors)	Moderate	Medium	Moderate	The Electrolytic Capacitors are the only components thought to be at risk of exploding. The FX enclosure is believed to be stronger than needed to contain any ejected parts	(1)(2)	III	IEC 60601-1 test report clause 15.4.3.1
4.1.5	Hazard due to the use of solid materials	Solid materials	Moderate	Medium	Moderate	All solid materials such as metals, plastics, terminal strips, PCB etc. are common materials are proven safe by long use or approved by UL (U94-0) No materials known to generate dangerous vapours or gases when heated or burned.	(1)(2)	III	IEC 60601-1 test report

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4.2 Mechanical Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.2.1	Sharp edge	Improper design	Moderate	Low	Minor	Mechanical hazards have been avoided and minimized by construction and good engineering practice and testing according to EN60601-1.	(1)	IV	Pass (IEC60601-1 test report no. 9012313978)
4.2.2	Stability hazards	The device is unstable	Moderate	Low	Minor				
4.2.3	Accidental mechanical damage	Improper mechanical packaging	Moderate	Low	Minor	Packaging instruction to production	(2)	III	Packaging Qualification
4.2.4	Accidental moving parts	Moving parts (The only used moving part the internal fan)	Moderate	Low	Minor	The fan is an internal part of the applicator and is not reachable to the user.	(1)	IV	IEC60601-1 test report no. 9012313978

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4.3 Fire Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.3.1	General Fire ignition Hazards in normal use	A thermo-plastic material located near a hot spot may catch fire	Moderate	Medium	Moderate	All thermo-plastic materials used in unit have the adequate flame protection according to UL94.	(3)(1)	IV	Pass *("FX – Plastic Parts" Data sheet)*
4.3.2	Electrical Fire Hazards in normal use	Overrating, Improper materials	Moderate	Medium	Moderate	Electrical fire hazards are avoided and minimized by construction and type testing according EN60601-1, and good engineering practice such as: Proper selection fuses, thermal fuses, type and wires size (UL listed). Operating all electrical components within their ratings. Protection of wires from sharp edges. All electrical components (IC, Capacitors, Transformers, resistor, etc) were choosing so	(2)(1)	IV	EN60601 test report Subclause 11.2.1 Pass *(IEC60601-1 test report no. 9012313978)*

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
						it operates below its rated (Temperature, Current, Voltage, etc). To verify this FX engineers has selected the components that are hot, and tested them with thermocouple during testing of design verification.			
4.3.3	Fire due to electric faults	[redacted] B4	Moderate	Medium	Moderate	Electrical power and circuitry designed conforming to EN60601-1 and certified.	(2)(1)	IV	EN60601 test report 9012313978 Clause 15.4.3.5
4.3.4	Fires when the device is not in use	Improper work instruction	Moderate	Low	Minor	The user manual instruct the user to shut down the system when it not in used, and to unplug the line cord, in this position it is believed to be impossible for fire to start in the FX device, if the device is plugged in but the switch is off,	(3)(1)	IV	Operator manual

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
						it's unlikely that fire can be start.			

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4.4 Environmental Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.4.1	EMI &RFI	Inadequate supply of power Restriction of cooling.	Moderate	Low	Minor	Self test and status poling detects power instability.	(1)(2)	III	Pass SW V&V 9.2.1
4.4.2	Operation above or beyond the pre-defined limits of environmental conditions	Environmental specifications are not clear	Moderate	Low	Minor	User Manual includes the environmental specifications.	(3)	III	Inspection of Operator Manual
4.4.3	Contamination	Due to waste procedure and/or rechargeable batteries	Moderate	Low	Minor	Users are instructed how to hand the batteries at the official collection point for recycling.	(3)	III	Inspection of Operator Manual
4.4.4	Inadequate material according to environment directives	Concentration of substances that are SVHC in REACH - regulation	Moderate	Low	Minor	The FX substances was tested by a certified laboratory to compliance with REACH	(2)	III	*In Process*

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4.5 Electrical Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.5.1	Electrical Shock Hazards in normal use.	Not connecting to a certified safety ground	Major	Medium	Major	Grounding of the accessible metallic parts. Mains Voltage isolation.	(1)(2)	II	EN 60601-1 Test report. 9012313978
4.5.2	Leakage current	High leakage current	Major	Low	Moderate	Leakage current complies in accordance with EN60601-1 section 8.7	(2)(1)	IV	EN 60601-1 Test report. 9012313978
4.5.3	BOM	Use of non-safety approved components	Major	Low	Moderate	All insulation materials and connections are in accordance with EN60601-1. Use of safety approved components.	(2)(1)	IV	BOM Control
4.5.4	High Potential	Output electrodes are not properly insulated	Major	Low	Moderate	Reinforced insulation. Each system is approved according to the relevant safety standards	(2)(1)	IV	FX safety certification

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.5.5	Manufacturing hazards	Human error during assembly	Moderate	Medium	Moderate	Production Ground continuation test	(2)	III	Working instruction and FX ATP
		Applicator is not connected	Minor	Medium	Minor	Maximum voltage at the applicator not connected 8.4 V	(3)	IV	Inspection of Operation manual
4.5.6	Electrostatic phenomena (Electrostatic charge build-up)	Improper materials and grounding	Major	Low	Moderate	Intrinsic safe design. Certification to IEC60601-1-2	(1)(2)	III	EN 60601-1-2 9012313993 Test report.
4.5.7	Hazards in normal use	Unstable electrical supply	Minor	Low	Negligible	Self-test is done after power electronics is initiated. Power on does not turned on automatically, system is turned on in Stand By mode Pooling of electrical parameters every 100[ms]	(1)	IV	FX System and Software V&V
		Abnormal charging	Major	Low	Moderate	Designed conforming to EN60601-1 and certified.	(2)(1)	IV	EN 60601-1 Test report. 9012313978

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.5.8	Heat	Due electrical short	Major	Low	Moderate	The treatment surface temperature is monitored and limited by hardware to 41°C and by software to 40°C	(2)(1)	IV	EN 60601-1 9012313978 Test report.
	electrical short	Mechanical force	Moderate	Low	Minor	Electrical short by mechanical force are avoided and minimized by construction and production testing in accordance with EN60601-1, good engineering and good manufacturing practices	(2)	III	EN 60601-1 9012313978 Test report. Safety test
4.5.9	Electrostatic phenomena (Electrostatic charge build-up)	Improper design of electrostatic discharge requirements	Moderate	Low	Minor	FX device is complies with electrostatic discharge requirements of EN 60601-1-2 Standard	(1)	IV	EN 60601-1 9012313978

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4.6 Radiation and Electromagnetic Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.6.1	Hazards of interaction with external medical devices due to Electromagnetic interference.	Interruption of functionality of external medical devices	Minor	Medium	Minor	The System is designed, built and tested to conform to IEC 60601-1-2 , tested to conform to: EN 60601-1-2	(1)	IV	EN 60601-1-2 9012313993 test report
4.6.2		Susceptibility to electromagnetic interference	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: EN 61000-4-2 (ESD) IEC 61010-1 EN 61000-4-4 (Radiated Susceptibility) EN 61000-4-4 (Electrical fast Transients) EN 61000-4-5 (Surge) EN 61000-4-5 (Conducted RF) EN 61000-4-8 (Power	(2)(1)	IV	FX Safety Certification report

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
						frequency Magnetic Field) EN 61000-4-11 (Voltage dips and interrupts)			
4.6.3	Unwanted and excessive optical radiation in normal use	Improper design of disabling the release of optical radiation in the absence of target tissue	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: IEC 60601-1	(2)(1)	IV	FX Safety Certification report
		Failure of controls and protection against hazards	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: IEC 60601-1	(2)(1)	IV	FX Safety Certification report
4.6.4	Unwanted and excessive optical radiation in single fault condition	Improper design that a single fault condition does not result in an increase of output	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: IEC 60601-1	(2)(1)	IV	FX Safety Certification report

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4.7 Human factors Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.7.1	Device - Confusing man machine interface	Poor mapping of controls to actions	Moderate	Medium	Moderate	Considerable thought has been devoted to making the interface natural and simple. The read-out device is a set of LEDs, with good brightness. In addition, an audible emission tone alerts the user of an emission in process. All Human-machine requirements of EN60601-1-6 have been met.	(3)(2)(1)	IV	*IEC 60601-1-6* *report* *DO102*
4.7.2	User/Device - Operation violates the intended use and instruction how to use	Intended use, indication for use and instruction how to use are not clear or ambiguous	Moderate	Low	Minor	User manual will instruct for safe operation and include section on "Safety with Silkn FX"	(3)	III	Inspection of User manual
4.7.3	Device - Improper maintenance of the	Instructions are not clear	Moderate	Low	Minor	User manual include maintenance instruction for safe	(3)	III	User manual

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	device					operation and labeling satisfies 21 CFR Part 801 (maximum light intensity, peak wavelength, warnings about optical radiation and thermal hazards)			

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4.8 *Thermal and Treatment Hazards*

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.8.1	Hazards because of the longest exposure times	Human errors, Violation of operation instructions	Minor	Medium	Minor	Warnings in operation manual	(1)(3)	III	Inspection of FX operation manual.
4.8.2	Hazards from insufficient Output from Applicator in single fault condition.	Violation of design	Moderate	Medium	Moderate	The System is designed, built and tested to conform to IEC 60601-1, tested to conform freedom of unacceptable risk under single fault condition	(2)(1)	IV	EN 60601-1 9012313978 Test report. Safety test

[redacted] B4

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Hazard Identification		Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description	Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
[redacted] B4		Moderate	Low	Minor	Design verification & validation. Compliance with standards: IEC60601-1 : 2010. Section 11.1.2.1 " applied parts intended to supply heat to patient" IEC60601-1 :2010 in clause 14	(1)(2)	III	EN 60601-1 9012313978 Test report. Safety test
		Moderate	Medium	Moderate	Design verification & validation. Compliance with standards IEC62304:2006 in sub-clause 4.3, clause 5, 7, 8 and 9; IEC60601-1-4:2000 IEC60601-1	(1)(2)	III	test report Silk'n FX Software V&V Test 9.4.1 test ID OPRN2
		Moderate	Low	Minor	Design verification & validation. Compliance with standards	(1)(2)	III	Silk'n FX System verification and Software V&V Silk'n FX

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
									Software V&V Test 9.4.6 test ID EINT41

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4.9 Software Hazards

Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.9.1	Device failed to Initialize	Firmware Code corruption (total code corruption). RAM failure	Moderate	Low	Minor	MCU load firmware software; but watchdog reset the MCU.	(1)	IV	Silk'n FX Software V&V Test id: 9.1.1
		Firmware Code corruption (errors in a few bytes)	Moderate	Low	Minor	MCU load firmware but software checks CRC and error led turn on.	(1)	IV	Silk'n FX Software V&V Test id: 9.1.1
		Omission – the system produce no flow at a time when one would be expected	Moderate	Low	Minor	Hardware watchdog expires, the watchdog de-energizes the system.	(1)	IV	Silk'n Fx System V&V

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
		Commission – the system produces a flow when a perfect system would not have	Moderate	Low	Minor	Watchdog uses logical program flow monitoring, the watchdog de-energizes the system.	(1)	IV	Silk'n FX Software V&V Test id: 9.4.3 ID CNST15
4.9.2	Error in downloading the software	Defective MCU is not identified Watchdog hardware defective Communication cable damage	Moderate	Low	Minor	1) Verification test in production 2) QC inspection for complete download before operates. 3) During Download the SW calculates the algorithm check sum versus the MCU and receives feedback to the parameters (CRC#). Noise during the download will cause failure of the download process.	(1)(2)	III	Silk'n FX System acceptance test
4.9.3	On /Off Button are not functioning	Improper man machine interface	Moderate	Low	Minor	Design reviews and production test	(1)(2)	III	Silk'n Face™

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
		design							System acceptance test
		Buttons decoding algorithm failure (users presses down on a key or press and release)	Moderate	Low	Minor	Design reviews and production test	(1)(2)	III	Silk'n Face™ System acceptance test
		Communication failure	Moderate	Medium	Moderate	Design reviews and production test	(3)(2)(1)	IV	Silk'n Face™ System acceptance test
4.9.4	User Confusion on the status of the system	Improper software error handling design	Moderate	Low	Minor	Error indication shall have explanation in the operation manual.	(3)	III	Refer to operation manual trouble shooting page 11
4.9.5	The software allow	SW Failure of	Moderate	Medium	Moderate	Operation will ignite if:	(3)(2)(1)	IV	Silk'n

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
	light energy before skin attachment	safety constraints				1) Touch sensor detects skin touch. 2) Temperature stabilizer 3) Battery monitor			Face™ Software V&V Test id: 9.4.1
[redacted]									

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4.10 Battery Hazards

Hazard Identification		Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description	Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.10.1	Maintenance failure for rechargeable batteries	The instruction for use does not ensure adequate maintenance	Moderate	Low	Minor	The instruction for use shall contain instructions to ensure adequate maintenance.	(3)	III	EN 60601-1 9012313978 Test report. Safety test
4.10.2	Leakage of liquid	Liquid that might escape in a single fault condition	Major	Low	Moderate	Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.	(1)	IV	EN 60601-1 9012313978 Test report. Safety test
4.10.3	Noxious gas	Gases escape during charging or discharging – leaked whilst deployed at water or salt water	Major	Low	Moderate	Hardware designed to prevent on-board continues charging of the device, including battery overheat.	(1)(2)	III	EN 60601-1 9012313978 Test report. Safety test
4.10.4	Explosion and burning	Overcharging of battery could result in an unacceptable risk	Major	Low	Moderate	Hardware designed to prevent on-board continues charging of the device.	(1)	IV	EN 60601-1 9012313978 Test report. Safety test

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
		Overheating	Major	Low	Moderate	Hardware designed to prevent battery overheating during charging and normal operation	(2)(1)	IV	EN 60601-1 9012313978 Test report. Safety test
4.10.5		Short circuit	Major	Low	Moderate	The battery pack contains battery protection circuit for avoiding short circuit.	(1)	IV	EN 60601-1 9012313978 Test report. Safety test

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5 Risk Estimation of Hazards Associated to the FACE™ device

Through hazard analysis, we determined that electric and battery hazards, thermal hazards, biological hazards and system used in contraindicated cases are the four significant hazards present with the Device. Neither of the hazards identified has been determined to be unacceptably high.

6 Conclusion of overall residual risk evaluation

The risks from all identified hazards have been evaluated and decided to be acceptable

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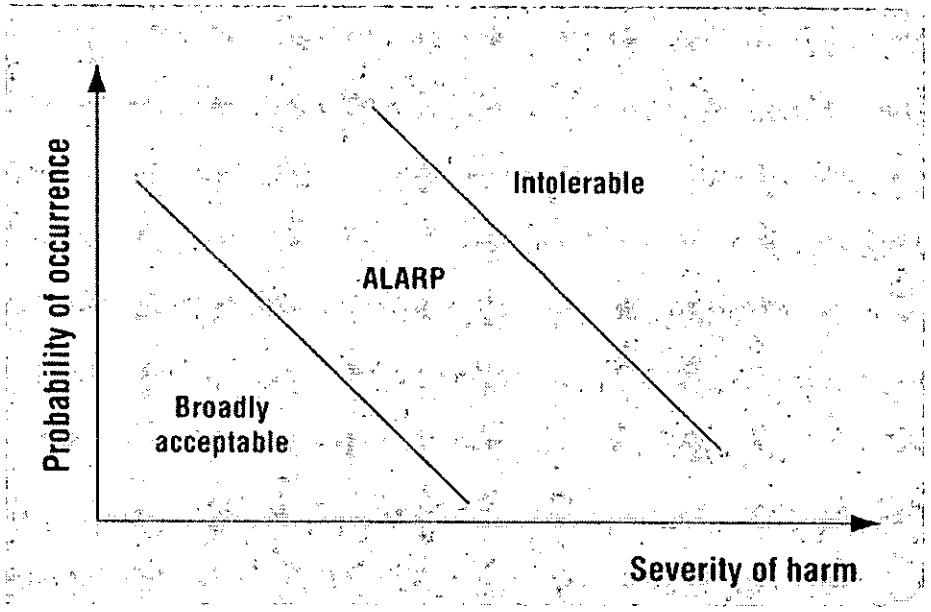
Appendix



- Figure 1.0 - Use an as low-as reasonably practicable approach,

Classification	Action required	Correlated risk region
Minor Risk	None	Broadly acceptable
Moderate Risk	Justification	ALARP
High Risk	Further risk reduction	Intolerable

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Fax: +972(4)9097471

Table 1.0

CONTENTS OF FDA SOFTWARE SUBMISSION

Software

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Silk'n FX Software Level of Concern

Section B- Software Description

Silk'n FX Software Device Description

Section C - SwRS

Silk'n FX Sofware Requirements Specification

Section D – Traceability Analysis

Silk'n FX Traceability Analaysis Document

Section E - Sw Life Cycle

Software Life Cycle SW-7.3.8

Section F - SwVV Verification and Validation

Silk'n FX Software Functional System Test Plan and Results

1 SOFTWARE AND FIRMWARE DEVELOPMENT PROCESSES

Reviewing FDA's "Approach to Deciding Level of Concern" as detailed in the Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005) (hereinafter Software Guidance Document.), the following becomes apparent :

- The software does not qualify as Blood Establishment Computer Software.
- The software is not intended to be used in combination with a drug or biologic.
- The software is not an accessory to a medical device that has a Major or Moderate Level of Concern.
- The software is not an accessory to a medical device that has a moderate level of conceren
- Prior to mitigation of hazards, a failure of the software could result in minor injury, either to a patient or to user of the device

Failures or latent design flaws in the software would be expected to result in minor injury to the patient and/or operator. a software level of concern document is attached in section A of appendix VII.

B4 [redacted]

1.1 SOFTWARE DESCRIPTION

B4 [redacted]

1.2 HAZARD ANALYSIS

The final hazard analysis for the Silk'n FX was developed from the system and software requirements and was refined during the design process. This hazard analysis includes potential, undesirable effects and identifies the hardware and software features or labeling that is designed to ensure that these potentially hazardous events do not occur.The hazard analysis is attached in chapter 5 of the submision

1.3 SOFTWARE REQUIREMENTS SPECIFICATIONS (SRS)

The software requirements for Silk'n FX were based on a value analysis approach, consisting of discussions with potential users, site visits, and a review of current, similar systems.The software requirements specifications were developed based on these findings.
The software requirements specifications documents are attached in section C (SwRS) of Appendix VI .

1.4 ARCHITECTURE DESIGN AND SOFTWARE DESIGN SPECIFICATION

No documentation is necessary in the submision.

1.5 TRACEABILITY ANALYSIS

The Traceability Matrix document gives information on the traceability between software requirements and corresponding verification and validation test that addresses that requirement. The Traceability Matrix document is attached in section D of Appendix VI .

1.6 SOFTWARE LIFE CYCLE DEVELOPMENT PLAN

The objective of the Software Life Cycle Development Plan is to present and justify a software life-cycle model that is to be followed during the development and installation of the FX software. The document identifies activities that are to be performed during the development process such that software failures, which may occur during the execution of the product in its intended environment and resulting from developmental errors, are reasonably controlled. These activities are a reduced subset of the generic, company-wide, software development guidelines that have been adapted specifically for the needs of this particular process.
The software life cycle development plan document is attached in section F (SW Life Cycle) of AppendixVI .

1.7 VERIFICATION AND VALIDATION DOCUMENTATION

The software verification and validation section contains the following documents:

a. Software Functional System Test Plan and Results- The complete software functional system test plan and results with pass/fail Criteria and testing results. are attached in section G (SW Verification and Validation) of AppendixVII.

1.8 REVISION HISTORY LOG

A software history revision log is provided in Table 1.Clearance is being disscuss for version SW1.00which is the most recent version of the software.

Table 1

File name/ Revision number	Creation date	Notes
1.00-7	10/01/2010	First system test cycle
1.00	20/05 /2010	Released version

1.9 UNRESOLVED ANOMALIES

The software problem were recorded in the sofware problem report, resolved and verified during the system test phase, for the current released version no known open bugs.

Table 2

Bug ID	Problem	Impact on device performance	Timeframes for correcting the problem (where appropriate).

Section A - Software Level

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December, 2010

Silkn FX Software Level of Concern

Determining Level of Concern

According to the "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

B4 [redacted]

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B4 [redacted]		
[redacted]	[redacted]	B4 [redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Section B- Software Description

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Silk'n FX Software Description

DO102043B

	Role	Name	Signature	Date
Written by	Software Manager.	Daniel Wainer		December,2010
Checked by	Quality Manager	S.Francis-Najjar		December,2010
Approved by	VP R&D	Ben Zion Levi		December,2010

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Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	all	First release	Ben-Zion Levi	May 2010
B	all	Second release	Ben-Zion Levi	December 2010

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Fax: +972(4)9097471

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Fax: +972(4)9097471

1 Intended Use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

2 Technological Characteristics

The technological characteristics available in Silk'n FX device include:

The submitted device provides a treatment method, based on well-established light energy and temperature stabilization technology for facial treatments

The Silk'n FX operates on 5V voltage regulator used for voltage regulation to the microcontroller and fan and is designed to automatically activate the LED light as soon as the device touches the skin.

The process of light emitting diodes (LED) bio-stimulation and temperature stabilization, into the skin that improves the appearance of the skin. It has been proven in clinical use around the world for over 15 years as a safe and effective way to treat periorbital wrinkles.

The Silk'n FX consists of 2 components:

Base unit
Base unit is used to charge the batteries of the applicator. On the Silk'n FX
It is a mechanical cradle for Hand Piece batteries charging and bridging connection between AC adaptor plug and charging contacts in Hand piece.

Applicator Hand Piece
B4 [redacted]

The Silk'n FX hardware utilizes a:

2.1 AC Adaptor

The AC Adaptor is used for the charging the rechargeable batteries. It is connected to the rear panel of the cradle.

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2.2 Cradle

The cradle is only a cradle which placing in the FX hand piece. Electrically it connects the AC wall adaptor output voltage to fast release spring contacts.

2.3 Hand piece

The hand piece contains the following accessories:

2.3.1 Main Card:

The Main card contains the following parts:
Rechargeable Li-ion batteries
Micro controller (µC) based on MicroChip PIC family.
Battery charger IC
Toggle switch circuit
5V voltage regulator
Temperature stabilizer driver
FAN driver
Touch sensor
Indications LEDs

2.3.2 B4 [redacted]

[redacted]

2.3.3 B4 [redacted] controller

The µC is responsible for the below tasks:
MMI - monitor the device operating and control the LED indicators.
Operating buttons:
Mode - Toggle the system between 3 different On states for 2 different treatments and a Off state. When at off state - maximum leakage current ~ 2µA.
Driving LED indicators:

- On state 0	Green
On state 1	Green
- Error/warning state	Yellow
- Battery charging	Orange/Green

Monitoring of safety statuses and stop operation at wrong statuses from hardware modules
Stop operation according to some certain threshold of Battery voltage.
FAN driving and control

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FAN current sensing
Driving the temperature stabilizer for achieving the required FX tip temperature.
Temperature sensing of device tip and batteries.
Optional RS232 and I2C communication to micro-controller via test point.
Low cost

2.3.4 Battery Charger

The battery charger is Dual Cell Lithium-Ion Charge Management Controllers which should have the following features:
High-Accuracy Preset Voltage Regulation
Programmable Charge Current
Programmable Safety Charge Timers
Automatic End-of-Charge Control
Cell Temperature Monitoring
Charge Status indication using LED
Automatic Power-Down when Input Power Removed
Low size Package
Low cost < 1$
Very low current consumption when the controller is disabled < 5μA

2.3.5 [redacted]

B4

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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2.3.6 5V voltage regulator

The 5V voltage regulator is regulating the voltage to the micro controller and Fan. It should meet the following requests:

Output voltage	5V
Output current	> 200mA
Low dropout voltage	<0.3V
Low consumption current	<10mA
Short Circuit Protection	
Low cost	< 0.3$
Small case size	

2.4 The Silk'n FX Software utilizes:

2.5 Initialization and self test

The embedded application software is responsible for:

a) Initialize micro-controller.
b) Flashing LEDS.
c) Start temperature control.
d) Go to treatment mode.

2.6 B4 [redacted]

2.7 B4 [redacted]

2.8 Regular system diagnostics

Check system fan operation.
Check battery voltage

3 Principle of operation

- B4 [redacted]
- [redacted]

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B4 [redacted]

4 Role of Software

B4 [redacted]

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B4 [redacted]

5 Outputs

The energy output characteristics available in Silk'n FX device include:

5.1 B4 [redacted]

[redacted]

[redacted]

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Fax: +972(4)9097471

Silk'n FX
SOFTWARE REQUIREMENTS SPECIFICATION

DO102050B

Project:	**Silk'n FX**
Date:	**June, 2010**
Written by:	**Daniel Wainer**
Approval:	**Ben Zion Levi**

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	All	First Version	Ben Zion Levi	04 March 2010
B	All	Second Version	Ben Zion Levi	June 2010

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

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1 Introduction

1.1 Purpose

The purpose of this document is to provide a consistent and complete description of the requirements for the software of Silk'n FX. The requirements will be presented using textual descriptions to explain concepts, different types of diagrams to illustrate complicated interactions, and tables to relate relevant information.

The intended audience of this document is all of the managers and engineering involving the development of the processor embedded software. This includes, but is not limited to, software developers, project managers, quality assurance personnel, and customers.

1.2 Scope

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The real benefit of this product is its efficacy, safety and reduced procedure duration.
The embedded software purpose is to control and monitor the functions in order to provide light energy and temperature stabilization in a desired manner.

1.3 Definitions

The following table defines terms and definitions used in this SRS:

Term	Definition
SwRS	Software Requirements Specification
V&V	Verification and Validation
HMI	Human Machine Interface
CPU	Central Processing Unit
I/O	Input/ Output
Control Panel	LED indicators
C	C programming language
C++	C++ object oriented programming language
PS	Power Supply
RAM	Random Access Memory
I^2C communication	I2C communications standard
GPIO	General Purpose Input – Output
API	Applications Programming Interface

1.4 References

The following table lists all documents which supply inputs to this SRS:

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1) IEC 60601-1-4 General requirements for safety programmable electrical medical system.
2) IEEE 830-1998 standard for creating SRS documents is IEEE Recommended practice for software requirements specification by IEEE-SA computer society (IEEE-SA Standards Boards, 1998)
3) DO101950A Silk'n FX Operator Manual
4) DO1011683B Silk'n FX System Requirements Specification
5) DO101971A Silk'n FX Risk Analysis Report

1.5 SwRS Overview

The requirement statement identification convention is based on section numbering.

In section 2 we will give a general overview of the functionality of Silk'n FX embedded software. It is used to establish a context for both the informal requirements definition and for technical requirement specifications in the next chapter. This section consists of six subsections, as follows:

- Product perspective.
- Product functions.
- User characteristics.
- Constrains.
- Assumptions and dependencies.
- Apportioning and requirements.

In section 3 we will give a detailed overview of the functional and non-functional requirements of the Silk'n FX embedded software. This section consists of six subsections, as follows:

- External interfaces.
- System features.
- Performance requirements.
- Design constrains.
- Software system attributes.

2 Overall description

This section describes the general factors that affect the Silk'n FX embedded software requirements. This section does not state specific requirements; instead it provides a background for those requirements, which are defined in detail in Section 3.

The Silk'n FX embedded software will allow an operator to view system status and generate pulses.

The major functions of the Silk'n FX embedded software are: startup, status check; HMI and light energy delivery, and temperature stabilization.

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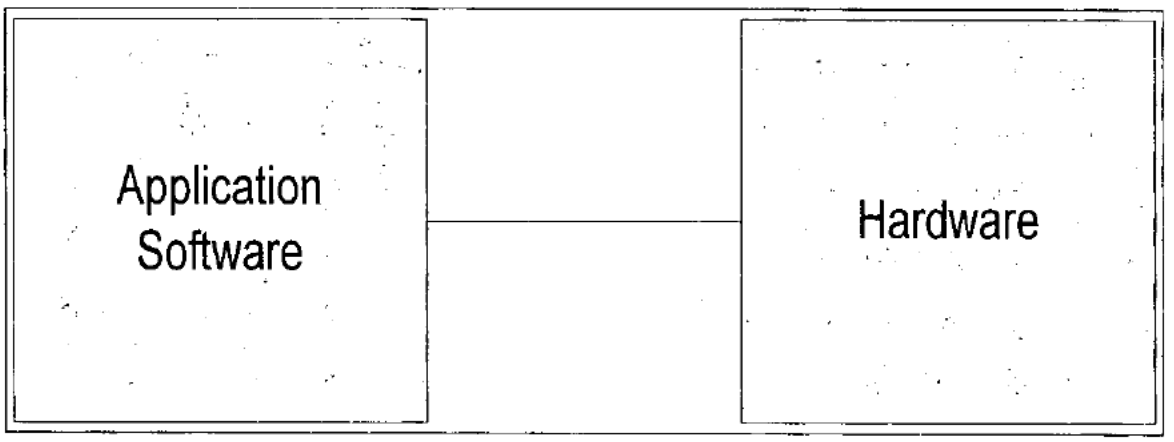
2.1 Product Perspective

B4

[redacted]



FX Software Diagram

The Silk'n FX embedded software directly interacts with the following other components of the entire device:

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2.1.1 System Interfaces

The software interfaces to the system via hardware interfaces, see below and section 3.

2.1.2 User Interfaces

2.1.2.1 Components of the user interface

LED indicators

Yellow, Orange and Green Light emitting diodes, controlled directly by GPIO. The orange LED is for future use.

2.1.3 Hardware interfaces

The head interface performs the energy delivery functions as well as temperature monitoring (See 3.1.1)

HMI Interface: deals with the visual user interface (See 3.1.2).
Miscellaneous interfaces: Fan, battery voltage, skin touch (See 3.1.3).

2.1.4 Software interfaces.

No actual software interfaces

2.1.5 Communication interfaces

No communication interfaces to other systems are provided.

2.1.6 Memory constraints

[MCNT1] The memory constraints are related to the micro-controller internal flash memory for software code, as well as the internal RAM memory.

2.1.7 Operations

There are three basic operations:

[OPRN1]User operations: when the touch sensor detects skin touch, light energy delivery will start.

[OPRN2]Temperature dependent control stabilizer and fan speed for temperature control.

[OPRN3]Battery monitor: warn when battery is close to low limit, stop system when battery is at lower limit.

[OPRN4]Idle mode: light energy is not delivered.

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2.1.8 Site Adaptations Requirements

There are no site adaptation requirements.

2.2 Product Functions

The embedded application software is responsible for the following functions:

a) Initialization and self test.
   1) Initialize micro-controller
   2) Flashing LEDS
   3) Start temperature control.
   4) Go to treatment mode

b) B4 [redacted]

c) B4 [redacted]

   1) Check system fan operation.
   2) Check battery voltage

2.3 User characteristics

B4 [redacted]

2.4 Constrains

The following constraints were factors in the development of the detailed requirements for the Silk'n FX embedded software:

[CNST1] Safety Constraints

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The following are special constraints related to safety. Redundancy with other requirements may occur, but the importance of this issue allows including them together in one section.

B4 [redacted]

[CNST15]The software should trigger periodically the built-in watch-dog timer in a wise manner, in order to bring the microprocessor to restart in the case the software does not follow the defined sequence of tasks.

2.5 Assumptions and dependencies

The software is moderately hardware dependent, it requires special driver modifications, but it can be easily exported to other members of the micro-controller family.

2.6 Apportioning of requirements

There are no delayed requirements to future versions.

3 Specific Requirements

This section of the SwRS contains the Silk'n FX embedded software requirements to a level of detail sufficient to enable designers to design the system, and acceptance testers to test that the device satisfies the requirements.

These software requirements will be revised by the system engineer to reflect the final approved Silk'n FX architecture design. This will be done before high-level software design phase. Every stated requirement is externally perceivable by users, operators, or other external systems.

This section describes each input into the software, every output from the software, and all functions performed by the software.

3.1 External Interfaces

3.1.1 Head interface

The head module has two interfaces: the temperature stabilizer and light output, together with the temperature and touch sensor inputs.

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B4 [redacted]

3.1.2 HMI interfaces

LED indications:

[EINT3]All user interface visual outputs are delivered by LEDs.

1) **[EINT31]**Green LEDs turns on at start-up – Flashes during temperature stabilization, then it turn on permanent.
2) **[EINT32]**Yellow LED flashes when the battery voltage is between 6.0 and 6.5 volts (2 flashes per second)
3) **[EINT33]**Yellow LED turns on permanent when the battery voltage is below 6.0 volts.

Mode Switch:

4) **[EINT34]**The power switch turns the power on, and then it is sensed by the microcontroller in order to change the treatment mode (Red or IR LED's)
   The sequence is as follow: First push: turn the device on in Red mode, second push: change to IR mode, third push: turn the device off.

3.1.3 Miscellaneous interfaces

[EINT41]Fan status: a GPIO input that indicates the fan is functioning.
A fan status fail will shut-down the system by turning off the power

[EINT42]Battery voltage and temperature monitoring: two GPIOs for measuring the battery voltage and temperature. Low battery voltage or high temperature will be reported to the HMI interface.

[EINT43]Power control: A GPIO turning off the device (it will shut-down also the running software).

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3.2 Functions

B4

[redacted]

3.2.1 Initialization

The application software shall initialize the software and hardware:
The initialization and self test shall include this functionality:

3.2.1.1 Microcontroller initialization

ID	[FUNC01]
Description	Initializes microcontroller registers and internal variables, hardware is initialized to default state

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B4 [redacted]	[redacted]
[redacted]	[redacted]
Error Messages	N/A
Tasks	
Remarks	

3.2.1.2 Go to treatment mode

ID	[FUNC02]
Description	This function starts the treatment mode state
Inputs	None
Outputs	LEDs refer to SRS Table " a summary of the above states is shown below"
Error Messages	None
Tasks	
Remarks	

3.2.1.3 HMI Treatment Mode

ID	[FUNC03]
Description	This function implements the human machine interface in treatment mode.
Inputs	Diagnostics task.
Outputs	Energy Delivering Task Visual indications
B4 [redacted]	[redacted]
[redacted]	[redacted]
Remarks	

3.2.1.4 Temperature Stabilization

ID	[FUNC04]
Description	This function controls the stabilization temperature

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Inputs	Temperature
B4 [redacted]	[redacted]
Error Messages	None
Tasks	B4 [redacted]
Remarks	

3.2.1.5 Diagnostic Functions

ID	**[FUNC05]**
Description	This function checks that the device functions properly
Inputs	Fan B4 [redacted]
Outputs	HMI interface, system shut down GPIO
Error Messages	None
Tasks	Check Battery voltage and temperature is between limits. Check Fan functions properly B4 [redacted] Report results to HMI and/or shut-down device. Check that the treatment duration is less than 20 minutes, otherwise, turn off the device. Turn off the device after 1 minute without skin contact.
Remarks	

3.3 Performance Requirements

[PERF 1]The software shall have the capability of responding to user inputs within 1 second.

B4 [redacted]
B4 [redacted]

[PERF 3]The software shall detect abnormalities every 1 second.

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3.4 Logical Database Requirements

N/A

3.5 Design Constrains

There are no special design constraints out of the specified in 2.4.

3.6 Software system attributes

3.6.1 B4 [redacted]

[redacted]

3.6.2 Availability

[AVLB1]The software shall work continuously under the system specified environment conditions (see user manual), if a hardware failure occurs, it shall behave according to the specified actions (shut-down, warning, or self-recovery).

3.6.3 Security Requirements

[SECU1]The software shall not require user identification.

3.6.4 Maintainability

[MANT1]The software shall be implemented in a modular way following accepted coding standards. The company policy is to give the developer freedom to choose the exact implementation, with the condition that it is explained in a separate document. This shall be sufficient in order to assure good software maintainability.

3.6.5 Portability

The software shall be developed under Microchip™ IDE and Hi-TECH compiler implementation for Microchip™ micro-controller family.

The software shall be written in C/C++ preferable in standard C for performance reasons.

The software shall be able to migrate to another processor by modifying application defined drivers (minor changes). The last paragraph is also applicable.

By minor modifications it should be understood as application hardware driver changes.

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4 Appendix A: Visual indications

1) **Yellow LED:**
   a. **Continuous:** Error condition
   b. **Flashing**: Battery close to be low.

2) **Green LED:**
   a. **Continuous:** Normal operation mode
   b. **Flashing**: Stabilizing.

Section D– Traceability Analysis

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Silk'n FX – Traceability Analysis

DO102063B

Project:	Silk'n FX
Date:	December, 2010
Written by:	Daniel Wainer
Approval:	Ben Zion Levi

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
1		First Verison	Ben Zion Levy	7/2010
2		Second Version	Ben Zion Levy	12/2010

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Tel: +972(4)9097470
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1. Traceability Analysis 4

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1. Traceability Analysis

Traceability between Software Requirements Specifications and Functional System Test Plan is Straight forward by using the requirement ID (first column), that is that test ID corresponds to the requirements ID. Any requirement exception will be detailed in the table below.

Software Requirement Identifier	Software Functional System Test Plan and Results
Software integrity accepted test by changing a byte.	9.1.1
2.1.6 [MCNT1]	9.4.1 test ID MCNT1
2.1.7 [OPRN1]	9.4.1 test ID OPRN1
2.1.7 [OPRN2]	9.4.1 test ID OPRN2
2.1.7 [OPRN3]	9.4.1 test ID OPRN3
2.1.7 [OPRN4]	9.4.1 test ID OPRN4
2.4 [CNST1]	9.4.3 test
2.4 [CNST11]	9.4.3 test ID CNST11
2.4 [CNST12]	9.4.3 test ID CNST12
2.4 [CNST13]	9.4.3 test ID CNST13
2.4 [CNST14]	9.4.3 test ID CNST14
2.4 [CNST15]	9.4.3 test ID CNST15
3.1.1.1 [EINT1]	9.4.4 test ID EINT1
3.1.1.1 [EINT11]	Refer to system verification
3.1.1.1 [EINT12]	Refer to system verification
3.1.1.2 [EINT2]	9.4.4 test ID EINT2
3.1.1.1 [EINT21]	9.4.4 test ID EINT21
3.1.1.1 [EINT22]	9.4.4 test ID EINT22
3.1.2[EINT3]	Inspection
3.1.2[EINT31]	9.4.5 test ID EINT31
3.1.2[EINT32]	9.4.5 test ID EINT32
3.1.2[EINT33]	9.4.5 test ID EINT33
3.1.2[EINT34]	9.4.4 test ID EINT34
3.1.3[EINT41]	9.4.6 test ID EINT41
3.1.3[EINT42]	9.4.6 test ID EINT42
3.1.3[EINT43]	9.4.6 test ID EINT43
3.2.1.1[FUNC01]	9.2.1 test ID FUNC01
3.2.1.2[FUNC02]	9.2.1 test ID FUNC02
3.2.1.3[FUNC03]	9.2.1 test ID FUNC03
3.2.1.4[FUNC04]	9.2.1 test ID FUNC04
3.2.1.5[FUNC05]	9.2.1 test ID FUNC05
3.3 [PERF1]	9.3.1 test ID PERF1
3.3 [PERF2]	9.3.1 test ID PERF2
3.3 [PERF3]	9.3.2 test ID PERF3
3.6.1 [RLBT1]	9.4.7 test ID RLBT1
3.6.2 [AVLB1]	9.4.7 test ID AVLB1
3.6.3 [SECU1]	9.4.7 test ID SECU1
3.6.4 [MANT1]	Software development life cycle

7.3.8 Software Life Cycle Procedure

1.1 General Policy

B4 [redacted]

1.2 Procedure

1.0 Software Life Cycle Management

- *A Software team leader will be assigned for every SW product.*
- *Activities in the SW life cycle will include 6 phases: Requirements, Design, Implementation (Coding), Verification and Validation and maintenance. Some stages will not be necessary for certain projects. In those cases, only the relevant required development phases will be applied. Each phase*
- *The main DRs will be the SWRS DR at the end of SW requirements specification phase and the SDD DR at the end of the SW Design Phase. Other DRs will be performed when applicable. The responsibility of each DR will be defined in the SW Project Plan.*

2.0 Software Development Process:

The following paragraphs address the software life-cycle phases. The software shall be designed to perform as intended by the Home Skinovations, and the performance of the software shall be validated.

2.1 SW Requirements Phase I

The requirements phase is one of the most important phases of software engineering. Studies show that the top problems in the software industry are due to poor requirements elicitation, inadequate requirements specification, and inadequate management of changes to requirements. Requirements provide the foundation for the entire life cycle as well as for the software product. Requirements also provide a basis for planning and estimating.

Requirements are based on customer, user, and other stakeholder needs and design and development constraints. The development of requirements includes elicitation, analysis, documentation, verification, and validation. It is important that there is ongoing customer validation of the requirements to ensure the end products meet the customer needs. This can be accomplished via rapid prototyping and customer involved reviews of iterative and final software requirements.

B4

[redacted]

Software Life Cycle flowchart

2.1.1 Requirements Development

- *The project shall document the software requirements.*
- *The project shall identify, develop, document, approve, and maintain software requirements based on analysis of customer and other stakeholder requirements and the operational concepts.*
- *The project shall perform software requirements analysis based on flowed-down and derived requirements from the top-level systems engineering requirements and the hardware specifications and design*
- *The project shall perform, document, and maintain bi- directional traceability between the software requirement and the higher level requirement.*

2.1.2 Requirements Management

- *The project shall collect and manage changes to the software requirements.*
- *The project shall identify inconsistencies between requirements, project plans, and software products and initiate corrective actions*
- *The project shall perform requirements validation to ensure that the software will perform as intended in the customer environment*

2.2 Software Risk Analysis Phase II

Identification and management of risks provides a basis for systematically examining changing situations over time to uncover and correct circumstances that impact the ability of the project to meet its objectives.

The project shall identify, analyze, plan, track, control, communicate, and document software risks (potential issues, hazards, threats, and vulnerabilities) in accordance with Risk Management Plan Procedural (7.1.1)

2.3 Software Design Phase III

Architectural design is concerned with creating a strong overall structure for software entities that fulfill allocated system and software- level requirements. Typical views captured in an architectural design include the decomposition of the software subsystem into design entities, definitions of external and internal interfaces, dependency relationships among entities and system resources, and finite state machines. Detailed design further refines the design into lower level entities that permit the implementation by coding in a programming language. Typical attributes that are documented for lower level entities include: identifier, type, purpose, function, constraints, subordinates, dependencies, interface, resources, processing, and data.

2.3.1 The project shall document the software design.

- *The project shall transform the allocated and derived requirements into a documented architectural design.*
- *The project shall develop and record a detailed design based on the architectural design that describes the lower level units so that they can be coded, compiled, and tested.*
- *The project shall perform and maintain bi-directional traceability between the software requirements and the software design.*

2.4 Software Implementation Phase IV

Software implementation consists of implementing the requirements and design into code, data, and documentation. Software implementation also consists of following

coding methods and standards. Unit testing is also usually a part of software implementation (unit testing can also be conducted during the testing phase).

- *The project shall implement the software design into software code.*
- *The project shall ensure that software coding methods, standards, and/or criteria are adhered to and verified.*
- *The project shall ensure that the software code is unit tested per the plans for software testing.*
- *The project shall provide a Software Version Description document for each software release*
- *The project shall provide and maintain traceability from software design to the software code.*

2.5 Software Testing Phase V

B4 [redacted]

2.6 Software Release Process

B4 [redacted]

2.6.6 *Summary status for all open system problems to be resolved in future releases.*
2.6.7 *A new software baseline established for future maintenance.*

2.7 Software Maintenance Phase VI

B4 [redacted]

2.8 Software Documentation Process

The list of documents to be produced during the life cycle of the software product shall be defined in the Program Plan.
The rules for documents control, approval and changes are described in the Control of Documents Procedure (4.2.3).

2.9 Software Configuration Management Process

B4 [redacted]

2.10 Software Problem Resolution Process

B4 [redacted]

The bug list will include full disclosure of any unresolved anomalies, discuss the impact on safety or effectiveness, No anomaly shall have an unacceptable risk associated with it.

3.0 External reference

3.1 ISO 13485:2003 par. 7.3
3.2 21 CFR 820.30
3.3 MDR SOR/98-282(20)
3.4 IEC 62304, Medical device software – software life cycle processes.
3.5 IEC 60601-1-4; Medical electrical equipment: General requirements for safety – Collateral standard: Programmable electrical medical system.

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Tavor building, POB 533
Yokneam 20692, ISRAEL
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Fax: +972(4)9097471

Silk'n FX
Software Functional System Test Plan and Results

DO102051B

Project:	**Silk'n FX**
Date:	**December , 2010**
Written by:	**Yehoram Bar**
Approval:	**Ben Zion Levi**

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	All	First Version	Ben Zion Levi	May 2010
B	All	Second Version	Ben Zion Levi	December 2010

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Yokneam 20692, ISRAEL
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Fax: +972(4)9097471

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1. Introduction

1.1. Purpose

The Silk'n FX Software System Test Plan establishes and provides program visibility and control of the approach, requirements and plans for validation and testing of the Silk'n FX

1.2. Scope

B4 [redacted]

1.3. Definitions

Term	Definition
STP	System Test Plan
SRS	System requirements specification
SwRS	Software requirements specification
VVP	Verification and validation plan
DHF	Design History File

1.4. References

Document	Location
DO1011683B Silk'n FX System Requirements Specification	DHF
DO102050B Silk'n FX Software Requirements Specification	DHF
DO101971B Silk'n FX Risk Analysis Report	DHF

2. Test Plan Type & Attribute Refinement

2.1. Test Plan Type

This test plan is functional, stress, performance, safety, and error handling testing used to verify the SR SW release.

2.2. Level

System Level

2.3. Objective

The objectives of the system test plan are:

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B4 [redacted]

2.4. Approach

Testing methods used to achieve the objective of this test plan:
Black box technique: Data-Flow testing.
Black box technique: Domain testing & boundary value analysis.

The developer will assist in developing the test cases; this will help ensure that the tests represent the production use of the system.

2.5. Readiness Criteria

The Unit and Integration testing shall have been passed and completed successfully.
The software is stable (means a reliable software with no major issues).
The SW Packages under test have been collected under a system test build in configuration management.
All test Hardware and environments must be in place, and free for system test use.
All Human resources must be assigned and in place

2.6. Input Work Products

The input work product used for the system test plan is the:

- DO102050BSilk'n FX Software Requirements Specification
- DO101971B Silk'n FX Risk Analysis Report

2.7. Test Environment

The tests require a system with the software fully installed and the options (hardware and software) available.

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2.7.1. Hardware

Silk'n FX device consists of a Base unit and an Applicator.

2.7.2. Software

Software version: 1.00-8

2.7.3. Security

NA.

2.7.4. Tools

2.7.4.1. Error reporting Tools

Bug report file.

2.8. Publications

NA.

2.9. Roles & Responsibilities

2.9.1. Test Plan generation

B4 [redacted]

2.9.2. Test Execution

Test Procedures shall be executed by a team member not directly involved in the design and implementation of the component.

2.9.2.1. Test Phases and Cycles

There will be two main stages of testing for the Software during system testing:

System Testing

Acceptance Testing

2.9.2.1.1. System Testing Cycles

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B4 [redacted]

B4 [redacted]	[redacted]	[redacted]

2.9.2.1.2. *Acceptance Testing Cycles*

The main thrust of the approach is to test the usability of the device after approval of the system test.

2.9.2.2. *Software Delivery*

During System Test the release of new versions of the software will be coordinated between the Development SW engineer and the Development System engineer. However, unless it concerns a fix to a very serious error, new versions should only be released when agreed targets have been reached (i.e. the next version contains fixes to X or more numbers of bugs).

Notes:

It is intended that 80% of the functionality will have been tested in full prior to the Phase 1 Release.
All the functionality must be present in the Phase 2 Release. No previously undelivered functionality will be accepted for testing after Phase 2.

2.10. Formal Reviewing

There will be several formal review points before and during system test, including the review of this document. This is a vital element in achieving a quality product.

- Design Documentation - Requirements Specification & Functional Specification
- System Test Plans & Test conditions.
- System Test results
- Post system test review.

3. Test Items

All items that makeup the software SR device will be tested during the system test. The versions to be tested will be downloaded to the device

4. Features to be tested

B4 [redacted]

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- [redacted]
- [redacted]

5. Features not to be tested

NA

6. Tester Skills

The following staff is needed to carry out this testing project:

- System engineer: he provides the overall management of the testing and technical testing expertise.
- SW engineer: he transmits the system to be tested and responds to the system test Incident reports he does any program debugging that required. It also supplies the version control.
- All the staff must be trained to perform the test.

7. Safety Issues

B4 [redacted]

8. Test Termination Criteria

This test plan terminates normally if the execution of each test procedures results in a passed condition. The test plan may be terminated abnormally under the following conditions:

- Upon reaching a "Fail" condition on for any test case within a test procedure, the tester may terminate the test procedure.
- Upon reaching a failed condition in one test procedure, the tester may continue testing if the preconditions of subsequent test procedures can be satisfied. Otherwise, the tester may terminate execution of the test plan.

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If the preconditions of a test procedure cannot be satisfied, the tester may proceed to execute subsequent test procedure as long as the preconditions of those procedures can be satisfied. Otherwise, the tester may terminate execution of the test plan."

9. Test Procedures

9.1. Installation

9.1.1. Verify firmware integrity

B4

[redacted]

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B4

[redacted]

9.3. Performance

9.3.1. Verify system responding to user input

B4

[redacted]

9.4. Verify Interfaces

9.4.1. Verify Other Product Perspective Requirements

ID	Action	Expected result	Verification Test result	Comments and Recommendations

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[redacted]

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9.4.5. Verify Miscellaneous Interfaces [EINT4].

B4

[redacted]

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10. Test Plan Results Summary

Test Equipment

Equipment	S/N	Calibration Expiry
Scope Fluke 196C	DM9660290	10/2010
Thermometer	CENTER 304	10/2010

Tester Name: _____

Date: _____ Signature: _____

Comments: _____

Approved by: _____

Date: _____ Signature: _____

Comments: _____

Chapter 17

Electromagnetic Compatibility and Electrical Safety

THE STANDARDS INSTITUTION OF ISRAEL

Electronics & Telematics Laboratory

CERTIFICATE OF CONFORMITY

This is to certify that:

Equipment Under Test:

The Personal home use skin rejuvenation device

Name: ***Silk'n Reju***

Model: ***AS1018321***

Tested: ***24, 25, 27/05/2010***

Manufactured by: ***Home Skinovations Ltd.***

Address: ***Apolo Building, Shaar Yokneam, P.O.Box 533, Yokneam 20692, Israel***

Has been tested by SII and was found to comply with the requirements of the following standard:

- IEC 60601-1-2: "Medical electrical equipment; Part 1-2: Collateral Standard: Electromagnetic compatibility - Requirements and tests", Ed.2.1 (2004); sec. 36.201 (Emission) & sec.36.202 (Immunity).

Test results are detailed in SII's Test Report No: 9012313993.

Certificate No.: 9012313993

Date of issue: 31 May 2010

Eng. Yuri Rozenberg

Head of EMC Branch

42 Chaim Levanon St. Tel-Aviv 69977 Israel. Management: Tel: 972-3-6467800 Fax: 972-3-6467779 www.sii.org.il
Electronics: Tel: 972-3-6465050 Fax: 972-3-7454026 - Alarms Systems Section: Tel: 972-3-6465370 Fax: 972-3-6467262

The Standards Institution of Israel

CERTIFICATE OF CONFORMITY

This is to certify that:

Skin rejuvenation device

Trademark: HomeSkinovations

Model: ***Reju (p/n AS1018321)***

Applicant: HomeSkinovations Ltd.
Address : Apolo building, Shaar Yokneam, POB 533, Yokneam 20692, Israel

Manufacturer: HomeSkinovations Ltd.
Address : Apolo building, Shaar Yokneam, POB 533, Yokneam 20692, Israel

Has been tested by SII and was found to comply with the assessed requirements of :

IEC 60601-1 : "Medical Electrical Equipment"
Part 1:"General requirements for safety"
1988, including amendments
#1(1991),#2(1995).

Test results are detailed in SII's Test Report No.: 9012313978

Certificate No.: 9012313978

Date of issue: 20 May, 2010

Dr. Irina Antonov
Head of MED & Lasers Safety Branch
Electronics and Telematics Laboratory

42 Chaim Levanon st. Tel-Aviv 69977, Israel. Telematics Laboratory. Tel. 972-3-6467800 Fax. 972-3-6467779

Chapter 18

Performance Testing – Bench

B4, Testing Data

B4, Testing Data

B4, Testing Data

B4, Testing Data

Chapter 20
Performance Testing B4, Testing Data [redacted]

B4, Testing Data

B4, Testing Data

B4, Testing Data

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Abbas Bandukwala

Subject: 510(k) Number K110301 | S4

To: The Record

Please list CTS decision code SG

x Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

x Hold (Additional Information or Telephone Hold).

x Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

x	NO	NSE for lack of predicate
x	NI	NSE for new intended use
x	NQ	NSE for new technology that raises new questions of safety and effectiveness
x	NP	NSE for lack of performance data
x	NM	NSE requires PMA
x	NS	NSE no response
x	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?		✓	
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?		✓	
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old)	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*	✓

Regulation Number	Class*	Product Code
878.4810	II	OHS

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Neil R.P. Ogden (Branch Chief) GSDB (Branch Code) 8/19/11 (Date)

Final Review: Mark N. Melkerson (Division Director) 8/19/11 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K110301

Date: March 3, 2011
To: The Record
From: LTJG Abbas Bandukwala, USPHS
Biomedical Engineer

Office: HFZ-410
Division: DSORD/GSDB

510(k) Holder: Home Skinovations LTD
Device Name: Silk' N FX
Contact: Amir Waldman
Phone: 972 547 04616
Fax: 972 490 97471
Email: amirw@silkn.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Silk' N FX into interstate commerce.

II. Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Prescription)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?			X

B4 [redacted]

B4 [redacted]

IV. Indications for Use: Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

V. Predicate Device Comparison:
Omnilux New-U (K072459) - The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

	Silkn Reju	Ominlux New- U (K072459)
B4 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

VI. Labeling: Sponsor has provided user instruction in the submission only. Sponsor has not provided package labeling. Sponsor has not provided usability study or self selection study to demonstrate lay persons can correctly select and use the device. User manual is inadequate when compared to the predicate labeling manual. The labeling, self-selection and usability study were reviewed by Mr. Jack McCracken. Many of his comments were added to the deficiencies sent to the sponsor. His full review will be attached to this review.

VIII. Sterilization/Shelf Life/Reuse: Device has cleaning instructions in the manual. The treatment surface area needs to wiped clean with isopropyl alcohol wipes.

IX. Biocompatibility: Sponsor has provided a biocompatibility statement in the submission. It states that the only portion of the device that comes into patient contact is a stainless steel component of the device.

X. Software:

Version:		
Level of Concern: Major		
	Yes	**No**
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Development:	X	

Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:	X	

Sponsor provides proper software documentation in accordance with FDA guidelines.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety:
Sponsor provided certificates from third party company stating device is in compliance with the following standards:

- IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

XII. Performance Testing – Bench: The sponsor provides the power density results of both the subject and predicate devices.

Table 1 OmniLux New – U Power Density

B4 [redacted]

Table 2 Silk n Face Power Density

B4 [redacted]

XIII. Performance Testing – Animal: N/A

XIV. Performance Testing – Clinical: B4 [redacted]

B4

[redacted]

XV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		X	If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: The indication for use statement is identical to the Omnilux New-U (K072459) predicate device.

2. Explain why there is or is not a new effect or safety or effectiveness issue: The subject device is identical to the Omnilux New-U (K072459) predicate device.

3. Describe the new technological characteristics: There are no new technological characteristics. The device is identical to the predicate device.

4. Explain how new characteristics could or could not affect safety or effectiveness: There are no new characteristics to affect the safety or effectiveness of the device.

5. Explain how descriptive characteristics are not precise enough: The output of the device is identical to the predicate device, therefore the descriptive characteristics are precise enough to determine the device is substantial equivalent.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: The device indication for use and technological characteristics are the same as the predicate device. There are no new types of safety or effectiveness questions raised.

7. Explain why existing scientific methods can not be used: The device description is precise enough.

8. Explain what performance data is needed: Performance data is not needed.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: Performance data was not needed to determine substantial equivalence.

XVI. <u>Deficiencies:</u>

1. Sponsor has not provided the outside package labeling for the device. Because this device is an over-the counter device, the outside package labeling must be evaluated. Please provide an exact copy of the package labeling that will be used to sell the device in the United States.
Response: Sponsor has provided a black and white version of the package labeling.

2. The treatment course for the Silkn Face device is different then the treatment course for the Omnilux predicate device. Different treatment regimens could provide less effective and less safe results. Please provide clinical data that demonstrates the treatment regimen in the Silkn Face manual is safe and effective for the indicated use or provide literature to support the safety and efficacy of your treatment.
Response: Treatment regime was changed and is now identical to the predicate device treatment regime.

3. Please add a picture in the user manual and on the package of periorbital wrinkles (crows feet). People who are selecting this device and using this device might not know this condition by the name itself or may confuse this condition for another type of condition that the device is not intended to treat.
Response: Page 9 of the manual states "Typical areas for treatment are the cheeks, the forehead and around the eyes". There is a diagram but it does not have much detail. The package labeling and user manual should have pictures of what periorbital wrinkles (crows feet) are. Please add these pictures on the package labeling and in the user manual. The general population may not be familiar with the term periorbital wrinkles or crow feet. A picture identifying these types of wrinkles will help potential users understand what the device is intended to treat.

4. The device uses LED's to treat the indication for use. LED's after a certain amount of use and time become less effective and do not produce the same light output. The manual should inform the user that after a certain period of time the device will become less effective and at that point the user should no longer use the device. Please add this information into the user manual.
Response: Sponsor states that number of battery charges determines the effective time period for the device. The manual states the device will be effective up to 300 full battery charge cycles.

5. On page 7 of the manual, the word "in" is spelled "Id". Please correct this error.
Response: The error was corrected.

B4 [redacted]

The additional information provided the most of the needed information but some deficiencies still remain.

1. Package labeling states the device uses "HF energy to rejuvenate the skin". The word rejuvenate is not accepted word for these types of devices. Please replace the word rejuvenate on the package labeling.
   Response: The label now says refresh the skin.

2. B4 [redacted]

3. Page 9 of the manual states "Typical areas for treatment are the cheeks, the forehead and around the eyes". There is a diagram but it does not have much detail. The package labeling and user manual should have pictures of what periorbital wrinkles (crow's feet) are. Please add these pictures on the package labeling and in the user manual. The general population may not be familiar with the term periorbital wrinkles or crow's feet. A picture identifying these types of wrinkles will help potential users understand what the device is intended to treat.
   Response: Sponsor has clarified this portion of the manual and clear identified periorbital wrinkles with pictures.

4. B4 [redacted]

B4, B5

B4, B5

B4, B5

B4, B5

B4, B5

B4 [redacted]

[redacted] the manual and then stated they are not able to use this device according to the warning instruction on page 8. This difference in the exclusion criteria and the user manual is confusing, and the result makes it unclear if the subjects understood your user's manual. Please revise your exclusion criteria to be consistent with your user's manual and conduct another usability study. People under the age of 35 can be part of the self selection study, but these people should identify that the device is not intended for them.

B4 [redacted]

[redacted] the warning, precautions and "when to avoid using Silk' n FX sections of the manual. The questionnaire should test the subjects on all parts of the manual. The investigator should observe that the subjects are using the device correctly and also make the proper determination if a warning or precaution applies to him/her.

Response: The manual does have specific guidelines on when not to use the device and when to seek help for an adverse reaction. Sponsor states that none of the subjects in the study needed to be overruled by the investigator and therefore understood the warnings, precautions, and contraindications.

7. B4 [redacted]

On page 7 of the user manual, in the "when to avoid using Silk' n FX", the following points should be moved to the contraindication section of the manual:
Do not use Silk' N FX if the treated skin is not healthy and clear. If you have any skin condition including brown or black spots, birth marks, moles warts , eczema, psoriasis, lesions.
Do not use Silk' N FX if you have diabetes
Do not use Silk N' FX if you are currently or have recently been treated with Alpha-Hydroxi Acids, Beta-Hydroxi Acids, Retin – A, topical retinoids or azelaic acid.

The statement "Open wounds and active infections, such as cold sore on the area to be treated", can remain in this section.
Response: Sponsor made these minor changes and emailed the changes.

XVII. <u>Contact History:</u>

On March 8, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

On May 3, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

XVIII. Recommendation:

Regulation Number: 878.4810
Regulation Name:
Regulatory Class: II
Product Code: OHS

Abbas Bandukwala, Reviewer
General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

August 18, 2011
Date

Neil R.P. Ogden, M.S.
Chief, General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

8/19/11
Date

Bandukwala, Abbas

To: Amir Waldman

Subject: RE: Home Skinovations LTD Silk' N FX (K110301)

Mr. Waldman,
Could you make the following changes and then email the updated page. If you are able to make these changes by late Friday afternoon. I will not need to put the submission on hold.

On page 7 of the user manual, in the "when to avoid using Silk' n FX", the following points should be moved to the contraindication section of the manual:
Do not use Silk' N FX if the treated skin is not healthy and clear. If you have any skin condition including brown or black spots, birth marks, moles warts , eczema, psoriasis, lesions.
Do not use Silk' N FX if you have diabetes
Do not use Silk N' FX if you are currently or have recently been treated with Alpha-Hydroxi Acids, Beta-Hydroxi Acids, Retin – A, topical retinoids or azelaic acid.

The statement "Open wounds and active infections, such as cold sore on the area to be treated", can remain in this section.

Sincerely,

Abbas Bandukwala
Biomedical Engineer
General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices
abbas.bandukwala@fda.hhs.gov
301 796 6386
New Address
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

From: Amir Waldman [mailto:amirw@silkn.com]
Sent: Wednesday, July 13, 2011 10:58 AM
To: Bandukwala, Abbas
Subject: RE: Home Skinovations LTD Silk' N FX (K110301)

Mr. Bandukwala
Thank you very much for your prompt reply.
Will explain it with the additional information.

Amir Waldman
Home Skinovations Ltd.

20

Fife, Elizabeth *

From: Microsoft Exchange
To: 'amirw@silkn.com'
Sent: Wednesday, August 17, 2011 4:19 PM
ıbject: Relayed: K110301 Additional Information Received

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'amirw@silkn.com'

Subject: K110301 Additional Information Received

Sent by Microsoft Exchange Server 2007

21

* * * COMMUNICATION RESULT REPORT (AUG. 5. 2011 11:06AM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : AUG. 5. 2011 11:00AM

FILE MODE	OPTION	ADDRESS	RESULT	PAGE
7900 MEMORY TX		DIR COMM RIC MKT	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 05, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301
Product: SILKN FX

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Abbas Bandukwala

Subject: 510(k) Number K110301/S3

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number 878.4811 **Class*** II **Product Code** OHS

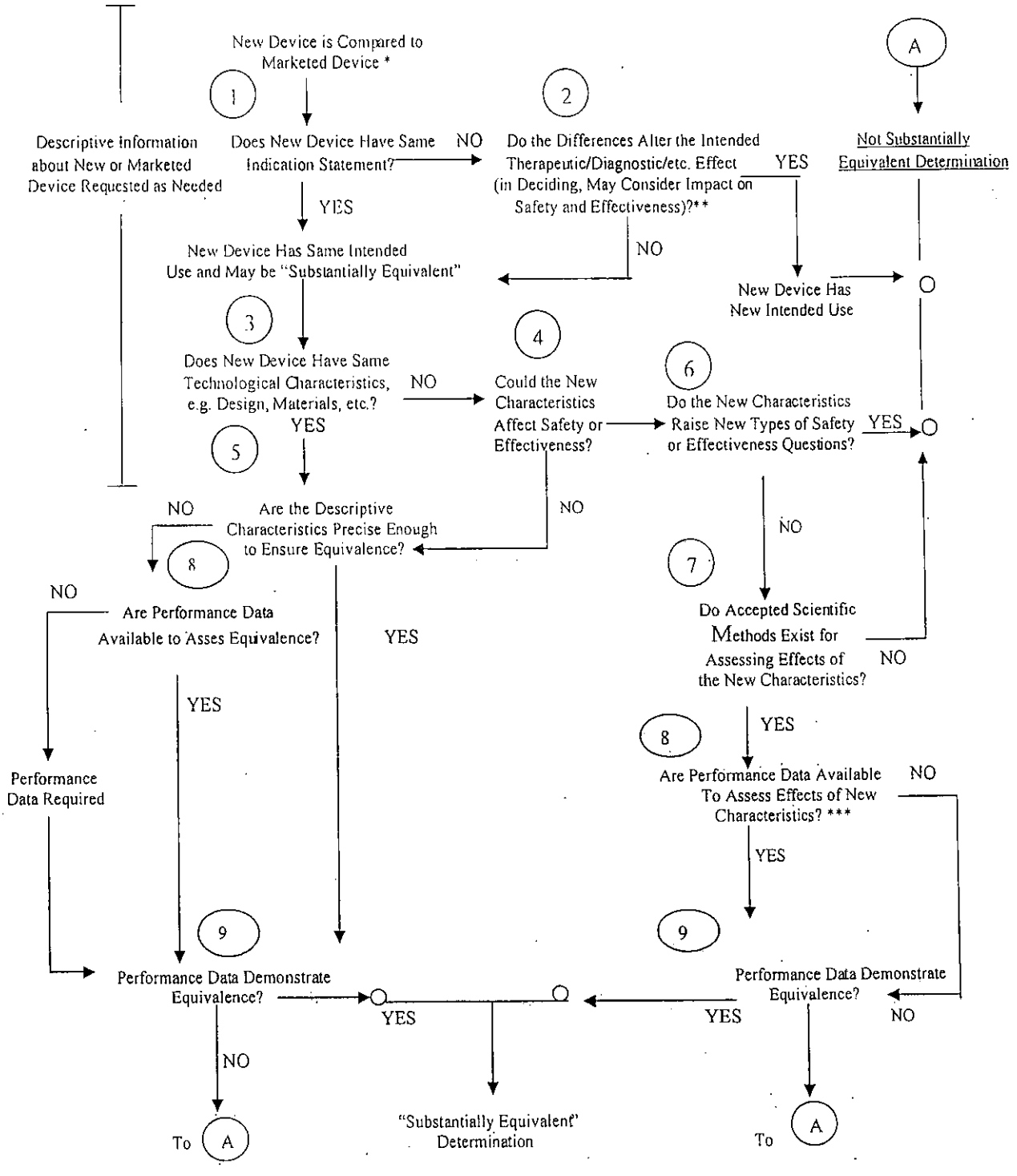
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) GSDB (Branch Code) 8/4/11 (Date)

Final Review: (Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Bandukwala, Abbas

From: Bandukwala, Abbas
Sent: Thursday, August 04, 2011 12:35 PM
To: 'Amir Waldman'
Subject: RE: Home Skinovations LTD Silk' N FX (K110301)

B4

[redacted]

From: Amir Waldman [mailto:amirw@silkn.com]
Sent: Friday, July 29, 2011 2:43 AM
To: Bandukwala, Abbas
Subject: RE: Home Skinovations LTD Silk' N FX (K110301)

Dear Mr. Bandukwala,
Please find a revised version of the manual including the changes requested in pages 7 and 8.

Amir Waldman
Home Skinovations Ltd.

From: Bandukwala, Abbas [mailto:Abbas.Bandukwala@fda.hhs.gov]
Sent: Thursday, July 28, 2011 10:03 PM
To: 'Amir Waldman'
Subject: RE: Home Skinovations LTD Silk' N FX (K110301)

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Abbas Bandukwala

Subject: 510(k) Number K110301/52

To: The Record

Please list CTS decision code AE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Rev. 5/12/11

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

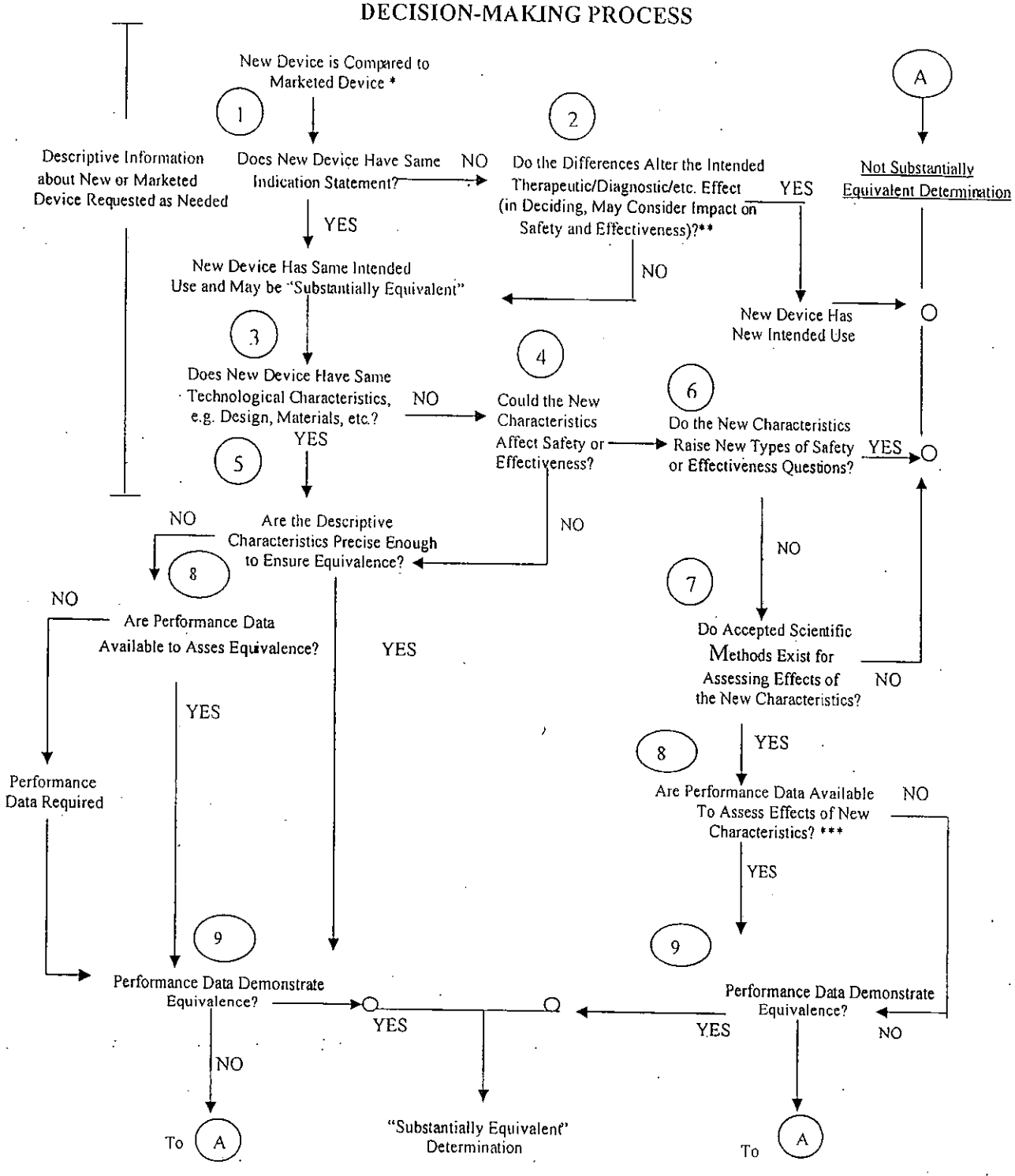
Additional Product Codes:

Review: (Branch Chief) GSDB (Branch Code) 7/8/11 (Date)

Final Review:

(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K110301

Date: July 8, 2011
To: The Record
From: LTJG Abbas Bandukwala, USPHS
Biomedical Engineer

Office: HFZ-410
Division: DSORD/GSDB

510(k) Holder: Home Skinovations LTD
Device Name: Silk' N FX
Contact: Amir Waldman
Phone: 972 547 04616
Fax: 972 490 97471
Email: amirw@silkn.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Silk' N FX into interstate commerce.

II. Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Prescription)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?			X

B4 [redacted]

B4

B4

IV. **Indications for Use:** Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

XVI. Deficiencies:

Sponsor correct or answered most of deficiencies above but some errors still remain.

1. The package labeling provided in the manual is too small to read. Please provide a larger version of the package labeling.

2. In the table of contents of the user manual, there are two instances where the following statement is made "Error! Bookmark not defined". Please correct this error in the manual.

3. You have replaced the phrase "HF energy to rejuvenate the skin" to say "HF energy to refresh the skin". Because the term "refresh" does not correctly explain the actions and effects of the device, this word should not be used to describe the device. Please revise this phrase or remove it from the manual.

4. On page 12 of the instruction manual, in section 4. "Follow the recommended Silk' N FX treatment course:", the word "recommend" is used twice. Please remove the word recommend from the title of this section and in the instructions part below it. The treatment course is not a recommendation. The manual should state "To achieve optimal results it is necessary to follow the treatment course provided below". The title of the section should say "Silk' n FX Treatment Course".

5. The user manual states that the device should not be used by subject who are below the age of 35. In the usability study, several of the subjects were below the age of 35. The exclusion criteria was set for persons under the age of 21. Using people below the age of 35 for the study is not consistent with the instructions provided in the manual. Subjects who were below the age of 35 should have read the manual and then stated they are not able to use this device according to the warning instruction on page 8. This difference in the exclusion criteria and the user manual is confusing, and the result makes it unclear if the subjects understood your user's manual. Please revise your exclusion criteria to be consistent with your user's manual and conduct another usability study. People under the age of 35 can be part of the self selection study, but these people should identify that the device is not intended for them.

6. B4

B4

[redacted] B4 [redacted] B4 [redacted] all eduction levels are covered in the subject sample.

XVII. Contact History:

On March 8, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

On May 3, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

On July 8, 2011, the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

XVIII. Recommendation:

Regulation Number: 878.4810
Regulation Name:
Regulatory Class: II
Product Code: OHS

Abbas Bandukwala, Reviewer
General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

July 8, 2011
Date

I concur with AI issues,

Neil R.P. Ogden, M.S.
Chief, General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

7/8/11
Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K110301

Date: March 3, 2011
To: The Record
From: LTJG Abbas Bandukwala, USPHS
Biomedical Engineer

Office: HFZ-410
Division: DSORD/GSDB

510(k) Holder: Home Skinovations LTD
Device Name: Silk' N FX
Contact: Amir Waldman
Phone: 972 547 04616
Fax: 972 490 97471
Email: amirw@silkn.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Silk' N FX into interstate commerce.

II. Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Prescription)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?			X

[redacted] B4

[redacted]

IV. Indications for Use: Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

V. Predicate Device Comparison:
Omnilux New-U (K072459) - The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

	Silkn Reju	Ominlux New- U (K072459)
Wavelengths (nm)	633nm , 830nm	633nm, 830nm
Power mW/cm^2	70 mW/cm^2 for 633nm 55 mW/cm^2 for 830nm	633nm red light 70 mW/cm^2 830nm 55 mW/cm^2
Recommended treatment time	20 minutes	20 minutes

The subject device has a different treatment area size from the predicate device. The predicate device treats an area of 5 x 6cm while the subject device has a spot size of 7cm^2. Even though the treatment area of the devices are different, the energy provided by both devices are the same for both red and IR light.

VI. Labeling: Sponsor has provided user instruction in the submission only. Sponsor has not provided package labeling. Sponsor has not provided usability study or self selection study to demonstrate lay persons can correctly select and use the device. User manual is inadequate when compared to the predicate labeling manual. The labeling, self-selection and usability study were reviewed by Mr. Jack McCracken. Many of his comments were added to the deficiencies sent to the sponsor. His full review will be attached to this review.

VIII. Sterilization/Shelf Life/Reuse: Device has cleaning instructions in the manual. The treatment surface area needs to wiped clean with isopropyl alcohol wipes.

IX. Biocompatibility: Sponsor has provided a biocompatibility statement in the submission. It states that the only portion of the device that comes into patient contact is a stainless steel component of the device.

X. Software:

Version:

Level of Concern: Minor

	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:	X	
Development:	X	

Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:	X	

Sponsor provides proper software documentation in accordance with FDA guidelines.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety:
Sponsor provided certificates from third party company stating device is in compliance with the following standards:

- IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

XII. Performance Testing – B4 [redacted]

[redacted]

[redacted]	[redacted]

[redacted]	[redacted]

XIII. Performance Testing – B4 [redacted] N/A

XIV. Performance Testing – B4 [redacted]

[redacted]

B4 [redacted]

[redacted]

XV. Substantial Equivalence Discussion

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: See performance testing, animal testing and deficiency sections.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XVI. Deficiencies:

1. Sponsor has not provided the outside package labeling for the device. Because this device is an over-the counter device, the outside package labeling must be evaluated. Please provide an exact copy of the package labeling that will be used to sell the device in the United States.
Response: Sponsor has provided a black and white version of the package labeling.

2. B4 [redacted]

B4 [redacted]

[redacted] **wrinkles will help potential users understand what the device is intended to treat.**

4. The device uses LED's to treat the indication for use. LED's after a certain amount of use and time become less effective and do not produce the same light output. The manual should inform the user that after a certain period of time the device will become less effective and at that point the user should no longer use the device. Please add this information into the user manual.
Response: Sponsor states that number of battery charges determines the effective time period for the device. The manual states the device will be effective up to 300 full battery charge cycles.

5. On page 7 of the manual, the word "in" is spelled "Id". Please correct this error.
Response: The error was corrected.

6. Manual does not state the device will not function unless the device is in full contact with the skin. Please add this statement into the manual.
Response: On page 12, the instructions state, "Attach the treatment surface to your skin. The LED light will automatically activate". The manual should state that the device will not activate unless the device is in contact with the skin. The manual should also inform the patient that the device will turn off if there is no skin contact.

7. B4 [redacted]

package labeling.
Response: The label now says refresh the skin.

2. On page 9 of the user manual, the sponsor states that "Typical areas for treatment are the cheeks, the forehead and around the eyes". This statement is vague and allows the user to interpret that the device can be used on the cheeks and forehead. The diagram on this page makes it appear that there are four places to use the device, the right and left side forehead and the right and left side cheek. The directions in the manual states to treat each area for 20 minutes. This statement is also vague. Should the patient treat one of these areas for 20 minutes each for a total treatment time of 80 minutes? Please clarify these portions of the manual. The device is intended to treat periorbital wrinkles only. Please remove the statement that treatment areas are the cheeks, foreheads and around the eyes. The manual and package should have B4 [redacted] **sponsor also states to treat each side for 20 minutes for a total of 40 minutes.**

3. Page 9 of the manual states "Typical areas for treatment are the cheeks, the forehead and around the eyes". There is a diagram but it does not have much detail. The package labeling and user manual should have pictures of what periorbital wrinkles (crow's feet) are. Please add these pictures on the package labeling and in the user manual. The general population may not be familiar with the term periorbital wrinkles or crow's feet. A picture identifying these types of wrinkles will help potential users understand what the device is intended to treat.
Response: Sponsor has clarified this portion of the manual and clear identified periorbital wrinkles with pictures.

4. On page 12, the instructions state, "Attach the treatment surface to your skin. The LED light will automatically activate". The manual should state that the device will not activate unless the device is in contact with the skin. The manual should also inform the patient that the device will turn off if there is no skin contact. Please add these instructions in the manual. The current instructions does not emphasize the necessity for skin contact to activate the device.
Response: Sponsor has added this statement.

5. Sponsor should include the some information about the subjects that participated in the study. Please give age range, how many male and female subjects, severity of wrinkles using the Fitzpatrick scale and any other pertinent information of the subjects in the study.
Response: Sponsor has provided the age and gender of the subjects.

6. The details of the self selection study are insufficient. Please describe how were the subjects drawn to or given the package labeling.
    a. Did some one give the subject the labeling and then described the study to the subject?
    b. Was the box placed on a display table with a poster board instructing the patient to read the package? Were any subjects who did not have periorbital wrinkles read the package labeling and determine the device is not intended for them?

   Please answer the above listed questions. Please also provide more details and description of the self selection study.
   Response: Sponsor provided more description of the self selection and usability study.

7. An informed consent form (ICF) was used for the study. Information on the ICF could have biased the self selection study results. Please include the informed consent form that is used in the study.
Response: Sponsor provided the informed consent form.

8. B4 [redacted]

B4 [redacted]

- You expand on this use to the treatment of wrinkles anywhere on the body through your statement, "If you have noticed development of fine lines and wrinkles, especially in the area around your eyes, Silk'n may help reducing them."
- Graphics on the external package labeling show persons using the device in areas outside the usual "crows feet" area beside the eye.
- The labeling says, "Typical areas for Silk'n FX treatment are the cheeks, the forehead around the eyes."
- There is a graphic showing shaded areas below, above and beside the eye. It appears that you are using these shaded areas to show possible treatment areas. It is not clear what the labeling is intended to imply by these areas.
- The graphic on page 12 in the directions shows a person treating the left cheek

Thus, the treatment area you designate as periorbital wrinkles appears to have no boundaries. Please be specific on what the boundaries of the treatment area is so lay persons will know what areas to treat and what areas not to treat with your device.
Response: Sponsor revised the manual to clarify or incorporated the recommend changes listed above.

11. You describe the treatment areas under your "Benefits" section. This seems inappropriate because it does not describe benefits. Please move this information to be near your indications for use statement where you describe what your device treats. You may want to place it in your instructions section so users will know what the allowed treatment areas are.
Response: Sponsor revised the manual to incorporate this change.

12. In your section on treatment schedule, you have a statement, "according to the frequency of use". Please emphasize that a person must use the schedule you present.
Response: Sponsor incorporated the recommendation above.

13. In your benefits section, you refer to the "recommended course of treatment". It is unclear what your "recommended treatment" is. The course of treatment you state on page 10 is not a "recommended treatment". Refer instead to the directed treatment plan you give on page 10 so lay persons will not be confused by your terms. On page 10, the treatment plan does not seem to fit under its heading, "Before Using Silk'n FX" because it is integral to the treatment you propose.

Please revise your heading and instructions to integrate your treatment plan into your procedure so it is clearly part of the procedure.
Response: Sponsor revised the manual according to the above recommendation.

14. You intend to sell your device over the counter (OTC) in the US. Thus, any person may buy it and use it. Your labeling should be adequate for any of these persons to determine from your external label alone:

- that your device is correct for a condition they have
- that your device is suitable for them to use based on comprehending at least your
    - contraindications
    - warnings
    - precautions
    - risk information
    - benefit information
- that they will be able to use your device correctly based on comprehending at least your
    - frequency of use information
    - treatment intervals and period
    - device set up
    - sensitivity testing
    - device operation and treatment manipulation
    - device cleaning and maintenance
    - device storage
    - troubleshooting
    - monitoring for adverse event and effects
- that the benefit they can derive from your device is greater than the risk of their using it

Response: Sponsor revised the manual according to the above recommendation.

15. There are reasons your study of the usability of your device labeling and your device do not support the idea that the US population buying your device OTC will be able to accomplish at least these things. The main reasons are:

- It is unknown what your sample of persons represents. There is no evidence that it represents the US population. Your sample is not a random sample of the US population.
- Your subjects were all patients at one doctor's office. By using one location, you limited the applicability of your sample. By using a doctor's office, you probably introduced bias because persons had to qualify in unknown ways to be patients in this office.
- There were inclusion and exclusion criteria, but you did not say what they were.
- Subjects were given an informed consent document before they had an opportunity to read the user manual. It is unknown what your subjects may have learned from your informed consent process, so it is unclear what subjects learned from your labeling.
- All of your subjects had periorbital wrinkles. It is not clear what kind of wrinkles they had, where they were, or how you determined that they had them, or whether they self diagnosed their wrinkles. Further, because your labeling is unclear on what periorbital wrinkles are or where they are, it is unclear what you or your subjects diagnosed as periorbital wrinkles.
- You gave no details on how you observed your subjects, what you looked for, your criteria for success, and how you acquired your data.
- You did not appear to have a detailed protocol for your study.
- You did not study the ability of your subjects to correctly diagnose their condition based on your label.
- You did not study the ability of your subjects to correctly select your device to treat themselves based on your label.
- It is unclear who filled out the questionnaire.

- All the questions you asked were for the purpose of getting your subjects' opinions. You did not measure their abilities of your subjects to accomplish any tasks required of users of your device.
- You gave no individual data for your subjects.
- You did not describe how you analyzed your data.
- It is unknown what label and labeling you tested in your study or how it relates to your labeling.

Response: Sponsor revised the study and provided all the information listed above.

16. You have no information on contraindications, warnings, precautions or risks on your external package label. Lay persons need this information to enable them to select a device to treat their condition. Include the same information on these issues as you have in your internal labeling to correctly inform lay persons about your device.
    Response: The package labeling is too small to read. Sponsor will be asked to provide a larger copy.

17. Lay persons need to be able to comprehend your warning statements to use your device correctly. Many of your warnings have vague and undefined words that lay persons may not understand to correctly use your device. Express your warnings in terms and words lay persons will understand and be able to know they are following your warnings. Examples of vague and undefined terms are:

- dark brown-term is vague
- large freckles-term is vague
- birth marks-persons may not know a lesion is a birthmark
- moles-persons may not know this without consulting with their doctor

Response: Sponsor revised the manual to remove vague terms.

18. In your Risks section, you use terms too vague to be useful.

    Examples are:

- rare-use a numerical frequency like "1 out of 100", for example.
- generally very well tolerated-use a frequency like "95 out of 100 consumers", for example
- typical-use a frequency like "85 out of 100", for example
- transient-use a time of "3-5 days", for example
- slightly red-say how red is slightly red, perhaps by using a graphic.
- small quantity-say how much to add or show it with a graphic; remove this from risks and place it in your precautions or warnings if there risk from not doing this, or instructions for use if there is no hazard from not doing it.
- should disappear, few hours-use a likelihood instead of "should" and a number instead of "few", like "for 60 out of 100 consumers their skin color returned to normal in 3 hours after treatment and for 40 out of 100 consumers their skin color returned to normal in 6 hours after treatment."

Please place your warning statements in your sections devoted to them. In your risks section, place the events and effects and their frequencies. For example, you say, "If irritation does not disappear within three days, please consult a physician or dermatologist." This statement belongs in a warning statement. Further, for this particular item, please tell the consumer to, for example, "not use the device again because you can injure your skin or have more serious damage, such as blisters, infections and scars."

Your risk section should cite all known risks with the device, such as those inherent in the contraindications, warnings, and precautions.

List all the known risks attending use in accord with labeled instructions.

List known risks attending ways people will obviously use the device outside the indications and instructions because they understand the labeling and choose to ignore it or they do not understand the labeling.

B4 [redacted]

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

B4 B4 B4 B4 B4

[redacted]

[redacted]

B4 [redacted]

skin". Because the term "refresh" does not correctly explain the actions and effects of the device, this word should not be used to describe the device. Please revise this phrase or remove it from the manual.

4. On page 12 of the instruction manual, in section 4. "Follow the recommended Silk' N FX treatment course:", the word "recommend" is used twice. Please remove the word recommend from the title of this section and in the instructions part below it. The treatment course is not a recommendation. The manual should state "To achieve optimal results it is necessary to follow the treatment course provided below". The title of the section should say "Silk' n FX Treatment Course".

5. The user manual states that the device should not be used by subject who are below the age of 35. In the usability study, several of the subjects were below the age of 35. The exclusion criteria was set for persons under the age of 21. Using people below the age of 35 for the study is not consistent with the instructions provided in the manual. Subjects who were below the age of 35 should have read the manual and then stated they are not able to use this device according to the warning instruction on page 8. This difference in the exclusion criteria and the user manual is confusing, and the result makes it unclear if the subjects understood your user's manual. Please revise your exclusion criteria to be consistent with your user's manual and conduct another usability study. People under the age of 35 can be part of the self selection study, but these people should identify that the device is not intended for them.

6. B4 [redacted]

7. B4 [redacted] In the next self selection and usability study, please ensure that all eduction levels are covered in the subject sample.

XVII. Contact History:

On March 8, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

On May 3, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

XVIII. Recommendation:

Regulation Number: 878.4810
Regulation Name:
Regulatory Class: II
Product Code: OHS

Abbas Bandukwala, Reviewer
General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

July 8, 2011
Date

Neil R.P. Ogden, M.S.
Chief, General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

Date

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Abbas Bandukwala

Subject: 510(k) Number K110302/S1

To: The Record

Please list CTS decision code AF

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	Class*	Product Code
878.4810	II	FOIFS

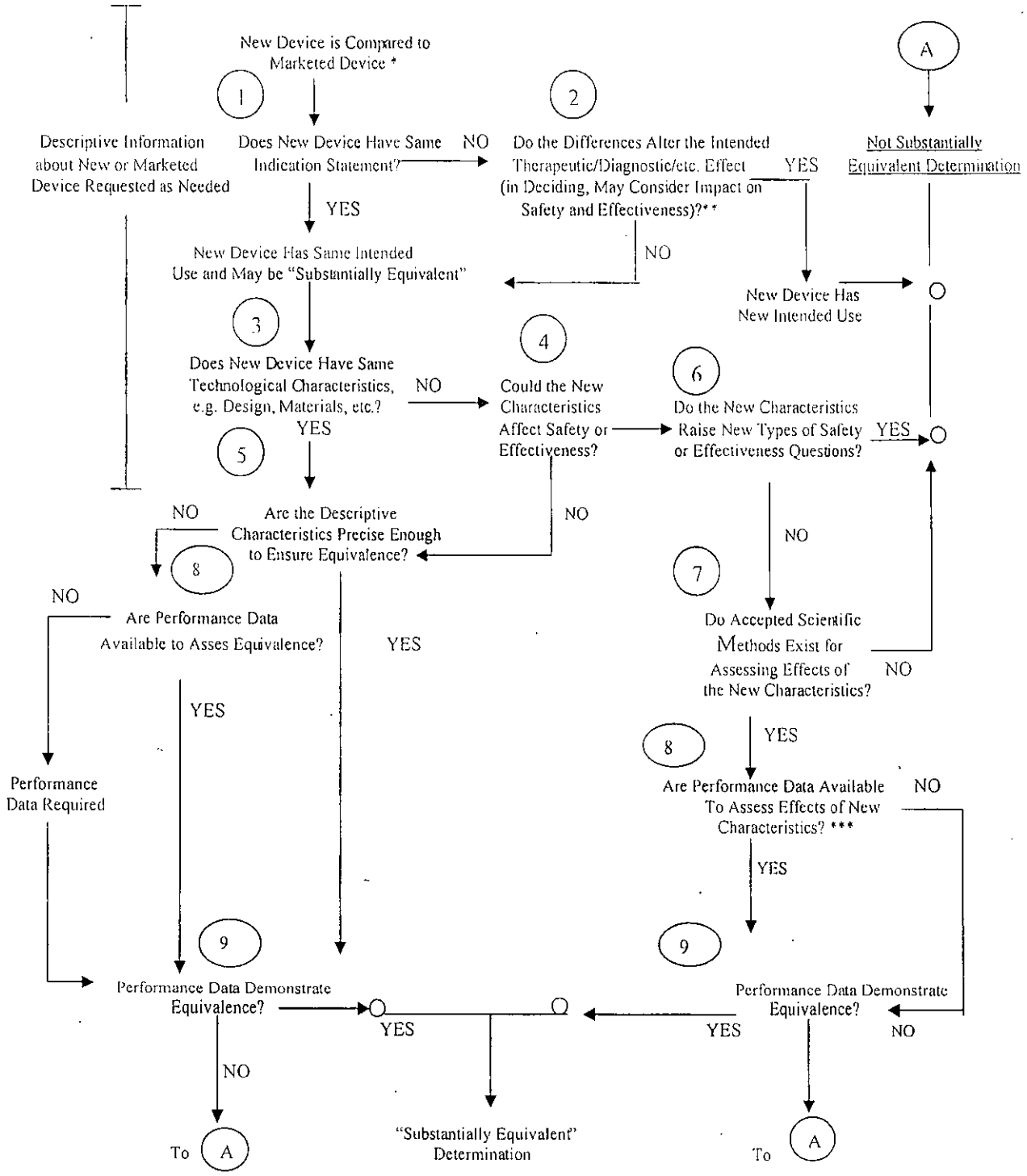
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ (Branch Chief) GSDB (Branch Code) 5/3/11 (Date)

Final Review: _____ (Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K110301

Date: March 3, 2011
To: The Record
From: LTJG Abbas Bandukwala, USPHS
Biomedical Engineer

Office: HFZ-410
Division: DSORD/GSDB

510(k) Holder: Home Skinovations LTD
Device Name: Silk' N FX
Contact: Amir Waldman
Phone: 972 547 04616
Fax: 972 490 97471
Email: amirw@silkn.com

emailed.
May 3, 2011

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Silk' N FX into interstate commerce.

II. Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Prescription)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?			X

B4 [redacted]

B4

IV. **Indications for Use:** Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

V. **Deficiencies:**

The additional information provided the most of the needed information but some deficiencies still remain.

1. Package labeling states the device uses "HF energy to rejuvenate the skin". The word rejuvenate is not accepted word for these types of devices. Please replace the word rejuvenate on the package labeling.

B4

3. Page 9 of the manual states "Typical areas for treatment are the cheeks, the forehead and around the eyes". There is a diagram but it does not have much detail. The package labeling and user manual should have pictures of what periorbital wrinkles (crow's feet) are. Please add these pictures on the package labeling and in the user manual. The general population may not be familiar with the term periorbital wrinkles or crow's feet. A picture identifying these types of wrinkles will help potential users understand what the device is intended to treat.

4. On page 12, the instructions state, "Attach the treatment surface to your skin. The LED light will automatically activate". The manual should state that the device will not activate unless the device is in contact with the skin. The manual should also inform the patient that the device will turn off if there is no skin contact. Please add these instructions in the manual. The current instructions does not emphasize the necessity for skin contact to activate the device.

B4

7. B4 [redacted]

8. B4 [redacted]

9. B4 [redacted]

10. You say the intended use of this device is the "use in dermatology for the treatment of periorbital wrinkles." However, in seeming contrast to this:

- You expand on this use to the treatment of wrinkles anywhere on the body through your statement, "If you have noticed development of fine lines and wrinkles, especially in the area around your eyes, Silk'n may help reducing them."
- Graphics on the external package labeling show persons using the device in areas outside the usual "crows feet" area beside the eye.
- The labeling says, "Typical areas for Silk'n FX treatment are the cheeks, the forehead around the eyes."
- There is a graphic showing shaded areas below, above and beside the eye. It appears that you are using these shaded areas to show possible treatment areas. It is not clear what the labeling is intended to imply by these areas.
- The graphic on page 12 in the directions shows a person treating the left cheek

Thus, the treatment area you designate as periorbital wrinkles appears to have no boundaries. Please be specific on what the boundaries of the treatment area is so lay persons will know what areas to treat and what areas not to treat with your device.

11. You describe the treatment areas under your "Benefits" section. This seems inappropriate because it does not describe benefits. Please move this information to be near your indications for use statement where you describe what your device treats. You may want to place it in your instructions section so users will know what the allowed treatment areas are.

12. In your section on treatment schedule, you have a statement, "according to the frequency of use". Please emphasize that a person must use the schedule you present.

13. In your benefits section, you refer to the "recommended course of treatment". It is unclear what your "recommended treatment" is. The course of treatment you state on page 10 is not a "recommended treatment". Refer instead to the directed treatment plan you give on page 10 so lay persons will not be confused by your terms. On page 10, the treatment plan does not seem to fit under its heading, "Before Using Silk'n FX" because it is integral to the treatment you propose. Please revise your heading and instructions to integrate your treatment plan into your procedure so it is clearly part of the procedure.

14. You intend to sell your device over the counter (OTC) in the US. Thus, any person may buy it and use it. Your labeling should be adequate for any of these persons to determine from your external label alone:

- that your device is correct for a condition they have
- that your device is suitable for them to use based on comprehending at least your
  - contraindications
  - warnings
  - precautions
  - risk information
  - benefit information
- that they will be able to use your device correctly based on comprehending at least your
  - frequency of use information
  - treatment intervals and period
  - device set up
  - sensitivity testing
  - device operation and treatment manipulation
  - device cleaning and maintenance
  - device storage
  - troubleshooting
  - monitoring for adverse event and effects
- that the benefit they can derive from your device is greater than the risk of their using it

15. B4 [redacted]

16. You have no information on contraindications, warnings, precautions or risks on your external package label. Lay persons need this information to enable them to select a device to treat their condition. Include the same information on these issues as you have in your internal labeling to correctly inform lay persons about your device.

17. B4 [redacted]

[redacted]

18. In your Risks section, you use terms too vague to be useful.

    Examples are:

B4 [redacted]

Please place your warning statements in your sections devoted to them. In your risks section, place the events and effects and their frequencies. For example, you say, "If irritation does not disappear within three days, please consult a physician or dermatologist." This statement belongs in a warning statement. Further, for this particular item, please tell the consumer to, for example, "not use the device again because you can injure your skin or have more serious damage, such as blisters, infections and scars."

Your risk section should cite all known risks with the device, such as those inherent in the contraindications, warnings, and precautions.

List all the known risks attending use in accord with labeled instructions.

List known risks attending ways people will obviously use the device outside the indications and instructions because they understand the labeling and choose to ignore it or they do not understand the labeling.

Please construct a 4-column table of risks.

For the table column headings, use, for example, Event, Likelihood of Event, Harm, Likelihood of Harm.

Items in the Event column are the things that may happen, such as overuse of the device in one area.

B4

[redacted]

VI. Contact History:

On March 8, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

On May 3, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

VII. Recommendation:

Regulation Number: 878.4810
Regulation Name:
Regulatory Class: II
Product Code: OHS

Abbas Bandukwala, Reviewer
General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

May 3, 2011
Date

I concur with AI.

Neil R.P. Ogden, M.S.
Chief, General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

5/3/11
Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K110301

Date: March 3, 2011
To: The Record
From: LTJG Abbas Bandukwala, USPHS
Biomedical Engineer

Office: HFZ-410
Division: DSORD/GSDB

510(k) Holder: Home Skinovations LTD
Device Name: Silk' N FX
Contact: Amir Waldman
Phone: 972 547 04616
Fax: 972 490 97471
Email: amirw@silkn.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Silk' N FX into interstate commerce.

II. Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Prescription)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?			X

B4 [redacted]

B4

[redacted]

VI. Labeling: Sponsor has provided user instruction in the submission only. Sponsor has not provided package labeling. Sponsor has not provided usability study or self selection study to demonstrate lay persons can correctly select and use the device. User manual is inadequate when compared to the predicate labeling manual. The labeling, self-selection and usability study were reviewed by Mr. Jack McCracken. Many of his comments were added to the deficiencies sent to the sponsor. His full review will be attached to this review.

VIII. Sterilization/Shelf Life/Reuse: Device has cleaning instructions in the manual. The treatment surface area needs to wiped clean with isopropyl alcohol wipes.

IX. Biocompatibility: Sponsor has provided a biocompatibility statement in the submission. It states that the only portion of the device that comes into patient contact is a stainless steel component of the device.

X. Software:

Version:

Level of Concern: Minor

	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:	X	
Development:	X	

Verification & Validation Testing:	X
Revision level history:	X
Unresolved anomalies:	X

Sponsor provides proper software documentation in accordance with FDA guidelines.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety:
Sponsor provided certificates from third party company stating device is in compliance with the following standards:

- IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

XII. Performance Testing – Bench: The sponsor provides the power density results of both the subject and predicate devices.

B4

[redacted]

manual. The study includes the results from the questionnaires.

XV. Substantial Equivalence Discussion
http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: See performance testing, animal testing and deficiency sections.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XVI. Deficiencies:

1. Sponsor has not provided the outside package labeling for the device. Because this device is an over-the counter device, the outside package labeling must be evaluated. Please provide an exact copy of the package labeling that will be used to sell the device in the United States.
Response: Sponsor has provided a black and white version of the package labeling.

2. B4 [redacted] **regime was changed and is now identical to the predicate device treatment regime.**

3. Please add a picture in the user manual and on the package of periorbital wrinkles (crows feet). People who are selecting this device and using this device might not know this condition by the name itself or may confuse this condition for another type of condition that the device is not intended to treat.
Response: Page 9 of the manual states "Typical areas for treatment are the cheeks, the forehead and around the eyes". There is a diagram but it does not have much detail. The package labeling and user manual should have pictures of what periorbital wrinkles (crows feet) are. Please add these pictures on the package labeling and in the user manual. The general population may not be familiar with the term periorbital wrinkles or crow feet. A picture identifying these types of wrinkles will help potential users understand what the device is intended to treat.

4. B4 [redacted]

5. On page 7 of the manual, the word "in" is spelled "Id". Please correct this error.
Response: The error was corrected.

6. Manual does not state the device will not function unless the device is in full contact with the skin. Please add this statement into the manual.
Response: On page 12, the instructions state, "Attach the treatment surface to your skin. The LED light will automatically activate". The manual should state that the device will not activate unless the device is in contact with the skin. The manual should also inform the patient that the device will turn off if there is no skin contact.

7. [redacted] B4

The additional information provided the most of the needed information but some deficiencies still remain.

1. Package labeling states the device uses "HF energy to rejuvenate the skin". The word rejuvenate is not accepted word for these types of devices. Please replace the word rejuvenate on the package labeling.

2. On page 9 of the user manual, the sponsor states that "Typical areas for treatment are the cheeks, the forehead and around the eyes". This statement is vague and allows the user to interpret that the device can be used on the cheeks and forehead. The diagram on this page makes it appear that there are four places to use the device, the right and left side forehead and the right and left side cheek. The directions in the manual states to treat each area for 20 minutes. This statement is also vague. Should the patient treat one of these areas for 20 minutes each for a total treatment time of 80 minutes? Please clarify these portions of the manual. The device is intended to treat periorbital wrinkles only. Please remove the statement that treatment areas are the cheeks, foreheads and around the eyes. The manual and package should have a picture of periorbital wrinkles and designate the specific area of treatment.

3. Page 9 of the manual states "Typical areas for treatment are the cheeks, the forehead and around the eyes". There is a diagram but it does not have much detail. The package labeling and user manual should have pictures of what periorbital wrinkles (crow's feet) are. Please add these pictures on the package labeling and in the user manual. The general population may not be familiar with the term periorbital wrinkles or crow's feet. A picture identifying these types of wrinkles will help potential users understand what the device is intended to treat.

4. On page 12, the instructions state, "Attach the treatment surface to your skin. The LED light will automatically activate". The manual should state that the device will not activate unless the device is in contact with the skin. The manual should also inform the patient that the device will turn off if there is no skin contact. Please add these instructions in the manual. The current instructions does not emphasize the necessity for skin contact to activate the device.

5. B4 [redacted]

B4 [redacted]

- You expand on this use to the treatment of wrinkles anywhere on the body through your statement, "If you have noticed development of fine lines and wrinkles, especially in the area around your eyes, Silk'n may help reducing them."
- Graphics on the external package labeling show persons using the device in areas outside the usual "crows feet" area beside the eye.
- The labeling says, "Typical areas for Silk'n FX treatment are the cheeks, the forehead around the eyes."
- There is a graphic showing shaded areas below, above and beside the eye. It appears that you are using these shaded areas to show possible treatment areas. It is not clear what the labeling is intended to imply by these areas.
- The graphic on page 12 in the directions shows a person treating the left cheek

  Thus, the treatment area you designate as periorbital wrinkles appears to have no boundaries. Please be specific on what the boundaries of the treatment area is so lay persons will know what areas to treat and what areas not to treat with your device.

11. You describe the treatment areas under your "Benefits" section. This seems inappropriate because it does not describe benefits. Please move this information to be near your indications for use statement where you describe what your device treats. You may want to place it in your instructions section so users will know what the allowed treatment areas are.

12. In your section on treatment schedule, you have a statement, "according to the frequency of use". Please emphasize that a person must use the schedule you present.

13. In your benefits section, you refer to the "recommended course of treatment". It is unclear what

your "recommended treatment" is. The course of treatment you state on page 10 is not a "recommended treatment". Refer instead to the directed treatment plan you give on page 10 so lay persons will not be confused by your terms. On page 10, the treatment plan does not seem to fit under its heading, "Before Using Silk'n FX" because it is integral to the treatment you propose. Please revise your heading and instructions to integrate your treatment plan into your procedure so it is clearly part of the procedure.

14. You intend to sell your device over the counter (OTC) in the US. Thus, any person may buy it and use it. Your labeling should be adequate for any of these persons to determine from your external label alone:

- that your device is correct for a condition they have
- that your device is suitable for them to use based on comprehending at least your
    - contraindications
    - warnings
    - precautions
    - risk information
    - benefit information
- that they will be able to use your device correctly based on comprehending at least your
    - frequency of use information
    - treatment intervals and period
    - device set up
    - sensitivity testing
    - device operation and treatment manipulation
    - device cleaning and maintenance
    - device storage
    - troubleshooting
    - monitoring for adverse event and effects
- that the benefit they can derive from your device is greater than the risk of their using it

15. B4 [redacted]

[redacted]

B4 [redacted]

- It is unknown [redacted]

16. You have no information on contraindications, warnings, precautions or risks on your external package label. Lay persons need this information to enable them to select a device to treat their condition. Include the same information on these issues as you have in your internal labeling to correctly inform lay persons about your device.

17. B4 [redacted]

- B4 [redacted]

18. B4 [redacted]

[redacted]

Please place your warning statements in your sections devoted to them. In your risks section, place the events and effects and their frequencies. For example, you say, "If irritation does not disappear within three days, please consult a physician or dermatologist." This statement belongs in a warning statement. Further, for this particular item, please tell the consumer to, for example, "not use the device again because you can injure your skin or have more serious damage, such as blisters, infections and scars."

Your risk section should cite all known risks with the device, such as those inherent in the contraindications, warnings, and precautions.

List all the known risks attending use in accord with labeled instructions.

List known risks attending ways people will obviously use the device outside the indications and instructions because they understand the labeling and choose to ignore it or they do not understand the labeling.

B4

[redacted]

XVII. Contact History:

On March 8, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

On May 3, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

XVIII. Recommendation:

Regulation Number: 878.4810
Regulation Name:
Regulatory Class: II
Product Code: OHS

Abbas Bandukwala, Reviewer
General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

May 3, 2011
Date

Neil R.P. Ogden, M.S.
Chief, General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

Date

Patient Labeling Review and Comments

Comments for CDRH internal use:

Document Number:	K110301/S001
Device Name:	Silk'n fx
Application Submitter:	Home Skinovations Ltd.
Description of Device:	B4 [redacted]
Description of Labeling Reviewed and Commented On:	Information received by FDA 4/6/11: Proposed OTC box label;proposed package insert labeling;labeling usability study results
Other Pertinent References:	
Recommendations:	As a consultant to the office responsible for approving or clearing this device, I defer to that office to make the decision on whether to approve or clear this device.
Requestor:	Abbas Bandukwala, CDRH/ODE/DSORD/GSDB, WO66 RM1441
OCER/DHC Reviewer(s):	Jack McCracken, CDRH/OCER/DHC/WCB, WO66 RM4500
DHC Review Comments Clearer:	N/A
Date DHC Received Request:	4/27/11
Review Due Date:	5/6/11
Review Completion Date:	4/29/11
Comments Sent To eRoom, Lead Reviewer, 'CDRH DHC-PL-REVIEW' (m/d/yy):	4/29/11

I reviewed this application and its patient labeling. I hope my comments are useful to you and the applicant. I have based my recommendations on our guidance document, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm.

There is patient labeling in the application.

Because of the way a health care practitioner, patient, or caregiver will use this device, patients and caregivers can benefit from patient labeling.

They can benefit because they need to be able to:

- select among similar devices or device procedures
- be involved in deciding whether to have a procedure involving the device
- maintain the device
- monitor and report on the operation or output of the device
- know how to alter their lifestyles or care regimens to properly integrate the use of the device
- operate, interpret, and manipulate the device
- cooperate with the prevention, treatment, or diagnosis of an illness or condition
- know how to be careful in using the device, such as understanding the basis for warnings, precautions, and contraindications

Therefore, I agree with the applicant that this device should have patient labeling.

Comments for the applicant:

Device Description and Use

In your description of your device, the legend item and arrow for the treatment surface is misleading. The treatment surface is not the side of the top of your device as the arrow shows. Please revise the graphic to accurately show where the treatment surface is.

Your device makes no record of the area treated and with what kind of radiation. Your device is not capable of reproducing a treatment location so that when continuing treatment is done later according to your treatment schedule, the device is located in the correct place. Correct repeated placement 7 times relies solely on the user remembering where they treated and with what kind of radiation. This will be a difficult task. Thus your device's design makes it highly unlikely that a user will be able to treat as your schedule directs. Please revise your device and its labeling so it enables users to accomplish treatment at precisely the location they have treated before on your treatment schedule.

Information on Condition or Disease

B4 [redacted]

B4 [redacted]

B4 [redacted] boundaries of the periorbital area is so lay persons will know what areas to treat and what areas not to treat with your device.

You describe the treatment areas under your "Benefits" section. This seems inappropriate because it does not describe benefits. Please move this information to be near your indications for use statement where you describe what your device treats. You may want to place it in your instructions section so users will know what the allowed treatment areas are.

In your section on treatment schedule, you have a statement, "according to the frequency of use". Please emphasize that a person must use the schedule you present.

In your treatment schedule, you list day numbers for events on which a person must do something. Please place blanks in the schedule where persons can write the calendar dates on which they must act, to make it easier for them to remember to treat themselves. Consider modifying your device so it will remind users when they are to use it to treat themselves.

B4 [redacted]

[redacted] They do not

have reason and consequences elements. Please revise your warning statements so they have all four elements. You may group a type of warning statement, for example, warnings, under a single signal word if it is clear that they are part of a group of like warning statements. There are four elements generally supported by research as necessary for an effective warning statement:

- a signal word (**, Contraindication, Warning, Caution**) to alert the reader that what follows is important hazard information. A symbol or icon may emphasize the effect of the signal word. Additional enhancement, such as bolding, larger type, underlining, italics, or color may help the information stand out from the rest of the text. However, studies have demonstrated that a large difference in font size between the signal word and the text may de-emphasize the importance of the text and therefore reduce the likelihood that the text will be read.
- B4 [redacted]

Make sure that your action statements in your procedure that have a hazard associated with them have all four elements of useful warning statements. For example, you say, "Make sure your skin is clean. . . ." without a signal word, a reason, or a consequence statement.

Lay persons need to be able to comprehend your warning statements to use your device correctly. Many of your warnings have vague and undefined words that lay persons may not understand to correctly use your device. Express your warnings in terms and words lay persons will understand and be able to know they are following your warnings. Examples of vague and undefined terms are:

- dark brown-term is vague
- large freckles-term is vague
- birth marks-persons may not know a lesion is a birthmark
- moles-persons may not know this without consulting with their doctor
- warts-persons may not know this without consulting with their doctor
- eczema-persons may not know this without consulting with their doctor
- psoriasis-persons may not know this without consulting with their doctor
- lesions-term is vague
- open wounds
- active infections
- cold sores
- effected [sic] area

- heal
- abnormal skin conditions caused by diabetes or other systemic or metabolic diseases-persons will not know their conditions are caused by the diseases, persons will not know what abnormal means
- recently
- alpha-hydroxi acids-persons may not know this without consulting with their doctor
- beta hydroxi acids-persons may not know this without consulting with their doctor
- Retin-A-persons may not know this without consulting with their doctor
- topical retinoids-persons may not know this without consulting with their doctor
- azelaic acid-persons may not know this without consulting with their doctor
- have been treated with Accutane-persons may not know this without consulting with their doctor
- have been on a steroid regimen-persons may not know this without consulting with their doctor
- history of herpes outbreaks-persons may not know this without consulting with their doctor
- preventive treatment-persons may not know this without consulting with their doctor
- out of reach of children-who are children is unclear
- out of reach of persons with reduced physical, sensory, or mental capabilities-how one decides this is unclear
- between the ages of
- trails [sic]
- as soon as possible
- suspect you have had an adverse reaction from use-if you have an adverse reaction from use and do no suspect it is from the device, what you do is unclear
- if you are pregnant-women may be pregnant and not know it and use your device
- force-one has to force a plug into a socket to make the connection
- connect easily
- damaged in any way
- before-your instructions say to clean after use
- longer than the recommended time-the recommended time is unclear; the device shuts off in 20 minutes; whether there is a problem with use for less than 20 minutes is unclear.
- more often than recommended-there seems to be no recommended frequency but there is a "treatment course"; there is no way to determine whether there is overlap of one treatment with another
- heated surfaces, High temperatures-all surfaces are heated to some extent; high is a relative term
- authorized representative
- work normally
- exhibits a distinct change
- internal pads
- dusty or dirty environment-consumer environments are naturally dusty and dirty
- away from water-water is nearly everywhere and part of nearly everything, including a person's body
- dry-dry is a relative term

- near a shower or bathtub-it is unclear how near one can store it
- damaged-it is unclear how to know it is damaged; it is unclear how you expect a person to determine that it is not damaged
- dedicated transformer
- clean, dry, and free-these words can be either relative or absolute measurements and their meanings are unclear
- shake, drop, severe shocks-it is unclear what movements fall into these categories.
- extreme change in temperature-how rapid a change is unclear
- do not expose to temperatures higher than 95F. This conflicts with your instruction to place it on the skin or hold it in your hand.
- lengthy direct sunlight or UV-in about any use situation there will be these kinds of radiation
- occasional home use, exhaustive use-these terms are undefined
- avoid covering-this probably depends on the type of covering or how tightly the cover covers.
- dry clean place free of dust-these terms seem to imply absolute dryness, cleanliness, and dust freedom, conditions homes do not have
- official recycling collection point, official collection point for batteries-it is unclear what "official" means.
- completely empty and cannot be recharged-you give no instructions on how to tell a battery is "completely empty" and "cannot be recharged"
- tow [sic] wires
- currently-give the date on which the telephone number is correct because currently conveys variable meaning.

B4 [redacted]

402

Please place your warning statements in your sections devoted to them. In your risks section, place the events and effects and their frequencies. For example, you say, "If irritation does not disappear within three days, please consult a physician or dermatologist." This statement belongs in a warning statement. Further, for this particular item, please tell the consumer to, for example, "not use the device again because you can injure your skin or have more serious damage, such as blisters, infections and scars."

Your risk section should cite all known risks with the device, such as those inherent in the contraindications, warnings, and precautions.

List all the known risks attending use in accord with labeled instructions.

B4 [redacted]

B4 [redacted]

B4

[redacted]

Benefits

In your benefits section, you refer to the "recommended course of treatment". It is unclear what your "recommended treatment" is. The course of treatment you state on page 10 is not a "recommended treatment". Refer instead to the directed treatment plan you give on page 10 so lay persons will not be confused by your terms. On page 10, the treatment plan does not seem to fit under its heading, "Before Using Silk'n FX" because it is integral to the treatment you propose. Please revise your heading and instructions to integrate your treatment plan into your procedure so it is clearly part of the procedure.

You say the "best results can be expected 3-7-weeks" after completing the recommended course of treatment. It is unclear what course of treatment you are referring to. Please clarify whether you are referring to the directed 10 week course of treatment on page 10. If you are, state that the best results can be expected 13-17 weeks after starting the course of treatment.

You gave no measure of the improvement one can expect after using your device. However, you imply there will be a measurable reduction in fine lines and wrinkles by saying there will be a "reduction of fine lines and wrinkles". This suggests you have evidence that your device may reduce periorbital wrinkles in some people but you can't say who will have a reduction and who will not. If you have any information from your clinical trial about the reduction seen in the trial, place that

information in your Benefits section to allow users to better evaluate whether they can expect an effect or not and what effect they may get.

Readability

Lay readers with all degrees of literacy will likely be the patients or other consumers who need to understand the patient or consumer labeling for this device. Before you test the usability of your labeling, as mentioned elsewhere in these comments, you may want to use one or more of various methods of estimating the reading level of the text. If any of the algorithms estimates the reading level to be higher than the reading level of many who will use your device, your text probably needs more simplification before you use resources to actually test its usability.

In general, you can probably reduce the complexity of your language by using shorter sentences, words of fewer syllables, and more familiar words. Some readability tests like the Dale-Chall test base their readability scores on familiarity of words, perhaps one of the better ways to quickly test for ease of reading before you test using a robust usability study.

B4 [redacted]

[redacted]

B
4

[redacted]

Operating Instructions

In your operating instructions, you say "attach the Treatment Surface to your skin". The word, "Attach" may suggest a more permanent arrangement than if you said, "hold the Treatment Surface against your skin." Consider changing your potentially misleading wording.

Other Issue(s)

On your external package, you say, "Safe and user friendly". You may not say your device is safe if you obtain clearance through the 510(k) mechanism. Remove all references to your device being safe from your label and labeling. It is unclear what the claim "user friendly" means in your labeling. Please explain what the term means.

On your external label, you say your device can "rejuvenate the appearance of your skin." This claim differs from your indications for use statement on treating periorbital wrinkles. Please remove this claim.

You have no information on contraindications, warnings, precautions or risks on your external package label. Lay persons need this information to enable them to select a device to treat their condition. Include the same information on these issues as you have in your internal labeling to correctly inform lay persons about your device.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Abbas Bandukwala

Subject: 510(k) Number K110301

To: The Record

Please list CTS decision code AF

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category ✓, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Rev. 7/2/07

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number 876.4410 **Class*** II **Product Code** OHS.

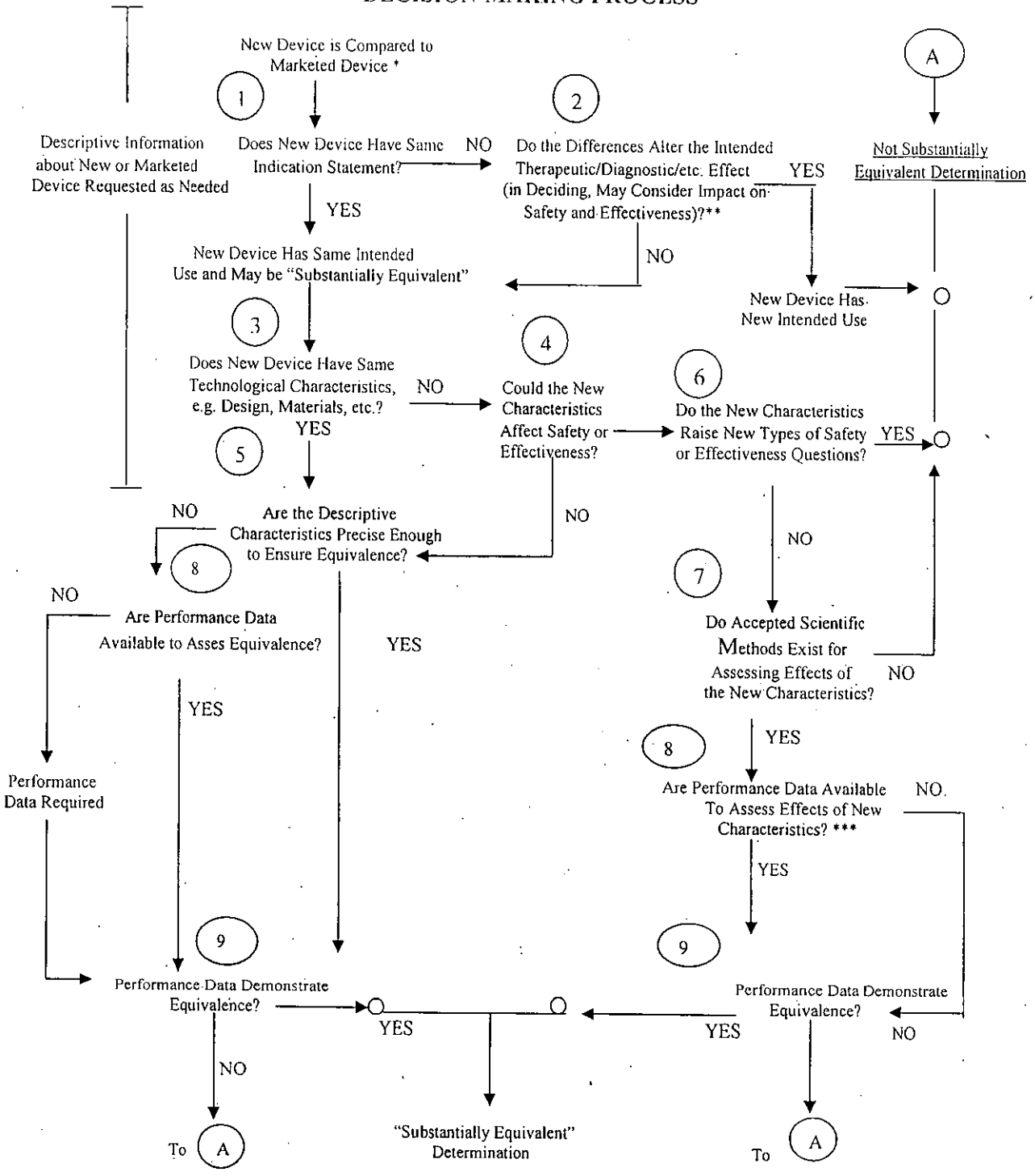
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) GSDB (Branch Code) 3/8/11 (Date)

Final Review: (Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K110301

Date: March 8, 2011
To: The Record
From: LTJG Abbas Bandukwala, USPHS
Biomedical Engineer

Office: HFZ-410
Division: DSORD/GSDB

510(k) Holder: Home Skinovations LTD
Device Name: Silk' N FX
Contact: Amir Waldman
Phone: 972 547 04616
Fax: 972 490 97471
Email: amirw@silkn.com

Emailed March 8/2011

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Silk' N FX into interstate commerce.

II. Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Prescription)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?			X

B4 [redacted]

B4 [redacted]

IV. Indications for Use: Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

XVI. Deficiencies:

1. Sponsor has not provided the outside package labeling for the device. Because this device is an over-the counter device, the outside package labeling must be evaluated. Please provide an exact copy of the package labeling that will be used to sell the device in the United States.

B4 [redacted]

3. Please add a picture in the user manual and on the package of periorbital wrinkles (crows feet). People who are selecting this device and using this device might not know this condition by the name itself or may confuse this condition for another type of condition that the device is not intended to treat.

4. B4 [redacted]

5. On page 7 of the manual, the word "in" is spelled "Id". Please correct this error.

6. Manual does not state the device will not function unless the device is in full contact with the skin. Please add this statement into the manual.

7. B4 [redacted]

XVII. Contact History:

On March 8, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

XVIII. Recommendation:

Regulation Number: 878.4810
Regulation Name:
Regulatory Class: II
Product Code: OHS

Abbas Bandukwala, Reviewer
General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

March 8, 2011
Date

I concur with AI.

Neil R.P. Ogden, M.S.
Chief, General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

3/8/11
Date

466

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K110301

Date: March 3, 2011
To: The Record
From: LTJG Abbas Bandukwala, USPHS
Biomedical Engineer

Office: HFZ-410
Division: DSORD/GSDB

510(k) Holder: Home Skinovations LTD
Device Name: Silk' N FX
Contact: Amir Waldman
Phone: 972 547 04616
Fax: 972 490 97471
Email: amirw@silkn.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Silk' N FX into interstate commerce.

II. Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Prescription)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?			X

B4 [redacted]

B4 [redacted]

IV. Indications for Use: Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

V. Predicate Device Comparison:

B4 [redacted]

VI. Labeling: Sponsor has provided user instruction in the submission only. Sponsor has not provided package labeling. Sponsor has not provided usability study or self selection study to demonstrate lay persons can correctly select and use the device. User manual is inadequate when compared to the predicate labeling manual.

VIII. Sterilization/Shelf Life/Reuse: Device has cleaning instructions in the manual. The treatment surface area needs to wiped clean with isopropyl alcohol wipes.

IX. Biocompatibility: Sponsor has provided a biocompatibility statement in the submission. The statement is not enough for the biocompatibility. It states that the only portion of the device that comes into patient contact is a stainless steel component of the device.

X. Software:

Version:

Level of Concern: Minor

	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:		
Design Specifications:		

Traceability Analysis/Matrix:	X
Development:	X
Verification & Validation Testing:	X
Revision level history:	X
Unresolved anomalies:	X

Sponsor provides proper software documentation in accordance with FDA guidelines.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety:
Sponsor provided certificates from third party company stating device is in compliance with the following standards:

- IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

XII. Performance Testing - B4 [redacted]

[redacted]

[redacted]

XIII. Performance Testing – B4 [redacted] N/A

XIV. Performance Testing - B [redacted] N/A

XV. Substantial Equivalence Discussion
http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: See performance testing, animal testing and deficiency sections.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XVI. Deficiencies:

1. Sponsor has not provided the outside package labeling for the device. Because this device is an over-the counter device, the outside package labeling must be evaluated. Please provide an exact copy of the package labeling that will be used to sell the device in the United States.

2. B4 [redacted]

3. Please add a picture in the user manual and on the package of periorbital wrinkles (crows feet). People who are selecting this device and using this device might not know this condition by the name itself or may confuse this condition for another type of condition that the device is not intended to treat.

4. B4 [redacted]

5. On page 7 of the manual, the word "in" is spelled "Id". Please correct this error.

6. Manual does not state the device will not function unless the device is in full contact with the skin. Please add this statement into the manual.

7. B4 [redacted]

XVII. Contact History:

On March 8, 2011 the sponsor was informed that the subject submission would be placed on hold until receipt of the above referenced information to the FDA.

XVIII. Recommendation:

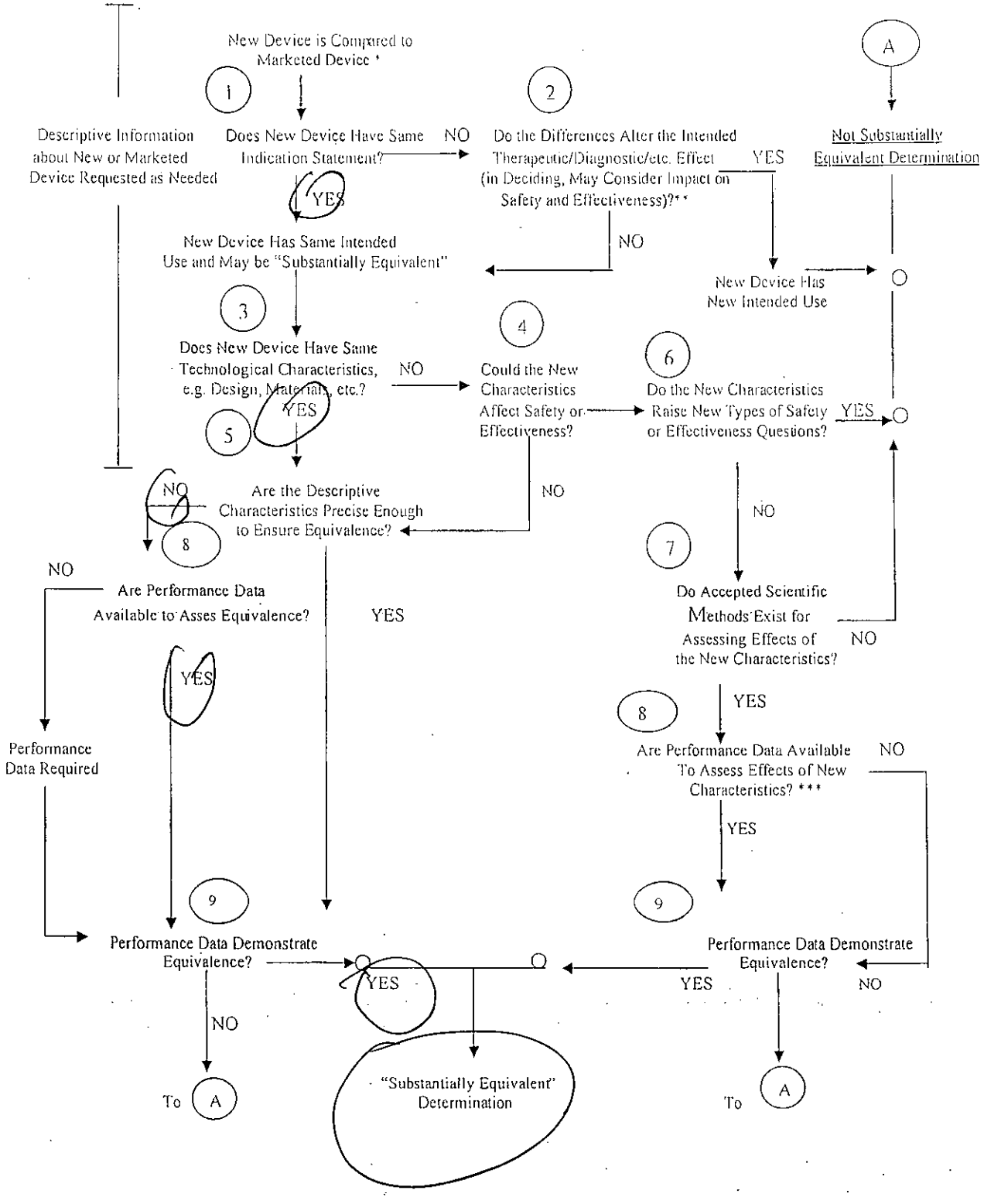
Regulation Number: 878.4810
Regulation Name:
Regulatory Class: II
Product Code: OHS

Neil I Concur with AI. 3/8/11

Neil R.P. Ogden, M.S.
Chief, General Surgery Device Branch
Division of Surgical, Orthopedic and Restorative Devices

Date

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 06, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301

Product: SILK'N FX

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K110301/S1

HomeSkinovations

Apolo building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

March 31 , 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
APR 06 2011
Received
R-32

Re: Letter dated March 8, 2011 K110301

Dear Mr. Bandukwala

Thank you for your letter dated March 8, 2011 in response to our 510K submission for the Silk'n FX (K110301).

Please find the requested information asked in your letter:

1. Sponsor has not provided the outside package labeling for the device. Because this device is an over-the counter device, the outside package labeling must be evaluated. Please provide an exact copy of the package labeling that will be used to sell the device in the United States.

Attached exact copy of the package labeling.

2. B4 [redacted]

3. Please add a picture in the user manual and on the package of periorbital wrinkles (crows feet). People who are selecting this device and using this device might not know this condition by the name itself or may confuse this condition for another type of condition that the device is not intended to treat.

Please refer to page 9 in the FX user manual and the package.

4. B4 [redacted]

HomeSkinovations

Apolo building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

B4 [redacted]

[redacted]

5. On page 7 of the manual, the word "in" is spelled "Id". Please correct this error.

Error corrected see page 7 of the user manual.

6. Manual does not state the device will not function unless the device is in full contact with the skin. Please add this statement into the manual.

Statement added to the user manual see page 12.

7. B4 [redacted]

We trust that the information included in this application will be adequate to allow for its prompt review. Please contact me if there are any questions.

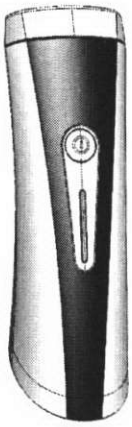
Sincerely yours,

Dr. Amir Waldman
VP regulatory affairs
Home Skinovations Ltd.

Package labeling

Silk'n
FX
DISCOVER YOUR TRUE BEAUTY!
With Silk'n FX Light Based Treatment for
Periorbital Wrinkles
Clinically tested
Recommended by dermatologists
Safe and user friendly
For men and women
DISCOVER YOUR TRUE BEAUTY!
Silk'n FX device for the treatment
of Periorbital wrinkles
Offering advanced HF technology to rejuvenate the
appearance of your skin
in the comfort of your own home.
HomeSkinovations™
MADE IN ISRAEL
Questions? Please contact us:
1-877-DO-SILKN (1-877-367-4556)
www.silkn.com / contact@silkn.com
DISCOVER YOUR TRUE BEAUTY!

Silk'n FX



Instructions for use

DO101950B

HomeSkinovations

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Print date: June 2010

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Specifications are subject to change without notice.

Home Skinovations Ltd.
Tavor Building, Shaar Yokneam
POB 533
Yokneam 20692
ISRAEL

Website: **www.silkn.com**

e-mail: **info@silkn.com**

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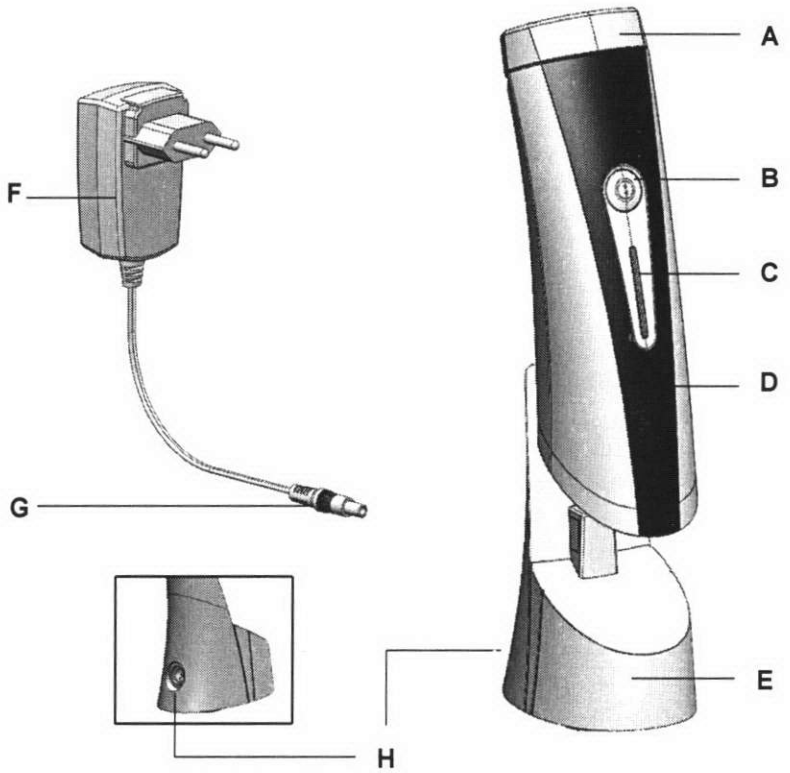
Silk'n FX device description

Your Silk'n FX device consists of a ***Base Unit*** an ***Applicator*** and an ***Adaptor.***

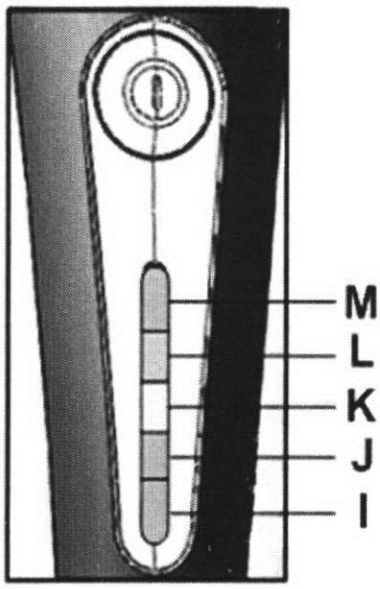
The Silk'n FX ***Applicator*** is a hand held unit used for treatment, as the ***Treatment surface*** at the *Applicator* tip is in contact with the skin. On the *Applicator* you can find the *Mode* ***switch*** and the ***Indicators Panel***.

The FX ***Base Unit*** is used to place the *applicator* while resting, and to charge the *applicator* batteries.

The ***Adaptor*** connects the ***Base Unit*** to the electrical outlet for battery recharging, using its ***Plug*** and the ***Base Unit socket.***



A	*Treatment surface*
B	*Mode Switch*
C	*Indicators Panel*
D	*Applicator*
E	*Base Unit*
F	*Adaptor*
G	*Plug*
H	*Base Unit socket*



J ***READY/TREATMENT*** - *INDICATOR LIGHT*

K ***SYSTEM ERROR*** - *INDICATOR LIGHT*

L ***BATTERY – CHARGING*** - *INDICATOR LIGHT*

M ***BATTERY – FULL*** - *INDICATOR LIGHT*

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(I)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to Red.

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(J)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to IR.

The orange ***BATTERY – CHARGING - INDICATOR LIGHT*** **(L)** illuminates while the *APPLICATOR* is placed in the *BASE & CHARGING UNIT* and charging.

The green ***BATTERY – FULL - INDICATOR LIGHT*** **(M)** illuminates when the batteries are fully charged.

The yellow ***SYSTEM ERROR - INDICATOR LIGHT*** **(K)** illuminates when a system error/malfunction occurs.

Package contents

Upon opening the Silk'n FX package, you will find the following parts:

- FX *BASE UNIT* and *APPLICATOR*
- Adaptor
- User's Manual

Silk'n FX - Indications For Use

Silk'n FX intended use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

As we grow older, the amount of collagen, the major supporting protein of the skin, diminishes and our skin becomes less flexible. In addition, our skin becomes drier and thinner, and as the body's natural regeneration process slows down, the skin slowly loses its ability to retain moisture and loses the "teenage" glow. The harmful rays in sunlight further damage the skin's supportive structure and prevent the creation of new collagen. This leads to the development of fine lines and wrinkles, especially in the area around the eye (periorbital wrinkles – crows feet). HF™ technology in Silk'n FX works with the body's natural processes to reduce the appearance of periorbital wrinkles.

If you have noticed development of fine lines and wrinkles, especially in the area around your eyes, Silk'n FX may help reducing them.

Contraindications

- Do not use Silk'n FX except for its indications for use to treat periorbital wrinkles.

When to avoid using Silk'n FX?

Certain conditions may prevent the use of Silk'n FX temporarily. **DO NOT USE Silk'n FX** if any of the following conditions apply to you:

- If you have dark brown or black spots, such as large freckles, birth marks, moles or warts on the area to be treated.
- If you have eczema, psoriasis, lesions, open wounds or active infections, such as cold sore in the area to be treated. Wait for the effected area to heal before using Silk'n FX™.
- If you have abnormal skin conditions caused by diabetes or other systemic or metabolic diseases
- If you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.
- If you have been treated with Accutane® (isotretinoin) within the past 6 months.
- If you have been on a steroid regimen within the past 3 months.
- If you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using Silk'n FX.

Precautions and Warnings

- Keep Silk'n FX out of the reach of children.
- Keep Silk'n FX out of the reach of persons with reduced physical, sensory or mental capabilities.
- Do not use the Silkn FX unless you are between the ages of 35-57. The treatment of this device outside this age range has not been tested in trails.
- CONTACT your healthcare professional as soon as possible if you suspect that you have had an adverse reaction from use of the Silkn FX. If you do not obtain medical advice your reaction may get worse.
- DO NOT use the Silkn FX if you are pregnant. The safety of the treatment for pregnant women has NOT been tested in clinical trials.
- NEVER use the Silkn FX or the Wall Power Supply when bathing or standing in water.
- NEVER use the Silkn FX or the Wall Power Supply if you think they may have been immersed in water, may have become wet, or if you have spilt any liquids on them.
- NEVER remove any covers from the Silkn FX or the Wall Power Supply. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect reassembly could cause an electric shock when the Silkn FX is subsequently used.
- DO NOT try and force the plug of the Power Supply into an outlet. If the plug does not connect easily with the outlet there may be a mismatch.
- DO NOT attempt to operate the Silkn FX with any Wall Power Supply other than the one provided.
- DO NOT use the Silkn FX if it is damaged in any way.
- DO NOT use the Wall Power Supply if it is damaged in any way or if its cord or plug is damaged.
- ALWAYS clean the Silkn FX before each treatment. See the Care and Maintenance section for details on how to clean your Silkn FX.
- DO NOT treat the affected area for longer than the recommended time at each session. If you treat the affected area for longer than the recommended time the effectiveness of the treatments may be reduced.
- DO NOT treat the affected area more often than recommended. If you treat the affected area more often than recommended the effectiveness of the treatments may be reduced.
- NEVER cover the air vents in the Silkn FX they are provided for ventilation. Be aware of objects, items of clothing or material that may accidentally block the air vents.
- ALWAYS keep the Silkn FX, its Wall Power Supply, and cord away from heated surfaces. High temperatures may damage the plastic cases or the internal pads.
- ALWAYS unplug the Wall Power Supply from the AC electrical outlet and refer to a authorized representatives if the Silkn FX does not work normally by following the operating instructions or if it exhibits a distinct change in performance.
- AVOID scratching the lens cover as scratches may reduce the efficiency of the treatment.
- AVOID placing the Silkn FX unit in a dusty or dirty environment. Dirt or dust may restrict the airflow through the Silkn FX causing it to switch off before the end of the treatment time.

- Keep Silk'n FX away from water!
  Do not use or store Silk'n FX in a wet environment (e.g. near a shower or a bathtub)!
  Keep the device and its adaptor dry!
- Do not use Silk'n FX if the *ADAPTOR* or the *APPLICATOR* is damaged!
- If the *ADAPTOR* is damaged, make sure it is replaced with an original part from Home Skinovations!

- The *ADAPTOR* contains a dedicated transformer. Never replace the *ADAPTOR* with another plug!

Risks - Possible Side Effects of using FX

When used according to the instructions, side effects and complications associated with use of Silk'n FX are rare. However every cosmetic procedure, including those designed for home use, involve some degree of risk. Therefore it is important that you understand and accept the risks and complications that can occur with Light Emitting Diodes for home use.

Silk'n FX treatments are generally very well-tolerated. Most users sense the moderate heat applied by the device during use, with no further discomfort.

- **Minor Skin Discomfort**

  Your skin may become slightly irritated after using Silk'n FX. This is a typical and transient phenomenon. If the irritation does not disappear within three days, please consult a physician or a dermatologist.

- **Skin Redness**

  Your skin may become slightly red right after using FX. This should disappear a few hours after treatment.

  Following the treatment it is recommended to apply a small quantity of moisturizer. This will help eliminating any minor skin discomfort or redness.

The benefits of Silk'n FX

The outcome of using Silk'n FX according to the instructions will be the reduction of fine lines and wrinkles in the perorbital area.

Best results can be expected 3-7 weeks after completing the recommended course of treatment.

Silk'n FX facial treatment areas

Typical areas for Silk'n FX treatment are the cheeks, the forehead around the eyes.

Before Using Silk'n FX

1. Plan your Silk'n FX treatment for best results

The efficiency of the results varies from person to person and according to the frequency of use. Some may see results sooner than others.

A full Silk'n FX treatment course:

1	**Forearm test***	20 minutes **RED** Light
2	**Forearm test***	20 minutes **IR** Light
3	**Week 1, first day (Day 1)**	20 minutes **IR** Light on EACH AREA
4	**Two days later (Day 3)**	20 minutes **RED** Light on EACH AREA
5	**Week 2, first day (Day 8)**	20 minutes **IR** Light on EACH AREA
6	**Two days later (Day 10)**	20 minutes **RED** Light on EACH AREA
7	**Week 3, first day (Day 15)**	20 minutes **IR** Light on EACH AREA
8	**Two days later (Day 17)**	20 minutes **RED** Light on EACH AREA
9	**Week 4, first day (Day 22)**	20 minutes **IR** Light on EACH AREA
10	**Two days later (Day 24)**	20 minutes **RED** Light on EACH AREA

* Some people may be sensitive to light. If you are sensitive to light Silkn FX may not be suitable for you. To determine if you are sensitive to light, we recommend you carry out a skin test on your forearm. If no adverse reaction appears within 24 hours, continue with step 2.

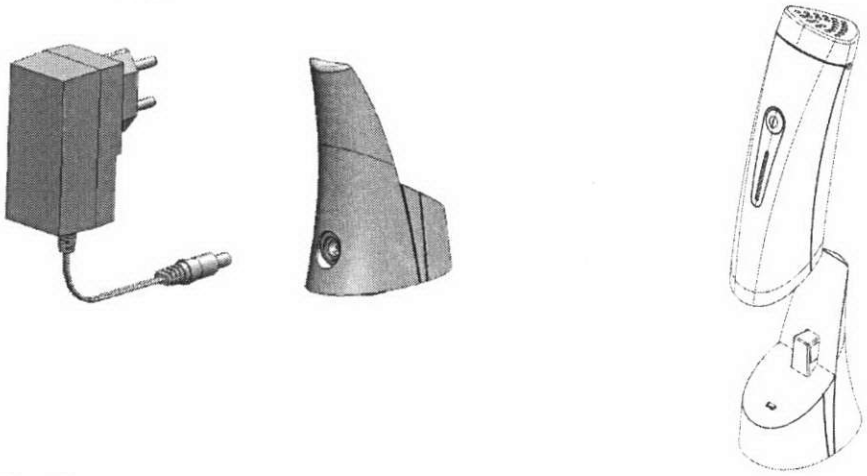
2. Silk'n FX Setup

1. Remove Silk'n FX *BASE UNIT, APPLICATOR, ADAPTOR* and other components from box.
2. Before using the Silk'n FX for the first time, fully charge its batteries. This may take up to 6 hours.

3. Silk'n FX Battery Charging

- Insert the *APPLICATOR* into its cradle in the FX *BASE UNIT.*
- Plug the *ADAPTOR PLUG* into the Base Unit socket.

- Plug the *ADAPTOR* into an electrical outlet. An orange *BATTERY – CHARGING - INDICATOR LIGHT* (L) will illuminate to indicate that your Silk'n FX is in the process of charging.



Caution! Never cover Silk'n FX and its adaptor while recharging!

Note! Silk'n FX can not be used while recharging

- When *BATTERY – CHARGING - INDICATOR LIGHT* (L) turns off and *BATTERY – FULL - INDICATOR LIGHT* (M) illuminates, **your Silk'n FX is fully charged and ready to start.**
  (Recharging will be needed when *BATTERY – CHARGING - INDICATOR LIGHT* (L) illuminates again.)

Treating with Silk'n FX

Prepare your skin for treatment

Make sure your skin is **clean**, **dry** and **free** of any powder, gel or cream.

Prepare your Silk'n FX device for treatment

- Remove the charged Silk'n FX *APPLICATOR* from its cradle in the *BASE UNIT*.
- Turn Silk'n FX on selecting the desired light mode:
  - For **RED** Light treatment
    - Press the *MODE SWITCH*. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (I) will start blinking, and shortly afterwards will be lit steadily.
      Your Silk'n FX device is ready for **RED** Light treatment.

- For **IR** Light treatment
  - Press the *MODE SWITCH* twice. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (J) will start blinking, and shortly afterwards will be lit steadily.
    Your FX is ready for **IR** Light treatment.

Perform the treatment

- Attach the *TREATMENT SURFACE* to your skin. The LED light will automatically activate.

- Perform the treatment for 20 minutes on each area.
- **Note:** After 20 minutes the device is automatically shut off. To reactivate the device push the Mode switch.

What to Expect when Treating with Silk'n FX?

During a Silk'n FX session it is **normal** to experience and feel:

- **A Sensation of Warmth** – During the Silk'n FX session you may feel slight warmth. This is normal and should disappear up to an hour after the session.
- **Some Mild Red Color** – After each Silk'n FX session you may notice a slight reddening of the skin (mild erythema) over the treated area. This is normal and should fade within an hour or two.

Best results can be expected 3-7 weeks after completing the recommended course of treatment, as the light stimulates process that continue the improvement after the completion of the treatment.

End the Silk'n FX treatment

- When Silk'n FX session has been completed turn the device off by pressing the *MODE SWITCH*. All indicator lights will be turned off.
- Finally place the applicator in its Base Unit cradle to recharge the batteries (See Section: "Silk'n FX Battery Charging").

After the Silk'n FX treatment

- Following a Silk'n FX treatment it is recommended to apply a small amount of a moisturizing cream on the treated skin areas and to massage it gently in circular motions.
- After each session it is recommended that you clean your Silk'n FX device, especially the *APPLICATOR TIP* (See Section: "Cleaning Silk'n FX").
- Store Silk'n FX according to the instructions (See Section: "Storage").

Alternative procedures and treatments?

Contact your dermatologist for treatment of periorbital wrinkles.

Silk'n FX Treatment Troubleshooting

What can go wrong?

Please see section: Risks - Possible Side Effects of using FX

When to call a doctor?

In case you experience one or more of the detailed possible side effects, please contact your physician or dermatologist.

Clinical Studies

In clinical studies using similar products, 7 out of 10 subjects reported a visible reduction in fine lines and wrinkles, and 7 out of 10 reported an improvement in skin clarity.

Care and Manitenance

1. Protect your Silk'n FX

- Do not cover the ventilation slots during use.
- Remove any obstruction to air flow through the ventilation slots.
- Never shake or drop Silk'n FX or subject it to severe shocks.
- Silk'n FX is sensitive to environmental temperature during use.
  Do not expose the FX to environmental temperatures lower than 15°C / 59°F or higher than 35°C / 95°F during use.
- Silk'n FX cannot tolerate extreme change of environment temperature.
  When moved from a cold environment (under 10°C / 50°F) to a warm environment, avoid use for approximately 3 hours.
- Do not expose Silk'n FX to a lengthy direct sunlight or UV light.
- Silk'n FX is designed for occasional home use (as opposed to an exhaustive commercial or professional use). Avoid such exhaustive use.
- Avoid covering Silk'n FX and its adaptor during recharge.

2. Cleaning Silk'n FX

After each session, it is recommended to clean your Silk'n FX device, and especially its *TREATMENT SURFACE*.

- Turn Silk'n FX off by pressing the *MODE SWITCH*.
- Unplug Silk'n FX from the electrical outlet
- Allow cooling down of its *TREATMENT SURFACE*.
- The exterior of the Silkn FX unit may be cleaned by wiping it with a damp (not wet) cloth or isopropyl alcohol wipe. Please refrain from using any other cleaning products as these may damage the plastic parts.

- Never immerse Silk'n FX or any of its parts in water!
- Never clean the FX or any of its parts under the tap or in the dishwasher.

3. Silk'n FX Storage

- Clean Silk'n FX according to the instructions (See "Cleaning Silk'n FX")
- Store the clean device and all its parts in a dry clean place free of dust, at a temperature of between -10°C to 60°C / 14°F to 140°F

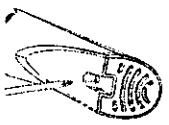
4. To protect the Environment

At the end of its life, do not discard Silk'n FX with the normal household waste. Hand it at an official recycling collection point.

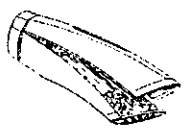
Always remove the batteries before discarding or handing at a recycling collection point (See section: "Removing the rechargeable batteries"). Dispose of the batteries at an official collection point for batteries. If you have trouble removing the batteries, you can take the device to a Home Skinovations service centre.

Removing the rechargeable batteries

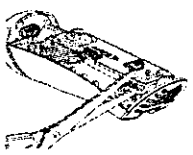
Remove the rechargeable batteries only if they are completely empty and cannot be recharged.



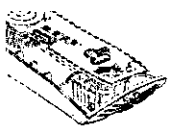
- Undo the screw at the bottom panel of the *APPLICATOR*.



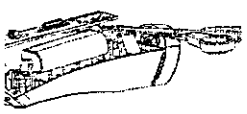
- Lift and remove the top panel of the *APPLICATOR*.



- Cut the tow wires that connect the electronics card to the lower panel of the *APPLICATOR*.



- Push the three snaps and pull out the electronics card.



- Cut the tow wires that connect the rechargeable batteries pack to the *APPLICATOR*.

5. Silk'n FX Troubleshooting

This chapter summarizes the most common problems you could encounter. If you are unable to solve the problem with the information below, contact your local Silk'n customer Service center for further support.

Problem	Possible cause	Solution
Silk'n FX does not work	The rechargeable batteries are empty	Charge the *APPLICATOR*
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
Silk'n FX suddenly switches off	The rechargeable batteries are empty	Charge the *APPLICATOR*
Device temperature rises during recharge	This is normal	No action is required
BATTERY – CHARGING - INDICATOR LIGHT (L) **does not turn on when connecting the *PLUG* into the *BASE UNIT SOCKET*.**	The *ADAPTOR* is not plugged in the electrical outlet	Insert the *PLUG* into the *BASE UNIT SOCKET*,
		Connect another appliance the wall socket to check if the electrical outlet is live.
		If the *APPLICATOR* still does not charge, Contact your local Silk'n customer Service center
	The *ADAPTOR* is not inserted properly into the electrical outlet and/or the *PLUG* is not inserted properly into the *BASE UNIT SOCKET*	Make sure the *ADAPTOR* is inserted properly into the electrical outlet and/or *PLUG* is inserted properly into the *BASE UNIT SOCKET*.
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
APPLICATOR **temperature rises during use.**	This is normal	No action is required
READY/TREATMENT MODE - INDICATOR LIGHT (I) **does not illuminate when pressing the *MODE SWITCH***	The *APPLICATOR* needs to be reset	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *READY/TREATMENT MODE - INDICATOR LIGHT* (I) does not illuminate again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is lit.**	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *SYSTEM ERROR - INDICATOR LIGHT* (K) illuminates again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is blinking**	The rechargeable batteries are empty	Charge the *APPLICATOR*
The Green *BATTERY – CHARGING* and Orange *BATTERY – FULL - INDICATOR LIGHTS* are	Malfunction of the *ADAPTOR*	Disconnect the *ADAPTOR* from the electrical outlet, press the *MODE SWITCH* twice to switch the *APPLICATOR* on and off again. Connect the Adaptor to the wall socket, If the problem persists,

illuminated alternately		contact your local Silk'n customer Service center
	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If the problem persists, contact your local Silk'n customer Service center

User Assistance and Customer Service

1. For USA and Canada customers:

For more information about Silk'n™ products please enter www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact Silk'n™ Customer Service: **1-877-DO-SILKN / 1-877-367-4556**, contact@silkn.com

2. For customers in other countries:

For more information about Silk'n™ products please enter your local Silk'n™ website, www.silkn.eu or www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact your local Silk'n™ Customer Service or write to: info@silkn.com.

Warranty information

1. What does the Silk'n FX Warranty Cover?

Subject to the terms and conditions of this warranty, Home Skinovations Inc. warrants that it will repair or replace the FX device that accompanies this warranty (the "Device") to the extent that the Device exhibits material defects in materials or workmanship caused by Home Skinovations Inc.

2. Who Is Entitled To The Protections Of the Silk'n FX Warranty?

Only you, the original purchaser of the Device are entitled to the protections of this warranty. Home Skinovations Inc. may require original proof of purchase of the Device by having you provide your invoice or receipt from the purchase of the Device.

3. How Long Does The Coverage Last?

This warranty covers claims filed with Home Skinovations Inc. within one (1) year from the date of the original purchase of the Device. Claims filed after one (1) year from the date of purchase of the Device by you are not covered. Home Skinovations Inc. may require that you prove the date you purchased the Device by providing an invoice or receipt that specifically lists the date of purchase of the Device. Claims in respect of a repaired or replaced device must be filed with Home Skinovations Inc. within the later of (a) one (1) year from the date of purchase of the original Device by you or (b) ninety (90) days from the date that the Home Skinovations Inc.

service center ships the repaired or replaced Device back to you.

4. How Do You Get Warranty Service?

In order to obtain warranty service on the Device, go to the customer service section of www.silkn.com or call the then-current customer service telephone number (currently 877-367-4556) for assistance. You must obtain a Return Goods Authorization (RGA) number and an RGA form which will be sent to you before shipping the Device to Home Skinovations Inc. You must also comply with Home Skinovations Inc.'s instructions concerning shipment and the materials that must accompany the Device (such as a copy of the invoice that proves your status as the original purchaser and the date of purchase and the completed RGA form). It is suggested for your protection that you insure your shipment to Home Skinovations Inc. Damage during shipment to Home Skinovations Inc. is not covered by this warranty. It is also suggested that you ship the Device using a tracked method so that you can ensure that Home Skinovations Inc. has received the Device.

5. Shipping Charges

You are required to pay for packaging and shipping of the Device to the applicable Home Skinovations Inc. service center. Home Skinovations Inc. will pay for packaging and shipping of the Device back to you; provided that if upon receipt, inspection and testing of the Device by Home Skinovations Inc., Home Skinovations Inc. determines that the Device does not exhibit material defects in materials or workmanship, then you will be required to pay for return packaging and shipping back to you.

6. What Does the Silk'n FX Warranty Not Cover?

This warranty does not cover damage resulting from accident, misuse (including use not described in the user manual or instructions accompanying the Device), abuse, lack of reasonable care, the affixing of any attachment not provided with the device, loss of parts, use of unauthorized replacement parts or subjecting the device to any but the specified voltage.* This warranty is void if the Device is repaired by anyone other than an authorized Home Skinovations Inc. service center, and Home Skinovations Inc. will not have any liability for damage resulting from service performed by anyone other than an authorized Home Skinovations Inc. service center.

Travel with device

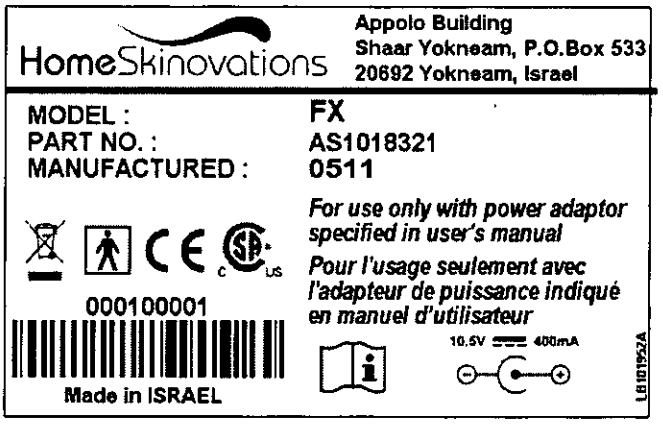
Silk'n FX is designed for your personal use wherever you are, at home or traveling.

- When fully charged, the device will provide continuous operation enough for a full treatment of the face.
- If you intend to use Silk'n FX more then once during your trip, be sure to carry all parts including applicator, charging base unit and cord with you.
- For recharge a 100V - 240V electrical outlet is required.

Specifications

Rated voltage (Adaptor)	100V - 240V
	Model: UE08WCP-105040SPA
Rated frequency (Adaptor)	50Hz – 60Hz
Rated currant (Adaptor)	400 mA
Applied part	Type BF
Protecting rating	IP20 (EN60529)
Storage condition	Temperature: -10°C to 60°C / 14°F to 140°F
	Relative humidity: 5% to 95%
Operating condition	Temperature: 15°C to 35°C / 59°F to 95°F
	Relative humidity: 10% to 80%
	Atmospheric pressure: 700 to 1060 hPa
Light source	Light Emitting Diodes
	Wavelengths peak emission wavelength: 633, 830nm
	Intensity power: 70,55mW/cm^2 ±10%
Lithium ion battery	2 x 3.7V, 750±50mAh
Max. charging time	180 minutes
Product life time	300 full battery charging cycle

Labeling



Degree of protection against electric shock: type BF applied part

WEEE - Waste Electrical and Electronic Equipment

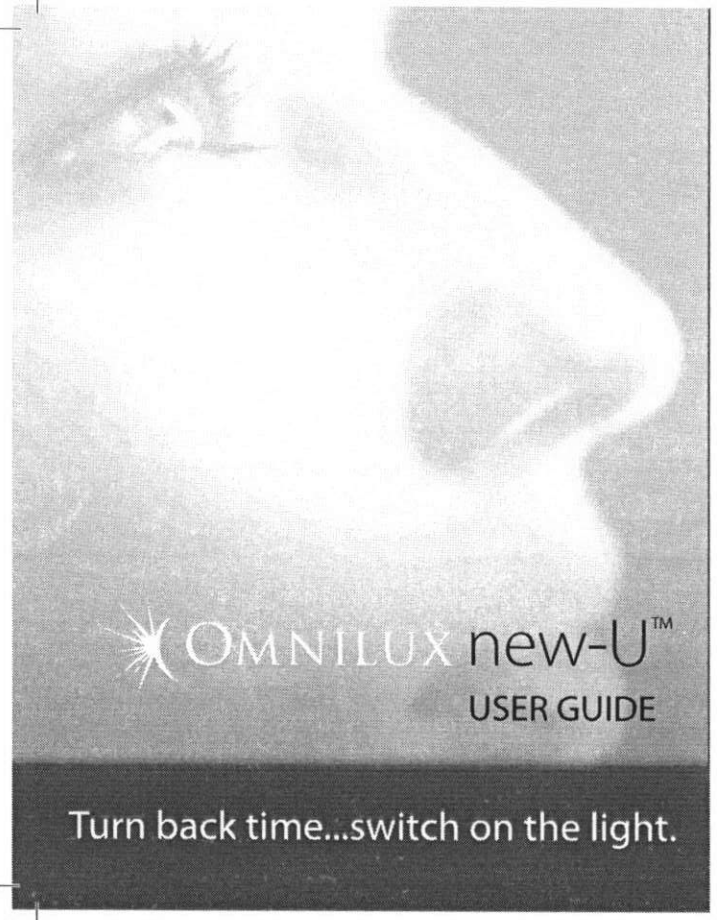
CSA Mark

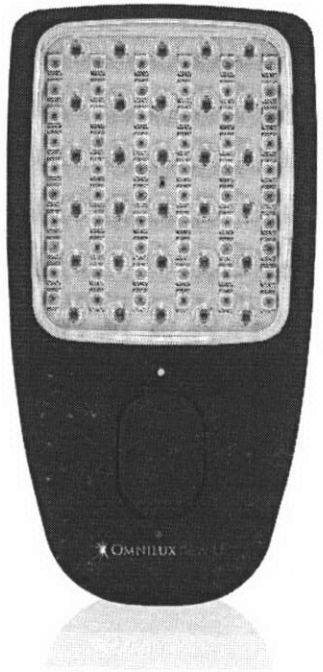
CE Mark

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

The symbol on the label affixed to this device means "Attention, consult accompanying documents".


OMNILUX new-U™
USER GUIDE
Turn back time...switch on the light.


OMNILUX

Specifications are subject to change without notice or obligation on the part of the manufacturer.

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OMNILUX new-U™

Introduction

Thank you for choosing Omnilux new-U, an FDA cleared, handheld, Light Emitting Diode (LED) device for the treatment of periorbital wrinkles (crows feet). Its patented technology bathes the skin in alternating red and infrared light, stimulating the deeper skin tissue, leading to reduction of periorbital wrinkles. (See the 'Indications for Use' section for more information about periorbital wrinkles).

Dermatologists all over the world have been using Professional Omnilux products for many years to successfully treat periorbital wrinkles. Omnilux new-U uses the same LED technology but in a small and convenient home use package.

Now the power of light is in your hands!

To help you get started, we have put together some of the frequently asked questions about periorbital wrinkles - crows feet. Please read the entire Omnilux new-U user guide before operating the unit.

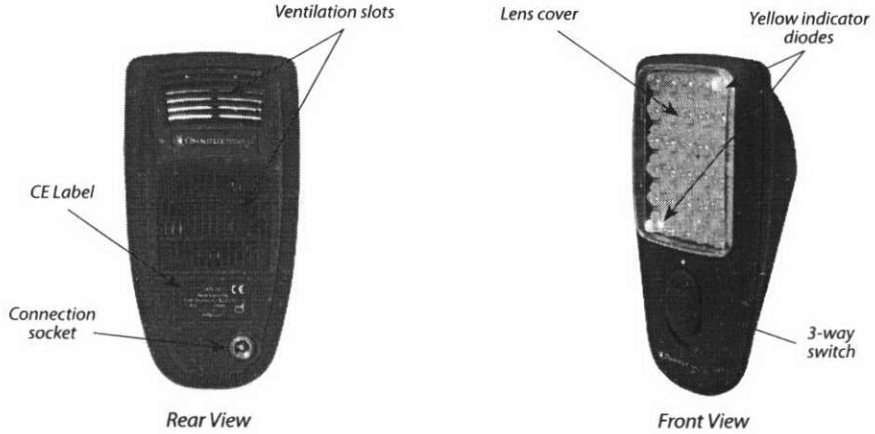
As we grow older, the amount of collagen, the major supporting protein of the skin, diminishes and our skin becomes less flexible. In addition, our skin becomes drier and thinner, and as the body's natural regeneration process slows down, the skin slowly loses its ability to retain moisture and loses that "teenage" glow. The harmful rays in sunlight further damage the skin's supportive structure and prevent the creation of new collagen. This leads to the development of fine lines and wrinkles, especially in the area around the eye (periorbital wrinkles – crows feet). Omnilux new-U LED therapy works with the body's own natural processes to reduce the appearance of perioribital wrinkles. Medical research has demonstrated that light can target cells within the body, which are responsible for the synthesis of collagen. [1,2,3,4,5]

In a trial using Omnilux new-U, 7 out of 10 subjects reported a visible reduction in fine lines and wrinkles and 7 out of 10 reported an improvement in skin clarity.

Please feel free to contact Customer Service with your comments and/or thoughts on the Omnilux new-U product, its use, or the literature that accompanies the product.

The Omnilux new-U

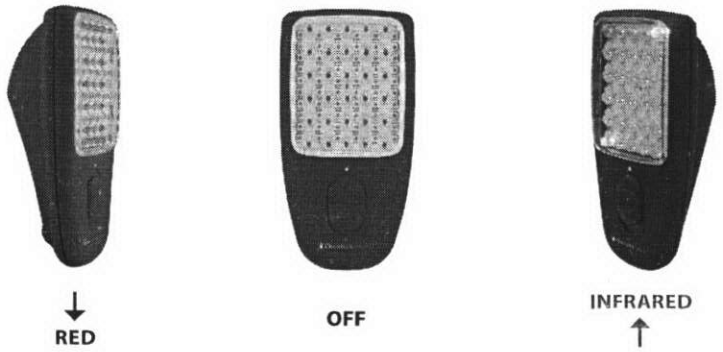
The Omnilux new-U system comprises of a treatment unit and a separate Wall Power Supply with Cord.



The Omnilux new-U treatment unit contains an array of Light Emitting Diodes (LEDs), a ventilation fan, a three-position switch, and a connection socket.

Each array is a matrix of Light Emitting Diodes (LED's) designed to emit light of a specific brightness (intensity) and color (wavelength). The switch on the front of the Omnilux new-U allows you to choose between the RED light output, the INFRARED light output or the OFF position.

Omnilux new-U treatment unit – Switch Positions

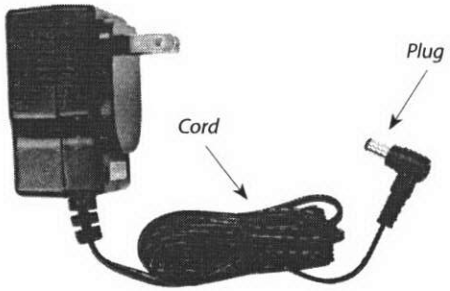


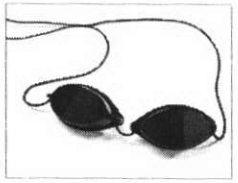
Move the switch **DOWN** for **RED** light. Move the Switch **UP** for **INFRARED** light. Move the switch to the **CENTER** position for **OFF**. Since infrared light is not visible to the eye, the Omnilux new-U has two yellow LEDs (as shown above) which light up when the device is emitting infrared light.

The Omnilux new-U Wall Power Supply is designed to power the Omnilux new-U treatment unit. Power from the Wall Power Supply is fed to the Omnilux new-U through the flexible cord to a small coaxial connector which plugs into the socket on the rear of the Omnilux new-U.

Omnilux Wall Power Supply with Cord

*Power supply may vary depending on country





The Omnilux new-U has been tested to International standards to ensure that its outputs are safe for the eyes. However, we have supplied a set of patient goggles that we recommend you wear for your own comfort.

Omnilux new-U Lifetime

All LEDs, including those used in the Omnilux new-U, gradually lose brightness the longer they are used. This loss of brightness is very slow indeed. An LED would need to be run continuously for one or two years before the eye might begin to notice the change.

The Omnilux new-U has been designed with both these effects in mind. The brightness and lifetime of the LEDs used in the Omnilux new-U have been carefully selected so that you can rely on it to give effective treatments.

Indications for Use

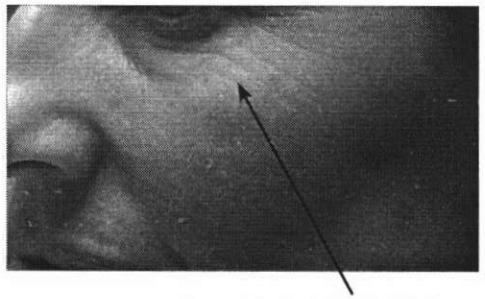
The Omnilux new-U is a medical device intended to be used for the reduction of periorbital wrinkles. Periorbital wrinkles are wrinkles around the eye, often referred to as 'crows feet'.

Crows feet tend to appear as the skin ages or becomes sun damaged.

Visible signs of aging can be the appearance of fine lines and wrinkles around the eye area.

Sun damaged skin tends to be darker, more coarse, mottled or freckled and possess an uneven and dull complexion.

To help you decide whether the skin condition you have is periorbital wrinkles, we've included an example.



Example of periorbital wrinkle

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Contraindications

- **DO NOT** use the Omnilux new-U except for the reduction of periorbital wrinkles.

Warnings

To reduce the risk of an adverse reaction:
An adverse reaction is any pain or discomfort in the treatment area or any skin redness that lasts for longer than 24 hours.

- **CONTACT** your healthcare professional as soon as possible if you suspect that you have had an adverse reaction from use of the Omnilux new-U. If you do not obtain medical advice, your reaction may get worse.

- **DO NOT** use your Omnilux new-U if you suspect that you have had an adverse reaction from use of the Omnilux new-U. If you continue to use the Omnilux new-U, your reaction may get worse.

- **DO NOT** use the Omnilux new-U if you are pregnant. The safety of the treatment for pregnant women has NOT been tested, and the risk is unknown.

To reduce the risk of serious injury or fatal electrical shock:

- **NEVER** use the Omnilux new-U or the Wall Power Supply where they can fall or be pulled into water.

- **NEVER** use the Omnilux new-U or the Wall Power Supply when bathing or standing in water.

- **NEVER** use the Omnilux new-U or the Wall Power Supply if you think they may have been immersed in water, may have become wet, or if you have spilled any liquids on them.

- **NEVER** remove any covers from the Omnilux new-U or the Wall Power Supply. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect reassembly could cause an electric shock when the Omnilux new-U is subsequently used.

- **DO NOT** try and force the plug of the Power Supply into an outlet. If the plug does not connect easily with the outlet there may be a mismatch.

- **DO NOT** attempt to operate the Omnilux new-U with any Wall Power Supply other than the one provided.

- **DO NOT** use the Omnilux new-U if it is damaged in any way.

- **DO NOT** use the Wall Power Supply if it is damaged in any way or if its cord or plug is damaged.

Precautions

To help give treatment:

- **ALWAYS** clean the Omnilux new-U before each treatment. See the Care and Maintenance section for details on how to clean your Omnilux new-U.

To reduce the risk of damaging your Omnilux new-U:

- **NEVER** cover the air vents in the Omnilux new-U. They are provided for ventilation. Be aware of objects, items of clothing or material that may accidentally block the air vents.

- **ALWAYS** keep the Omnilux new-U, its Wall Power Supply, and cord away from heated surfaces. High temperatures may damage the plastic cases or the internal parts.

- **ALWAYS** unplug the Wall Power Supply from the AC electrical outlet and refer to Photo Therapeutics Inc. or its authorized representatives if:
  - the Omnilux new-U does not work normally by following the operating instructions
  - if it exhibits a distinct change in performance.

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Risks and Benefits

Omnilux new-U is a handheld, Light Emitting Diode (LED) device for the treatment of crows feet. Its patented technology bathes the skin in red and infrared light, stimulating the deeper skin tissue, leading to the reduction of fine lines and wrinkles in the periorbital area (crows feet).

The best results will be seen between 3 – 7 weeks **after you have completed the recommended course of treatments**. The light stimulates natural processes that continue after the treatment has stopped.

You may experience erythema (mild skin redness). If it lasts longer than 24 hours, you should stop using Omnilux new-U and seek advice from a healthcare professional.

What to expect after a course of treatments:

Before (top) and after (bottom) the recommended course of treatments clearly demonstrating a reduction in periorbital wrinkles.

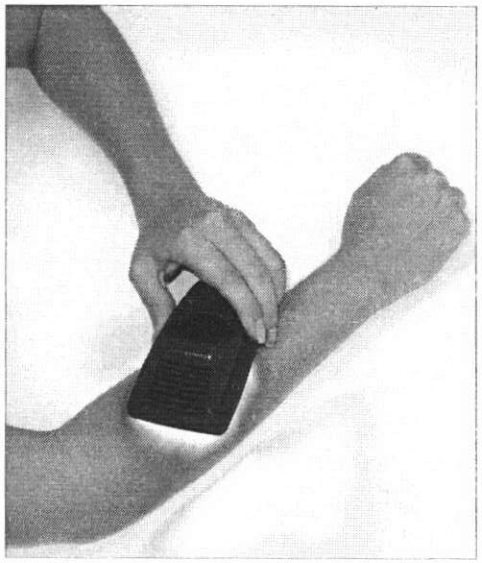
The Omnilux new-U has been tested to International standards to ensure that its outputs are safe for use on the skin. The outputs of the Omnilux new-U are less than 1/20th of the safe limit.

The Omnilux new-U has been tested to International standards to ensure that its outputs are safe for the eyes.

The red light output of the Omnilux new-U is less than 1/6th of the safe limit. The infrared light output of the Omnilux new-U is less than 1/600th of the safe limit.

Before you use the Omnilux new-U

Some people are sensitive to light. If you are one of these people the Omnilux new-U may not be suitable for you. To determine if you are sensitive to light, we recommend that you carry out a test on your forearm. (see steps on page 10)



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1. **ALWAYS** switch the wall outlet socket off. If you do not switch the outlet off there is a risk that you may touch a live pin when plugging the Wall Power Supply into the outlet.

2. **PLUG** the wall power supply into the wall outlet socket.

3. **PLUG** the wall power supply connector into the Omnilux new-U.

4. **SWITCH** the wall outlet socket on.

5. **OPERATE** the selector switch on the front of the Omnilux new-U to turn on the red LEDs, place the transparent lens of the Omnilux new-U in contact with treatment area or at a maximum of 1cm/0.5" from your upper forearm and leave in position for 20 minutes. You should NOT experience any adverse reaction during the next 24 hours. An adverse reaction is any pain or discomfort in the treatment area or any skin redness that lasts for longer than 24 hours.

If after 24 hours you have not experienced an adverse reaction to the red light, repeat the test on the other forearm BUT this time using the infrared light. If after 24 hours you have not experienced an adverse reaction to the infrared light it is safe for you to use the Omnilux new-U.

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Using Omnilux new-U

Treatment Recommendations

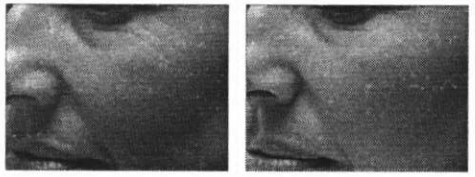
A full course of treatment consists of eight treatments spread over four weeks as shown in the chart below. **Note: If you are treating multiple areas; each area must be exposed to the light for the full 20 minutes, no more than 1/2" from the skin's surface.**

1. Forearm test If no adverse reaction within 24 hours, continue with test 2	**20 minutes RED light**
2. Forearm test If no adverse reaction within 24 hours, start treatment regime	**20 minutes IR light**
3. Week 1, first day (Day 1)	**20 minutes IR light on EACH AREA**
4. Two days later (Day 3)	**20 minutes RED light on EACH AREA**
5. Week 2, first day (Day 8)	**20 minutes IR light on EACH AREA**
6. Two days later (Day 10)	**20 minutes RED light on EACH AREA**
7. Week 3, first day (Day 15)	**20 minutes IR light on EACH AREA**
8. Two days later (Day 17)	**20 minutes RED light on EACH AREA**
9. Week 4, first day (Day 22)	**20 minutes IR light on EACH AREA**
10. Two days later (Day 24)	**20 minutes RED light on EACH AREA**

What to expect

After each session you may notice a slight reddening of the skin (mild erythema) over the treated area. This is normal and should fade within an hour or two.

The best results will be seen between 3 – 7 weeks **after you have completed the recommended course of treatments**. The light stimulates natural processes that continue after the treatment has stopped.



Before (left) and after (right) the recommended course of treatments clearly demonstrating a reduction in periorbital wrinkles.

How to use the Omnilux new-U

Before a treatment session ALWAYS wash the skin with a suitable skin cleanser to remove all product residues, pollutants, and any traces of make-up. This will make sure that all the light from the Omnilux new-U reaches the skin.

1. **ALWAYS** switch the wall outlet socket off. If you do not switch the outlet off there is a risk that you may touch a live pin when plugging the Wall Power Supply into the outlet.
2. **PLUG** the wall power supply into the wall outlet socket.
3. **PLUG** the wall power supply connector into the Omnilux new-U.
4. **SWITCH** the wall outlet socket on.
5. **FIT** patient goggles.
6. **OPERATE** the selector switch on the front of the Omnilux new-U to turn on the correct color LEDs for the treatment session. (See 'Treatment Recommendations').
7. **PLACE** the transparent lens of the Omnilux new-U in contact with treatment area or at a maximum of 1cm/0.5" from the treatment area. (See photo on page 13).
8. **REMOVE** the Omnilux new-U from the affected area after the correct treatment time. (See 'Treatment Recommendations').
9. **MOVE** the selector switch to the center OFF position.

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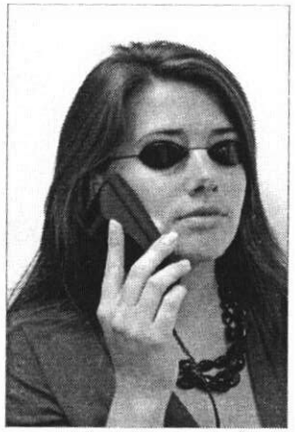

10. **SWITCH** off the wall outlet socket.

11. **REMOVE** the wall power supply from the wall socket.

12. **REMOVE** the wall power supply connector from the Omnilux new-U.

13. **CLEAN** the transparent lens of the Omnilux new-U with a damp (not wet) cloth or an isopropyl alcohol wipe.

14. **PLACE** the Omnilux new-U and the wall power supply in a safe storage area.

Care and Maintenance

To obtain the best from your Omnilux new-U you should follow these few simple rules.

- **AVOID** scratching the lens cover as scratches may reduce the efficiency of the treatment.
- **AVOID** placing the Omnilux new-U face down on a hard surface as this may scratch the lens cover.
- **AVOID** placing the Omnilux new-U unit in a dusty or dirty environment. Dirt or dust may restrict the airflow through the Omnilux new-U causing it to switch off before the end of the treatment time.

The exterior of the Omnilux new-U unit may be cleaned by wiping it with a damp (not wet) cloth or an isopropyl alcohol wipe. Please refrain from using any other cleansing products as these may damage the plastic casing.

To reduce the risk of serious injury or fatal electrical shock:

- ENSURE the Omnilux new-U unit is switched off and unplugged before the lamp is cleaned.

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Outside the United States

The Wall Power Supply which comes with your Omnilux new-U is designed to operate with an electrical input between 90-250 Volts, at 50-60 Cycles.

When traveling outside the United States, you should check the local electrical service for suitability if you are in any doubt.

The Wall Power Supply plug may not fit AC outlets in countries outside the United States.

Storage

Avoid placing the Omnilux new-U in a dusty or dirty environment. Dirt entering the air intake or ventilation flutes will shorten the life of the unit.

The wall power supply lead should never be sharply bent, kinked, strained or crushed.

Store the new-U in a dry environment, avoiding extreme temperatures and direct sunlight.

Disposal

For protection of the environment, please package and return this unit to Photo Therapeutics Inc. at the end of its working life.

Labeling

The label on the rear face of the Omnilux new-U contains the following information:

- Model Number
- Electrical Requirements
- Date of Manufacture

Troubleshooting

Photo Therapeutics Inc. record and analyze all faults reported to them. The majority of faults reported have a simple cause and can be readily put right by the user. They are listed in the troubleshooting table on the next page. If the actions suggested fail to rectify the problem, or the fault reoccurs, please refer to Photo Therapeutics Inc. or their authorized representative to arrange servicing of your Omnilux new-U.

Do not attempt to investigate any further; the Omnilux new-U has no user-serviceable parts.

NOTE that Infrared light is invisible to the eye, therefore the Omnilux new-U is fitted with two yellow LED indicators to show when the infrared output is on. If the yellow LEDs do not light up when the switch is moved to the 'Infrared' position, then there is no Infrared output.

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Problem	Possible Cause	Action Required
No red or Infrared light output (fan not running)	No power	Check power cord and power plug are in good condition. Check that the wall power supply is plugged into the Omnilux new-U. Outside the USA, check the mains outlet switch is turned on.
Light cuts out during treatment (fan running)	Overheating	Ensure ventilation slots are not blocked. Allow a few minutes for the Omnilux new-U to cool and try again. If the problem persists, return your device to Photo Therapeutics Inc. for servicing.
No red or Infrared light output (fan running)	Faulty switch	Return to Photo Therapeutics Inc. for servicing.
No red light output (fan running)	Faulty switch	Return to Photo Therapeutics Inc. for servicing.
No Infrared light output (fan running)	Faulty switch	Return to Photo Therapeutics Inc. for servicing.
Light will not switch off	Faulty switch	Return to Photo Therapeutics Inc. for servicing.
Light cuts out during treatment (fan not running)	Faulty fan	Return to Photo Therapeutics Inc. for servicing.
Light flickers during treatment	Power intermittent	Check that the power cord and power plug are in good condition. Check that the power plug is a good fit into the Omnilux new-U socket. If the problem persists, return your device to Photo Therapeutics Inc. for servicing.

Warranty

Your Omnilux new-U is warranted to be free from defect in material and workmanship for a period of one year under normal use after its original purchase date. This warranty extends only to the original retail purchaser and only when purchased from an authorized retailer.

If the product should become defective within the warranty period, contact Photo Therapeutics at the following numbers for repair or replacement:

For the USA Customer Service team call toll free 1-800-743-8150

For the Rest of the World Customer Service team call +44 1827 252830

Photo Therapeutics Inc. reserves the right to replace a defective product with the most comparable product currently available.

This warranty does not cover products damaged by the following:

- Accident, misuse, abuse or alteration
- Servicing by unauthorized persons
- Use with unauthorized accessories
- Connecting to incorrect current and voltage
- Any other conditions beyond our control

PHOTO THERAPEUTICS INC. SHALL NOT BE RESPONSIBLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF THIS PRODUCT. ALL IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF FITNESS AND MERCHANTABILITY ARE LIMITED IN DURATION TO ONE YEAR FROM DATE OF ORIGINAL PURCHASE.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, or limitations on how long an implied warranty lasts, so the above limitations and exclusions may not apply to you.

Money Back Guarantee

If you find that having purchased the Omnilux new-U, you do not have periorbital wrinkles as defined in the 'Indications for use' section, simply return your Omnilux new-U within 30 days of the original purchase and we will refund your money. The Omnilux must be returned, unused, in the original packaging along with all the package contents and your original store sales receipt.

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Declaration of Conformity

When emitting its red light the Omnilux new-U has been classified as a CLASS 1 LED PRODUCT in accordance with the requirements of the International standard IEC 60825-1:2001 – Safety of LED Products.

When emitting its IR light output, the Omnilux new-U has been classified as a CLASS 1 LED PRODUCT in accordance with the requirements of the International standard IEC 60825-1:2001 – Safety of LED Products.

IR light cannot be seen with the eye, therefore the IR output of the Omnilux new-U is classified as 'Invisible LED Radiation'.

This standard also recommends Maximum Permissible Exposures (MPEs) to light sources in order that the risk of damage to eyes is eliminated.

When used correctly for the recommended treatments the outputs of the Omnilux new-U are less than the maximum recommended MPEs.

CLASS 1 products are safe for unprotected exposure of the eyes.

References

1. **Takezaki S, Omi T, Sato S, Kawana S**; '*Light-emitting diode phototherapy at 630 +/- 3 nm increases local levels of skin-homing T-cells in human subjects*'. - J Nippon Med Sch, 2006; 73: 75-81.

2. **Takezaki I et al**; '*Ultrastructural Observations Of Human Skin Following Irradiation With Visible Red Light-Emitting Diodes (LEDs): A Preliminary In Vivo Report*'. - Laser Therapy 14.4: 153-160.

3. **Lee SY et al**; '*A prospective, randomized, placebo-controlled, double-blinded, and split-face clinical study on LED phototherapy for skin rejuvenation: Clinical, profilometric, histologic, ultrastructural, and biochemical evaluations and comparison of three different treatment settings*'. - Journal of Photochemistry and Photobiology B: Biology 88; (2007): 51-67.

4. **Russell B et al**; '*A study to determine the efficacy of combination LED light therapy (830 nm and 633 nm) in facial skin rejuvenation*'. - Journal of Cosmetic and Laser Therapy volume 7 issue 3/4.

5. **Calderhead RG**; '*The Photobiological Basics Behind Light-Emitting Diode (LED) Phototherapy*'. - Laser Therapy 16.2: 97-108 2007.

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OMNILUX new-U™

Photo Therapeutics Ltd.
Unit 3 Bonehill Mews, Lichfield Street,
Fazeley, Staffordshire B78 3QU
United Kingdom

Sales: +44 (0) 1827 252 830
Support: +44 (0) 161 925 5610
Facsimile: +44 (0) 1827 287 391

Photo Therapeutics Inc.
2335 Camino Vida Roble, Suite A
Carlsbad, CA 92011
USA

Tel: (760) 607-0488
Toll Free: (800) 743-8150
Fax: (760) 607-0288

Contact us at www.phototherapeutics.com

B4 [redacted] testing

Introduction

B4 [redacted]

[redacted] study

Method

The information, which is presented in this report, was obtained from clinical usability study that worked under the device labeling.

Study Sponsor:
Home Skinovations Ltd.
Apolo building
POB 533
Yokneam 20692
ISRAEL

Study monitor:
Dr. Amir Waldman
Home Skinovations Ltd.
Apolo building
POB 533
Yokneam 20692

B4, Testing Data

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 28, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301

Product: SILK'N FX

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K110301/S2

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

June 23, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
JUN 27 2011
Received

Re: Letter from May 3, 2011 K110301

Dear Mr. Bandukwala

Thank you for your letter from May 3, 2011 in response to our 510K submission for the Silk'n FX (K110301).

Please find the requested information asked in your letter:

1. B4 [redacted]

2. On page 9 of the user manual, the sponsor states that "Typical areas for treatment are the cheeks, the forehead and around the eyes". This statement is vague and allows the user to interpret that the device can be used on the cheeks and forehead. The diagram on this page makes it appear that there are four places to use the device, the right and left side forehead and the right and left side cheek. The directions in the manual states to treat each area for 20 minutes. This statement is also vague. Should the patient treat one of these areas for 20 minutes each for a total treatment time of 80 minutes? Please clarify these portions of the manual. The device is intended to treat periorbital wrinkles only. Please remove the statement that treatment areas are the cheeks, foreheads and around the eyes. The manual and package should have a picture of periorbital wrinkles and designate the specific area of treatment.

   Replaced with: "Silk'n FX is designed to treat the periorbital wrinkles around the eyes" (See new user manual page 7).

   Right and left periorbital areas only = total of 40 minutes per treatment.

K-48

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Apolo building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
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3. Page 9 of the manual states "Typical areas for treatment are the cheeks, the forehead and around the eyes". There is a diagram but it does not have much detail. The package labeling and user manual should have pictures of what periorbital wrinkles (crow's feet) are. Please add these pictures on the package labeling and in the user manual. The general population may not be familiar with the term periorbital wrinkles or crow's feet. A picture identifying these types of wrinkles will help potential users understand what the device is intended to treat.

   Picture added (see new package and user manual pages: 7, 12).

4. On page 12, the instructions state, "Attach the treatment surface to your skin. The LED light will automatically activate". The manual should state that the device will not activate unless the device is in contact with the skin. The manual should also inform the patient that the device will turn off if there is no skin contact. Please add these instructions in the manual. The current instructions does not emphasize the necessity for skin contact to activate the device.

   Comment added: "Note that the device will not activate without skin contact and will deactivate when removed from the skin." (See page 13).

5. B4 [redacted]

6. B4 [redacted]

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ISRAEL
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Fax: +972(4)9097471

B4 [redacted]

10. You say the intended use of this device is the "use in dermatology for the treatment of periorbital wrinkles." However, in seeming contrast to this:

- You expand on this use to the treatment of wrinkles anywhere on the body through your statement, "If you have noticed development of fine lines and wrinkles, especially in the area around your eyes, Silk'n may help reducing them."

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Sentence replaced with: "If you have noticed development of fine lines and wrinkles around your eyes, Silk'n FX may help reducing them." (see page 7).

- Graphics on the external package labeling show persons using the device in areas outside the usual "crows feet" area beside the eye.

Pictures replaced: (see new package).

- The labeling says, "Typical areas for Silk'n FX treatment are the cheeks, the forehead around the eyes."

See above comment

- There is a graphic showing shaded areas below, above and beside the eye. It appears that you are using these shaded areas to show possible treatment areas. It is not clear what the labeling is intended to imply by these areas.

See above comment

- The graphic on page 12 in the directions shows a person treating the left cheek

See revised illustration on page 13.

Thus, the treatment area you designate as periorbital wrinkles appears to have no boundaries. Please be specific on what the boundaries of the treatment area is so lay persons will know what areas to treat and what areas not to treat with your device.

Resolved by adding a photo where the periorbital area is clearly highlighted (see user manual pages: 7, 12).

11. You describe the treatment areas under your "Benefits" section. This seems inappropriate because it does not describe benefits. Please move this information to be near your indications for use statement where you describe what your device treats. You may want to place it in your instructions section so users will know what the allowed treatment areas are.

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ISRAEL
Tel: +972(4)9097440
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Section removed from Benefits and added to Indications (see user manual page 7) and to "Using Silk'n FX" chapter under subchapter "Choose your treatment areas carefully" (see user manual page 12).

12. In your section on treatment schedule, you have a statement, "according to the frequency of use". Please emphasize that a person must use the schedule you present.

    The sentence: "To achieve optimal results it is necessary to follow the recommended treatment course." Is added under "Follow the recommended Silk'n FX treatment course (See user manual page 13.

13. In your benefits section, you refer to the "recommended course of treatment". It is unclear what your "recommended treatment" is. The course of treatment you state on page 10 is not a "recommended treatment". Refer instead to the directed treatment plan you give on page 10 so lay persons will not be confused by your terms.

    Chapter's name changed to: "7. Follow the recommended Silk'n FX treatment course" (see user manual page 12).

14. On page 10, the treatment plan does not seem to fit under its heading, "Before Using Silk'n FX" because it is integral to the treatment you propose. Please revise your heading and instructions to integrate your treatment plan into your procedure so it is clearly part of the procedure.

    Name and subchapter structure of instructions chapter is revised according to the comment (see user manual pages 11, 12).

B4 [redacted]

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ISRAEL
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Fax: +972(4)9097471

- B4 [redacted]

See new package for added information.

15. B4 [redacted]

See above comment

- There were inclusion and exclusion criteria, but you did not say what they were.

See above comment

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Fax: +972(4)9097471

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17. B4 [redacted]

These bullets in the contraindication section were revised to be more strict and plain:
DO NOT USE SILK'N FX if the treated skin is not healthy and clear. If you have any skin condition including brown or black spots, birth marks, moles, warts, eczema, psoriasis, lesions, open wounds or active infections, such as cold sore on the area to be treated, do not use Silk'nFX.
See new user manual page 8

18. In your Risks section, you use terms too vague to be useful.

Examples are:

B4 [redacted]

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See new user manual

Please place your warning statements in your sections devoted to them. In your risks section, place the events and effects and their frequencies. For example, you say, "If irritation does not disappear within three days, please consult a physician or dermatologist." This statement belongs in a warning statement. Further, for this particular item, please tell the consumer to, for example, "not use the device again because you can injure your skin or have more serious damage, such as blisters, infections and scars."

Your risk section should cite all known risks with the device, such as those inherent in the contraindications, warnings, and precautions.

List all the known risks attending use in accord with labeled instructions.

List known risks attending ways people will obviously use the device outside the indications and instructions because they understand the labeling and choose to ignore it or they do not understand the labeling.

Please construct a 4-column table of risks.

B4

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Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

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Apolo building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

Sincerely yours,

Dr. Amir Waldman
VP regulatory affairs
Home Skinovations Ltd.

Silk'n
FX
ANTI-AGING
For men and women
DISCOVER YOUR TRUE BEAUTY!
Silk'n
FX
Silk'n FX device for the treatment
of Periorbital wrinkles
Clinical advanced HF energy to refresh the skin
in the comfort of your own home
DISCOVER YOUR TRUE BEAUTY!
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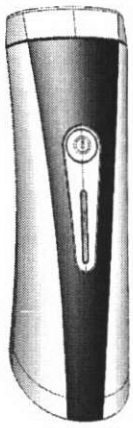
FX
ANTI-AGING
DISCOVER YOUR TRUE BEAUTY!
With Silk'n FX Light Based Treatment for
Periorbital Wrinkles
Clinically tested
Recommended by dermatologists
Safe and user friendly
IMPORTANT!
Read before purchasing!
What is Silk'nFX for?
Is Silk'n FX suitable for you?
What does Silk'n FX treatment course require?

Silk'n FX



Instructions for use

DO101950B

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Print date: June 2010

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Home Skinovations Ltd.
Tavor Building, Shaar Yokneam
POB 533
Yokneam 20692
ISRAEL

Website: **www.silkn.com**

e-mail: **info@silkn.com**

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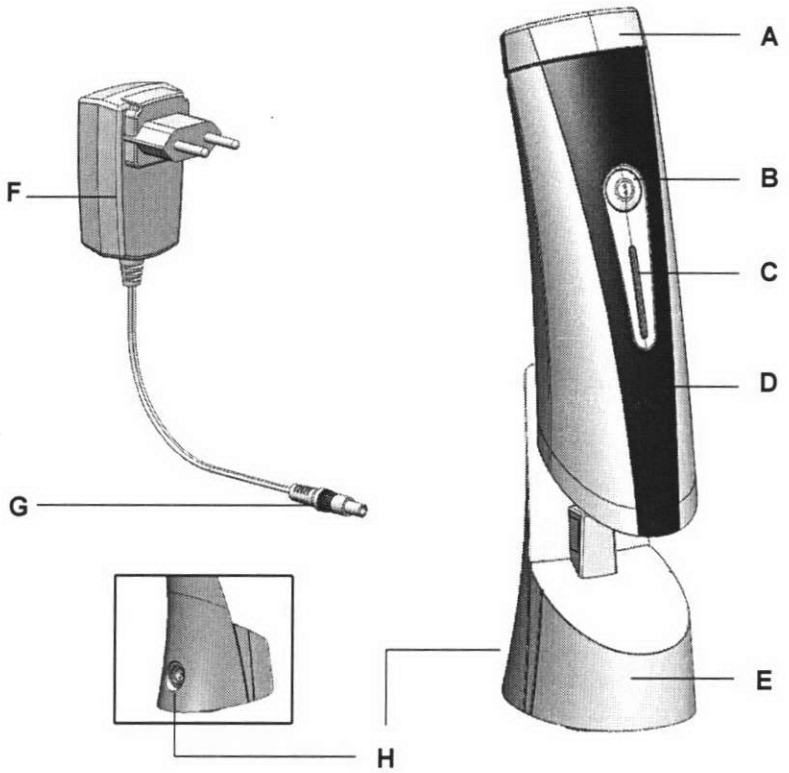
Silk'n FX device description

Your Silk'n FX device consists of a ***Base Unit*** an ***Applicator*** and an ***Adaptor.***

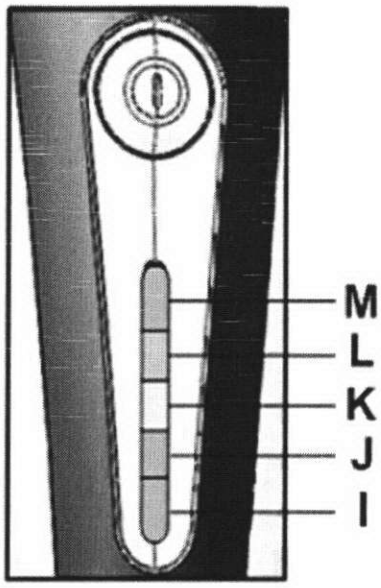
The Silk'n FX ***Applicator*** is a hand held unit used for treatment, as the ***Treatment surface*** at the *Applicator* tip is in contact with the skin. On the *Applicator* you can find the *Mode* ***switch*** and the ***Indicators Panel***.

The FX ***Base Unit*** is used to place the *applicator* while resting, and to charge the *applicator* batteries.

The ***Adaptor*** connects the ***Base Unit*** to the electrical outlet for battery recharging, using its ***Plug*** and the ***Base Unit socket.***



A	*Treatment surface*
B	*Mode Switch*
C	*Indicators Panel*
D	*Applicator*
E	*Base Unit*
F	*Adaptor*
G	*Plug*
H	*Base Unit socket*



J ***READY/TREATMENT*** - *INDICATOR LIGHT*

K ***SYSTEM ERROR*** - *INDICATOR LIGHT*

L ***BATTERY – CHARGING*** - *INDICATOR LIGHT*

M ***BATTERY – FULL*** - *INDICATOR LIGHT*

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(I)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to Red.

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(J)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to IR.

The orange ***BATTERY – CHARGING - INDICATOR LIGHT*** **(L)** illuminates while the *APPLICATOR* is placed in the *BASE & CHARGING UNIT* and charging.

The green ***BATTERY – FULL - INDICATOR LIGHT*** **(M)** illuminates when the batteries are fully charged.

The yellow ***SYSTEM ERROR - INDICATOR LIGHT*** **(K)** illuminates when a system error/malfunction occurs.

Package contents

Upon opening the Silk'n FX package, you will find the following parts:

- FX *BASE UNIT* and *APPLICATOR*
- Adaptor
- User's Manual

Silk'n FX - Indications For Use

Silk'n FX intended use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

As we grow older, the amount of collagen, the major supporting protein of the skin, diminishes and our skin becomes less flexible. In addition, our skin becomes drier and thinner, and as the body's natural regeneration process slows down, the skin slowly loses its ability to retain moisture and loses the "teenage" glow. The harmful rays in sunlight further damage the skin's supportive structure and prevent the creation of new collagen. This leads to the development of fine lines and wrinkles.

HF™ technology in Silk'n FX harnesses the body's natural processes to reduce the appearance of fine lines and wrinkles around the eye (periorbital wrinkles – crows feet).

If you have noticed development of fine lines and wrinkles around your eyes, Silk'n FX may help reducing them.

Silk'n FX facial treatment areas

Silk'n FX is designed to treat the periorbital wrinkles around the eyes.

Contraindications

- Do not use Silk'n FX except for its indications for use to treat periorbital wrinkles.

When to avoid using Silk'n FX?

Certain conditions may prevent the use of Silk'n FX temporarily. **DO NOT USE Silk'n FX** if any of the following conditions apply to you:

- **DO NOT USE SILK'N FX AGAIN and CONSULT YOUR PHYSICIAN OR DERMATOLOGIST** if after using Silk'nFX you experience skin redness or discomfort that lasts for over three days.
- **DO NOT USE SILK'N FX** if the treated skin is not healthy and clear. If you have any skin condition including brown or black spots, birth marks, moles, warts, eczema, psoriasis, lesions, open wounds or active infections, such as cold sore on the area to be treated, do not use Silk'nFX.
- **DO NOT USE SILK'N FX** If you have diabetes
- **DO NOT USE SILK'N FX** if you are currently or have recently been treated with Alpha-

Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.

- **DO NOT USE SILK'N FX** if you have been treated with Accutane® (isotretinoin) within the past 6 months.
- **DO NOT USE SILK'N FX** if you have been on a steroid regimen within the past 3 months.
- **DO NOT USE SILK'N FX** if you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using Silk'n FX.

Precautions and Warnings

- Keep Silk'n FX out of the reach of children.
- Keep Silk'n FX out of the reach of persons with reduced physical, sensory or mental capabilities.
- Do not use the Silkn FX unless you are between the ages of 35-57. The treatment of this device outside this age range has not been tested in trails.
- CONTACT your healthcare professional as soon as possible if you suspect that you have had an adverse reaction from use of the Silkn FX.
- DO NOT use the Silkn FX if you are pregnant. The safety of the treatment for pregnant women has NOT been tested in clinical trials.
- NEVER use the Silkn FX or the Wall Power Supply when bathing or standing in water.
- NEVER use the Silkn FX or the Wall Power Supply if you think they may have been immersed in water, may have become wet, or if you have spilt any liquids on them.
- NEVER remove any covers from the Silkn FX or the Wall Power Supply. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect reassembly could cause an electric shock when the Silkn FX is subsequently used.
- DO NOT try and force the plug of the Power Supply into an outlet. If the plug does not connect easily with the outlet there may be a mismatch.
- DO NOT attempt to operate the Silkn FX with any Wall Power Supply other than the one provided.
- DO NOT use the Silkn FX if it is damaged in any way.
- DO NOT use the Wall Power Supply if it is damaged in any way or if its cord or plug is damaged.

Note!

- ALWAYS clean the Silkn FX before each treatment. See the Care and Maintenance section for details on how to clean your Silkn FX.
- DO NOT treat the affected area for longer than the recommended time at each session. If you treat the affected area for longer than the recommended time the effectiveness of the treatments may be reduced.
- DO NOT treat the affected area more often than recommended. If you treat the affected area more often than recommended the effectiveness of the treatments may be reduced.
- NEVER cover the air vents in the Silkn FX they are provided for ventilation. Be aware of

objects, items of clothing or material that may accidentally block the air vents.

- ALWAYS keep the Silkn FX, its Wall Power Supply, and cord away from heated surfaces. High temperatures may damage the plastic cases or the internal pads.
- ALWAYS unplug the Wall Power Supply from the AC electrical outlet and refer to a authorized representatives if the Silkn FX does not work normally by following the operating instructions or if it exhibits a distinct change in performance.
- If the *ADAPTOR* is damaged, make sure it is replaced with an original part from Home Skinovations!
- The *ADAPTOR* contains a dedicated transformer. Never replace the *ADAPTOR* with another plug!

Risks - Possible Side Effects of using FX

1. Normal reaction of using Silk'nFX

Silk'n FX treatments are generally very well-tolerated, and reported as such by 96 out of 100 study subjects. Most users sense the moderate heat applied by the device during use, with no further discomfort.

Typically, when using Silk'n FX, you may sense:

- **Minor Skin Discomfort**

  Your skin may become slightly irritated after using Silk'n FX. This is a typical and transient phenomenon that is reported by 30 out of 100 users, and for 29 out of the 30 disappears within 30 minutes after the treatment. 24 hours after the treatment all skin irritations disappear.

- **Skin Redness**
  Your skin may become slightly red right after using FX.
  For 99 out of 100 users - skin color returns to normal within 2 hours after treatment, and for the rest, within 24 hours after treatment.

2. Risks of Silk'nFX when used according to instructions

When used according to the instructions, side effects and complications associated with use of Silk'n FX are rare (less than 1 out of 100). However every cosmetic procedure, including those designed for home use, involve some degree of risk. Therefore it is important that you understand and accept the risks and complications that can occur with Light Emitting Diodes for home use.

Risks and complications of **correct use** (use according to the directions in this user manual)

Harm	Likelihood of Harm
Redness of the skin lasting for over 24 hours	Less than 1/100
Minor skin discomfort lasting for over 24 hours	Less than 1/100

3. *Risks of Silk'nFX when used not according to instructions*

Risks and complications of **incorrect use** (use not according to the directions in this user manual)

Event	Likelihood of Event	Harm	Likelihood of Harm
Silk'n FX used for longer than recommended.	5/100	Skin irritation and redness	40/100
Silk'n FX used on skin areas outside the periorbital wrinkles	3/100	Skin irritation and redness	30/100
Silk'n FX used although previously caused skin redness or irritation	2/100	Skin irritation and redness	100/100
Silk'n FX used on unclear skin	1/100	Specific skin condition will become more severe	10/100
Silk'n FX used by persons with diabetes	1/100	Skin irritation and redness	40/100
Silk'n FX used by person treated with Alpha-Hydroxi Acids	1/100	Excessive skin redness	40/100
Silk'n FX used by person treated with Accutane® (isotretinoin) within the past 6 months.	1/100	Excessive skin redness	40/100
Silk'n FX used by persons who have been on a steroid regimen within the past 3 months.	1/100	Excessive skin redness	40/100
Silk'n FX used by persons who have a history of herpes outbreaks	1/100	Herpes outbreak	10/100
Silk'n FX used by children	1/100	Skin irritation and redness	30/100
Silk'n FX used by persons with reduced physical, sensory or mental capabilities	1/100	Skin irritation and redness	30/100
Failing to get medical advice after suffering from excessive redness of the skin following Silk'n FX treatment	1/100	Reaction gets worse	50/100
Silk'n FX used by pregnant women	Not tested	Unknown	Not tested
Silk'n FX used while bathing or standing in water	1/100000	Electrical shock	1/100
Silk'n FX used while wet	1/100000	Electrical shock	1/100
Silk'n FX or wall power supply opened or their covers removed	1/100000	Electrical shock	1/100
Silk'n FX used after forcing the plug of the Power Supply into an outlet	1/100000	Electrical shock	1/100
operating Silkn FX with Wall Power Supply other than the one provided.	1/100000	Electrical shock	1/100

Event	Likelihood of Event	Harm	Likelihood of Harm
Silk'n FX used although device, power supply cord or plug are damaged	1/100000	Electrical shock	1/100

The benefits of Silk'n FX

The outcome of using Silk'n FX according to the instructions will be the reduction of fine lines and wrinkles in the perorbital area.

Best results can be expected 3-7 weeks after completing the recommended Silk'n FX treatment course.

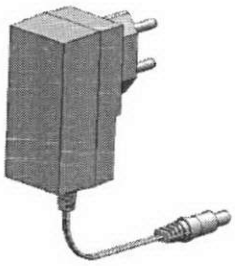
Using Silk'n FX

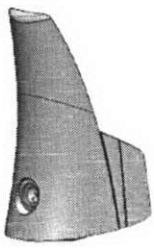
1. Silk'n FX Setup

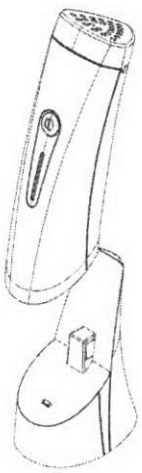
1. Remove Silk'n FX *BASE UNIT, APPLICATOR, ADAPTOR* and other components from box.
2. Before using the Silk'n FX for the first time, fully charge its batteries. This may take up to 6 hours.

2. Charge the Silk'n FX Battery

- Insert the *APPLICATOR* into its cradle in the FX *BASE UNIT*.
- Plug the *ADAPTOR PLUG* into the Base Unit socket.
- Plug the *ADAPTOR* into an electrical outlet. An orange *BATTERY – CHARGING - INDICATOR LIGHT* (L) will illuminate to indicate that your Silk'n FX is in the process of charging.







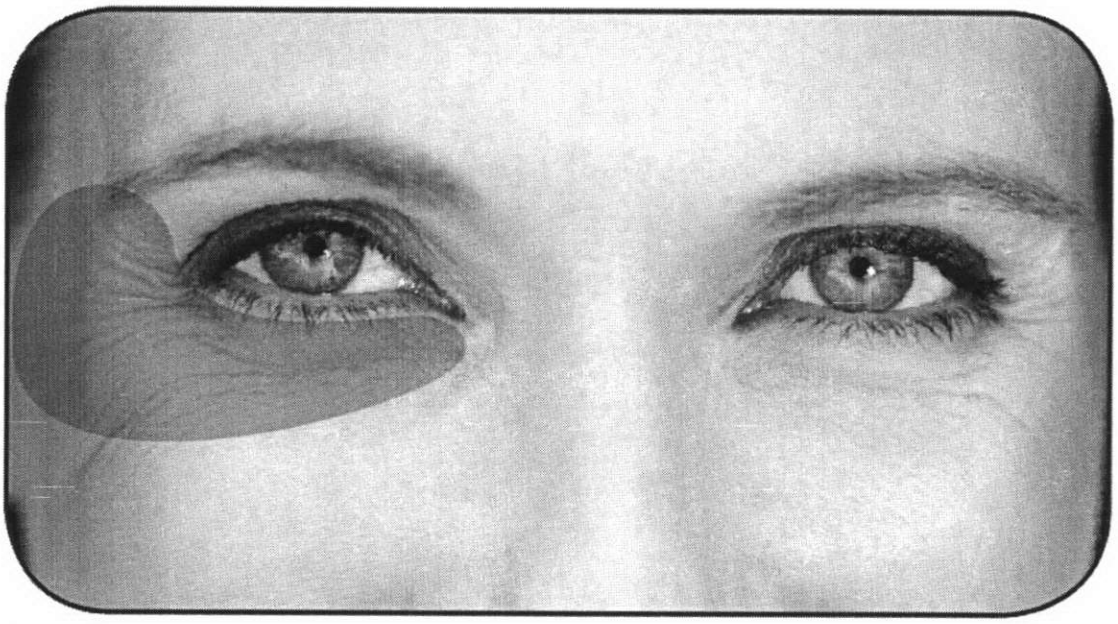
Caution! Never cover Silk'n FX and its adaptor while recharging!

Note! Silk'n FX can not be used while recharging

- When *BATTERY – CHARGING - INDICATOR LIGHT* (L) turns off and *BATTERY – FULL - INDICATOR LIGHT* (M) illuminates, **your Silk'n FX is fully charged and ready to start.**
  (Recharging will be needed when *BATTERY – CHARGING - INDICATOR LIGHT* (L) illuminates again.)

3. Choose your treatment areas carefully

Silk'n FX is designed to treat the periorbital wrinkles around the eyes.



Periorbital wrinkles

4. Follow the recommended Silk'n FX treatment course:

The efficiency of the results varies from person to person and according to the frequency of use. Some may see results sooner than others.

To achieve optimal results it is necessary to follow the recommended treatment course.

1	**Forearm test***	20 minutes **RED** Light
2	**Forearm test***	20 minutes **IR** Light
3	**Week 1, first day (Day 1)**	20 minutes **IR** Light on EACH AREA

4	**Two days later (Day 3)**	20 minutes **RED** Light on EACH AREA
5	**Week 2, first day (Day 8)**	20 minutes **IR** Light on EACH AREA
6	**Two days later (Day 10)**	20 minutes **RED** Light on EACH AREA
7	**Week 3, first day (Day 15)**	20 minutes **IR** Light on EACH AREA
8	**Two days later (Day 17)**	20 minutes **RED** Light on EACH AREA
9	**Week 4, first day (Day 22)**	20 minutes **IR** Light on EACH AREA
10	**Two days later (Day 24)**	20 minutes **RED** Light on EACH AREA

* Some people may be sensitive to light. If you are sensitive to light Silkn FX may not be suitable for you. To determine if you are sensitive to light, we recommend you carry out a skin test on your forearm. If no adverse reaction appears within 24 hours, continue with step 2.

5. Prepare your skin for treatment

Make sure your skin is **clean**, **dry** and **free** of any powder, gel or cream.

6. Prepare your Silk'n FX device for treatment

- Remove the charged Silk'n FX *APPLICATOR* from its cradle in the *BASE UNIT*.
- Turn Silk'n FX on selecting the desired light mode:
  - For **RED** Light treatment
    - Press the *MODE SWITCH*. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (I) will start blinking, and shortly afterwards will be lit steadily.
      Your Silk'n FX device is ready for **RED** Light treatment.
  - For **IR** Light treatment
    - Press the *MODE SWITCH* twice. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (J) will start blinking, and shortly afterwards will be lit steadily.
      Your FX is ready for **IR** Light treatment.

7. Perform the treatment

- Attach the *TREATMENT SURFACE* to your skin. The LED light will automatically activate.
  Note that the device will not activate without skin contact and will deactivate when removed from the skin.

- Perform the treatment for 20 minutes on each side.
- **Note:** A full 20 minutes treatment is necessary for optimal results.
- After 20 minutes the device is automatically shut off. To reactivate the device push the Mode switch.

What to Expect when Treating with Silk'n FX?

During a Silk'n FX session it is **normal** to experience and feel:

- **A Sensation of Warmth** – During the Silk'n FX session you may feel slight warmth. This is normal and should disappear up to an hour after the session.
- **Some Mild Red Color** – After each Silk'n FX session you may notice a slight reddening of the skin (mild erythema) over the treated area. This is normal and should fade within an hour or two.

Best results can be expected 3-7 weeks after completing the recommended course of treatment, as the light stimulates process that continue the improvement after the completion of the treatment.

8. End the Silk'n FX treatment

- When Silk'n FX session has been completed turn the device off by pressing the *MODE SWITCH*. All indicator lights will be turned off.
- Finally place the applicator in its Base Unit cradle to recharge the batteries (See Section: "Silk'n FX Battery Charging").

9. After the Silk'n FX treatment

- Following a Silk'n FX treatment it is recommended to apply a small (the size of a pea) amount of a moisturizing cream on the treated skin areas and to massage it gently in circular motions.
- After each session it is recommended that you clean your Silk'n FX device, especially the *APPLICATOR TIP* (See Section: "Cleaning Silk'n FX").
- Store Silk'n FX according to the instructions (See Section: "Storage").

Alternative procedures and treatments?

Contact your dermatologist for treatment of periorbital wrinkles.

Silk'n FX Treatment Troubleshooting

What can go wrong?

Please see section: Risks - Possible Side Effects of using FX

When to call a doctor?

In case you experience one or more of the detailed possible side effects, please contact your physician or dermatologist.

Clinical Studies

In clinical studies using similar products, 7 out of 10 subjects reported a visible reduction in fine lines and wrinkles, and 7 out of 10 reported an improvement in skin clarity.

Care and Manitenance

1. Protect your Silk'n FX

- Do not cover the ventilation slots during use.
- Remove any obstruction to air flow through the ventilation slots.
- Never shake or drop Silk'n FX or subject it to severe shocks.
- Silk'n FX is sensitive to environmental temperature during use.
  Do not expose the FX to environmental temperatures lower than 15°C / 59°F or higher than 35°C / 95°F during use.
- Silk'n FX cannot tolerate extreme change of environment temperature.
  When moved from a cold environment (under 10°C / 50°F) to a warm environment, avoid use for approximately 3 hours.
- Do not expose Silk'n FX to a lengthy direct sunlight or UV light.
- Silk'n FX is designed for occasional home use (as opposed to an exhaustive commercial or professional use). Avoid such exhaustive use.
- Avoid covering Silk'n FX and its adaptor during recharge.

2. Cleaning Silk'n FX

After each session, it is recommended to clean your Silk'n FX device, and especially its *TREATMENT SURFACE*.

- Turn Silk'n FX off by pressing the *MODE SWITCH*.
- Unplug Silk'n FX from the electrical outlet
- Allow cooling down of its *TREATMENT SURFACE*.

- The exterior of the Silkn FX unit may be cleaned by wiping it with a damp (not wet) cloth or isopropyl alcohol wipe. Please refrain from using any other cleaning products as these may damage the plastic parts.
- Never immerse Silk'n FX or any of its parts in water!
- Never clean the FX or any of its parts under the tap or in the dishwasher.

3. Silk'n FX Storage

- Clean Silk'n FX according to the instructions (See "Cleaning Silk'n FX")
- Store the clean device and all its parts in a dry clean place free of dust, at a temperature of between -10°C to 60°C / 14°F to 140°F

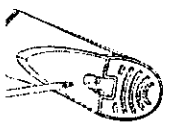
4. To protect the Environment

At the end of its life, do not discard Silk'n FX with the normal household waste. Hand it at an official recycling collection point.

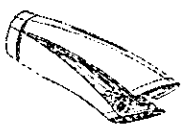
Always remove the batteries before discarding or handing at a recycling collection point (See section: "Removing the rechargeable batteries"). Dispose of the batteries at an official collection point for batteries. If you have trouble removing the batteries, you can take the device to a Home Skinovations service centre.

Removing the rechargeable batteries

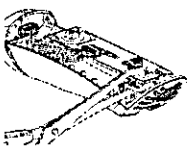
Remove the rechargeable batteries only if they are completely empty and cannot be recharged.



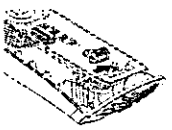
- Undo the screw at the bottom panel of the *APPLICATOR*.



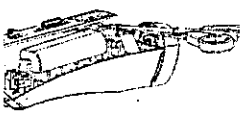
- Lift and remove the top panel of the *APPLICATOR*.



- Cut the tow wires that connect the electronics card to the lower panel of the *APPLICATOR*.



- Push the three snaps and pull out the electronics card.



- Cut the tow wires that connect the rechargeable batteries pack to the *APPLICATOR*.

5. Silk'n FX Troubleshooting

This chapter summarizes the most common problems you could encounter. If you are unable to solve the problem with the information below, contact your local Silk'n customer Service center for further support.

Problem	Possible cause	Solution
Silk'n FX does not work	The rechargeable batteries are empty	Charge the *APPLICATOR*
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
Silk'n FX suddenly switches off	The rechargeable batteries are empty	Charge the *APPLICATOR*
Device temperature rises during recharge	This is normal	No action is required
BATTERY – CHARGING - INDICATOR LIGHT (L) **does not turn on when connecting the *PLUG* into the *BASE UNIT SOCKET*.**	The *ADAPTOR* is not plugged in the electrical outlet	Insert the *PLUG* into the *BASE UNIT SOCKET*,
		Connect another appliance the wall socket to check if the electrical outlet is live.
		If the *APPLICATOR* still does not charge, Contact your local Silk'n customer Service center
	The *ADAPTOR* is not inserted properly into the electrical outlet and/or the *PLUG* is not inserted properly into the *BASE UNIT SOCKET*	Make sure the *ADAPTOR* is inserted properly into the electrical outlet and/or *PLUG* is inserted properly into the *BASE UNIT SOCKET*.
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
***APPLICATOR* temperature rises during use.**	This is normal	No action is required
READY/TREATMENT MODE - INDICATOR LIGHT (I) **does not illuminate when pressing the *MODE SWITCH***	The *APPLICATOR* needs to be reset	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *READY/TREATMENT MODE - INDICATOR LIGHT* (I) does not illuminate again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is lit.**	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *SYSTEM ERROR - INDICATOR LIGHT* (K) illuminates again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is blinking**	The rechargeable batteries are empty	Charge the *APPLICATOR*
The Green *BATTERY – CHARGING* and Orange *BATTERY – FULL - INDICATOR LIGHTS* are	Malfunction of the *ADAPTOR*	Disconnect the *ADAPTOR* from the electrical outlet, press the *MODE SWITCH* twice to switch the *APPLICATOR* on and off again. Connect the Adaptor to the wall socket, If the problem persists,

illuminated alternately		contact your local Silk'n customer Service center
	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If the problem persists, contact your local Silk'n customer Service center

User Assistance and Customer Service

1. For USA and Canada customers:

For more information about Silk'n™ products please enter www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact Silk'n™ Customer Service: **1-877-DO-SILKN / 1-877-367-4556**, contact@silkn.com

2. For customers in other countries:

For more information about Silk'n™ products please enter your local Silk'n™ website, www.silkn.eu or www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact your local Silk'n™ Customer Service or write to: info@silkn.com.

Warranty information

1. What does the Silk'n FX Warranty Cover?

Subject to the terms and conditions of this warranty, Home Skinovations Inc. warrants that it will repair or replace the FX device that accompanies this warranty (the "Device") to the extent that the Device exhibits material defects in materials or workmanship caused by Home Skinovations Inc.

2. Who Is Entitled To The Protections Of the Silk'n FX Warranty?

Only you, the original purchaser of the Device are entitled to the protections of this warranty. Home Skinovations Inc. may require original proof of purchase of the Device by having you provide your invoice or receipt from the purchase of the Device.

3. How Long Does The Coverage Last?

This warranty covers claims filed with Home Skinovations Inc. within one (1) year from the date of the original purchase of the Device. Claims filed after one (1) year from the date of purchase of the Device by you are not covered. Home Skinovations Inc. may require that you prove the date you purchased the Device by providing an invoice or receipt that specifically lists the date of purchase of the Device. Claims in respect of a repaired or replaced device must be filed with Home Skinovations Inc. within the later of (a) one (1) year from the date of purchase of the original Device by you or (b) ninety (90) days from the date that the Home Skinovations Inc.

service center ships the repaired or replaced Device back to you.

4. How Do You Get Warranty Service?

In order to obtain warranty service on the Device, go to the customer service section of www.silkn.com or call the then-current customer service telephone number (currently 877-367-4556) for assistance. You must obtain a Return Goods Authorization (RGA) number and an RGA form which will be sent to you before shipping the Device to Home Skinovations Inc. You must also comply with Home Skinovations Inc.'s instructions concerning shipment and the materials that must accompany the Device (such as a copy of the invoice that proves your status as the original purchaser and the date of purchase and the completed RGA form). It is suggested for your protection that you insure your shipment to Home Skinovations Inc. Damage during shipment to Home Skinovations Inc. is not covered by this warranty. It is also suggested that you ship the Device using a tracked method so that you can ensure that Home Skinovations Inc. has received the Device.

5. Shipping Charges

You are required to pay for packaging and shipping of the Device to the applicable Home Skinovations Inc. service center. Home Skinovations Inc. will pay for packaging and shipping of the Device back to you; provided that if upon receipt, inspection and testing of the Device by Home Skinovations Inc., Home Skinovations Inc. determines that the Device does not exhibit material defects in materials or workmanship, then you will be required to pay for return packaging and shipping back to you.

6. What Does the Silk'n FX Warranty Not Cover?

This warranty does not cover damage resulting from accident, misuse (including use not described in the user manual or instructions accompanying the Device), abuse, lack of reasonable care, the affixing of any attachment not provided with the device, loss of parts, use of unauthorized replacement parts or subjecting the device to any but the specified voltage.* This warranty is void if the Device is repaired by anyone other than an authorized Home Skinovations Inc. service center, and Home Skinovations Inc. will not have any liability for damage resulting from service performed by anyone other than an authorized Home Skinovations Inc. service center.

Travel with device

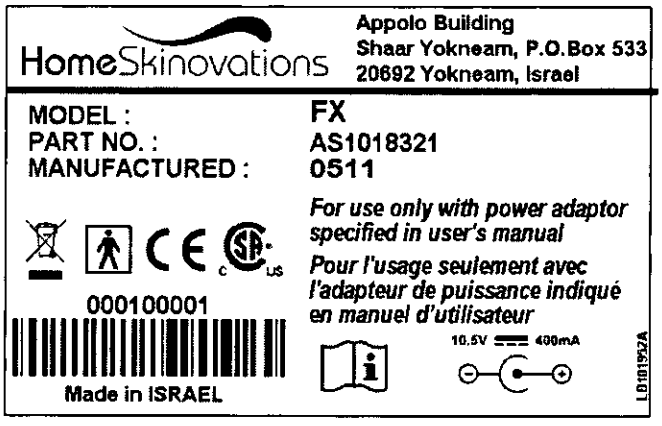
Silk'n FX is designed for your personal use wherever you are, at home or traveling.

- When fully charged, the device will provide continuous operation enough for a full treatment of the face.
- If you intend to use Silk'n FX more then once during your trip, be sure to carry all parts including applicator, charging base unit and cord with you.
- For recharge a 100V - 240V electrical outlet is required.

Specifications

Rated voltage (Adaptor)	100V - 240V
	Model: UE08WCP-105040SPA
Rated frequency (Adaptor)	50Hz – 60Hz
Rated currant (Adaptor)	400 mA
Applied part	Type BF
Protecting rating	IP20 (EN60529)
Storage condition	Temperature: -10°C to 60°C / 14°F to 140°F
	Relative humidity: 5% to 95%
Operating condition	Temperature: 15°C to 35°C / 59°F to 95°F
	Relative humidity: 10% to 80%
	Atmospheric pressure: 700 to 1060 hPa
Light source	Light Emitting Diodes
	Wavelengths peak emission wavelength: 633, 830nm
	Intensity power: 70,55mW/cm^2 ±10%
Lithium ion battery	2 x 3.7V, 750±50mAh
Max. charging time	180 minutes
Product life time	300 full battery charging cycle

Labeling



Degree of protection against electric shock: type BF applied part

WEEE - Waste Electrical and Electronic Equipment

CSA Mark

CE Mark

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

The symbol on the label affixed to this device means "Attention, consult accompanying documents".

Usability testing

Introduction

Usability test was carried out in order to verify that average user can decide what the device use for based on the package information and user manual, and properly use the device based on it latest version of labeling.

The usability study was carried out on users with different degree of periorbital winkles. Total of 100 users choose to participate in the usability study based on the latest package content that was presented at doctor office in Toronto Canada, and Irvine Medical Center, California, USA. Users decided, based on the package presented in the investigator's office, if they should participate in the study. Based on user's decision, the investigator re-evaluated the users that choose to participation in the usability study, and none of the patients were excluded by the investigator, all participants sign inform consent form.

After completing the informed consent form, Users read the user manual, and observed to see if they can properly use the device. Users took the device out of the box prepared it for use, charged it according to the instructions, perform a treatment session and finally clean and stored the device. The users were asked to fill a questionnaire regarding the device use and labeling.

Safety was evaluated by monitoring immediate reaction and adverse effects. There were no other adverse effects associated with the treatment.

Usability study

Method

The information, which is presented in this report, was obtained from clinical usability study that worked under the device labeling.

Study Sponsor:
Home Skinovations Ltd.
Apolo building
POB 533
Yokneam 20692

Study monitor:
Dr. Amir Waldman
Home Skinovations Ltd.
Apolo building
POB 533

ISRAEL

Yokneam 20692
ISRAEL

The centers that conducted the study:

Dr. Steve Mulholland	SpaMedica 66 Avenue Rd. Toronto Ontario, M5R 3N8 Canada
Dr. Malcolm Paul	Irvine Medical Center, California, USA

Treatment protocol

B4

B4, Testing Data

B4, Testing Data

B4, Testing Data

B4, Testing Data

B4, Testing Data

B4, Testing Data

B4, Testing Data

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 22, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301

Product: SILK'N FX

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K110301/S3

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

July 17, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
JUL 22 2011
Received

Re: Letter from July, 8 , 2011 K110301

Dear Mr. Bandukwala

Thank you for your letter from July, 8, 2011 in response to our Letter from June 23regarding the Silk'n FX (K110301).

Please find the requested information asked in your letter:

1. The package labeling provided in the manual is too small to read. Please provide a larger version of the package labeling.

   Since there is a lot of text on the labeling the font is small and hard to read the way it was send to you. Appendix 1 is enlargement of the text section.

2. In the table of contents of the user manual, there are two instances where the following statement is made "Error! Bookmark not defined". Please correct this error in the manual

   Table of content revised see Appendix 2 user manual page 3.

3. B4 [redacted] Please revise this phrase or remove it from the manual.

   The term removed from the manual see Appendix 2 user manual page 7.

1511

258

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

4. On page 12 of the instruction manual, in section 4. "Follow the recommended Silk' N FX treatment course:", the word "recommend" is used twice. Please remove the word recommend from the title of this section and in the instructions part below it. The treatment course is not a recommendation. The manual should state "To achieve optimal results it is necessary to follow the treatment course provided below". The title of the section should say "Silk' n FX Treatment Course".

   The term removed from the manual see Appendix 2 user manual page 12.

5. The user manual states that the device should not be used by subject who are below the age of 35. In the usability study, several of the subjects were below the age of 35. The exclusion criteria was set for persons under the age of 21. Using people below the age of 35 for the study is not consistent with the instructions provided in the manual. Subjects who were below the age of 35 should have read the manual and then stated they are not able to use this device according to the warning instruction on page 8. This difference in the exclusion criteria and the user manual is confusing, and the result makes it unclear if the subjects understood your user's manual. Please revise your exclusion criteria to be consistent with your user's manual and conduct another usability study. People under the age of 35 can be part of the self selection study, but these people should identify that the device is not intended for them

   The user manual state that the Silk'n FX should not be used outside of the group age 35-57 based on the previous usability study that tested this age group.
   All participant outside of this age group, in the new usability study raised this point with the investigator. Based on the exclusion criteria and consent form, that state that the age group for the study should be 21-60 the investigator decided to enroll them into the study.
   We believe that the age should not be restricted to the age group on the original usability study.
   The user manual was changed accordingly to reflect the new usability study age group 26-60. Appendix 2 page 8.

6. B4 [redacted]

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

B4 [redacted]

[redacted]

[redacted] B4 [redacted]

[redacted]

Sincerely yours,

Dr. Amir Waldman
VP regulatory affairs
Home Skinovations Ltd.

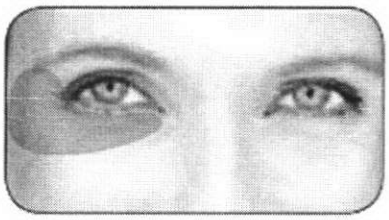
Appendix 1

Silk'n
FX
ANTI-AGING
For men and women
DISCOVER YOUR TRUE BEAUTY!
Silk'n
FX
Silk'n FX device for the treatment
of Periorbital wrinkles
Offering advanced HF energy to refresh the skin
in the comfort of your own home
HOME SIMULATION
NOT IN SALE
DISCOVER YOUR TRUE BEAUTY!
Silk'n
FX
Silk'n
FX
ANTI-AGING
DISCOVER YOUR TRUE BEAUTY!
With Silk'n FX Light Based Treatment for
Periorbital Wrinkles
Clinically tested
Recommended by dermatologists
Safe and user friendly
IMPORTANT!
Read before purchasing!
What is Silk'nFX for?
Is Silk'n FX suitable for you?
What does Silk'n FX treatment course require?

262

IMPORTANT!
Read before purchasing!

What is Silk'nFX for?



HF™ technology in Silk'n FX harnesses the body's natural processes to reduce the appearance of fine lines and wrinkles around the eye (periorbital wrinkles – crows feet).
If you are age 35-57 and have noticed development of fine lines and wrinkles around your eyes, Silk'n FX may help reducing them.
The outcome of using Silk'n FX according to the instructions will be the reduction of fine lines and wrinkles in the perorbital area.
Best results can be expected 3-7 weeks after completing the recommended Silk'n FX treatment course.

Is Silk'n FX suitable for you?

Silk'nFX is not suitable for everybody. Before purchasing, please read the following to determine weather it is suitable for you.

Silk'nFX will not be suitable for you:

- If your periorbital-wrinkles area is not healthy and clear or you suffer from any skin condition in this area.
- If you suffer from diabetes
- If you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.
- If you have been treated with Accutane® (isotretinoin) within the past 6 months.
- If you have been on a steroid regimen within the past 3 months.
- If you have a history of herpes outbreaks in the area of treatment.

Silk'n FX is a powerful electrical device and as such, it should be used with special attention to safety.
Please read the entire "Precautions and warnings" section of the user manual before using it for the first time!
When used according to the instructions, Silk'nFX may cause minor skin discomfort and skin redness after use.

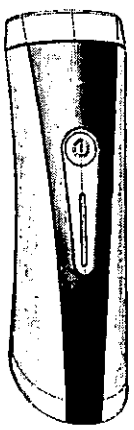
What does Silk'nFX treatment course require?

- A full Silk'nFX treatment course takes 24 days.
- It is necessary to perform a 40 minutes forearm test before using Silk'nFX for the first time.
- Silk'nFX Sessions should be scheduled for day 1, 3, 8, 10, 15, 17, 22 and 24
- Allow a total of 40 minutes per Silk'nFX session

For complete treatment course instructions please read the user manual.
Read the user manual for instructions regarding device set up, device operation, device cleaning and maintenance, device storage and troubleshooting.

Appendix 2

Silk'n FX



Instructions for use

DO101950B

HomeSkinovations

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Print date: June 2010

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Home Skinovations Ltd.
Tavor Building, Shaar Yokneam
POB 533
Yokneam 20692
ISRAEL

Website: **www.silkn.com**

e-mail: **info@silkn.com**

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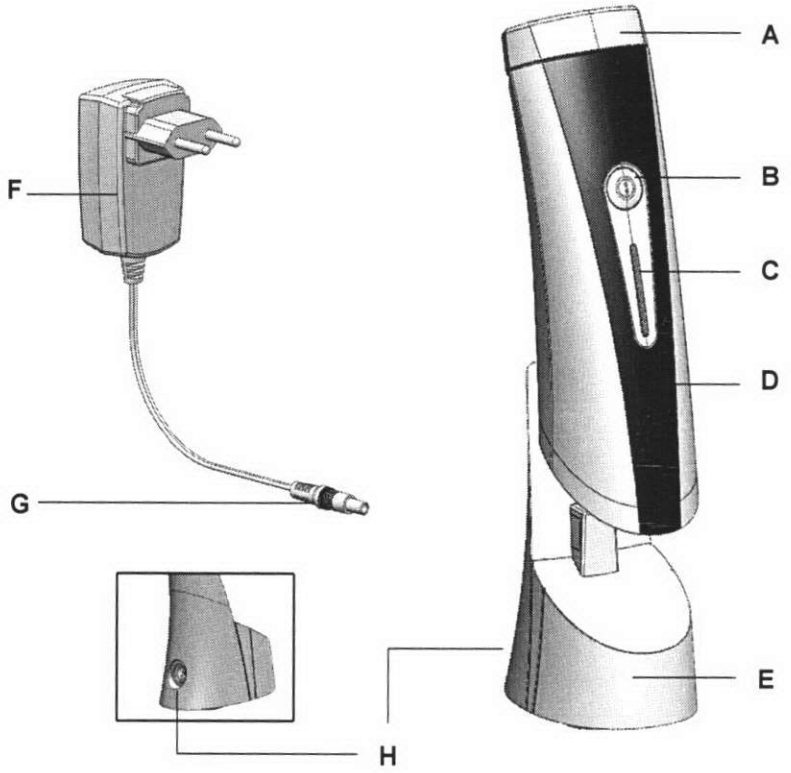
Silk'n FX device description

Your Silk'n FX device consists of a ***Base Unit*** an ***Applicator*** and an ***Adaptor.***

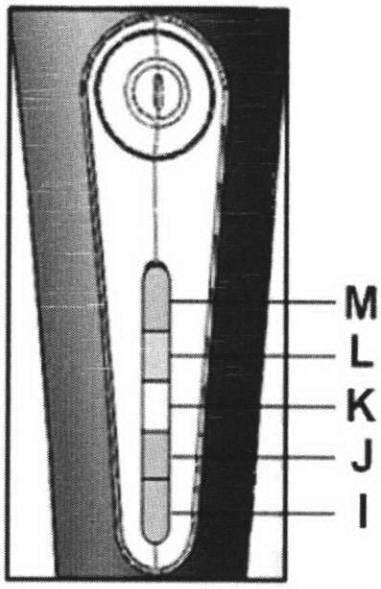
The Silk'n FX ***Applicator*** is a hand held unit used for treatment, as the ***Treatment surface*** at the *Applicator* tip is in contact with the skin. On the *Applicator* you can find the *Mode* ***switch*** and the ***Indicators Panel***.

The FX ***Base Unit*** is used to place the *APPLICATOR* while resting, and to charge the *APPLICATOR* batteries.

The ***Adaptor*** connects the ***Base Unit*** to the electrical outlet for battery recharging, using its ***Plug*** and the ***Base Unit socket.***



A	*Treatment surface*
B	*Mode Switch*
C	*Indicators Panel*
D	*Applicator*
E	*Base Unit*
F	*Adaptor*
G	*Plug*
H	*Base Unit socket*



J ***READY/TREATMENT*** - *INDICATOR LIGHT*

K ***SYSTEM ERROR*** - *INDICATOR LIGHT*

L ***BATTERY – CHARGING*** - *INDICATOR LIGHT*

M ***BATTERY – FULL*** - *INDICATOR LIGHT*

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(I)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to Red.

The green ***READY/TREATMENT - INDICATOR LIGHT*** **(J)** illuminates when pressing the *MODE SWITCH* while Silk'n FX is connected and the LED mode is set to IR.

The orange ***BATTERY – CHARGING - INDICATOR LIGHT*** **(L)** illuminates while the *APPLICATOR* is placed in the *BASE & CHARGING UNIT* and charging.

The green ***BATTERY – FULL - INDICATOR LIGHT*** **(M)** illuminates when the batteries are fully charged.

The yellow ***SYSTEM ERROR - INDICATOR LIGHT*** **(K)** illuminates when a system error/malfunction occurs.

Package contents

Upon opening the Silk'n FX package, you will find the following parts:

- FX *BASE UNIT* and *APPLICATOR*
- Adaptor
- User's Manual

Silk'n FX - Indications For Use

Silk'n FX intended use

Silkn FX is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

As we grow older, the amount of collagen, the major supporting protein of the skin, diminishes and our skin becomes less flexible. In addition, our skin becomes drier and thinner, and as the body's natural regeneration process slows down, the skin slowly loses its ability to retain moisture and loses the "teenage" glow. The harmful rays in sunlight further damage the skin's supportive structure and prevent the creation of new collagen. This leads to the development of fine lines and wrinkles.

HF™ technology in Silk'n FX harnesses the body's natural processes to reduce the appearance of fine lines and wrinkles around the eye (periorbital wrinkles – crows feet).

If you have noticed development of fine lines and wrinkles around your eyes, Silk'n FX may help reducing them.

Silk'n FX facial treatment areas

Silk'n FX is designed to treat the periorbital wrinkles around the eyes.

Contraindications

- **DO NOT USE SILK'N FX** except for its indications for use to treat periorbital wrinkles.
- **DO NOT USE SILK'N FX** if the treated skin is not healthy and clear. If you have any skin condition including brown or black spots, birth marks, moles, warts, eczema, psoriasis, lesions.
- **DO NOT USE SILK'N FX** If you have diabetes
- **DO NOT USE SILK'N FX** if you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.

When to avoid using Silk'n FX?

Certain conditions may prevent the use of Silk'n FX temporarily. **DO NOT USE Silk'n FX** if any of the following conditions apply to you:

- **DO NOT USE SILK'N FX AGAIN and CONSULT YOUR PHYSICIAN OR DERMATOLOGIST** if after using Silk'n FX you experience skin redness or discomfort that lasts for over three days.

Silk'n FX - Indications For Use

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- **DO NOT USE SILK'N FX AGAIN and CONSULT YOUR PHYSICIAN OR DERMATOLOGIST** if after using Silk'nFX you experience skin redness or discomfort that lasts for over three days.
- **DO NOT USE SILK'N FX** if the treated skin is not healthy and clear. If you have any skin condition including brown or black spots, birth marks, moles, warts, eczema, psoriasis, lesions, open wounds or active infections, such as cold sore on the area to be treated, do not use Silk'nFX.
- **DO NOT USE SILK'N FX** If you have diabetes
- **DO NOT USE SILK'N FX** if you are currently or have recently been treated with Alpha-

- **DO NOT USE SILK'N FX** if you have any skin condition including open wounds or active infections, such as cold sore.
- **DO NOT USE SILK'N FX** if you have been treated with Accutane® (isotretinoin) within the past 6 months.
- **DO NOT USE SILK'N FX** if you have been on a steroid regimen within the past 3 months.
- **DO NOT USE SILK'N FX** if you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using Silk'n FX.

Precautions and Warnings

- Keep Silk'n FX out of the reach of children.
- Keep Silk'n FX out of the reach of persons with reduced physical, sensory or mental capabilities.
- Do not use the Silkn FX unless you are between the ages of 26-60. The treatment of this device outside this age range has not been tested in trails.
- CONTACT your healthcare professional as soon as possible if you suspect that you have had an adverse reaction from use of the Silkn FX.
- DO NOT use the Silkn FX if you are pregnant. The safety of the treatment for pregnant women has NOT been tested in clinical trials.
- NEVER use the Silkn FX or the Wall Power Supply when bathing or standing in water.
- NEVER use the Silkn FX or the Wall Power Supply if you think they may have been immersed in water, may have become wet, or if you have spilt any liquids on them.
- NEVER remove any covers from the Silkn FX or the Wall Power Supply. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect reassembly could cause an electric shock when the Silkn FX is subsequently used.
- DO NOT try and force the plug of the Power Supply into an outlet. If the plug does not connect easily with the outlet there may be a mismatch.
- DO NOT attempt to operate the Silkn FX with any Wall Power Supply other than the one provided.
- DO NOT use the Silkn FX if it is damaged in any way.
- DO NOT use the Wall Power Supply if it is damaged in any way or if its cord or plug is damaged.
-

Note!

- ALWAYS clean the Silkn FX before each treatment. See the Care and Maintenance section for details on how to clean your Silkn FX.
- DO NOT treat the affected area for longer than the recommended time at each session. If you treat the affected area for longer than the recommended time the effectiveness of the treatments may be reduced.
- DO NOT treat the affected area more often than recommended. If you treat the affected area more often than recommended the effectiveness of the treatments may be reduced.
- NEVER cover the air vents in the Silkn FX they are provided for ventilation. Be aware of

Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.

- **DO NOT USE SILK'N FX** if you have been treated with Accutane® (isotretinoin) within the past 6 months.
- **DO NOT USE SILK'N FX** if you have been on a steroid regimen within the past 3 months.
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- DO NOT treat the affected area more often than recommended. If you treat the affected area more often than recommended the effectiveness of the treatments may be reduced.
- NEVER cover the air vents in the Silkn FX they are provided for ventilation. Be aware of

objects, items of clothing or material that may accidentally block the air vents.

- ALWAYS keep the Silkn FX, its Wall Power Supply, and cord away from heated surfaces. High temperatures may damage the plastic cases or the internal pads.
- ALWAYS unplug the Wall Power Supply from the AC electrical outlet and refer to a authorized representatives if the Silkn FX does not work normally by following the operating instructions or if it exhibits a distinct change in performance.
- If the *ADAPTOR* is damaged, make sure it is replaced with an original part from Home Skinovations!
- The *ADAPTOR* contains a dedicated transformer. Never replace the *ADAPTOR* with another plug!

Risks - Possible Side Effects of using FX

1. Normal reaction of using Silk'nFX

Silk'n FX treatments are generally very well-tolerated, and reported as such by 96 out of 100 study subjects. Most users sense the moderate heat applied by the device during use, with no further discomfort.

Typically, when using Silk'n FX, you may sense:

- **Minor Skin Discomfort**

  Your skin may become slightly irritated after using Silk'n FX. This is a typical and transient phenomenon that is reported by 30 out of 100 users, and for 29 out of the 30 disappears within 30 minutes after the treatment. 24 hours after the treatment all skin irritations disappear.

- **Skin Redness**
  Your skin may become slightly red right after using FX.
  For 99 out of 100 users - skin color returns to normal within 2 hours after treatment, and for the rest, within 24 hours after treatment.

2. Risks of Silk'nFX when used according to instructions

When used according to the instructions, side effects and complications associated with use of Silk'n FX are rare (less than 1 out of 100). However every cosmetic procedure, including those designed for home use, involve some degree of risk. Therefore it is important that you understand and accept the risks and complications that can occur with Light Emitting Diodes for home use.

Risks and complications of **correct use** (use according to the directions in this user manual)

Harm	Likelihood of Harm
Redness of the skin lasting for over 24 hours	Less than 1/100
Minor skin discomfort lasting for over 24 hours	Less than 1/100

3. Risks of Silk'nFX when used not according to instructions

Risks and complications of **incorrect use** (use not according to the directions in this user manual)

Event	Likelihood of Event	Harm	Likelihood of Harm
Silk'n FX used for longer than recommended.	5/100	Skin irritation and redness	40/100
Silk'n FX used on skin areas outside the periorbital wrinkles	3/100	Skin irritation and redness	30/100
Silk'n FX used although previously caused skin redness or irritation	2/100	Skin irritation and redness	100/100
Silk'n FX used on unclear skin	1/100	Specific skin condition will become more severe	10/100
Silk'n FX used by persons with diabetes	1/100	Skin irritation and redness	40/100
Silk'n FX used by person treated with Alpha-Hydroxi Acids	1/100	Excessive skin redness	40/100
Silk'n FX used by person treated with Accutane® (isotretinoin) within the past 6 months.	1/100	Excessive skin redness	40/100
Silk'n FX used by persons who have been on a steroid regimen within the past 3 months.	1/100	Excessive skin redness	40/100
Silk'n FX used by persons who have a history of herpes outbreaks	1/100	Herpes outbreak	10/100
Silk'n FX used by children	1/100	Skin irritation and redness	30/100
Silk'n FX used by persons with reduced physical, sensory or mental capabilities	1/100	Skin irritation and redness	30/100
Failing to get medical advice after suffering from excessive redness of the skin following Silk'n FX treatment	1/100	Reaction gets worse	50/100
Silk'n FX used by pregnant women	Not tested	Unknown	Not tested
Silk'n FX used while bathing or standing in water	1/100000	Electrical shock	1/100
Silk'n FX used while wet	1/100000	Electrical shock	1/100
Silk'n FX or wall power supply opened or their covers removed	1/100000	Electrical shock	1/100
Silk'n FX used after forcing the plug of the Power Supply into an outlet	1/100000	Electrical shock	1/100
operating Silkn FX with Wall Power Supply other than the one provided.	1/100000	Electrical shock	1/100

Event	Likelihood of Event	Harm	Likelihood of Harm
Silk'n FX used although device, power supply cord or plug are damaged	1/100000	Electrical shock	1/100

The benefits of Silk'n FX

The outcome of using Silk'n FX according to the instructions will be the reduction of fine lines and wrinkles in the perorbital area.

Best results can be expected 3-7 weeks after completing the recommended Silk'n FX treatment course.

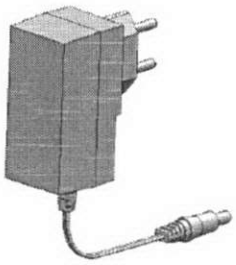
Using Silk'n FX

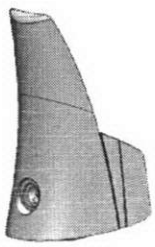
1. Silk'n FX Setup

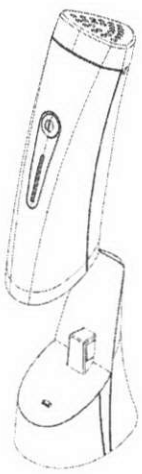
1. Remove Silk'n FX *BASE UNIT, APPLICATOR, ADAPTOR* and other components from box.
2. Before using the Silk'n FX for the first time, fully charge its batteries. This may take up to 6 hours.

2. Charge the Silk'n FX Battery

- Insert the *APPLICATOR* into its cradle in the FX *BASE UNIT*.
- Plug the *ADAPTOR PLUG* into the Base Unit socket.
- Plug the *ADAPTOR* into an electrical outlet. An orange *BATTERY – CHARGING - INDICATOR LIGHT* (L) will illuminate to indicate that your Silk'n FX is in the process of charging.







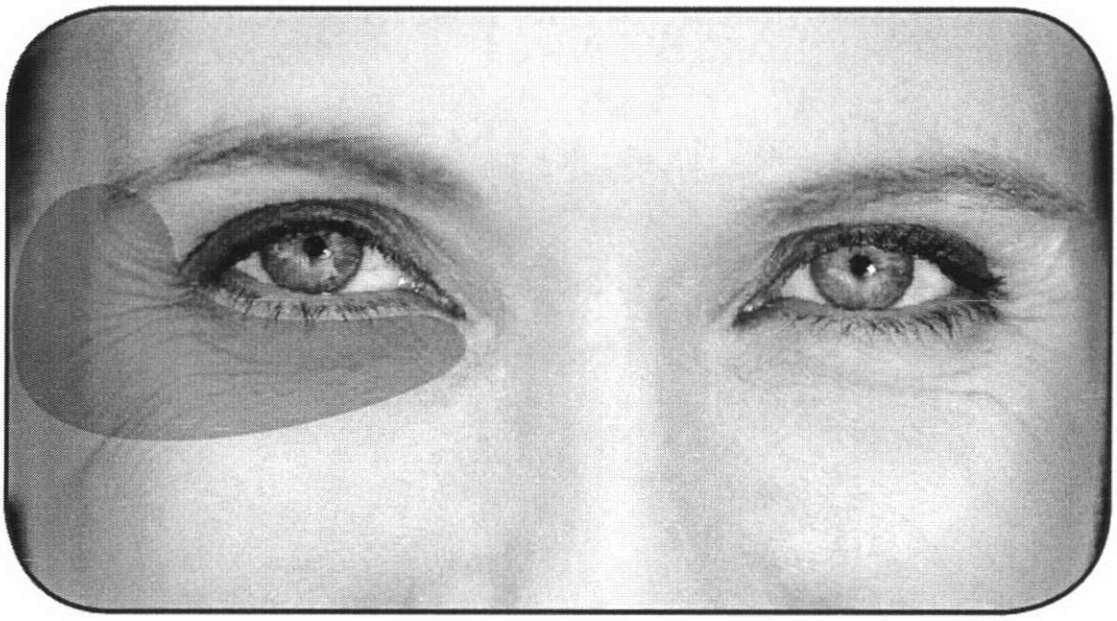
Caution! Never cover Silk'n FX and its adaptor while recharging!

Note! Silk'n FX can not be used while recharging

- When *BATTERY – CHARGING - INDICATOR LIGHT* (L) turns off and *BATTERY – FULL - INDICATOR LIGHT* (M) illuminates, **your Silk'n FX is fully charged and ready to start.**
  (Recharging will be needed when *BATTERY – CHARGING - INDICATOR LIGHT* (L) illuminates again.)

3. Choose your treatment areas carefully

Silk'n FX is designed to treat the periorbital wrinkles around the eyes.



Periorbital wrinkles

4. Silk'n FX treatment course:

The efficiency of the results varies from person to person and according to the frequency of use. Some may see results sooner than others.

To achieve optimal results it is necessary to follow the treatment course.

1	**Forearm test***	20 minutes **RED** Light
2	**Forearm test***	20 minutes **IR** Light
3	**Week 1, first day (Day 1)**	20 minutes **IR** Light on EACH AREA

4	**Two days later (Day 3)**	20 minutes **RED** Light on EACH AREA
5	**Week 2, first day (Day 8)**	20 minutes **IR** Light on EACH AREA
6	**Two days later (Day 10)**	20 minutes **RED** Light on EACH AREA
7	**Week 3, first day (Day 15)**	20 minutes **IR** Light on EACH AREA
8	**Two days later (Day 17)**	20 minutes **RED** Light on EACH AREA
9	**Week 4, first day (Day 22)**	20 minutes **IR** Light on EACH AREA
10	**Two days later (Day 24)**	20 minutes **RED** Light on EACH AREA

* Some people may be sensitive to light. If you are sensitive to light Silkn FX may not be suitable for you. To determine if you are sensitive to light, we recommend you carry out a skin test on your forearm. If no adverse reaction appears within 24 hours, continue with step 2.

5. Prepare your skin for treatment

Make sure your skin is **clean**, **dry** and **free** of any powder, gel or cream.

6. Prepare your Silk'n FX device for treatment

- Remove the charged Silk'n FX *APPLICATOR* from its cradle in the *BASE UNIT*.
- Turn Silk'n FX on selecting the desired light mode:
  - For **RED** Light treatment
    - Press the *MODE SWITCH*. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (I) will start blinking, and shortly afterwards will be lit steadily.
      Your Silk'n FX device is ready for **RED** Light treatment.
  - For **IR** Light treatment
    - Press the *MODE SWITCH* twice. The green *READY/TREATMENT MODE 1 - INDICATOR LIGHT* (J) will start blinking, and shortly afterwards will be lit steadily.
      Your FX is ready for **IR** Light treatment.

7. Perform the treatment

- Attach the *TREATMENT SURFACE* to your skin. The LED light will automatically activate.
  Note that the device will not activate without skin contact and will deactivate when removed from the skin.

- Perform the treatment for 20 minutes on each side.
- **Note:** A full 20 minutes treatment is necessary for optimal results.
- After 20 minutes the device is automatically shut off. To reactivate the device push the Mode switch.

What to Expect when Treating with Silk'n FX?

During a Silk'n FX session it is **normal** to experience and feel:

- **A Sensation of Warmth** – During the Silk'n FX session you may feel slight warmth. This is normal and should disappear up to an hour after the session.
- **Some Mild Red Color** – After each Silk'n FX session you may notice a slight reddening of the skin (mild erythema) over the treated area. This is normal and should fade within an hour or two.

Best results can be expected 3-7 weeks after completing the recommended course of treatment, as the light stimulates process that continue the improvement after the completion of the treatment.

8. End the Silk'n FX treatment

- When Silk'n FX session has been completed turn the device off by pressing the *MODE SWITCH*. All indicator lights will be turned off.
- Finally place the applicator in its Base Unit cradle to recharge the batteries (See Section: "Silk'n FX Battery Charging").

9. After the Silk'n FX treatment

- Following a Silk'n FX treatment it is recommended to apply a small (the size of a pea) amount of a moisturizing cream on the treated skin areas and to massage it gently in circular motions.
- After each session it is recommended that you clean your Silk'n FX device, especially the *APPLICATOR TIP* (See Section: "Cleaning Silk'n FX").
- Store Silk'n FX according to the instructions (See Section: "Storage").

Alternative procedures and treatments?

Contact your dermatologist for treatment of periorbital wrinkles.

Silk'n FX Treatment Troubleshooting

What can go wrong?

Please see section: Risks - Possible Side Effects of using FX

When to call a doctor?

In case you experience one or more of the detailed possible side effects, please contact your physician or dermatologist.

Clinical Studies

In clinical studies using similar products, 7 out of 10 subjects reported a visible reduction in fine lines and wrinkles, and 7 out of 10 reported an improvement in skin clarity.

Care and Manitenance

1. Protect your Silk'n FX

- Do not cover the ventilation slots during use.
- Remove any obstruction to air flow through the ventilation slots.
- Never shake or drop Silk'n FX or subject it to severe shocks.
- Silk'n FX is sensitive to environmental temperature during use.
  Do not expose the FX to environmental temperatures lower than 15°C / 59°F or higher than 35°C / 95°F during use.
- Silk'n FX cannot tolerate extreme change of environment temperature.
  When moved from a cold environment (under 10°C / 50°F) to a warm environment, avoid use for approximately 3 hours.
- Do not expose Silk'n FX to a lengthy direct sunlight or UV light.
- Silk'n FX is designed for occasional home use (as opposed to an exhaustive commercial or professional use). Avoid such exhaustive use.
- Avoid covering Silk'n FX and its adaptor during recharge.

2. Cleaning Silk'n FX

After each session, it is recommended to clean your Silk'n FX device, and especially its *TREATMENT SURFACE.*

- Turn Silk'n FX off by pressing the *MODE SWITCH.*
- Unplug Silk'n FX from the electrical outlet
- Allow cooling down of its *TREATMENT SURFACE.*

- The exterior of the Silkn FX unit may be cleaned by wiping it with a damp (not wet) cloth or isopropyl alcohol wipe. Please refrain from using any other cleaning products as these may damage the plastic parts.
- Never immerse Silk'n FX or any of its parts in water!
- Never clean the FX or any of its parts under the tap or in the dishwasher.

3. Silk'n FX Storage

- Clean Silk'n FX according to the instructions (See "Cleaning Silk'n FX")
- Store the clean device and all its parts in a dry clean place free of dust, at a temperature of between -10°C to 60°C / 14°F to 140°F

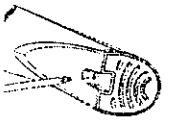
4. To protect the Environment

At the end of its life, do not discard Silk'n FX with the normal household waste. Hand it at an official recycling collection point.

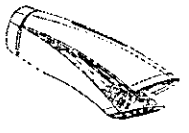
Always remove the batteries before discarding or handing at a recycling collection point (See section: "Removing the rechargeable batteries"). Dispose of the batteries at an official collection point for batteries. If you have trouble removing the batteries, you can take the device to a Home Skinovations service centre.

Removing the rechargeable batteries

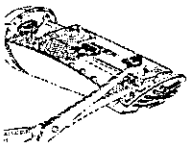
Remove the rechargeable batteries only if they are completely empty and cannot be recharged.



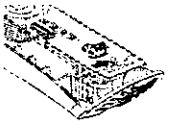
- Undo the screw at the bottom panel of the *APPLICATOR*.



- Lift and remove the top panel of the *APPLICATOR*.



- Cut the tow wires that connect the electronics card to the lower panel of the *APPLICATOR*.



- Push the three snaps and pull out the electronics card.

- Cut the tow wires that connect the rechargeable batteries pack to the *APPLICATOR*.

5. Silk'n FX Troubleshooting

This chapter summarizes the most common problems you could encounter. If you are unable to solve the problem with the information below, contact your local Silk'n customer Service center for further support.

Problem	Possible cause	Solution
Silk'n FX does not work	The rechargeable batteries are empty	Charge the *APPLICATOR*
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
Silk'n FX suddenly switches off	The rechargeable batteries are empty	Charge the *APPLICATOR*
Device temperature rises during recharge	This is normal	No action is required
BATTERY – CHARGING - INDICATOR LIGHT (L) **does not turn on when connecting the *PLUG* into the *BASE UNIT SOCKET*.**	The *ADAPTOR* is not plugged in the electrical outlet	Insert the *PLUG* into the *BASE UNIT SOCKET*,
		Connect another appliance the wall socket to check if the electrical outlet is live.
		If the *APPLICATOR* still does not charge, Contact your local Silk'n customer Service center
	The *ADAPTOR* is not inserted properly into the electrical outlet and/or the *PLUG* is not inserted properly into the *BASE UNIT SOCKET*	Make sure the *ADAPTOR* is inserted properly into the electrical outlet and/or *PLUG* is inserted properly into the *BASE UNIT SOCKET*.
	The *APPLICATOR* is broken	Contact your local Silk'n customer Service center
***APPLICATOR* temperature rises during use.**	This is normal	No action is required
READY/TREATMENT MODE - INDICATOR LIGHT (I) **does not illuminate when pressing the *MODE SWITCH***	The *APPLICATOR* needs to be reset	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *READY/TREATMENT MODE - INDICATOR LIGHT* (I) does not illuminate again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is lit.**	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If *SYSTEM ERROR - INDICATOR LIGHT* (K) illuminates again, contact your local Silk'n customer Service center
The Yellow *SYSTEM ERROR - INDICATOR LIGHT* (K) **is blinking**	The rechargeable batteries are empty	Charge the *APPLICATOR*
The Green *BATTERY – CHARGING* and Orange *BATTERY – FULL - INDICATOR LIGHTS* are	Malfunction of the *ADAPTOR*	Disconnect the *ADAPTOR* from the electrical outlet, press the *MODE SWITCH* twice to switch the *APPLICATOR* on and off again. Connect the Adaptor to the wall socket, If the problem persists,

illuminated alternately		contact your local Silk'n customer Service center
	Malfunction of the *APPLICATOR*	Press the *MODE SWITCH* twice to switch the Applicator off and on again. If the problem persists, contact your local Silk'n customer Service center

User Assistance and Customer Service

1. For USA and Canada customers:

For more information about Silk'n™ products please enter www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact Silk'n™ Customer Service: **1-877-DO-SILKN / 1-877-367-4556**, contact@silkn.com

2. For customers in other countries:

For more information about Silk'n™ products please enter your local Silk'n™ website, www.silkn.eu or www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact your local Silk'n™ Customer Service or write to: info@silkn.com.

Warranty information

1. What does the Silk'n FX Warranty Cover?

Subject to the terms and conditions of this warranty, Home Skinovations Inc. warrants that it will repair or replace the FX device that accompanies this warranty (the "Device") to the extent that the Device exhibits material defects in materials or workmanship caused by Home Skinovations Inc.

2. Who Is Entitled To The Protections Of the Silk'n FX Warranty?

Only you, the original purchaser of the Device are entitled to the protections of this warranty. Home Skinovations Inc. may require original proof of purchase of the Device by having you provide your invoice or receipt from the purchase of the Device.

3. How Long Does The Coverage Last?

This warranty covers claims filed with Home Skinovations Inc. within one (1) year from the date of the original purchase of the Device. Claims filed after one (1) year from the date of purchase of the Device by you are not covered. Home Skinovations Inc. may require that you prove the date you purchased the Device by providing an invoice or receipt that specifically lists the date of purchase of the Device. Claims in respect of a repaired or replaced device must be filed with Home Skinovations Inc. within the later of (a) one (1) year from the date of purchase of the original Device by you or (b) ninety (90) days from the date that the Home Skinovations Inc.

service center ships the repaired or replaced Device back to you.

4. How Do You Get Warranty Service?

In order to obtain warranty service on the Device, go to the customer service section of www.silkn.com or call the then-current customer service telephone number (currently 877-367-4556) for assistance. You must obtain a Return Goods Authorization (RGA) number and an RGA form which will be sent to you before shipping the Device to Home Skinovations Inc. You must also comply with Home Skinovations Inc.'s instructions concerning shipment and the materials that must accompany the Device (such as a copy of the invoice that proves your status as the original purchaser and the date of purchase and the completed RGA form). It is suggested for your protection that you insure your shipment to Home Skinovations Inc. Damage during shipment to Home Skinovations Inc. is not covered by this warranty. It is also suggested that you ship the Device using a tracked method so that you can ensure that Home Skinovations Inc. has received the Device.

5. Shipping Charges

You are required to pay for packaging and shipping of the Device to the applicable Home Skinovations Inc. service center. Home Skinovations Inc. will pay for packaging and shipping of the Device back to you; provided that if upon receipt, inspection and testing of the Device by Home Skinovations Inc., Home Skinovations Inc. determines that the Device does not exhibit material defects in materials or workmanship, then you will be required to pay for return packaging and shipping back to you.

6. What Does the Silk'n FX Warranty Not Cover?

This warranty does not cover damage resulting from accident, misuse (including use not described in the user manual or instructions accompanying the Device), abuse, lack of reasonable care, the affixing of any attachment not provided with the device, loss of parts, use of unauthorized replacement parts or subjecting the device to any but the specified voltage.* This warranty is void if the Device is repaired by anyone other than an authorized Home Skinovations Inc. service center, and Home Skinovations Inc. will not have any liability for damage resulting from service performed by anyone other than an authorized Home Skinovations Inc. service center.

Travel with device

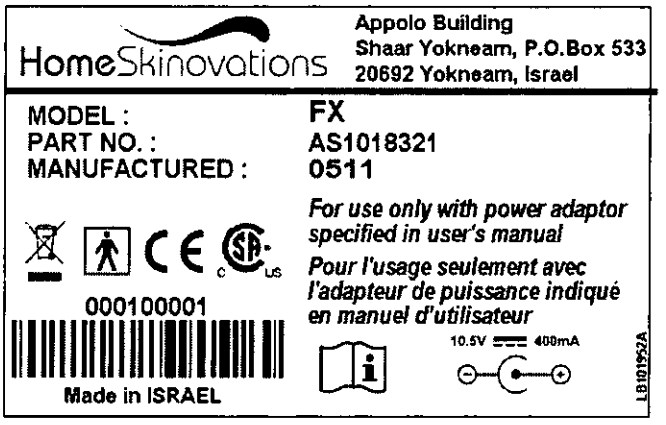
Silk'n FX is designed for your personal use wherever you are, at home or traveling.

- When fully charged, the device will provide continuous operation enough for a full treatment of the face.
- If you intend to use Silk'n FX more then once during your trip, be sure to carry all parts including applicator, charging base unit and cord with you.
- For recharge a 100V - 240V electrical outlet is required.

Specifications

Rated voltage (Adaptor)	100V - 240V
	Model: UE08WCP-105040SPA
Rated frequency (Adaptor)	50Hz – 60Hz
Rated currant (Adaptor)	400 mA
Applied part	Type BF
Protecting rating	IP20 (EN60529)
Storage condition	Temperature: -10°C to 60°C / 14°F to 140°F
	Relative humidity: 5% to 95%
Operating condition	Temperature: 15°C to 35°C / 59°F to 95°F
	Relative humidity: 10% to 80%
	Atmospheric pressure: 700 to 1060 hPa
Light source	Light Emitting Diodes
	Wavelengths peak emission wavelength: 633, 830nm
	Intensity power: 70,55mW/cm^2 ±10%
Lithium ion battery	2 x 3.7V, 750±50mAh
Max. charging time	180 minutes
Product life time	300 full battery charging cycle

Labeling



Degree of protection against electric shock: type BF applied part

WEEE - Waste Electrical and Electronic Equipment

CSA Mark

CE Mark

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

The symbol on the label affixed to this device means "Attention, consult accompanying documents".

Appendix 3

Patient ID	Education data

B4, B6

[redacted]

B4, B6

[redacted]

B4, B6

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 17, 2011

HOME SKINOVATIONS LTD.
TAVOR BULD. POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN PH. D.

510k Number: K110301

Product: SILK'N FX

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

22

K110301 / S4

HomeSkinovations

Tavor building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

August 14, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
AUG 17 2011
Received
K3

Re: Letter from August, 4 , 2011 K110301

Dear Mr. Bandukwala

Thank you for your letter from July, 8, 2011. Regarding the Silk'n FX (K110301).

B4 [redacted]

Sincerely yours,

Dr. Amir Waldman
VP regulatory affairs
Home Skinovations Ltd.

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CONTENTS OF FDA SOFTWARE SUBMISSION

Chapter 6 – Software

B4 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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[redacted]

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B4, Software Development

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B4, Software Development

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B4, Software Development

B4, Software Development

B4, Software Development

Section C - SwRS

HomeSkinovations

Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n Fx

Software Requirements Specification

Doc. P/N: DO102050D

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Ronen Ben Yosef	System Eng.	Jan 2011	
Checked by	Suhair Francis-Najjar	V&V & QA Manager	Jan 2011	S. Francis
Approved by	Benzi Levi	VP R&D	Jan 2011	

HomeSkinovations

Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	All	First Version	Ben Zion Levi	04 March 2010
B	All	Revised	Ben Zion Levi	Oct. 2010
C	All	Revised	Ben Zion Levi	Nov 2010
D	All	Revised	Ben Zion Levi	Jan 2011

B4, Software Req Specs

B4, Software Req Specs

B4, Software Req Specs

B4, Software Req Specs

B4, Software Req Specs

B4, Software Req Specs

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n Fx

Software Design Description

Doc. P/N: DO102377D

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Ronen Ben Yosef	System Eng.	Jan 2011	
Checked by	Suhair Francis-Najjar	V&V & QA Manager	Jan 2011	S. Francis
Approved by	Benzi Levi	VP R&D	Jan 2011	

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Yokneam 20692, ISRAEL
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Fax: +972(4)9097471

Revisions

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A	All	First version	Ben Zion Levi	March, 2010
B	All	Revised	Ben Zion Levi	Oct 2010
C	All	MMI change, Battery voltage change	Ben Zion Levi	16 Dec 2010
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1 Introduction

1.1 Purpose

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This document is used to describe co existence functionality, the behavior of the modes according to the software requirements specifications and detail of the software code.

1.2 Scope

This document applies to the design of the Silk'n Fx software.

This document is intended for the User, Managers, Developers and Testers of the Silk'n Fx software.

1.3 Synonyms, Acronyms, Thesaurus, Definitions

SwRS	Software Requirements Specification
V&V	Verification and Validation
MMI	Man Machine Interface
CPU	Central Processing Unit
I/O	Input/ Output
LED	Light Emitting Diode
C	C programming language
PS	Power Supply
RAM	Random Access Memory
GPIO	General Purpose Input – Output
HW	HardWare

1.4 References

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1.5 Design Conventions

Software design is based on a the IEEE standard 1016-1987

1.5.1 Design entity definition

The design entity is presented from the functional point of view.
The entity is based on modules consisting on procedures and/or functions and/or state machines containing data, and ISR functions.

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Software will support only one mode and this is user mode for normal operation to be used in production as well. The software will not support production mode.

2.1 Silk'n Fx system HW

The Silk'n Fx system HW is constructed from 3 parts

- Wall mount transformer
- Cradle
- Hand Piece

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2.2 *Firmware features*

This chapter is designed to give the software – hardware and software – software interfaces; this section shows those connections as part of the software and hardware features.

2.2.1 Communications

The communications of the Silk'n Fx are optional and can be used for debug. Un used for normal operation.

2.2.2 Proximity sensing

The proximity sensing capability of the Silk'n Fx system is based on the Capacitive Proximity sensing MCU's built-in features, with a small software portion. The proximity does not require calibration. Proximity sensing is described in this section. Using a HW timer (MCU) applying fixed time base and read count of the proximity sense cycles. A simple threshold level based on percent of maximal count will be used to define contact. The proximity interface is shown in the diagram bellow.

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[redacted]

Figure 2: Proximity sensing

2.2.3 Fan control

The Fan control interface is shown is the diagram below.
The fan shall be activated when temperature is above requested temperature, and stopped as long as the temperature is bellow requested temperature. A fan test is executed upon power on

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[redacted]

Figure 3: Fan control

2.2.4 Fan sense

The fan sense interface is shown in the diagram below.
The fan sense signal shall be used to check for fan fault. Ex. if the fan is stuck not connected etc.

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While fan is on expected voltage in the MCU I/O is in the range of 0.12 volts. A normal operation window is to range from 180mV to 60mV.
When fan is off, expected voltage in the MCU I/O is under 0.04 volts.
The monitoring parameters are retrieved from an analog to digital converter with output range from 0 to 5V. The converter has defined for 8 bits resolution, so a digital value of 255 corresponds to 5V.

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[redacted]

Figure 4: Fan sense

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Figure 7: Treatment light control

2.2.8 Indicators

The indicators (only SW controlled ones) interface is shown in the following diagram.

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[redacted]

Figure 8: Indicators control

The indicators are used to enable a visual feedback to the user regarding the device current status.

State	Description	On indicator	Error indicator	Remarks
Power off	System is powered off	Off	Off	
Fault (Self Test)	Self test (checksum)	Off	On	Turn system off, after a short time

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	failed			
On: Battery voltage OK	Battery voltage below 8.5V and above 6.8V	On	Off	Note 1
On: Battery voltage low	Battery voltage below 6.8V and above 5.5V	Blink (2Hz)	Off	Note2
Off: Batter voltage too low	Battery voltage under 5.5V	Off	Off	Note3
Fault condition	System is in error mode	Off	On	Note 4
Fan test	Fan test during power up	Blink	Off	
Lamp test	After Fan test	On	On	Note 5

Table 1: Indicator lights

Note 1: While the battery voltage is between 8.5V and 6.8V the On indicator is on
Note 2: While the battery voltage is between 6.8V and 5.5V the on indicator is blinking
Note 3: While the battery voltage is under 5.5V, software will shut down the system
Note 4: Any one or more of the following:

[redacted]

2.2.9 Key on/off

The on/off key is sensed via 2 I/O pins, enabling the MCU to detect up to 3 different modes, current application will enable only 1 state (On state). The key logic interface is shown in the diagram bellow.

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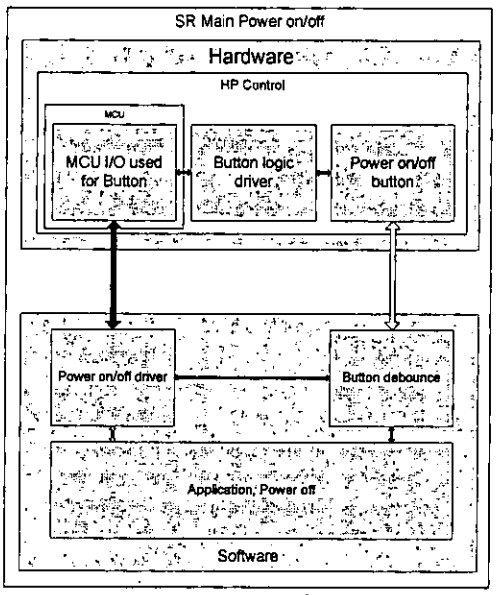

Figure 9: Power on/off key

2.2.10 Power off control

The power off control is used by the software to turn off the power to the device, upon user press the On/Off while on, during timeout after error or standby. The power off diagram is shown below.

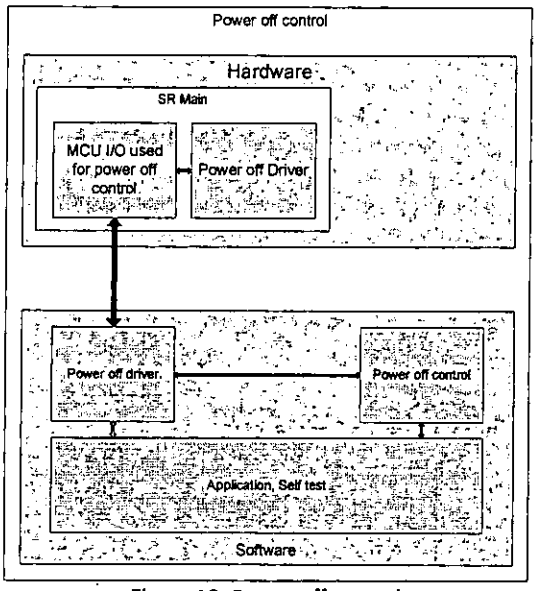

Figure 10: Power off control

2.2.11 Battery voltage sense

The battery voltage is monitored continuously by the software. The battery voltage monitoring is shown in the diagram bellow.

The monitoring parameters are retrieved from an analog to digital converter with output range from 0 to 5V. The converter has defined for 8 bits resolution, so a digital value of 255 corresponds to 5V.

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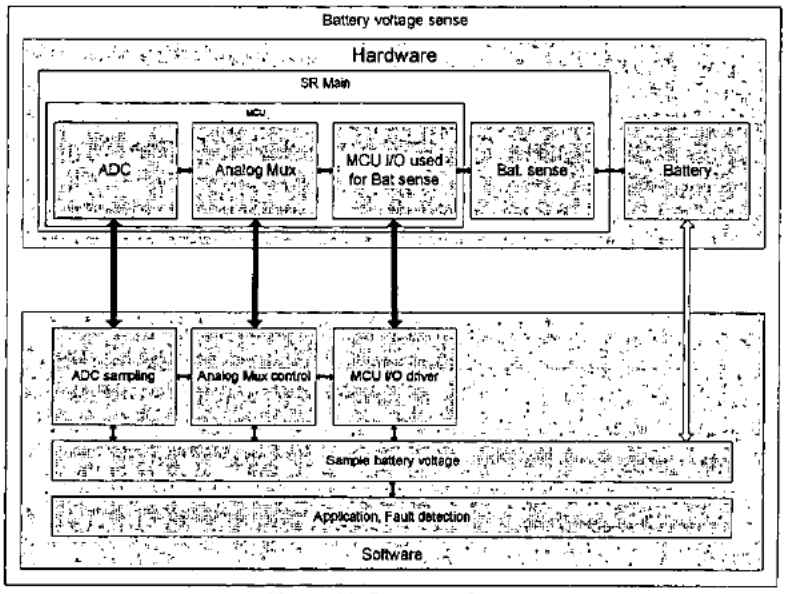

Figure 11: Battery voltage

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Figure 12: Battery temperature

The monitoring parameters are retrieved from an analog to digital converter with output range from 0 to 5V. The converter has defined for 8 bits resolution, so a digital value of 255 corresponds to 5V.

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3 Design Overview

The Silk'n Fx software is designed to control the Silk'n Fx device.

3.1 Software structure – modules

The Silk'n Fx software is distributed on several modules, this section describes each module and the functions it contains.

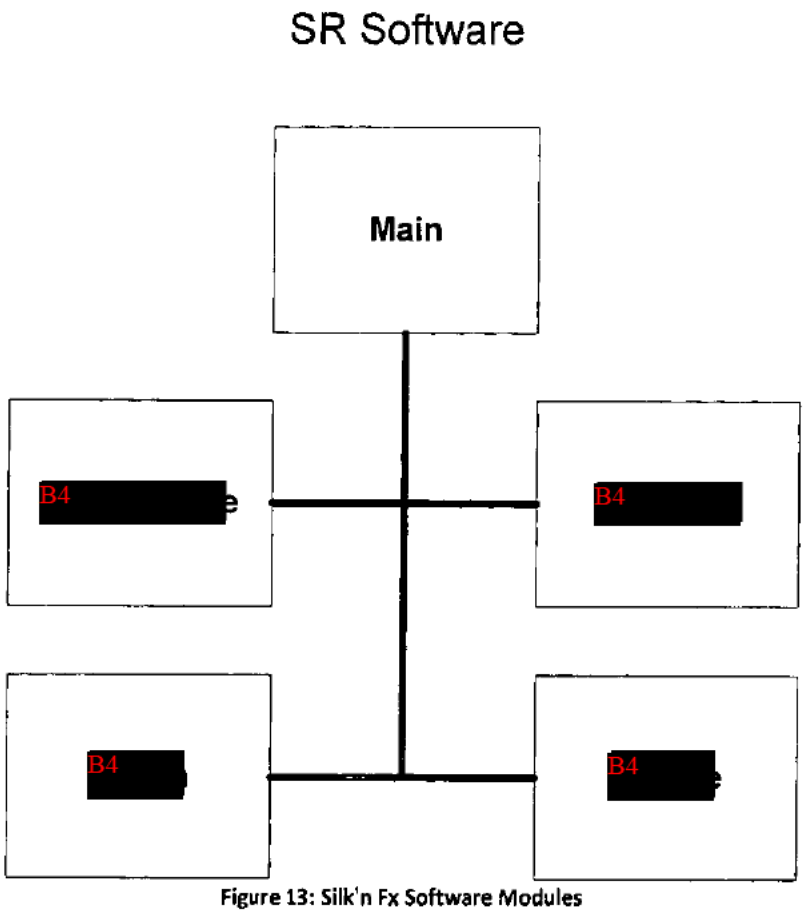

Figure 13: Silk'n Fx Software Modules

3.1.1 Main module

The main module is used to handle the initialization section, and the main loop. It also contains the Main state machine.

#	Function name	Description	SM section	Remarks
	ISR	Timer 1 intr. Used for proximity sensing Timer 2 intr. GP timer		
	FlashLED	Used to start indicator blinking		
	UnFlashLED	Used to stop indicator blinking		
	TurnOffLED	Used to turn indicator on		

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#	Function name	Description	SM section	Remarks
	TurnOnLED	Used to turn indicator on		
	Init	Used for CPU I/O and internal registers initialization		
	CheckBatNTC	Used to check battery temperature		
	CalcCheckSum	Used to check software code integrity		
	CheckFan	Check fan current consumption		
	Main	Used for executing CalcCheckSum, init function and every module's init function, than execute the main loop calling each module's task function		

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3.1.3 Proximity module

#	Function name	Description	SM section	Remarks
	CapInit	Used to initialize the MCUs internal registers for capacitive (proximity) sensing		

3.1.4 Sample module

The sample module is used to hold ADC related functions

#	Function name	Description	SM section	Remarks
	Sample	Sample requested analog input via the MCUs built-in ADC		

3.1.5 Comm. module

The comm. module is used to hold serial communication (UART) functions.

#	Function name	Description	SM section	Remarks
	ComInit	Used to initialize the communication related MCUs internal registers		
	Send_byte	Used to send a single byte via the MCU's UART		

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3.2 *Silk'n Fx SW structure – process*

The Silk'n Fx software is built as a main loop executing different tasks and processes. Those process executing in parallel to each other and described in this section.

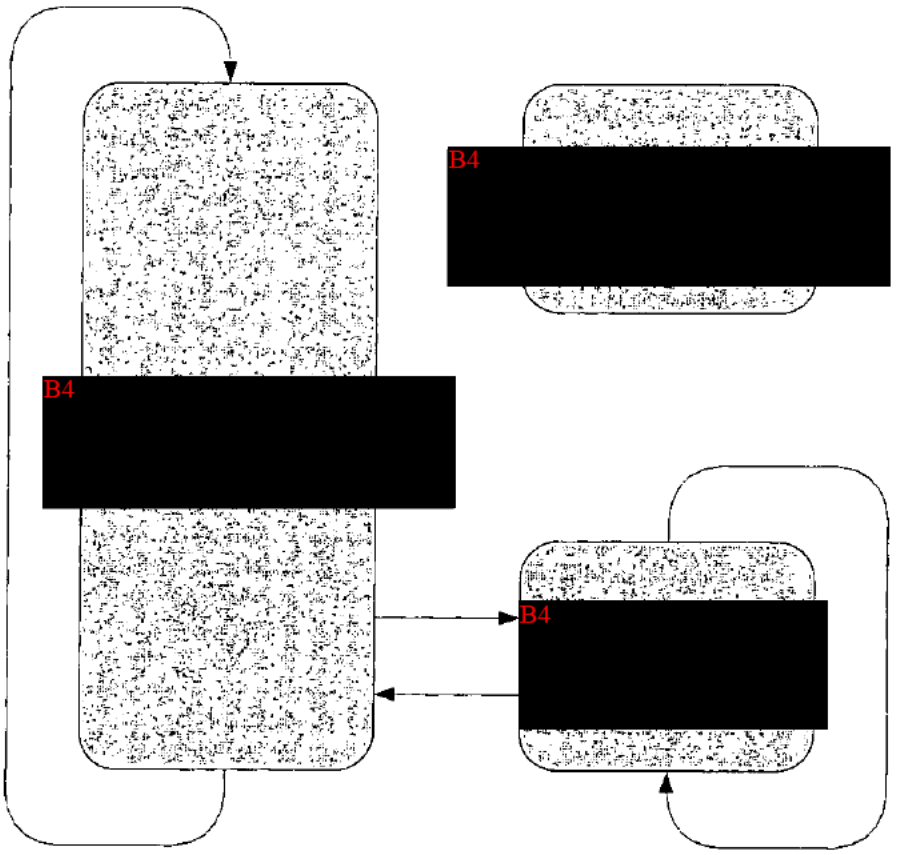

Figure 14: Silk'n Fx SW - processes

3.2.1 Main loop

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3.3.1 Main state machine

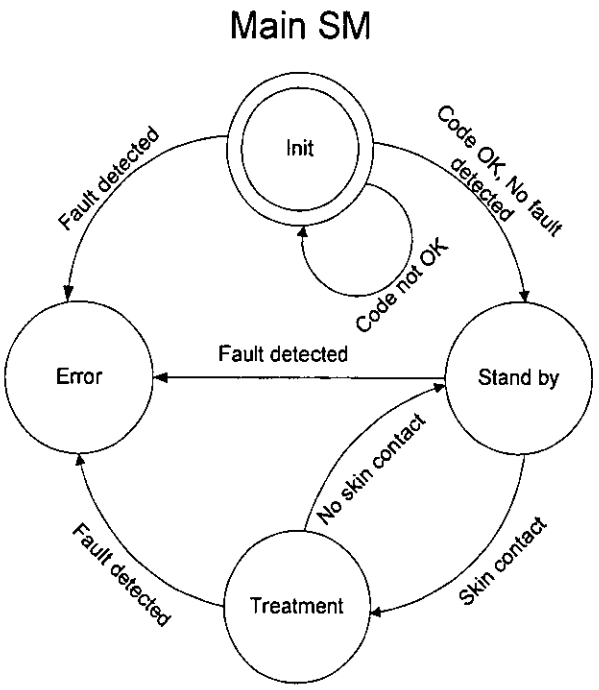

Figure 16: Main SM

State	Prev. state	Description	Exit condition	Next state	Remarks
Init	None	Power On Reset due to power up or WD	Code OK, Fault detected	Error	Part of init, Note3
			Code OK, No fault	Stand by	
Stand by	Init	Used to handle the device in a standby temperature	Fault detected	Error	Note2
			Prox. Sense	Treatment	
Treatment	Stand by	Used to handle the device in treatment temperature and light	Fault detected	Error	
			No Prox. Sense	Standby	
Error	None	Used to hold system during error	None		Note1

Table 2: Main state machine states

Note1: System will turn off after 60 seconds in error
Note2: System will turn off after 60 seconds when idle
Note3: System will turn off after 60 seconds after code check failed

3.4 *Theory of Operation*

The initialization sequence is as follow:

The microcontroller takes control after reset.
All variables and hardware pins are initialized
Interrupts are enabled.
The system shuts down by itself after an error (a period of time after it occurred).

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4 Design Rationale

The software rationale is to take advantage of the Microchip PIC family simplicity and to control directly the hardware.

4.1 Resets and Initialization

4.1.1 Power-On Reset

The microcontroller takes control of the operation immediately after reset.

4.1.2 Watch-Dog

A WD reset occurs if the software fails to clear the WD timeout counter with-in 1 second. Software will return to normal operation after WD reset event.

4.1.3 Complete initialization sequence

- Turn On indicator on
- B4 [redacted]
- Check battery voltage, if too low enter error state
- Execute main function

4.2 Main loop

The main loop is used to execute the following

- Check Fan operation
- Check battery voltage
- Check battery temperature
- Check temperature
- Check skin contact
- Execute the temperature task

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5 Safety

5.1 Code corruption

Code self check, using check sum will be executed when software is initialized during power up or watch dog event. Failed code will stop any further execution, turn error indicator on, and after 60 seconds turn power off

5.2 Watch dog

Watch dog, a MCU built in will be used to supervise normal software operation. Up on WD event the device will reset self check and resume normal operation.

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5.5 Fan

Fan operation will be checked during init, will be turned on for 4 seconds, then check if it is operating ok. If failed system will enter error state and after 60 seconds will turn off.

During normal operation the fan will be sensed while off and on to ensure proper operation of the fan. If failed system will enter error state and after 60 seconds will turn off.

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6 Appendix A: Build Environment

Fx Application's Software:

The application's software is built in MPLAB V8.43 or later development environment by writing applications in C and/or C++ language. The compiler used is HI-TECH version V9.70 standard mode.

The application software shall be debugged with the Microchip ICD-2 or ICD-3 in system debugger.

The application's software shall be stored in the microcontroller internal flash memory by programming it by using the microchip standard programmers.

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2.1 Silk'n Fx system HW

The Silk'n Fx system HW is constructed from 3 parts

- Wall mount transformer
- Cradle
- Hand Piece

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[redacted]

2.1.1 Wall mount transformer

The wall mount transformer is an off the shelf transformer used to supply the 10V required to the Silk'n Fx.

2.1.2 Cradle

The cradle is use only as a connector and place holder for the Hand Piece

2.1.3 Hand Piece

The HP (Hand Piece) is constructed from the following blocks:

- Silkn Fx Main – this is an electronic card controlling the device activities
- Batteries – Used to store and supply the device electrical power
- Fan – used for better control over temperature stabilization
- TIP – used to hold the temperature stabilizer, treatment light and proximity antenna

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2.1.3.1 Silkn Fx Main

The Silkn Fx Main HW includes the following blocks:

- MCU – Used to control and host the device software.
- Power On/Off – used to power on/off the device and select the operation mode (input)
- LED indicators – used for user interface (output)
- Fan control – used to control and monitor the fan. As part of temperature stabilization
- Temperature stabilizer – used to control the temperature stabilizer
- Proximity sensor – used to sense when skin contact occurs
- Power On/Off – this block is used to turn device power on or off
- LED – used for user interface
- Batteries charger – used to charger the batteries

B4 [redacted]

2.1.3.3 Batteries

- Batteries – used to hold electrical power for the device operation
- Sensor temperature – used to monitor batteries temperature

2.2 *Firmware features*

This chapter is designed to give the software – hardware and software – software interfaces; this section shows those connections as part of the software and hardware features.

2.2.1 Communications

The communications of the Silk'n Fx are optional and can be used for debug. Un used for normal operation.

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[redacted]

Figure 2: Proximity sensing

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[redacted]

Figure 3: Fan control

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The fan sense interface is shown in the diagram below.
The fan sense signal shall be used to check for fan fault. Ex. if the fan is stuck not connected etc.

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While fan is on expected voltage in the MCU I/O is in the range of 0.12 volts. A normal operation window is to range from 180mV to 60mV.
When fan is off, expected voltage in the MCU I/O is under 0.04 volts.
The monitoring parameters are retrieved from an analog to digital converter with output range from 0 to 5V. The converter has defined for 8 bits resolution, so a digital value of 255 corresponds to 5V.

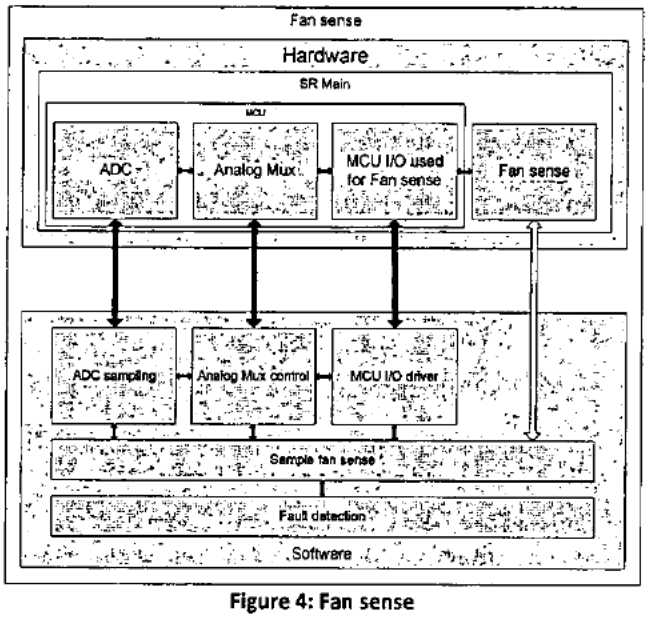

Figure 4: Fan sense

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Figure 5: Temperature sense

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2.2.8 Indicators

The indicators (only SW controlled ones) interface is shown in the following diagram.

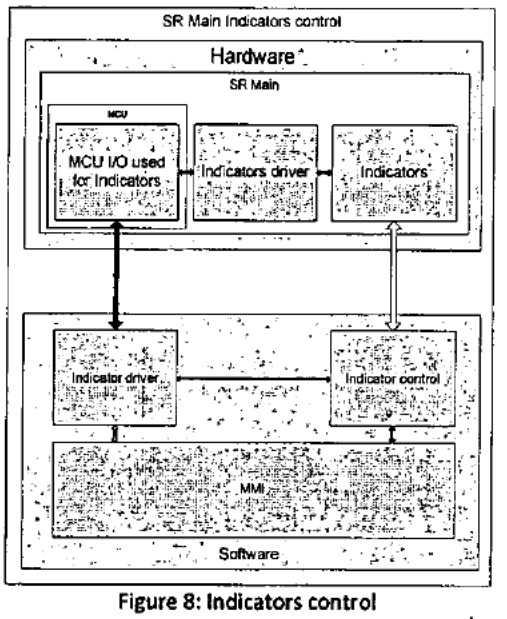

Figure 8: Indicators control

The indicators are used to enable a visual feedback to the user regarding the device current status.

State	Description	On indicator	Error indicator	Remarks
Power off	System is powered off	Off	Off	
Fault (Self Test)	Self test (checksum)	Off	On	Turn system off, after a short time

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	failed			
On: Battery voltage OK	Battery voltage below 8.5V and above 6.8V	On	Off	Note 1
On: Battery voltage low	Battery voltage below 6.8V and above 5.5V	Blink (2Hz)	Off	Note2
Off: Batter voltage too low	Battery voltage under 5.5V	Off	Off	Note3
Fault condition	System is in error mode	Off	On	Note 4
Fan test	Fan test during power up	Blink	Off	
Lamp test	After Fan test	On	On	Note 5

Table 1: Indicator lights

Note 1: While the battery voltage is between 8.5V and 6.8V the On indicator is on
Note 2: While the battery voltage is between 6.8V and 5.5V the on indicator is blinking
Note 3: While the battery voltage is under 5.5V, software will shut down the system
Note 4: Any one or more of the following:

B4 [redacted]

2.2.9 Key on/off

The on/off key is sensed via 2 I/O pins, enabling the MCU to detect up to 3 different modes, current application will enable only 1 state (On state). The key logic interface is shown in the diagram bellow.

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2.2.10 Power off control

The power off control is used by the software to turn off the power to the device, upon user press the On/Off while on, during timeout after error or standby. The power off diagram is shown below.

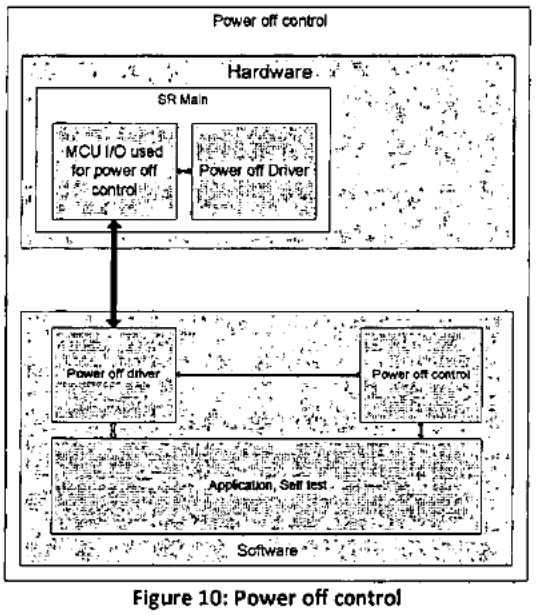

Figure 10: Power off control

2.2.11 Battery voltage sense

The battery voltage is monitored continuously by the software. The battery voltage monitoring is shown in the diagram bellow.

The monitoring parameters are retrieved from an analog to digital converter with output range from 0 to 5V. The converter has defined for 8 bits resolution, so a digital value of 255 corresponds to 5V.

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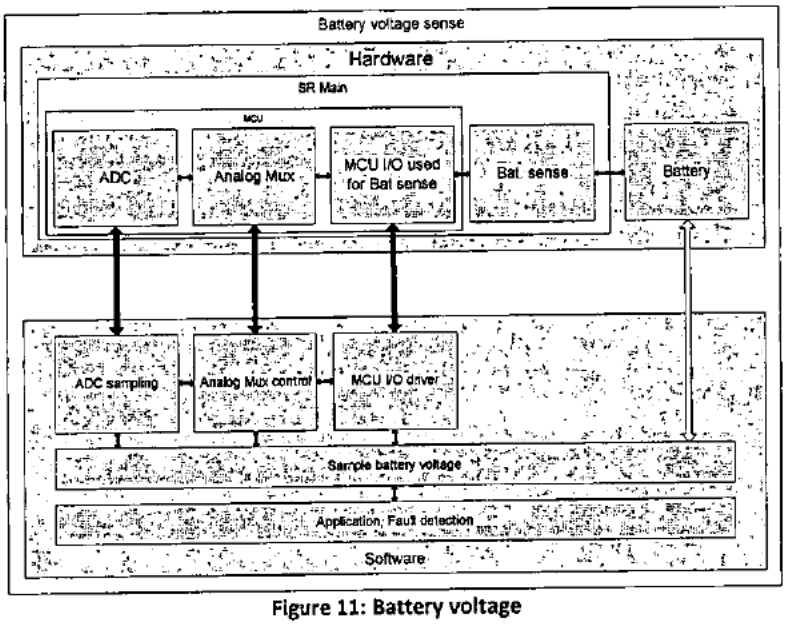

Figure 11: Battery voltage

$$Vadc = 5V * \frac{Digital_Value}{255}$$

There is a ½ voltage divider, so to calculate Vbat a 2 multiplier is used.

$$Vbat = 2 * Vadc$$

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Figure 12: Battery temperature

The monitoring parameters are retrieved from an analog to digital converter with output range from 0 to 5V. The converter has defined for 8 bits resolution, so a digital value of 255 corresponds to 5V.

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3 Design Overview

The Silk'n Fx software is designed to control the Silk'n Fx device.

3.1 Software structure – modules

The Silk'n Fx software is distributed on several modules, this section describes each module and the functions it contains.

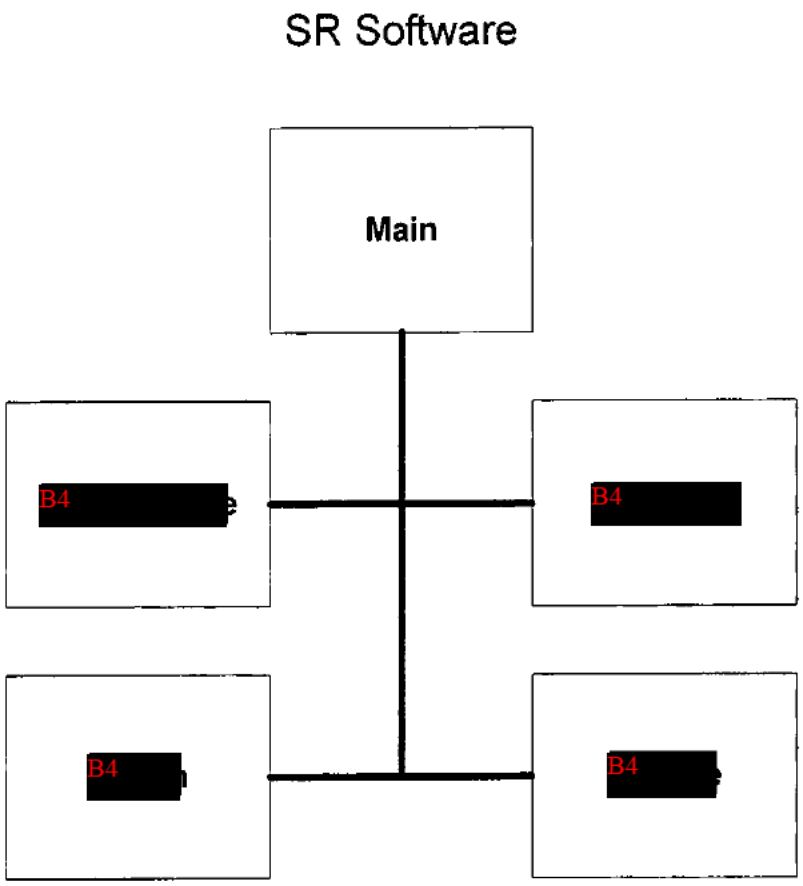

Figure 13: Silk'n Fx Software Modules

3.1.1 Main module

The main module is used to handle the initialization section, and the main loop. It also contains the Main state machine.

#	Function name	Description	SM section	Remarks
	ISR	Timer 1 intr. Used for proximity sensing Timer 2 intr. GP timer		
	FlashLED	Used to start indicator blinking		
	UnFlashLED	Used to stop indicator blinking		
	TurnOffLED	Used to turn indicator on		

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#	Function name	Description	SM section	Remarks
	TurnOnLED	Used to turn indicator on		
	Init	Used for CPU I/O and internal registers initialization		
	CheckBatNTC	Used to check battery temperature		
	CalcCheckSum	Used to check software code integrity		
	CheckFan	Check fan current consumption		
	Main	Used for executing CalcCheckSum, init function and every module's init function, than execute the main loop calling each module's task function		

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3.1.4 Sample module

The sample module is used to hold ADC related functions

#	Function name	Description	SM section	Remarks
	Sample	Sample requested analog input via the MCUs built-in ADC		

3.1.5 Comm. module

The comm. module is used to hold serial communication (UART) functions.

#	Function name	Description	SM section	Remarks
	ComInit	Used to initialize the communication related MCUs internal registers		
	Send_byte	Used to send a single byte via the MCU's UART		

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Figure 14: Silk'n Fx SW - processes

3.2.1 Main loop

The main loop is executed continually different tests are taken during the execution time.
The purpose of the main loop is to call the temperature stabilization routine and to implement the state machine (there are three basic states (Standby, treatment and error)

In stand by state the system is stabilizing temperature but no light is emitted.
In treatment state (entering while touch sense detected) the system controls temperature and emits light.
In error state the system shuts down heating and light emission, turns on error LED, then after a period of time, it powers off the system.

3.2.2 ISR

The ISR features a parallel function that in a timely fashion called to handle proximity and GP timers.

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3.3 Silk'n Fx SW- State machines

The Silk'n Fx software is designed as a round loop incorporates a single main state machine. The main state machine is shown in the diagram bellow.

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3.3.1 Main state machine

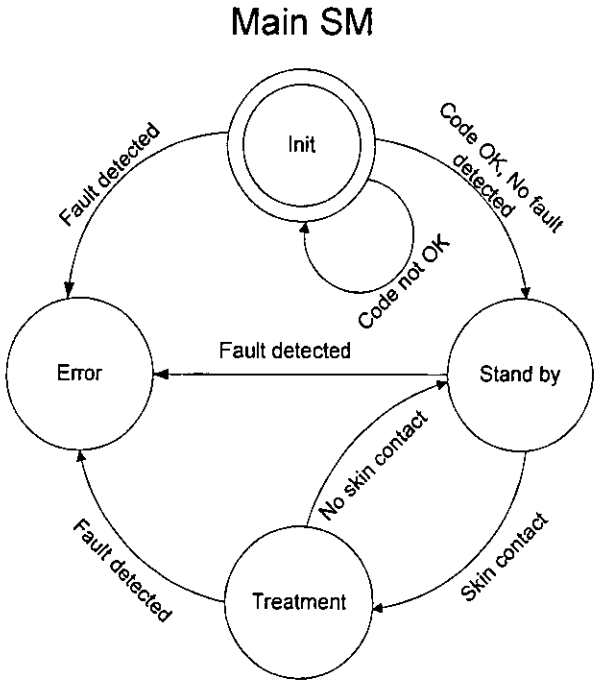

Figure 16: Main SM

State	Prev. state	Description	Exit condition	Next state	Remarks
Init	None	Power On Reset due to power up or WD	Code OK, Fault detected	Error	Part of init, Note3
			Code OK, No fault	Stand by	
Stand by	Init	Used to handle the device in a standby temperature	Fault detected	Error	Note2
			Prox. Sense	Treatment	
Treatment	Stand by	Used to handle the device in treatment temperature and light	Fault detected	Error	
			No Prox. Sense	Standby	
Error	None	Used to hold system during error	None		Note1

Table 2: Main state machine states

Note1: System will turn off after 60 seconds in error
Note2: System will turn off after 60 seconds when idle
Note3: System will turn off after 60 seconds after code check failed

3.4 Theory of Operation

The initialization sequence is as follow:

The microcontroller takes control after reset.
All variables and hardware pins are initialized
Interrupts are enabled.
The system shuts down by itself after an error (a period of time after it occurred).

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4 Design Rationale

The software rationale is to take advantage of the Microchip PIC family simplicity and to control directly the hardware.

4.1 Resets and Initialization

4.1.1 Power-On Reset

The microcontroller takes control of the operation immediately after reset.

4.1.2 Watch-Dog

A WD reset occurs if the software fails to clear the WD timeout counter with-in 1 second. Software will return to normal operation after WD reset event.

4.1.3 Complete initialization sequence

- Turn On indicator on
- Self test code section using a check sum for verification
- If failed self test, turn error indicator on, turn On indicator off, after 2 seconds, kill power and for safety enter endless loop
- If self test Ok, execute Init, Temp. init
- Check fan operation for 4 seconds, if Fan failed enter error state
- Check battery voltage, if too low enter error state
- Execute main function

4.2 Main loop

The main loop is used to execute the following

- Check Fan operation
- Check battery voltage
- Check battery temperature
- Check temperature
- Check skin contact
- Execute the temperature task

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5 Safety

5.1 Code corruption

Code self check, using check sum will be executed when software is initialized during power up or watch dog event. Failed code will stop any further execution, turn error indicator on, and after 60 seconds turn power off

5.2 Watch dog

Watch dog, a MCU built in will be used to supervise normal software operation. Up on WD event the device will reset self check and resume normal operation.

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[redacted]

5.5 Fan

Fan operation will be checked during init, will be turned on for 4 seconds, then check if it is operating ok. If failed system will enter error state and after 60 seconds will turn off.

During normal operation the fan will be sensed while off and on to ensure proper operation of the fan. If failed system will enter error state and after 60 seconds will turn off.

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6 Appendix A: Build Environment

Fx Application's Software:

The application's software is built in MPLAB V8.43 or later development environment by writing applications in C and/or C++ language. The compiler used is HI-TECH version V9.70 standard mode.

The application software shall be debugged with the Microchip ICD-2 or ICD-3 in system debugger.

The application's software shall be stored in the microcontroller internal flash memory by programming it by using the microchip standard programmers.

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7 Appendix B: List of diagrams tables & equations

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Section E – Traceability Analysis

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Silk'n Fx

Traceability Analysis

Doc. P/N: DO102063D

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Ronen Ben Yosef	System Eng.	Aug 2011	
Checked by	Suhair Francis-Najjar	V&V & QA Manager	Aug 2011	S. Francis
Approved by	Benzi Levi	VP R&D	Aug 2011	

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Revisions

Rev.	Page	Description	Approval	Date
A		First Version	Ben Zion Levy	Aug 2010
B	All	Revised	Ben Zion Levy	Oct 2010
C	All	SW Ver 1.10 release	Ben Zion Levy	19 Dec 2010
D	All	Revised	Ben Zion Levy	Aug 2011

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1. Traceability Analysis

Traceability between Software Requirements Specifications and Software Detailed Design, Functional System Test Plan is Straight forward by using the requirement ID (first column), that is that test ID corresponds to the requirements ID. Any requirement exception will be detailed in the table below.

1.1 Reference

- DO101683D Silk'n Fx – System Reuirements Specification
- DO102050D Silk'n Fx – Software Requirements Specification
- DO102377D Silk'n Fx – Software Design Description
- DO102051D Silk'n Fx SW Functional System Test Plan and Results

1.2 Integration Notes

This section is used to describe the notes abbreviation used in the traceability matrix

Note1: Requirement analysis; DR, Code review.
Note2: debugging tools (ICE, Scope, Multi meter)
Note3: communication sniffer, in house SW testing tools
Note4: Data sheets
Note5: Temperature meter

Tests sets: MPLAB ICD 2 emulator and developer environment, developer constructed debugger environment

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Req. Sec. #(s)	Req. #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
3.1		Software Structure Requirements						
	3.1.2	**Main Module**	3.1.1 Main module	Notes: 1	3.11	Notes:1; 2		
	3.1.3	**MMI**	3.1.1 Main module	Notes: 1		Notes:1; 2		
	3.1.4	**Error Handler**	3.1.1 Main module	Notes: 1	3.12 Notes:2, 3	Notes:1; 2		
	3.1.5	**Timer**	3.1.1 Main module	Notes: 1;4	Notes:2			
	3.1.6	**Self test**	3.1.1 Main module	Notes: 1	Notes: 2	Notes:2,3		
	3.1.7	**Temperature module**	3.1.2 Temperature module	Notes: 1;4	Notes: 2;5	Notes:2; 5		
	3.1.8	**Sample module**	3.1.4 Sample module	Notes: 1	Notes: 2			
	3.1.9	**Communication**	3.1.5 Communication module		Notes: 2			
	3.1.10	**Prox. Module**	3.1.3 Proximity module	Notes: 1;4				
3.2		**Interface requirements**			3.10			
3.2.1		**User Interfaces**						
	3.2.1.1	**Power On/Off switch**	2.2.9 Key on/off	Notes: 1			9.1.1(#5)	
	3.2.1.2	**ON state 0 indicator**	2.2.8 Indicators	Notes: 1			9.1.1(#2)	
	3.2.1.3	**ON state 1 indicator**	2.2.8 Indicators	Notes: 1			Not used	
	3.2.1.4	Error indicator	2.2.8 Indicators	Notes: 1			9.1.2(#1)	
	3.2.1.5	Proximity sensor	2.2.2 Proximity sensing	Notes: 1			9.1.1(#3,4)	
3.2.2		**Hardware Interface**						

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Req Sec #(s)	Req #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
	3.2.2.1	**Indication Lights**	2.2.8 Indicators	Notes: 1	3.10 Notes: 2			
	3.2.2.2	**Key Polling**	2.2.9 Key on/off	Notes: 1	Notes: 2			
[redacted]								
	3.2.2.6	**Fan control**	2.2.3 Fan control	Notes: 1	3.3 Notes: 2	Notes: 2	9.2.1(#11)	
	3.2.2.7	**Fan sense**	2.2.4 Fan sense	Notes: 1	3.3 Notes: 2	Notes: 2	9.5.2(#2)	
	3.2.2.8	**Battery voltage sense**	Battery voltage sense	Notes: 1	3.6 Notes: 2	Notes: 2	9.4.2	
	3.2.2.9	**Battery temperature sense**	2.2.12 Battery temperature	Notes: 1;4	3.7 Notes: 2;5	Notes: 2;5	9.5.2(#7-12)	
	3.2.2.10	**Power off**	2.2.10 Power off control	Notes: 1	3.9 Notes: 2	Notes: 2	9.3.1(#3)	
3.2.3		**Software Interfaces**	6 Appendix A: Build Environment	Notes: 1	Notes: 2	Notes: 2	9.1.4	SW development environment
3.2.4		**Communication Interfaces**	2.2.1 Communication 3.1.5 Comm. module					Comm. Debug tools for development only
	3.2.5.1	**RS-232**						
	3.2.5.2	I2C						Not implemented
3.2.5		**MMI interfaces**			3.10			

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Req Sec #(s)	Req #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
	3.2.5.1	**LED indicators**	2.2.8 Indicators 3.1.1 Main module					
	3.2.5.1.1	**All user visual interface outputs are delivered by LEDs**	2.2.8 Indicators					HW verification by inspection
	3.2.5.1.2	**On state 0**	2.2.8 Indicators	Notes: 1	Notes: 2	Notes: 2	9.1.1(#2)	
	3.2.5.1.3	**Error indicator**	2.2.8 Indicators	Notes: 1	Notes: 2	Notes: 2	9.1.2(#1); 9.1.3(#2)	
3.2.6		**Error handler**			3.12			
	3.2.6.1	**Fan fault (power-up)**	2.2.4 Fan sense 3.1.1 Main module 3.3.1 Main state machine 4.1.3 Complete initialization sequence 5.5 Fan	Notes: 1;4	Notes: 2	Notes: 2	9.1.3	
	3.2.6.2	**Fan fault**	2.2.4 Fan sense 3.1.1 Main module 3.3.1 Main state machine 5.5 Fan	Notes: 1;4	Notes: 2	Notes: 2	9.5.2(#1-3)	
	[redacted]							B4
	3.2.6.4	**Bat voltage too low**	2.2.8 Indicators	Notes: 1	Notes: 2	Notes: 2	9.4.2 (#4)	

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Req Sec #(s)	Req #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
			2.2.11 Battery voltage sense 3.3.1 Main state machine 4.1.3 Complete initialization sequence					
	3.2.6.5	**Bat voltage too high**	2.2.8 Indicators 2.2.12 Battery temperature 3.3.1 Main state machine 4.1.3 Complete initialization sequence	Notes: 1	Notes: 2	Notes: 2	9.5.2(#14)	
	3.2.6.6	**Bat temperature**	2.2.8 Indicators 2.2.11 Battery voltage sense 3.3.1 Main state machine	Notes: 1;4	Notes: 2	Notes: 2	9.5.2 (#7-12)	
3.3		**System features**						
3.3.1		**Initialization**						
	3.3.1.3.1	The On/Off Power Switch shall be used to turn the device on/off.	2.2.9 Key on/off 2.2.10 Power off control				9.3.1(#3)	
	3.3.1.3.2	The MCU internal registers and pin-outs shall be initialized	3.1.1 Main module	Notes: 1	Notes: 2	Notes: 2		
	3.3.1.3.3	The Software variables shall be initialized.	3.1.1 Main module	Notes: 1	Notes: 2	Notes: 2		
	3.3.1.3.4	The software shall	3.3.1 Main state	Notes: 1	Notes: 2	Notes: 2	9.1.2	

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Req. Sec #(s)	Req. #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
		check the hardware components	machine 4.1.3 Complete initialization sequence 5.3 Temperature stabilizer 5.4 Battery temperature 5.5 Fan				9.4.2 9.4.3 9.4.4	
	3.3.1.3.5	The software shall activate the temperature stabilizer	2.2.6 Temperature stabilizer control 3.2.2 Temperature task	Notes: 1	Notes: 2	Notes: 2	9.3.2	
3.3.2	[redacted]							
3.3.3		Power off			3.9			
	3.3.3.3.1	User press power on/off switch while system is on	2.2.9 Key on/off 2.2.10 Power off control	Notes: 1	Notes: 2	Notes: 2	9.1.1(#5)	
	3.3.3.3.2	System is in error state for 60 seconds	3.3.1 Main state machine 5.4 Battery temperature 5.5 Fan				9.5.2(#6,9,12,15)	

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Req. Sec #(s)	Req. #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
	3.3.3.3.3	System is idle for 60 seconds	3.3.1 Main state machine				9.4.1	
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Req Sec #(s)	Req #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
[redacted]								
3.3.6		**Fan control**			3.3			
	3.3.6.3.1	Temperature stabilizer is activated	2.2.6 Temperature stabilizer control	Notes: 1	Notes: 2	Notes: 2	9.2.1(#8)	
	3.3.6.3.2	Temperature is rising, and exceeds requested temperature	2.2.5 Temperature sense	Notes: 1	Notes: 2	Notes: 2	9.2.1(#11)	
	3.3.6.3.3	Fan is turned on	2.2.3 Fan control	Notes: 1	Notes: 2	Notes: 2	9.2.1(#11)	
3.3.7		**Fan fault monitoring**		Notes: 1	3.3 Notes: 2	Notes: 2	9.5.2(#1-3)	
	3.3.8.3.1	Fan current is monitored continuously	2.2.4 Fan sense 5.5 Fan	Notes: 1	Notes: 2	Notes: 2	9.5.2(#1-3)	
	3.3.8.3.2	Error indicator will turn on if fan current is too high	2.2.8 Indicators	Notes: 1	Notes: 2	Notes: 2	9.5.2(#1-3)	
	3.3.8.3.3	System is turned off after 60 seconds	2.2.10 Power off control	Notes: 1	Notes: 2	Notes: 2	9.5.2(#1-3)	
3.3.8		**Battery low voltage**			3.6			
	3.3.8.3.1	Battery voltage monitored continuously	2.2.11 Battery voltage sense	Notes: 1	Notes: 2	Notes: 2	9.4.2	
	3.3.8.3.2	Green indicator will blink if voltage between 5.5V and 6.8V	2.2.8 Indicators	Notes: 1	Notes: 2	Notes: 2	9.4.2	

B4

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Req. Sec. #(s)	Req. #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
3.3.9		**Battery voltage too low**						
	3.3.9.3.1	Battery voltage monitored continuously	2.2.11 Battery voltage sense	Notes: 1	Notes: 2	Notes: 2	9.4.2	
	3.3.9.3.2	Error indicator will turn on if battery voltage is under 5.5V	2.2.8 Indicators	Notes: 1	Notes: 2	Notes: 2	9.4.2	
	3.3.9.3.3	System is turned off	2.2.10 Power off control	Notes: 1	Notes: 2	Notes: 2	9.4.2	
3.3.10		**Battery voltage too high**						
	3.3.10.3.1	Battery voltage monitored continuously	2.2.11 Battery voltage sense	Notes: 1	Notes: 2	Notes: 2	9.5.2(#13-15)	
	3.3.10.3.2	Error indicator will turn on if battery voltage is above 8.5V	2.2.8 Indicators	Notes: 1	Notes: 2	Notes: 2	9.5.2(#13-15)	
	3.3.10.3.3	System is turned off after 60 seconds	2.2.10 Power off control	Notes: 1	Notes: 2	Notes: 2	9.5.2(#13-15)	
3.3.11		**Battery temperature too high or too low**						
	3.3.11.3.1	Battery temperature monitored continuously	2.2.12 Battery temperature	Notes: 1,5	Notes: 2;5	Notes: 2;5	9.5.2(#7-12)	
	3.3.11.3.2	Error indicator will turn on if battery temperature is above 57°C or below -7C	2.2.8 Indicators	Notes: 1,5	Notes: 2;5	Notes: 2;5	9.5.2(#7-12)	
	3.3.11.3.3	System is turned off after 60 seconds	2.2.10 Power off control	Notes: 1,5	Notes: 2;5	Notes: 2;5	9.5.2(#7-12)	
3.3.12		**Idle timeout**			3.9			
	3.3.12.3.1	Activate system by pressing the power on	2.2.9 Key on/off	Notes: 1	Notes: 2	Notes: 2	9.4.1	

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Req. Sec. #(s)	Req. #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
	[redacted]							B4
	3.3.12.3.3	System will turn off after 60 seconds	2.2.10 Power off control	Notes: 1	Notes: 2	Notes: 2	9.4.1	
3.4.		**Performance Requirements**						
	3.4.1	The software has the capability of responding to user inputs within a reasonable period of time	2.2.2 Proximity sensing 2.2.9 Key on/off		3.2		9.1.1	
	3.4.2	The software shall have the capability to allow temperature stabilization with a resolution of +/-1°C	2.2.5 Temperature sense	Notes: 1;4				
	3.4.3	The software shall detect abnormalities every 1 second.	5.3 Temperature stabilizer 5.4 Battery temperature 5.5 Fan	Notes: 1	Notes: 2	Notes: 2		
3.5.		**Safety Requirements**						
	3.5.1	The corrupt firmware will be stopped by watchdog	5.1 Code corruption	Notes: 1;4	Notes: 2	Notes: 2	9.5.3	

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Req. Sec. #(s)	Req. #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
	3.5.2	The software shall check the hardware and if error occurred; the system shall be switch to error state disabling all normal activities.	3.3.1 Main state machine 5.3 Temperature stabilizer 5.4 Battery temperature 5.5 Fan	Notes: 1;4	Notes: 2	Notes: 2	9.5.2	
3.6		**Logical Database Requirements**						N/A – no database requirements .
3.7.		**Design Constrains**						
	3.7.1	**Safety constrains**						
	3.7.1.1	The software shall not allow light energy delivery when there is no skin contact	3.2.3 Temperature task	Notes: 1	Notes: 2	Notes: 2	9.1.6	
	3.7.1.2	[redacted] B4						
	3.7.1.3							
	3.7.1.4	The software shall shut-down when a critical fault is detected.	5.3 Temperature stabilizer 5.4 Battery temperature 5.5 Fan	Notes: 1;4	Notes: 2	Notes: 2	9.5.1; 9.5.2	
	3.7.1.5	The software should	5.2 Watch dog	Notes: 1	Notes: 2	Notes: 2		

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Req. Sec. #(s)	Req. #	Software Requirement Description	Software Design Identifier	Verification Method				Remarks
				Walk-through	Unit test	Integration	System test	
		trigger periodically the built-in watch-dog timer in a wise manner, in order to bring the microprocessor to restart in the case the software does not follow the defined sequence of tasks						
3.8		**Software system attributes**					9.4.5	
3.9		**Testing Requirements**						All testing requirements are defined in the test plan and results
3.10		**Other Requirements**						
	3.10.1	Fault Detection and Isolation		Notes: 1	Notes: 2	Notes: 2	9.5	
	3.10.2	Self Test	5.1 Code corruption	Notes: 1	Notes: 2	Notes: 2	9.1.5	
	3.10.3	Redundancy Management and Hardware Re-configuration						Refer to HW detailed design documents
	3.10.4	Watchdog Reset and crash recovery	5.1 Watch dog	Notes: 1	3.1 Notes: 2	Notes: 2	9.5.3	

7.3.8 Software Life Cycle Procedure

1.1 General Policy

Home Skinovations plans and controls the life cycle and the SW design in a uniformed method, which ensures that the design stages are clearly defined.

The life cycle model covers the software from design concept to retirement.

It describes the various phases a software product should go before becoming an official released product.

1.2 Procedure

1.0 Software Life Cycle Management

- *A Software team leader will be assigned for every SW product.*
- *Activities in the SW life cycle will include 6 phases: Requirements, Design, Implementation (Coding), Verification and Validation and maintenance. Some stages will not be necessary for certain projects. In those cases, only the relevant required development phases will be applied. Each phase*
- *The main DRs will be the SWRS DR at the end of SW requirements specification phase and the SDD DR at the end of the SW Design Phase. Other DRs will be performed when applicable. The responsibility of each DR will be defined in the SW Project Plan.*

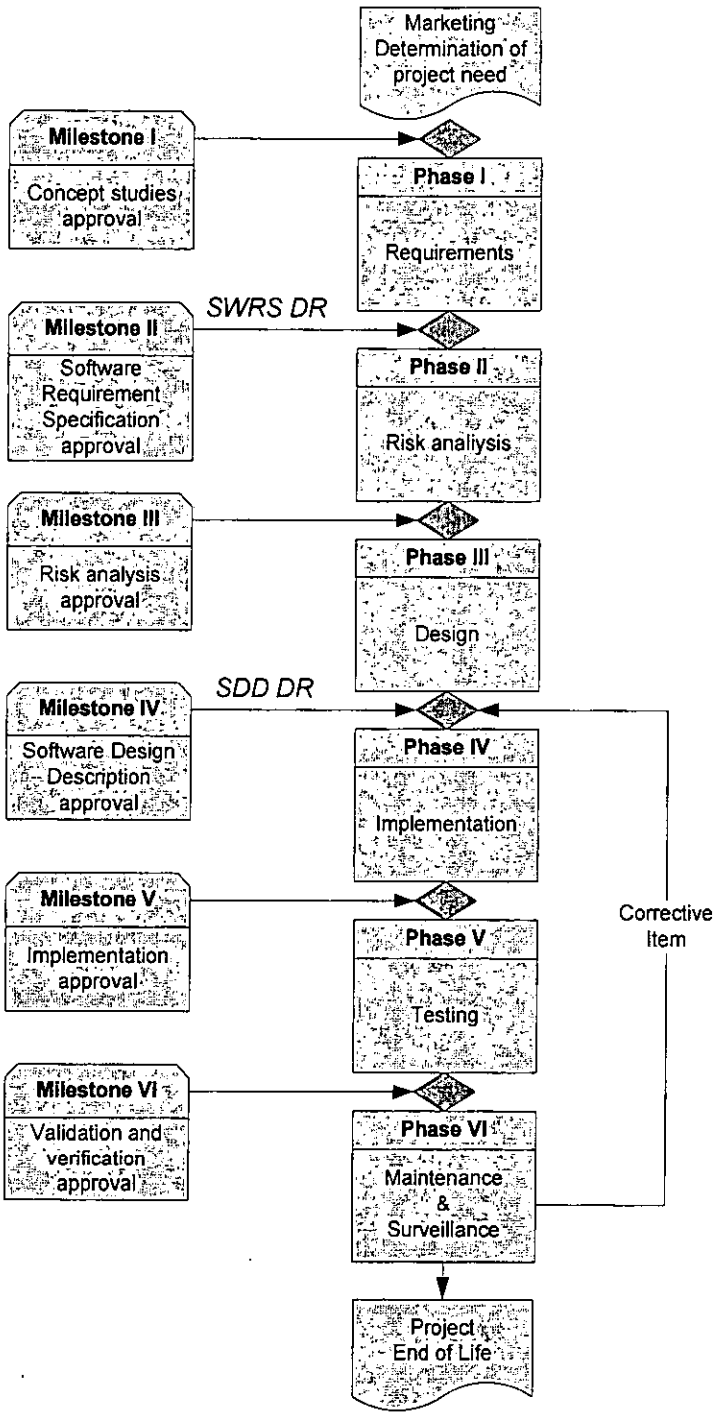
2.0 Software Development Process:

The following paragraphs address the software life-cycle phases. The software shall be designed to perform as intended by the Home Skinovations, and the performance of the software shall be validated.

2.1 SW Requirements Phase I

The requirements phase is one of the most important phases of software engineering. Studies show that the top problems in the software industry are due to poor requirements elicitation, inadequate requirements specification, and inadequate management of changes to requirements. Requirements provide the foundation for the entire life cycle as well as for the software product. Requirements also provide a basis for planning and estimating.

Requirements are based on customer, user, and other stakeholder needs and design and development constraints. The development of requirements includes elicitation, analysis, documentation, verification, and validation. It is important that there is ongoing customer validation of the requirements to ensure the end products meet the customer needs. This can be accomplished via rapid prototyping and customer involved reviews of iterative and final software requirements.



Software Life Cycle flowchart

2.1.1 Requirements Development

- *The project shall document the software requirements.*
- *The project shall identify, develop, document, approve, and maintain software requirements based on analysis of customer and other stakeholder requirements and the operational concepts.*
- *The project shall perform software requirements analysis based on flowed-down and derived requirements from the top-level systems engineering requirements and the hardware specifications and design*
- *The project shall perform, document, and maintain bi- directional traceability between the software requirement and the higher level requirement.*

2.1.2 Requirements Management

- *The project shall collect and manage changes to the software requirements.*
- *The project shall identify inconsistencies between requirements, project plans, and software products and initiate corrective actions*
- *The project shall perform requirements validation to ensure that the software will perform as intended in the customer environment*

2.2 Software Risk Analysis Phase II

Identification and management of risks provides a basis for systematically examining changing situations over time to uncover and correct circumstances that impact the ability of the project to meet its objectives.

The project shall identify, analyze, plan, track, control, communicate, and document software risks (potential issues, hazards, threats, and vulnerabilities) in accordance with Risk Management Plan Procedural (7.1.1)

2.3 Software Design Phase III

Architectural design is concerned with creating a strong overall structure for software entities that fulfill allocated system and software- level requirements. Typical views captured in an architectural design include the decomposition of the software subsystem into design entities, definitions of external and internal interfaces, dependency relationships among entities and system resources, and finite state machines. Detailed design further refines the design into lower level entities that permit the implementation by coding in a programming language. Typical attributes that are documented for lower level entities include: identifier, type, purpose, function, constraints, subordinates, dependencies, interface, resources, processing, and data.

2.3.1 The project shall document the software design.

- *The project shall transform the allocated and derived requirements into a documented architectural design.*
- *The project shall develop and record a detailed design based on the architectural design that describes the lower level units so that they can be coded, compiled, and tested.*
- *The project shall perform and maintain bi-directional traceability between the software requirements and the software design.*

2.4 Software Implementation Phase IV

Software implementation consists of implementing the requirements and design into code, data, and documentation. Software implementation also consists of following

coding methods and standards. Unit testing is also usually a part of software implementation (unit testing can also be conducted during the testing phase).

- *The project shall implement the software design into software code.*
- *The project shall ensure that software coding methods, standards, and/or criteria are adhered to and verified.*
- *The project shall ensure that the software code is unit tested per the plans for software testing.*
- *The project shall provide a Software Version Description document for each software release*
- *The project shall provide and maintain traceability from software design to the software code.*

2.5 Software Testing Phase V

The purpose of testing is to verify the software and remove defects. Testing verifies the code against the requirements and the design to ensure that the requirements are implemented. Testing also identifies problems and defects that are corrected and tracked to closure before product delivery. Testing should also validate that the software operates appropriately in the intended environment.

2.5.1 The project shall provide:
  a. Software Test Plan(s).
  b. Software Test Procedures.
  c. Software Test Reports.

2.5.2 The project shall perform software testing as defined in the Software Test Plan.

2.5.3 The project shall ensure that the implementation of each software requirement is verified to the requirement.

2.5.4 The project shall evaluate test results and document the evaluation.

2.5.5 The project shall document defects identified during testing and track to closure

2.5.6 The project shall test, validate, and certify software models, simulations, and analysis tools.

2.5.7 The project shall update Software Test Plan(s) and Software Test Procedure(s) to be consistent with software requirements.

2.5.8 The project shall provide and maintain traceability from the Software Test Procedures to the software requirements.

2.5.9 The project shall ensure that the software system is validated on the targeted platform or high-fidelity simulation.

2.6 Software Release Process

Software release process covers the transition of the software product from the development phase to completed product ready for distribution. The project shall:

2.6.1 Ensure that the software system testing has been completed and the results evaluated before software is released.

2.6.2 Document the versions of the software items and documentation that are being released. Document the reference/versions of the COTS (Commercial off the shelf) software that are used.

2.6.3 Document the process and environment used to create the released software

2.6.4 Document the content of the version in the Software Release Letter.

2.6.5 Archive and maintain master copies of the software and documentation for life of the software.

2.6.6 Summary status for all open system problems to be resolved in future releases.
2.6.7 A new software baseline established for future maintenance.

2.7 Software Maintenance Phase VI

Planning for operations, maintenance, and retirement begins early in the software life cycle. Operational concepts and scenarios are derived from customer requirements and validated in the operational or simulated environment. Software maintenance activities sustain the software product after it is delivered to the customer until retirement.

2.7.1 The project shall document the software maintenance plans in the Software Maintenance Plan document.
2.7.2 The project shall plan software operations, maintenance, and retirement activities.
2.7.3 The project shall implement software operations, maintenance, and retirement activities as defined in the respective plans.
2.7.4 The project shall complete and deliver the software product to the customer with appropriate documentation to support the operations and maintenance phase of the software life cycle.
2.7.5 The project shall deliver to the customer the as-built documentation to support the operations and maintenance phase of the software life cycle.

2.8 Software Documentation Process

The list of documents to be produced during the life cycle of the software product shall be defined in the Program Plan.
The rules for documents control, approval and changes are described in the Control of Documents Procedure (4.2.3).

2.9 Software Configuration Management Process

The Configuration Management Process is a process of applying administrative and technical procedures throughout the software life cycle to: identify, define, and baseline software items in a system; control modifications and releases of the items; record and report the status of the items and modification requests; ensure the completeness, consistency, and correctness of the items; and control storage, handling, and delivery of the items. It consist the following Tasks:

2.9.1 Document the procedures and tools used for configuration management.
2.9.2 Identify the software items to be controlled for the project.
2.9.3 Identify and record changes of the software units.
2.9.4 Prepare status reports with information such as history of controlled items, latest software items versions and release identifiers

2.10 Software Problem Resolution Process

To present the pending problems that is remaining in the software: All errors detected during testing should be logged and classified to be reviewed later; the SW Project leader will maintain the bug-list database. Development is in charge of accessing the bug list database, learning the errors and providing solutions to them in the next software revision and find bugs in it and log the bugs and fix the bugs and provide a new software revision will repeat it self as many times as necessary to proved reliable, stable, acceptable by Product manager software revision.

The bug list will include full disclosure of any unresolved anomalies, discuss the impact on safety or effectiveness, No anomaly shall have an unacceptable risk associated with it.

3.0 External reference

3.1 ISO 13485:2003 par. 7.3
3.2 21 CFR 820.30
3.3 MDR SOR/98-282(20)
3.4 IEC 62304, Medical device software – software life cycle processes.
3.5 IEC 60601-1-4; Medical electrical equipment: General requirements for safety – Collateral standard: Programmable electrical medical system.

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Tavor building, POB 533
Yokneam 20692,
ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n Silkn FX™

Software Configuration Management Plan

Doc. P/N: DO103014A

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Daniel Wainer	Software Eng.		
Checked by	Suhair Francis-Najjar	V&V & QA Manager		
Approved by	Benzi Levi	VP R&D		

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Tavor building, POB 533
Yokneam 20692,
ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

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Tavor building, POB 533
Yokneam 20692,
ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

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Yokneam 20692,
ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

1. INTRODUCTION

Purpose

The purpose of this document is to define a Software Configuration Management Plan for Silkn FX project, compliant with the industry regulation standards, QSR, CMM, ISO and the Company Engineering Quality Procedures Manual.

1.1 Scope

The scope of this plan is limited to the products of software projects. It does not include hardware developments, system requirements or manufacturing documents.

1.2 Definitions

CI	Configuration Item: an item (document, code, plans...) that is under SCM.
CMM	Capability Maturity Model
CMS	Configuration Management System
CSA	Configuration Status Accounting
FDA	Food and Drug Administration
Label	A distinctive name that may identify the status of a Configuration Item: Release version, checkout, check in, owner, ...
OTS	Off the Shelf
PPP	Primary Product Plan
SCM	Software Configuration Management
SCMP	Software Configuration Management Plan
SPP	Software Project Plan
SPR	System Problem Report
Baseline Configuration management	The establishment of baselines that are formally reviewed and agreed on and serve as the basis for further development. Some software work products, e.g., the software design and the code, should have baselines established at predetermined points, and a rigorous change control process should be applied to these items. These baselines provide control and stability when interacting with the customer.

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Fax: +972(4)9097471

2 Software Configuration Management Methodology

2.1 Software Configuration Management items

2.1.1 Source files

2.2 Branches schema

The ongoing development will be done on the Main line which is the trunk. Whenever there is a need for parallel development, a branch will be created on the relevant revision. The parallel development will continue on the created branch.

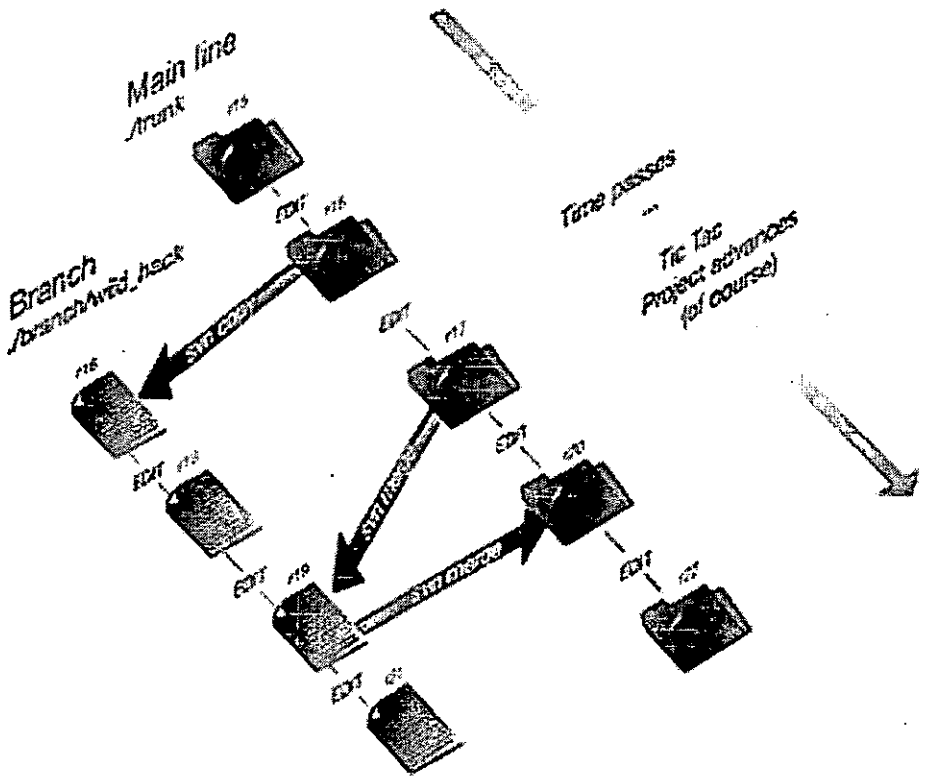
When the development on the branch is finished or whenever is needed, a merge may be done from the parent branch to the child branch or vice versa if the introduced changes are applicable to the parent branch.

Release development cycle:

Development phase - will be done on the Main line in continues to the previous development.

Integration phase – a dedicated branch may be created for the integration phase. The development of the future release will remain in the Main line and only the integration of the current release will be done on the dedicated branch. Whenever is needed, a merge will be done from the integration branch to the Main line (trunk). No need to do merge from the Main line to the integration branch during the integration phase. An internal release tag will be created on the integration branch whenever is needed.

Release phase – a final release tag is created on the integration branch (if exists, otherwise in the main branch) and a merge is done from the integration branch to the Main line (trunk). A snapshot of all the released file is **also** copied to the HSN ("R:") drive where the subdirectory is named accordingly to the release version number.



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2.3 Naming conventions

2.3.1 Branches

Integration branches - <project name>_<release number>_integration_<optional short description>

2.3.2 Tags

Build tags - <project name>_<release number>_<build number>_<optional short description>

Internal Release tags - <project name>_<release number>_<internal release number>_<optional short description>

Final Release tags - <project name>_<release number>_<optional short description>

3 SOFTWARE CONFIGURATION MANAGEMENT ORGANIZATION

This section outlines the roles and responsibilities for the SCM activities during the software development and/or maintenance effort.

3.1 SCM Organization and Responsibilities

Two engineers: one at the HSN team is designated primary CM and the second from the company IT backup CM respectively. The primary CM ensures all SCM activities and the backup CM supports him in his tasks. If for some reason the head CM can't perform his tasks any more, the backup CM will take over all the current tasks of the head CM. The backup is performed during the routinely company backup procedure.

3.1.1 Configuration Manager

The CM is responsible for organizing the SCM. His main duty is to install and maintain the SCM tools .
He is also responsible for maintaining this document and giving the team members support.

3.1.2 Backup Configuration Manager

The backup CM is the same IT person responsible for the routinely company backup procedure. He shall be able to respond to any restore requirements from the configuration manager.

3.1.3 Project Manager

The project manager approves the documents and makes sure they are available to the client. The project manager also plans the meetings and controls the deadlines.

3.1.4 Software Engineer

The SCMP acts as a reference for the engineers and all rules stated in it should be respected by them at all times.

3.2 Applicable Policies, Directives, and Procedures

- All documents should be publicly accessible at all times, unless permission to do otherwise is granted by the client.

  This will be achieved through the combination of VisualSVN server permissions.

- All source code and related files should be under control of Subversion version control system (SVN). Note however that only source should be placed under control of SVN, anything that can be derived from that source should not be included, with the exception of the final executable files, mainly .Hex.
- Non compiling code should not be placed on SVN even if it is committed and **not** tagged. Permission to do otherwise may be granted by the implementation manager. If the implementation manager granted this

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Yokneam 20692,
ISRAEL
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permission, it's his duty to fix the code as soon as possible and the non compiling files should be committed with a comment that states this situation. I

4 SCM ACTIVITIES

4.1 Configuration Identification

4.1.1 Identifying Configuration Items

Every member of SE is allowed to add CI's as long as they follow all the rules of the SCMP and the conventions stated in 3.1.2. The project manager and configuration manager may always overrule the decision to include a CI.

4.1.2 Naming Configuration Items

When a CI is included, a meaningful name should be chosen (for example a module that reads analog inputs may be named "AnalogInputs.cpp". Version numbers must not be included in the name ("AnalogInputsV1.0.cpp" is not valid); SVN takes care of version tracking.

The name of the CI can be overruled by the project manager and configuration manager. The following global structure should be followed when adding CI's.

<project Name>/ SVN project under the HSN repository.
branches/ SVN folder containing all branches of the project.
tags/ This SVN folder contains all the tags (labels).
trunk/ The main SVN folder where all the development cycle is stored, in most of the cases all the commits are performed in this node.

Acquiring configuration items is possible with the SVN checkout and update commands.

4.2 Configuration Control

4.2.1 Requesting Changes

All engineers may freely edit the CI's that were assigned to them. Minor changes, such as correcting spelling mistakes, are even allowed for all CI's. For other changes you need the permission of the owner of the CI or special permission of the project manager, or the web admin for the website directory and the implementation manager for the source directory.

The owner is equivalent to the author or authors as specified by the common QA procedure.

Changes should be requested by sending an email or in the future by a bug tracking tool.

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4.2.2 Evaluating Changes

For important changes there will be an evaluation at a meeting.

4.2.3 Approving or disapproving changes

The project manager can always overrule changes.

4.2.4 Implementing changes

The Project manager shall be responsible for coordinating the testing and integration of changed CIs. This should be performed in accordance with the regression test documentation described in the Software Test Strategy.

4.3 Configuration Status Accounting

SVN provides functionality for configuration status accounting. TortoiseSVN provides a better overview of this information.

4.4 Software Configuration Auditing

The project manager can schedule an audit when he deems necessary.

4.5 Interface Control

TortoiseSVN will be used to establish an interface between the user and the VisualSVN server.

4.6 Subcontractor/Vendor Control

VisualSVN: http://www.visualsvn.com, supplier of VisualSVN server.

TortoiseSVN: http:///www.tortoisesvn.org supplier of the SVN client and user interface.

5 SCM Schedule

Every deliverable should be reviewed and approved by the Product manager. When a deliverable is approved it should be tagged final.

6 SCM Resources

All Configuration Items shall be stored in designated repositories, the Configuration Libraries. This section describes the Silkn FX Configuration Libraries, their organization, their access control and version control policies as well as the required computer resources.

6.1 Tools

Subversion (SVN)

Used for version tracking of all CI's.

TortoiseSVN

User interface to SVN client

VisualSVN server: A ready to use package that controls the SVN server under apache web server. It includes the VisualSVN server manager console.

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6.2 Configuration Structure

The repository files are located in the corporate server. The physical location may be changed by the IT team when the will be consider it. Any location change is not expected to affect the repository URL.

Under the main repository the HSN repository exists. The Silkn FX project is placed under the main repository. The SVN project is names "Silkn FX", the name may change, and in this case the SCM manager will notify the users (clients) by email or verbally.

Under the Silkn FX SVN project, there are three folders named "trunk", "branches" and "tags", the purpose was explained above.

It is recommended to the developer team to keep the Silkn FX project local working copy folder the same name as the SVN project. If the project is branched, create a new working copy with the name of the branch.

6.3 Training

6.3.1 Configuration Manager

The head CM and backup CM must have a deep understanding of the working of SVN and the tools mentioned above. They will be responsible to update the tools (after a deep consideration of the pros and cons of updating to a new version)

6.3.2 Engineers

The other members of SE need to learn how to use SVN under the TortoiseSVN tool.

7 SCM Plan Maintenance

The primary CM will keep the SCMP up to date. If, for any reason, he can no longer fulfill his task, the backup CM will take his place. It's the primary CM's responsibility to keep it consistent with the rest of the project and adapt and maintain the system as decided on meetings.

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n Fx

Software Verification and Validation Plan

Doc. P/N: DO102391C

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Ronen Ben Yosef	System Eng.	Aug 2011	
Checked by	Suhair Francis-Najjar	V&V & QA Manager	Aug 2011	S. Francis
Approved by	Benzi Levi	VP R&D	Aug 2011	

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

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A	All	Release	Benzi	Jun 2010
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C	All	Update section 3 to support FDA release	Benzi	August 2011

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

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Yokneam 20692, ISRAEL
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Fax: +972(4)9097471

1 Introduction and overview

1.1 Purpose of this document

This document is to help with testing. Its major purposes are to provide a framework for testing each individual component, provide a framework for testing the system as a whole, describe a system for reports bugs that are found, and define what test cases need to be passed for the project to be determined to be deliverable.

1.2 Scope of the development Project

This project, named Silk'n Fx, will consist of Hand Piece that contain the MCU firmware and the Power on/off button, Temperature stabilizer and a proximity sensor.

1.3 Definitions, Acronyms and Abbreviations

Term	Definition
Validation	Assure that the software system (function and performance) conform to user needs and intended use(s). Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled
Verification	A systematic procedure of review, analysis, and testing, employed throughout the software development cycle to assure that the software design outputs meet the design inputs (all design requirements). Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
Walkthrough	A type of design review in which several participants review a work product. The objective of the meeting is to discover faults in the product
Black box testing	Also called "functional testing"; the module is treated as a "transfer function", so that all internal structure is ignored. The only purpose is to consider the functional performance as the module converts input to output
White box testing	Also called "structural testing"; as such, it takes into account the internal mechanism of a system or component. Includes branch testing, path testing, and statement testing.
SRS	System requirements specification
SwRS	Software requirements specification
VVP	Verification and validation plan
DHF	Design History File

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Fax: +972(4)9097471

1.4 References

ID	Reference
IEEE-Std-1012	Std 1012-1998 IEEE Standard for Software Verification and Validation. IEEE Standards Collection: Software Engineering. The Institute of Electrical and Electronics Engineers, Inc., 1998
DO102050D	Silkn Fx Software requirements specification
DO102377D	Silkn Fx Software Design specification
DO102063D	Silkn Fx Traceability Matrix
DO102051D	Silkn Fx SW Functional System Test Plan and Results
DO103012A	Silkn Fx Software Integration Plan and Results
DO103011A	Silkn FX Software Unit Test Plan and Results

1.5 Overview of Document

This document describes the testing procedures and requirements that will be implemented for our project. The first section goes over review, walkthroughs, inspections, and audits and gives a schedule for them the next section talks about how each component of the system will be tested. Then is a section of how the system will be tested as a whole. The following sections is about how to tract defects. After that we have a section that maps the requirements in the SwRS to their description in the SwDD. We next have a section that gives the test requirements for each of the components. And finally we have the test requirements for the release of the project.

2 Reviews; walkthroughs; inspections; and audits

2.1 Schedule of reviews, etc.

Refer to project development plan document.

2.2 Procedure for reviews, etc.

The following procedure has been used to review the documents that we have completed so far. First ideas are contributes as to what the document should contain, then one person from the group puts all idea into the document (refer to design verification SW Life Cycle).

Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

3 Component and Integration Test

3.1 Component and Integration Test strategy overview

Each software component should have the capability of being tested "individually" within the development environment. As a minimum, test cases should be developed to cover "black box" or functional requirements and component interfaces. "White box" testing to measure percentage code path coverage is also desirable.

Each component based on safety requirements shall have test case(s), and a test procedure(s).

Each software is developed according to the HW design, SwRS, Comm. Protocol, DataSheets in a module level, each HW interface feature is covered by a low level function, each of the other features is covered by a state machine function or a simple function a tasked function in a "Dry writing method".

SW HW integration is done by disabling all features and checking each of the features one by one as those are enabled.

Integration tools include:

- ICE – In circuit emulator
- Communication interface
- Communication sniffer

Full Integration testing will be performed in 2 cycles:

The first cycle focus on the interface requirements for the various design entity that make up Silkn Fx Firmware. Special tools and concepts may be developed in order to help facilitate integration testing. Emulator was used to test the functionality of each design entity and the following test attributes were applied:

- Critical functions and Tasks (Normal Task; Interrupt Tasks)
- Communication functionality
- Boundary conditions.
- Special features: such as proximity sensing.
- Incorrect and unexpected sequences and timing.
- Reaction of the firmware to system faults and failures.
- Go/No-Go and fail-safe mode
- The Man Machine Interface.

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The second cycle is integration with the real hardware and formal test procedures was followed and cover all the functional behavior of the system in normal progressive order and out of normal progressive order.

For detailed description refer to:

DO103012A	Silkn Fx Software Integration Plan and Results
DO103011A	Silkn FX Software Unit Test Plan and Results

3.2 Component and Integration Test description

For detailed description refer to:

DO103012A	Silkn Fx Software Integration Plan and Results
DO103011A	Silkn FX Software Unit Test Plan and Results

For Silkn Fx Traceability Analysis for summarize the modules, functionality, verification methods and test sets that we will be employing.

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4 System Test Plans and Procedures

4.1 System test Strategy Overview

System testing will be based on system level scenarios and system level requirements such as safety, regulatory, performance and capacity..

4.1.1 Scenarios

Each system level scenario should have an associated system level test case. This provides traceability and validates/verifies that the scenario has been implemented. The collection of "system" level scenarios tests could make up the majority of the tests called out in the software system test plan. Scenario test cases could be developed in parallel with Silkn Fx software.

4.1.2 Safety and Regulatory

Safety and regulatory requirements described in the Silkn Fx System SRS and Risk Analysis must have test cases that verify Silkn Fx software compliance.

4.1.3 Performance

Performance requirements such as Temperature stabilization need to be verified for all life cycle phases and should be part of the core system tests.

4.1.4 Regression

Testing that is used to confirm the system functionality has not been comprised by incremental code upgrades, improvements, and bug fixes. These tests may also have a specific focus on SPR resolution. A regression test should be developed to confirm that a SPR has been resolved. This test should remain in the regression test suite throughout product life.

4.1.5 Reliability/Stress/Simultaneity

Part of the system testing should include the means necessary to measure software reliability. Stress and Simultaneity testing should be designed to provide maximum functionality coverage.

4.2 System Test Description

Refer to Software System test plan and results

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5 Defect tracking plans

This defect tracking document will include severity of the error (critical, high, medium, trivial), the phase in which the error is inserted and detected (requirements, coding, design, alpha test, beta test or acceptance test) and the user responsible for following up on the error. An appropriate description of the error detected should be provided as an abstract.

As a tester the user will record the software fault detected. The user will then notify the development team that a defect has been opened. The developer will resolve the defect and give the tester a new fixed version.

After the defect is verified the initial tester will run through the same steps to ensure that the original problem is corrected. The error will be closed after ensuring the problem is fixed else reopened for revaluation. As a developer, the user will monitor the open defects. If the user comes across a defect that was opened against code that he/she is responsible for, the user will view the defects details. After proper understanding of the defect the user will correct the code and put it into the verify state.

6 Traceability from SRS to SDD

Refer to the traceability matrix document.

7 Test requirements cross-reference Matrix

Refer to the traceability matrix document.

8 Acceptance Test and Preparation for delivery

8.1 Procedure by which the software product will be acceptance tested

The Silkn Fx firmware will be tested by the team

- The team will test all the test cases defied in the software system test plan to ensure they work as they are expected.

8.2 Specific acceptance criteria

Refer to the acceptance criteria of the system V&V.

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

8.3 Scenario by which the software product will be installed.

The system will be delivered with the firmware download to the device at the production.

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n Fx

Software Unit Test Plan and Results

Doc. P/N: DO103011A

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Ronen Ben Yosef	System Eng.	Aug; 2011	
Checked by	Suhair Francis-Najjar	V&V & QA Manager	Aug; 2011	S. Francis
Approved by	Benzi Levi	VP R&D	Aug; 2011	

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Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	All	Initial version	Benzi	Aug 2011

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

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Tel: +972(4)9097470
Fax: +972(4)9097471

4 Test Plan Results Summary 20

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Tel: +972(4)9097470
Fax: +972(4)9097471

1 Introduction and overview

1.1 Purpose of this document

The Unit Test should ensure that code deployed to integration test works as per requirements when tested within the firmware software and technical environment

1.2 Scope of the development Project

This document describes the procedure followed for unit testing of the Silk'n Fx firmware software component.

1.3 Definitions, Acronyms and Abbreviations

Term	Definition
Validation	Assure that the software system (function and performance) conform to user needs and intended use(s). Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled
Verification	A systematic procedure of review, analysis, and testing, employed throughout the software development cycle to assure that the software design outputs meet the design inputs (all design requirements). Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
Walkthrough	A type of design review in which several participants review a work product. The objective of the meeting is to discover faults in the product
Black box testing	Also called "functional testing"; the module is treated as a "transfer function", so that all internal structure is ignored. The only purpose is to consider the functional performance as the module converts input to output
White box testing	Also called "structural testing"; as such, it takes into account the internal mechanism of a system or component. Includes branch testing, path testing, and statement testing.
SRS	System requirements specification
SwRS	Software requirements specification
VVP	Verification and validation plan
DHF	Design History File

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Fax: +972(4)9097471

1.4 References

ID	Reference
IEEE-Std-1012	Std 1012-1998 IEEE Standard for Software Verification and Validation. IEEE Standards Collection: Software Engineering. The Institute of Electrical and Electronics Engineers, Inc., 1998
IEEE-Std-1008	Std 830-1983 IEEE Standard for Software Test Documentation. IEEE Standards Collection: Software Engineering. The Institute of Electrical and Electronics Engineers, Inc., 1997
DO102050D	Silkn Fx Software requirements specification
DO102377D	Silkn Fx Software Design specification
DO102063D	Silkn Fx Traceability Matrix
DO102051D	Silkn Fx SW Functional System Test Plan and Results

2 Test Definition

2.1 Test type

This test plan is a unit test used to verify the Silk'n Fx firmware.

2.2 Test Objective

The objectives of the unit test plan are:

1) Checks that code is robust by determining if it performs correctly when it encounters unexpected input. This type of testing must be performed with full knowledge of the unit's implementation details as specified in the specifications/design
2) Exercise all error messages, return codes and response options.
3) Global parameter modification

2.3 Test Approach

Testing methods used to achieve the objective of this test plan:

- All branches are executed covering all known paths (best attempt).
- General logic is correct.
- Data paths are verified.
- Control paths are verified.

2.4 Readiness Criteria

- All code components implemented
- Safety components passed code review

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

- All hardware and software environments must be in place

2.5 Tools and test equipment required

- Debugging tools (ICE, Scope, Multi meter)
- Temperature meter
- Tests sets: MPLAB ICD 2 emulator and developer environment, developer constructed debugger environment

2.6 Test Definition Program Stubs and test data required

NA

2.7 Responsibilities and Schedule

2.7.1 Roles and Responsibilities and Schedule

Role	Name	Responsibility	Estimated time	Remarks
Software Eng.	Daniel Wiener	Check the software	3-5 days	
System Eng.	Ronen Ben Yosef	Supervise software tests and assist during debug	1 day	
Elct. Eng.	Yehoram Bar	Support during HW tests	1-3 days	
VP R&D	Benzion Levi	Check test execution		

2.8 Problem Recording and Resolution

Refer to problem resolution work instruction and BugReport.xls.

2.9 Rework, Review, and Retest Procedures

When all errors which potentially impact overall processing are fixed, an additional set of tests are processed to verify fixes are corrected.

2.10 Test Items

2.10.1 Modules to be tested

Expert	Module to be tested
Ronen, Daniel	SR.C
Daniel	Temperature.C
Daniel	Sample.C
Daniel	Comm.C
Daniel	Cap_Touch727.C

Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

3 Test Description

3.1 Watch Dog feature

Function name	*Main*
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	To verify that the WD timer is configured correctly to reset the system within 1 second, if WD timer is not cleared.
Test Description	Comment the WD clear function in the main loop, Set TP14 to toggle each time main loop is entered, compile software for release, and execute without any breakpoints set. Turn system on, system will reset within 1 second.
Pass Criteria	The system will reset after turned on. System will turn off with in 1second, TP14 pause toggling after 1 second.
SDD section	4.1.2
Test Results:	Pass

Verify Functionality

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	Special firmware code, Comment the WD timer clear command in the main loop. Download special firmware code to system,	Code is successfully compiled and programming successful	**PASSED**	
2	Turn the power switch on	The system will turn off after 1 second.	**PASSED**	

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

3.2 Proximity feature

Function name:	Main
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	To verify that the Proximity is sensing human body.
Test Description	Set TP14 to turn on if proximity is sensed, and off if not. Compile software for release, and execute without any breakpoints set. Turn system on, touch the tip, TP14 should change state from off to on.
Pass Criteria	TP14 will turn on when tip is touched, and off when un-touched.
SDD section	2.2.2
Test Results:	Pass

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Special firmware code, TP14 turn on when proximity is sensed. Download special firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Turn the power switch on	TP14 is off	**PASSED**	
3	Touch tip	TP14 is on	**PASSED**	
4	Un-touch tip	TP14 is off	**PASSED**	

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Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

3.3 Fan test feature

Function name	Main
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	To verify that the fan is tested during power on.
Test Description	Bypass power by shorting TP11, TP12. Set a break point (1) before fan test, and after fan test (break point 2). Set a break point (3) after CheckFan failed. Compile and program in debug mode. Disconnect fan and run software, run software after stopped in break point 1, software should stop in break point 2. Reset software, run until break point 1. Connect a low resistance load (R=20 OHM, 2W), run software. Software should stop in break point 2. Reset software, connect fan, run software, run software after stopped in break point 1, software should stop in break point 3.
Pass Criteria	PASS
SDD section	2.2.3, 2.2.4, 3.1.1
Test Results:	Pass

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Compile in debug. Download special firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Bypass power by shorting TP11 and TP12.	System is powered on.	**PASSED**	
3	Set brake points.	Break points are set	**PASSED**	See test description
4	Disconnect fan. And run software.	Software is running until break point 1	**PASSED**	
5	Run software	Software is running until break point 2	**PASSED**	
6	Reset the software	Software is reset	**PASSED**	
7	Connect a 20R 2W load to fan connector. A run software	Software is running until break point 1	**PASSED**	
8	Run software	Software is running until break point 2	**PASSED**	
9	Reset software	Software is reset	**PASSED**	
10	Connect fan, and run software	Software is running until break point 1	**PASSED**	
11	Run software	Software is running until break point 3	**PASSED**	

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3.4 Temperature sample feature

Function name	SampleTemperature
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	Verify temperature is sampled correctly
Test Description	Bypass power by shorting TP11, TP12. Compile code in debug. Turn system on, sample temperature of tip, using an external temperature meter verify that the readout is correct.
Pass Criteria	Software temperature readout is +/- 2°C from temperature meter readout
SDD section	2.2.6, 3.1.2
Test Results:	Pass

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Special firmware code, Download special firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Connect a Temperature meter to the tip as close as possible to the NTC position	Temperature meter probe is connected	**PASSED**	
3	Bypass power by shorting TP11 and TP12.	System is powered on.	**PASSED**	
4	Run software for 5 seconds	Stop software, check Temperature meter readout and compare to internal temperature value.	**PASSED**	Temp meter readout = 28.5 Temp value = 27.21

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B4 [redacted]

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Special firmware code, Download special firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Connect a Temperature meter to the tip external side.	Temperature meter probe is connected	**PASSED**	
3	Bypass power by shorting TP11 and TP12.	System is powered on.	**PASSED**	
4	Run the software, touch tip for 2 seconds every 30 seconds.	Software is running	**PASSED**	
5	B4 [redacted]	[redacted] B	B4 [redacted]	[redacted]

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Fax: +972(4)9097471

3.6 Bat voltage monitor feature

Function name	main
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	Verify battery voltage is accurate.
Test Description	Bypass power by shorting TP11, TP12. Compile code in debug. Place a break point after Vbat is sampled. Turn system on, using an external multi meter sample and verify battery voltage.
Pass Criteria	Battery voltage is within +/- 0.2V from sampled.
SDD section	2.2.11
Test Results:	Pass

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Standard firmware code, Download firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Connect a Multi meter between TP11 and GND	Multi meter is connected.	**PASSED**	
3	Bypass power by shorting TP11 and TP12.	System is powered on.	**PASSED**	
4	Run software.	Software is stoped in the brake point. Check Multi meter readout and compare to internal battery value.	**PASSED**	Multi meter readout 7.3V Internal value 185→7.25V

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B4 [redacted]

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Standard firmware code, Download firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Connect a Temperature meter between probe to the battery pack	Temperature meter is connected.	**PASSED**	
3	Bypass power by shorting TP11 and TP12.	System is powered on.	**PASSED**	
4	B4 [redacted]	B4 [redacted]	**PASSED**	

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Yokneam 20692, ISRAEL
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Fax: +972(4)9097471

3.8 Treatment light feature

Function name	main
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	Treatment light is turned on/off.
Test Description	Set TP14 to turn on if proximity is sensed, and off if not. Compile software for release, and execute without any breakpoints set. Turn system on, touch the tip, TP14 should change state from off to on. System light (ICT20) should turn on in the same time.
Pass Criteria	TP14 and ICT20 are turned on in the same time (within 2ms in between)
SDD section	2.2.7, 3.1.1, 3.2.1, 3.2.3
Test Results:	Pass

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Special firmware code, Download firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Monitor TP14, ICT20 using a scope with 2 probes.	Probes are connected	**PASSED**	
3	Turn system on	System is powered on.	**PASSED**	
4	After 5 seconds (after fan test), touch the tip	TP14, ICT20 change state, treatment light is turned on	**PASSED**	
5	Stop touching the tip	TP14, ICT20 change state, treatment light is turned off	**PASSED**	

Tavor building, POB 533
Yokneam 20692, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

3.9 Power off feature

Function name	Main
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	Verify software turns System power off.
Test Description	Connect probes to TP12 and TP14. Set TP14 to turn on as soon as the software start to run. Compile software for release, and execute without any breakpoints set. Turn system on, TP12 and TP14 should change state from off to on. Do not touch the tip, system will turn off after 60 seconds. TP12, TP14 will turn off.
Pass Criteria	TP12 and TP14 are turned off after 60 seconds
SDD section	2.2.10
Test Results:	Pass

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Special firmware code, Download firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Monitor TP12 and TP14 using a scope with 2 probes.	Probes are connected	**PASSED**	
3	Turn system on	System is powered on.	**PASSED**	
4	After 60 seconds system is turned off	TP12, TP14 change state from on to off	**PASSED**	

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Tel: +972(4)9097470
Fax: +972(4)9097471

3.10 Indicators feature

Function name	*Main*
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	Verify indicators.
Test Description	Prepare a special code that calls to the TurnOnLED, TurnOffLED function for each of the LEDs. Compile and step through using debugger. Verify that functions work as should. LEDs respond by turning On and Off.
Pass Criteria	LEDs turn on then turn off
SDD section	2.2.8, 3.1.1
Test Results:	Pass

Verify functionality

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	Special firmware code, Download firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Step through the code, verify LEDs are turned on then off one after the other.	LEDs turn on, then off one after the other	**PASSED**	

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3.11 Main state machine

Function name	***Main***
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	Verify main state machine change states correctly
Test Description	Prepare a special code with TP13, TP14 change in main loop. TP13 set to 1 when state = standby otherwise TP13= 0, TP14 set to 1 when state = treatment otherwise set to 0.
Pass Criteria	TP13 is turned on after power on tests (approx. 5 seconds), TP13 is turned off if tip is touched. TP14 is turned off until tip is touched, TP14 is turned on as long as the tip is touched.
SDD section	3.1.1
Test Results:	Pass

Verify functionality

ID	***Action***	***Expected result***	***Test result***	***Comments and Recommendations***
1	Special firmware code, Download firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Connect probes to TP13, TP14	Probes are connected	**PASSEDD**	
3	Turn system on	TP13, TP14 are off. After power on tests (approx. 4 seconds) TP13 is set on.	**PASSED**	
4	Touch the tip (change state to treatment)	TP13 is turned off, TP14 is turned on	**PASSED**	
5	Un-touch the tip (change state to standby)	TP13 is turned on, TP14 is turned off	**PASSED**	

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Fax: +972(4)9097471

3.12 Error handling

Function name	Main
Tester Name	Daniel
Test Date:	7-Aug-2011
Test Purpose	Verify error handling
Test Description	Short TP11, TP12. Prepare a special code with TP13, TP14 change in main loop. TP13 set to 1 when state = standby otherwise TP13= 0, TP14 set to 1 when state = error otherwise set to 0. During run time short ICT18 to GND, error temperature should be triggered.
Pass Criteria	TP13 is turned on after power on tests (approx. 5 seconds), TP13 is turned off if error is triggered. TP14 is turned off until as long as error is no triggered, when error is state is set TP14 is turned on.
SDD section	3.1.1, 3.3.1, 4.3, 5.3
Test Results:	Pass

Verify functionality

ID	Action	Expected result	Test result	Comments and Recommendations
1	Special firmware code, Download firmware code to system	Code is successfully compiled and programming successful	**PASSED**	
2	Connect probes to TP13, TP14	Probes are connected	**PASSEDD**	
3	Turn system on	TP13, TP14 are off. After power on tests (approx. 4 seconds) TP13 is set on.	**PASSED**	
4	Short ICT18 to GND	TP13 is turned off, TP14 is turned on	**PASSED**	Within 50 seconds from power on

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4 Test Plan Results Summary

The test results are as described below.

Test description ID	Results: Pass/Fail and Not-Tested	Comments
3.1	Pass	
3.2	Pass	
3.3	Pass	
3.4	Pass	
3.5	Pass	
3.4	Pass	
3.6	Pass	
3.7	Pass	
3.8	Pass	
3.9	Pass	
3.10	Pass	
3.11	Pass	
3.12	Pass	

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Fax: +972(4)9097471

Tester Name: Ronen Ben Yosef
Date: 10-Aug-2011 Signature:

Comments: Used fluke to verify voltages.

Approved by: Ben Zion Levi
Date: 10/8/2011 Signature:

Comments:

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Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n Reju™

Software Integration Plan and Results

Doc. P/N: DO103012A

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Ronen Ben Yosef	System Eng.	Aug 2011	
Checked by	Suhair Francis-Najjar	V&V & QA Manager	Aug 2011	S. Francis
Approved by	Benzi Levi	VP R&D	Aug 2011	

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Yokneam 20692, ISRAEL
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Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	All	Release	Benzi	Aug 2011

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Tel: +972(4)9097470
Fax: +972(4)9097471

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1 Introduction and overview

1.1 Purpose of this document

The Integration Test will ensure that code deployed to test works as per requirements when tested within the firmware software and technical environment

1.2 Scope of the development Project

This document describes the procedure followed for Integration testing of the device firmware software component

1.3 Definitions, Acronyms and Abbreviations

Term	Definition
Validation	Assure that the software system (function and performance) conform to user needs and intended use(s). Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled
Verification	A systematic procedure of review, analysis, and testing, employed throughout the software development cycle to assure that the software design outputs meet the design inputs (all design requirements). Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
Walkthrough	A type of design review in which several participants review a work product. The objective of the meeting is to discover faults in the product
Black box testing	Also called "functional testing"; the module is treated as a "transfer function", so that all internal structure is ignored. The only purpose is to consider the functional performance as the module converts input to output
White box testing	Also called "structural testing"; as such, it takes into account the internal mechanism of a system or component. Includes branch testing, path testing, and statement testing.
SRS	System requirements specification
SwRS	Software requirements specification
VVP	Verification and validation plan
DHF	Design History File

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1.4 References

ID	Reference
IEEE-Std-1012	Std 1012-1998 IEEE Standard for Software Verification and Validation. IEEE Standards Collection: Software Engineering. The Institute of Electrical and Electronics Engineers, Inc., 1998
DO102051D	SR SW Functional System Test Plan and Results

2 Integration Strategy

2.1 Entry criteria

Identify all the elements to be integrated by subsystem into which they will be integrated.

The Code review shall have been passed and completed successfully.

The Unit test shall have been passed and completed.

The SW Packages under test have been collected under an integration test build in configuration management.

All test Hardware and environments must be in place, and free for integration test use.

All Human resources must be assigned and in place

2.2 Hardware assembly

The HW assembly for integration includes:

1. Lamp card, tested and verified
2. Main card with a battery pack connected, both are tested verified, battery pack charged.
3. External PS with variable output.
4. Connection cables to connect the above.

2.3 Software readiness

Software structure is based on 3 layers, driver layer, control layer and application layer. Software is ready for integration and source is backed up in the source control.

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2.4 Tools and Test Equipment Required

The tools required for the software integration:

- External PS, with variable output
- IDE with debug capability (MPLAB IDE)
- ICE for debugging (ICD2)
- Calibrated Multi meter with DC voltage sampling
- Calibrated Temperature meter with a low thermal capacity temperature probe
- Calibrated Oscilloscope with 2 probes.

2.5 Program Stubs and Test Data Required

N/A

2.6 Responsibilities and Schedule

Role	Name	Responsibility	Estimated time	Remarks
Software Eng.	Daniel Wiener	Check the software	2-3 days	
System Eng.	Ronen Ben Yosef	Supervise software tests and assist during debug	1 day	
Elct. Eng.	Yehoram Bar	Support during HW tests	0.5 days	
VP R&D	Benzion Levi	Check test execution		

2.7 Approach

- All-at-once

The all-at-once method provides a useful solution for simple integration problems, involving a small program possibly using a few previously tested modules.

3 SW/HW Integration

Once all the prerequisites are ready, the SW/HW integration test can be started. The main purpose of the integration test is to verify that the software performs the required functions and features together with the target hardware.
The all-at-once approach is selected for testing system's SW-HW. For each feature a simple black box method is used to define pass/fail criteria. For those that require more detailed information, a step through using in-circuit debugger is applied. As per test HW changes or external intervention is applied to ensure test conditions. Ex. Battery voltage is applied using an external PS.

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3.1 Set Up Debugging Environment

Debugging environment Includes MPLAB IDE with the Microchip ICD2, the power source is either the External PS or the battery pack (depending on the test).

Make sure all wires are connected, PS is turned on, software is compiled, programmed before test start.

3.2 Debugging Hardware Drivers

Debugging a real-time embedded system starts from the debugging of the hardware drivers, which not only finds out the bugs in the various driver modules, but also verifies the correctness of the hardware. The typical aspects of hardware driver debugging include the following:

Make sure the ICE is connected to the target

Make sure the CPU clock is running at the designed frequency

Make sure the internal watchdog is turned off

Check memory integrity

Verify CPU clock configuration

Test initialization code of each hardware module

Check each digital I/O pins to be at its initial state

Test ADC/DAC conversions

Verify input/output analog signal scaling

Verify fault detection logic

Test any other hardware drivers

3.3 Debugging Application Code

The application code is tested and debugged as a full working unit.

The purpose of the debugging of this software is to verify that the response of the system corresponds to the command, and the outputs of the system correspond to the inputs, correctly and timely.

Testing features:

- Low battery voltage alert
- Low Battery shut down
- Fan over current fault
- Over temperature fault
- Safety

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3.4 Final Functional Tests.

SEE APPENDIX A

4 Problem Recording and Resolution

Software problems, bugs, requirements for new features will be filled in the BugsReport.Xls

5 Rework, Review, and Retest Procedures

Software will be tested where no severity 1 or 2 exist. Software with severity 1 or 2 will not be released, and problems will be fixed before software release. Software bugs will be logged in the BugsReport.Xls file. Failed software with severity 3 will be fixed before release. Failed software with severity 4 can be released and is subject to the decision of VP R&D. All software bugs will be logged in the excel file.

6 Suspension, Restart, and Exit Criteria.

Define criteria for a) suspending testing before completion (for instance, the discovery of major problems with a certain feature; b) criteria for restarting testing following such a suspension; and c) the criteria for determining that integration test is complete and system test can begin.

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Appendix A:

Subsystem or unit is part of : FaceFx					
Supporting information used : Software detailed design; flow charts					
Test Setup: The entire software and hardware integration test is ready.					
Test Record					
#	Protocol	Passed\Failed	Retest date and results	Related document	Comments
1	Verify Correctness of download procedure.	PASS		System test plan DO102051C TP 9.1.4	
2	Verify hardware and software initialization	PASS		System test plan DO102051C TP 9.1.4	
2	Verify User Interface	PASS		System test plan DO102051C TP 9.1.1	
3	Verify Self-test battery	PASS		System test plan DO102051C TP 9.1.2	
4	Verify Self-test fan	PASS		System test plan DO102051C TP 9.1.3	
5	Verify device initialized with corrupt code	PASS		System test plan DO102051C TP 9.1.5	
6	[redacted]	[redacted]		B4 [redacted]	
7	[redacted]	[redacted]		[redacted]	
[redacted]	[redacted]	[redacted]		[redacted]	
[redacted]	[redacted]	[redacted]		[redacted]	
10	Verify device operation	PASS		[redacted] plan DO102051C TP 9.2.1	
11	Verify system responding to user input	PASS		System test plan DO102051C TP 9.3.1	
12	Verify idle timeout	PASS		System test plan DO102051C TP 9.4.1	
13	Verify battery voltage detection	PASS		System test plan DO102051C TP 9.4.2	
14	Verify treatment light	PASS		System test plan	

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[redacted]

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Fax: +972(4)9097471

Tester Name: Ronen Ben Yosef
Date: 10-Aug-2011 Signature:

Comments: Software hardware integration was tested, all major features worked within the specified ranges, responded as defined/requested.

Approved by: Ben Zion Levi
Date: 10/8/2011 Signature:

Comments:

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Tel: +972(4)9097470
Fax: +972(4)9097471

Silk'n Fx

Software Functional System Test Plan and Results

Doc. P/N: DO102051D

Authorization				
	Name	**Position**	**Date**	**Signature**
Written by	Ronen Ben Yosef	System Eng.	Aug 2011	
Checked by	Suhair Francis-Najjar	V&V & QA Manager	Aug 2011	S. Francis
Approved by	Benzi Levi	VP R&D	Aug 2011	

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Fax: +972(4)9097471

Revisions

Rev.	Page	Description	Approval	Date
A	All	First Version	Ben Zion Levi	Aug 2010
B	All	Updated according to KEMA external audit AR03/Mi-01 (b)	Ben Zion Levi	Oct 2010
C	All	SW Ver. 1.1.0 release	Ben Zion Levi	Dec 2010
D	All	Update	Ben Zion Levi	Aug 2011

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1. Introduction

1.1. Purpose

The Silk'n Fx Software System Test Plan establishes and provides program visibility and control of the approach, requirements and plans for validation and testing of the Silk'n Fx

1.2. Scope

This test plan covers a full functional systems test of the Silk'n Fx Device. This includes operate and user procedures, as well as programs. In addition to comprehensively testing firmware functionality, hardware interfaces, performance, load test, download procedure, error handling and recovery and usability.
Ideal system testing presumes that all components have been previously, successfully, integrated.

1.3. Definitions

Term	Definition
STP	System Test Plan
SRS	System requirements specification
SwRS	Software requirements specification
VVP	Verification and validation plan
DHF	Design History File

1.4. References

Document	Location
DO101683D Silk'n Fx System Requirements Specification	DHF
DO102050D Silk'n Fx Software Requirements Specification	DHF
DO102377D Silk'n Fx Software Design Description	DHF
DO101971B Silk'n Fx Risk Analysis Report	DHF

2. Test Plan Type & Attribute Refinement

2.1. Test Plan Type

This test plan is functional, stress, performance, safety, and error handling testing used to verify the Silkn Fx SW release.

2.2. Level

System Level

2.3. Objective

The objectives of the system test plan are:

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- Functional testing: testing based on a comparison of a component's actual behavior with its specified behavior without regard to the component's implementation.
- Performance testing: tests that explore the consistency of a system with its performance objectives such as response time or throughput
- Stress testing - testing in which a system is subjected to unrealistically harsh inputs or load with inadequate resources with the intention of breaking it
- Recovery testing - testing that explores how well the system meets it objectives in recovering from programming errors, hardware failures, and data errors.
- Safety testing – aims at showing that an unsafe state cannot be reached although that state could be invalid (traceable to hazard analysis document)
- Regression testing – it assumed that several iterations of the system test will be done in order to test program modifications made during the system period. A regression test will be performed for each new version of the system to detect unexpected impact resulting from program modifications. The regression test will be done by running all of the tests on a new version that were run on the previous version and then comparing the results.

2.4. Approach

Testing methods used to achieve the objective of this test plan:
Black box technique: Data-Flow testing.
Black box technique: Domain testing & boundary value analysis.

The developer will assist in developing the test cases; this will help ensure that the tests represent the production use of the system.

2.5. Readiness Criteria

The Unit and Integration testing shall have been passed and completed successfully.
The software is stable (means a reliable software with no major issues).
The SW Packages under test have been collected under a system test build in configuration management.
All test Hardware and environments must be in place, and free for system test use.
All Human resources must be assigned and in place

2.6. Input Work Products

The input work product used for the system test plan is the:

- DO102050D Silk'n Fx Software Requirements Specification
- DO101971A Silk'n Fx Risk Analysis Report

2.7. Test Environment

The tests require a system with the software fully installed and the options (hardware and software) available.

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2.7.1. Hardware

Silk'n Fx device consists of a Base unit and an Applicator.

2.7.2. Software

Software version: 1.10

2.7.3. Security

NA.

2.7.4. Tools

2.7.4.1. Error reporting Tools

Bug report file named BugRepot.xls.

2.8. Publications

NA.

2.9. Roles & Responsibilities

2.9.1. Test Plan generation

Functional test plan is generated by the system engineer.

Test Procedures for safety related components shall be defined by a system engineer and a team regulatory& quality member.

2.9.2. Test Execution

Test Procedures shall be executed by a team member not directly involved in the design and implementation of the component.

2.9.2.1. Test Phases and Cycles

There will be two main stages of testing for the Software during system testing:

System Testing

Acceptance Testing

2.9.2.1.1. System Testing Cycles

The main thrust of the approach is to intensively test the SW in two releases, thus raising approximately 80% of errors in this period. With the majority of these errors fixed, standard and/or frequently used actions will be tested to prove individual elements and total system processing. Regression testing of outstanding errors will be performed on an ongoing basis.

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When all errors (which potentially impact overall processing) are fixed, an additional set of test cases are processed to ensure the system works in an integrated manner. It is intended that Release Silkn Fx SW 1.01 be the final proving of the system as a single application. There should be no severity 1 or 2 errors outstanding prior to the start of Release.

Revision number	Creation date	System Test Cycle
Silkn Fx User 1.01	Oct 2010	First Cycle
Silkn Fx User 1.10	Dec 2010	Second Cycle

2.9.2.1.2. Acceptance Testing Cycles

The main thrust of the approach is to test the usability of the device after approval of the system test.

2.9.2.2. Software Delivery

During System Test the release of new versions of the software will be coordinated between the Development SW engineer and the Development System engineer. However, unless it concerns a fix to a very serious error, new versions should only be released when agreed targets have been reached (i.e. the next version contains fixes to X or more numbers of bugs).

Notes:

It is intended that 80% of the functionality will have been tested in full prior to the Phase 1 Release.
All the functionality must be present in the Phase 2 Release. No previously undelivered functionality will be accepted for testing after Phase 2.

2.10. Formal Reviewing

There will be several formal review points before and during system test, including the review of this document. This is a vital element in achieving a quality product.

- Design Documentation - Requirements Specification & Functional Specification
- System Test Plans & Test conditions.
- System Test results
- Post system test review.

3. Test Items

All items that makeup the software Silk'n Fx device will be tested during the system test. The versions to be tested will be downloaded to the device

4. Features to be tested

- Initialization and self test
  - Checksum Test
  - Go to main loop (treatment mode).
- Man Machine Interface Parameters
  - Mode Switch

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Fax: +972(4)9097471

- Green LED
- B4 [redacted]
- B4 [redacted] Monitoring
  - Check temperature stabilization system
  - Battery Voltage

5. Features not to be tested

NA

6. Tester Skills

The following staff is needed to carry out this testing project:

- System engineer: he provides the overall management of the testing and technical testing expertise.
- SW engineer: he transmits the system to be tested and responds to the system test Incident reports he does any program debugging that required. It also supplies the version control.
- All the staff must be trained to perform the test.

7. Safety Issues

Safety issues have been analyzed. This test plan takes into account this analyze and all the tests associated to a safety issue are noted "safety related" in the title refer to risk analysis management file.

8. Test Termination Criteria

This test plan terminates normally if the execution of each test procedures results in a passed condition. The test plan may be terminated abnormally under the following conditions:

- Upon reaching a "Fail" condition on for any test case within a test procedure, the tester may terminate the test procedure.
- Upon reaching a failed condition in one test procedure, the tester may continue testing if. the preconditions of subsequent test procedures can be satisfied. Otherwise, the tester may terminate execution of the test plan.

If the preconditions of a test procedure cannot be satisfied, the tester may proceed to execute subsequent test procedure as long as the preconditions of those procedures can be satisfied. Otherwise, the tester may terminate execution of the test plan."

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9. Test Procedures

9.1. Verify interfaces

9.1.1. Verify User Interfaces

Test step#	Action	Expected result	Test result	Comments and Recommendations
1	Remove device from cradle	All LEDs are off	**PASSED**	
2	Press the Power on/off button	1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off.	**PASSED**	
3	Touch the device tip	Treatment light is turned on	**PASSED**	
4	Stop touching the device tip	Treatment light is turned off	**PASSED**	
5	Press the Power on/off button	The yellow led is turned on, and then device is turned off all LEDs are off.	**PASSED**	

9.1.2. Verify self test - battery

Test step#	Action	Expected result	Test result	Comments and Recommendations
1	Turn device on while battery voltage is under 5.5V	Yellow indicator is turned on, all other indicators are off.	**PASSED**	
2	Device is turned off	Within 5 seconds the device is turned off.	**PASSED**	

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9.1.3. Verify self test - fan

Test step#	Action	Expected result	Test result	Comments and Recommendations
1	Turn device on while fan is stuck	The green indicator is blinking, all other indicators are off.	**PASSED**	
2	After 4 seconds	The green indicator is off, yellow indicator is on	**PASSED**	
3	After 60 seconds device is turned off	Device is off, all indicators are off	**PASSED**	

9.1.4. Verify firmware download process

ID	Action	Expected result	Test result	Comments and Recommendations
1	The device for firmware burn is ready. Performs down load according to the device user manual instruction. Verify down load completed successfully	Firmware downloaded correctly.	**PASSED**	
2	Turn off system	Device is off, all indicators are off	**PASSED**	
B4 [redacted]				
4	Wait for 5 seconds, touch tip and verify treatment light is on	Treatment light is on	**PASSED**	

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9.1.5. Verify device initialized with corrupt firmware

Test step#	Action	Expected result	Test result	Comments and Recommendations
1	Turn On Device when it is cold. Verify system runs.	1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off. Device is ready for treatment.	**PASSED**	
2	Alter an un-used byte in the flash memory. Turn on the system,	The yellow led turns ON for a short time, the device is turned off and all indicators are off.	**PASSED**	
3	Touch device tip	Treatment light is off	**PASSED**	

9.1.6. Verify treatment li[redacted]

Test step#	Action	[redacted]	Test result	Comments and Recommendations
1	Turn On the device.		**PASSED**	
2	After 5 seconds, touch the tip		**PASSED**	
3	Un touch tip		**PASSED**	
4	Touch the tip		**PASSED**	
5	Press power on/off button		**PASSED**	

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9.3. Performance

9.3.1. Verify system responding to user input

ID	Action	Expected result	Verification Test result	Comments and Recommendations
1	Turn the device on	1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off.	**PASSED**	
2	After 5 seconds, touch the tip	The treatment light is turned on.	**PASSED**	
3	Press the on/off button	Device is turned off, all indicators are turned off	**PASSED**	

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9.4. Verify Interfaces

9.4.1. Verify idle timeout

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4	Turn the device off	Device is turned off, all indicators are turned off	**PASSED**	

9.4.4. Verify temperature control

ID	Action	Expected result	Verification Test result	Comments and Recommendations
1	Turn the device on, using a scope connect a probe to measure control signal on Q4 pin 3 and a probe to measure temperature on J2 pin 3	1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off.	**PASSED**	
2	Measure both signals verify that the control is active during heating	Control signal is active high, '1'	**PASSED**	
3	When the signal on J2 pin3 drop to 1.6V the control signal change to PWM	J2 pin 3 reach 1.6V, control signal is alternating in variable duty cycle	**PASSED**	
4	Turn the device off	Device is turned off, all indicators are off	**PASSED**	

9.4.5. Software System Attributes

ID	Action	Expected result	Verification Test result	Comments and Recommendations
1	Turn device on	Device is turned on, 1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off.	**PASSED**	Availability
2	After 5 seconds, touch the tip	Treatment light is turned on	**PASSED**	
3	The device is on until battery voltage drops below 6.8V	Device is on, treatment light is on	**PASSED**	
4	Battery voltage is below 6.8V	Green indicator is blinking,	**PASSED**	
5	After 60 seconds the device is turned off	Device is off, all indicators are off.	**PASSED**	

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6	Turn system On.	Device is turned on, Device is turned on, 1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off. Without requiring any user identification.	**PASSED**	Security
4	After 5 seconds touch the tip	Treatment light is turned on	**PASSED**	
5	Turn device off	Device is off, all indicators are off.	**PASSED**	

9.5. Verify safety

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9.5.2. B4 [redacted] system check abnormalities Periodically

ID	Action	Expected result	Test result	Comments and Recommendations
1	B4 [redacted]			
2	Stop fan, un touch tip	Green indicator is turned off, yellow indicator is turned on	**PASSED**	
3	Turn the device off	Device is turned off, all indicators are off	**PASSED**	
4	B4 [redacted]			
5				
6	Device is turned off after 60 seconds	After 60 seconds, device is turned off, all indicators are turned off	**PASSED**	
7	Turn device on	Device is turned on, 1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off.	**PASSED**	Battery temperature low

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8	After 5 seconds, disconnect NTC wire from J3 pin 2, connect 42K Ohm between J3 pins 2, 3	Green indicator is off, yellow indicator is on	**PASSED**	
9	Device is turned off after 60 seconds	After 60 seconds, device is turned off, all indicators are turned off	**PASSED**	
10	Turn device on	Device is turned on, 1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off.	**PASSED**	Battery temperature is ≈60°C
11	After 5 seconds, connect a 4K on J3 pins 2, 3	Green indicator is off, yellow indicator is on	**PASSED**	
12	Device is turned off after 60 seconds	After 60 seconds, device is turned off, all indicators are turned off	**PASSED**	
13	Connect external power supply set to 7V to J3 pins 1, 3. Connect a 10K Ohm to J3 pins 2, 3. Turn device on.	Device is turned on, 1st the green led is blinking, all other indicators are off. 2nd all indicators blink. 3rd the green led is on, all other indicators are off..	**PASSED**	Battery voltage too high
14	After 5 seconds, change the power supply to 8.7V	Green indicator is off, Yellow indicator is on	**PASSED**	
15	Device is turned off after 60 seconds	After 60 seconds, device is turned off, all indicators are turned off	**PASSED**	

9.5.3. Verify Watchdog functionality

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	Special firmware code, Add an infinite loop after all initialization sections executed. Download special firmware code to system,	Code is successfully compiled and programming successful	**PASSED**	
2	Turn the power switch on	The system will repeatedly restart, delay then reset	**PASSED**	

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10. Test Plan Results Summary

Test Equipment

Equipment	S/N	Calibration Expiry
Fluke 179	98100140	10/2011
Thermometer CENTER 301+ TP-K03	100800983	10/2011
Scope Tektronix TDS1012	WIT-227	10/2011
EP-613		10/2011

Tester Name: Ronen Ben Yosef

Date: 15-Dec-2010 Signature:

Comments: Used fluke to verify voltages.

Approved by: Ben Zion Levi

Date: 15/12/2010 Signature:

Comments:

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Silkn FX™ Risk Management File

DO101971B

Project	Silkn FX™
Date	August,2011
Written by	S.Francis-Najjar S. Francis
Approval	Ben Zion Levi

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Revisions

Rev.	Description	Updated by	Date
A	Initial release	S. Francis-Najjar	12/2010
B	Update to comply with SW level of concern Major: Question 31 / page 14 Add section 4.8.5 /page 34 Update section 4.9.5 / page 37	S. Francis-Najjar	08/2011

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1 Introduction

1.1 Purpose

This document is used to evaluate the risk associated with the Silk'n FX™. system.

1.2 Scope

This document identifies and describes the potential hazards and risks of Silk'n FX™. It also includes extensive risk analysis and describes the measures taken to ensure that SILK'N FX™ meets the appropriate safety requirements.

1.3 Overview

This document describes the safety hazards associated with the Silk'n FX™ It also describes the possible consequences of these hazards, their probability of occurrence, the Risk Level, how they will be mitigated and how and where that mitigation will be implemented.

1.4 Applicable Standards

- IEC 62304:2006 Medical device software – Software life-cycle processes.
- IEC 60601-1-4: edition 1.1 2004, General requirements for safety-collateral standard: Programmable electrical medical systems
- ANSI/AAMI/ISO 14971:2007, Medical devices - Application of risk management to medical devices.
- IEC 60601-1: "Medical Electrical Equipment" Part 1:"General requirements for safety"1988, including amendments #1(1991),#2(1995).

1.5 Core team

Ben Zion Levy	VP R&D and Engineering
Dr. Amir Waldman	VP Regulatory and clinical affairs
Suhair Francis-Najjar	V&V and Quality Manager

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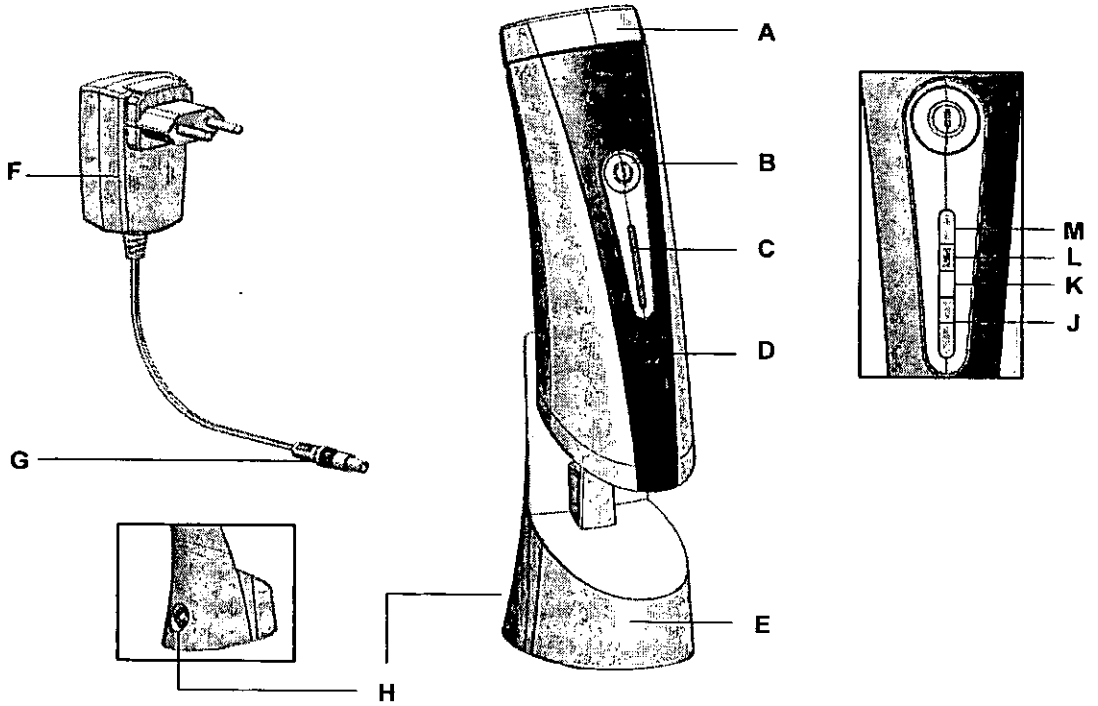
Fax: +972(4)9097471

Daniel Wainer — Software Engineering Manager
Yohram Bar — System Engineer

1.6 Device Description

The device is used for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

The Base Unit use to charge the batteries of the applicator. On the Silk'n FX™ Applicator you can find the on off switch as well as light indicators. The system contains the following parts:



A *Treatment surface.*
B *On/Off Switch*
C *Indicator Panel*
D *Applicator*
E *Base Unit*
F *Adaptor*
G *Plug*
H *Base Unit socket*
J *Treatment - indicator light*
K *System Error - indicator light*
L *Battery – charging - indicator light*
M *Battery – full - indicator light*

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In normal operation the Applicator is stand alone device.

Along the battery charging, the Applicator is inserted into the cradle which connected to the AC wall power adaptor.

Device is not required to interface with any other equipment.

The following table outlines the main system components and their functionality.

Module	Description
AC Adaptor	Switched-mode power supply that is built into the top of a plug. Supplies 10.5V DC regulated voltage for battery charger.
Base	Charging cradle for Applicator batteries charging and bridging connection between AC adaptor plug and charging contacts in Applicator
Applicator	Treatment appliance
Main Card	Battery charger, the micro controller IC, FAN driver, toggle switch detector, voltage regulator and indications LEDs. Responsible for: the man machine interface, control the machine stage software and control the light and temperature stabilizer functionality.
Lamp Card	Contains heater, LED array touch pad for touch sensor. Responsible for Light and heat sources circuit

Main system components and functionality.

1.7 Intended use

Silk'n FX is an over the counter device indicated for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated

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1.8 Contraindications

- Dark brown or black spots, such as large freckles, birth marks, moles or warts.
- Eczema, psoriasis, lesions, opens wounds.
- Active infections such as cold sore.
- Abnormal skin conditions caused by diabetes or other systemic or metabolic diseases.
- Photosensitizing disease, patient taking photosensitizing drugs

1.9 Possible Side Effects

- Minor skin discomfort, most feel slight heat that the device deploys into skin.
- Skin redness: skin may become a little red and irritated

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2 Finding possible hazards

2.1 Identification of Qualitative Characteristics Related to the Silk'n FX™ device

1) **What is the intended use and how is the medical device to be used**

   Silk'n FX is an over the counter device indicated for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated

2) **Is the medical device intended to be implemented?**

   No.

3) **Is the medical device intended to contact the patient or other persons?**

   The Applicator of the device comes into contact with the user skin surface during the treatment. Period and Frequency of contact: Transient normally intended for continuous use for less than 60 minutes (MDD 93/42/EEC Annex IX).

4) **What Materials and/or components are utilized in the medical device or are used with, or are in contact with, the medical device?**

   The material comes in contact with human body are biocompatible

Part	Description	Type of contact
Treatment surface	Medical grade stainless steel 17-4PH	Applied to the skin surface

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No.

7) **Are biological materials processed by medical device for subsequent re-use?**

No

8) **Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?**

No

9) **Is the medical device intended to be routinely cleaned and disinfected by the user?**

Yes, after each session, it is recommended to clean your Silk'n FX™ device, and especially the APPLICATOR TIP.

- Unplug Silk'n FX™ before cleaning.
- Use a dry, clean cloth and a specially formulated cleaner for electronic equipment to gently wipe Silk'n FX™ surface, and especially the APPLICATOR Tip.
- Never immerse Silk'n FX™ or any of its parts in water!
- Never clean the Silk'n FX™ or any of its parts under the tap or in the dishwasher.

10) **Is the medical device intended to modify the patient environment?**

No

11) **Are measurement taken?**

The Silk'n FX™ device does not provide vital sign monitoring. the Silk'n FX™ measures some variables for functional purpose: temperature sensing of the treated skin surface.

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12) Is the medical device interpretative?

No, the Silk'n FX™ device is a home use device, and does not provide diagnostic.

13) Is the medical device intended for use in conjunction with medications or other medical technologies?

No

14) Are there unwanted outputs of energy or substances?

Radiation

Optical radiation: The Silk'n FX™ device emitting CW optical radiation and shall be assigned to the exempt risk group as its accessible emission does not exceed emission limits in any of the hazard spectral regions of table 201.101 (page 11 of standard IEC 60601-2-57) when assessed for the angle of acceptance γ specified in Table 201.103 (page 13 of standard IEC 60601-2-57)

Ionizing radiation.-Silk'n FX™ does not radiate ionizing radiation.

Electromagnetic Compatibility- is compliant with regard to the harmonized standard EN60601-1-2

15) Is the medical device susceptible to environmental influences?

Transport environment:

Vibrations during transportation and normal use.

Normal use vibrations: According to EN60601-1 there is no general requirement for vibrations, although the systems were designed to be transported on smooth surfaces.

Electromagnetic Environment

The device complies with the requirements of the EMC standard for medical equipment EN 60601-1-2.

Spillage

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

16) Does the Medical device influence the environment?

Do not throw away the Silk'n FX™ with the normal household waste at the end of its life, hand it at an official collection point for recycling.

17) Are the essentials consumables or accessories associated with medical device?

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No.

18) Is maintenance and/or calibration necessary

No.

19) Does the medical device contained software?

The Silk'n FX™ is operated and controlled by software. The software is fully verified and validated according to all relevant standards and installed by the manufacture.

20) Does the medical device have a restricted shelf time?

Yes. – the batteries has 6 month shelf time .

21) Are there any delayed and/ or long term use effects

No.

22) To what mechanical forces will medical device be subjected?

The Applicator of the device is held against the face and body skin by hand during the treatment.

23) What determines life time of the device?

The batteries determine the device Life time.

24) Is the medical device intended for single use?

No

25) Is safe decommissioning or disposal of the medical device necessary?

Yes – according to the user manual the batteries must be removed out of the device at the end of the batteries shelf life.

26) Does installation for use of the medical device require special training?

No

27) How will information for safe use provided?

By Instruction for Use (IFU).

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28) Will new manufacturing processes need to be established or introduced?

No

29) Is successful application of the medical device critically dependent on human factors such as the user interface?

Yes

I. **Can the user interface design features contribute to use error?**

Yes. But the controls and indicators, symbols used, Buttons, visibility of warnings, and standardization of color coding are designed according to IEC60601-1-6.

II. **Is the medical device used in an environment where distractions can cause use error**

No

III. **Does the medical device have connecting parts or accessories?**

Yes. External adapter

IV. **Does the medical device have a control interface?**

Yes. On/Off button.

V. **Does the medical device display information**

The device has LEDs indicator.

VI. **Is the medical device controlled by a menu**

No.

VII. **Will the medical device be used by persons with special needs?**

No.

VIII. **Can the user interface be used to initiate user actions**

No.

30) Does the medical device use an alarm system?

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No.

31) In what way(s) might the medical device be deliberately misused?

Factors that should be considered are:

1) the device is only for facial treatment areas for more detailed refer to User manual page 8

2) To avoid misused conditions refer to user manual pages 5-7.

32) Does the medical device hold data critical to patient care?

No

33) Is the medical device intended to mobile or portable?

Yes.

34) Does the use of the medical device depend on essential performance?

Yes. Refer to section 4

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3 Risk Method

3.1 *Risk estimation*

Various methods can be used to estimate risk. While the international standard does not require that a particular method be used, it does require that risk estimation be carried out. And accordingly we follow in the Silk'n FX™ project the qualitative methods.

Risk level = *probability of failure x severity category*

3.1.1 Qualitative analysis

Several approaches can be used for qualitative analysis. A typical approach is to use an N-by-M matrix to describe the propabilites and severities of the risk associated with each hazardous situation.

Qualitative **Severity** level

Rating	Description
Negligible	Nuisance only / Cosmetic in nature / User Inconvenience / Will not cause personal injury or harm
Minor	Loss of efficacy but patient safety not compromised / Will not cause personal injury or harm
Moderate	Non-functional or poor functional performance of device requiring additional medical intervention to compensate /Injury to patient or user requiring no or minor medical intervention to compensate
Major	Incapacitating / Serious injury or death

Note: 1) Safety function requirements (what the function does.

2) Safety integrity requirements (the likelihood of a safety function being performed satisfactory

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Qualitative **Probability** levels

Rating	Description
High	Likely to occur frequently
Medium	Likely to occur sometime in the life of an item
Low	So unlikely that occurrence may not be experienced

Qualitative 3x4 **risk matrix**:

Qualitative probability Levels	Qualitative severity levels			
	Negligible	Minor	Moderate	Major
High	Minor	Moderate	[illegible]	[illegible]
Medium	Negligible	Minor	Moderate	[illegible]
Low	Negligible	Negligible	Minor	Moderate

Risk acceptability

Assessment Risk Index	Necessary Actions
[illegible]	Unacceptable under existing circumstances requires immediate action
Moderate	Corrective actions are needed and a plan must be developed to incorporate these actions within a reasonable period of time
Minor	The core team must determine whether corrective actions are still required or decide to accept the risk
Negligible	Corrective actions are not required or decide to accept the risk

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3.2 Risk Control method

An as low as reasonably achievable approach is used:

Level	Methods of control	Description
1	Inherent safe design	This strategy includes system functionality and features that have been especially incorporated to alleviate safety hazards.
2	Manufacturing control	This includes protective measures in the device itself/ in the manufacturing process, and testing
3	Adequate USER information	This includes the provision of adequate user information, training, and labeling

Risk mitigation measure

	Negligible(1)	Minor(2)	Moderate(3)	Major (4)
Adequate USER information (3)	IV	III	II	I
Manufacturing control (2)	IV	III	III	II
Inherent safe design (1)	IV	IV	IV	III

RISK IV: Acceptable Risk
RISK III: Medium risk
RISK II: High Risk.
RISK I: Very High Risk, Intolerable risk

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4 Risk Analysis

4.1 Chemical and biological Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Residual Risk Evaluation		V&V
Item / Hazard Description		Cause(s) of the Hazard Harm	Severity	Occurrence	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.1.1	Bio Compatibility	Improper Materials	Moderate	Low	Minor	The parts in contact with the patient is medical grade stainless steel 17-4PH	(1)	IV	
4.1.2	Bio-burden/ contamination /Inability to maintain hygienic	Improper hygienic and contamination	Moderate	Medium	Moderate	Applicator supplied clean and Instructions for use in Operator Manual include maintain hygienic instruction.	(1)(3)	IV	Inspection of the operator manual
		toxicity	Moderate	Medium	Moderate	The parts in contact with the patient is medical grade stainless steel 17-4PH	(1)(3)	IV	
		allergenicity	Moderate	Medium	Moderate	No metal allergen parts are in contact with the user.	(1)(3)	IV	
4.1.3	Liquids	Hazard due to the presence of dangerous liquids.	Moderate	Medium	Moderate	The only liquid is sealed in approved electrolytic capacitors	(3)(2)	III	IEC 60601-1 test report

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Hazard Identification			Initial risk estimation				Residual Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard Harm	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.1.4	Hazards of Implosion and Explosion (Electrolytic Capacitors)	Implosion and Explosion (Electrolytic Capacitors)	Moderate	Medium	Moderate	The Electrolytic Capacitors are the only components thought to be at risk of exploding. The SILK'N FX™ enclosure is believed to be stronger than needed to contain any ejected parts	(1)(2)	III	IEC 60601-1 test report clause 15.4.3.1
4.1.5	Hazard due to the use of solid materials	Solid materials	Moderate	Medium	Moderate	All solid materials such as metals, plastics, terminal strips, PCB etc. are common materials are proven safe by long use or approved by UL (U94-0) No materials known to generate dangerous vapours or gases when heated or burned.	(1)(2)	III	IEC 60601-1 test report

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4.2 Mechanical Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.2.1	Unable to start/stop/ insert into the cradle	Broken part	Moderate	Low	Minor	Mechanical hazards have been avoided and minimized by construction and good engineering practice and testing according to EN60601-1.	(1)	IV	Pass (IEC60601-1 test report no. 9012313978)
4.2.2	Sharp edge	Improper design	Moderate	Low	Minor	Mechanical hazards have been avoided and minimized by construction and good engineering practice and testing according to EN60601-1.	(1)	IV	Pass (IEC60601-1 test report no. 9012313978)
4.2.3	Stability hazards	The device is unstable	Moderate	Low	Minor				
4.2.4	Accidental mechanical damage	Improper mechanical packaging	Moderate	Low	Minor	Packaging instruction to production	(2)	III	Packaging Qualification
4.2.5	Accidental moving parts	Moving parts (The only used moving part the internal fan)	Moderate	Low	Minor	The fan is an internal part of the applicator and is not reachable to the user.	(1)	IV	IEC60601-1 test report no. 9012313978

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4.3 Fire Hazards

Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.3.1	General Fire ignition Hazards in normal use	A thermo-plastic material located near a hot spot may catch fire	Moderate	Medium	Moderate	All thermo-plastic materials used in unit have the adequate flame protection according to UL94.	(3)(1)	IV	Pass *("SILK'N FX™ – Plastic Parts"Data sheet)*
4.3.2	Electrical Fire Hazards in normal use	Overrating, Improper materials	Moderate	Medium	Moderate	Electrical fire hazards are avoided and minimized by construction and type testing according EN60601-1, and good engineering practice such as: Proper selection fuses, thermal fuses, type and wires size (UL listed). Operating all electrical components within their ratings. Protection of wires from sharp edges. All electrical components (IC, Capacitors, Transformers, resistor, etc) were choosing so it operates below its rated (Temperature, Current,	(2)(1)	IV	EN60601 test report Subclause 11.2.1 Pass *(IEC60601-1 test report no. 9012313978)*

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Like-lihood	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
						Voltage, etc). To verify this SILK'N FX™ engineers has selected the components that are hot, and tested them with thermocouple during testing of design verification.			
[redacted]									
4.3.4	Fires when the device is not in use	Improper work instruction	Moderate	Low	Minor	The user manual instruct the user to shut down the system when it not in used, and to unplug the line cord, in this position it is believed to be impossible for fire to start in the SILK'N FX™ device, if the device is plugged in but the switch is off, it's unlikely that fire can be start.	(3)(1)	IV	Operator manual

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4.4 Environmental Hazards

Hazard Identification			Initial risk estimation						
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.4.1	EMI &RFI	Inadequate supply of power Restriction of cooling.	Moderate	Low	Minor	Self test and status poling detects power instability.	(1)(2)	III	Pass SW V&V 9.2.1
4.4.2	Operation above or beyond the pre-defined limits of environmental conditions	Environmental specifications are not clear	Moderate	Low	Minor	User Manual includes the environmental specifications.	(3)	III	Inspection of Operator Manual
4.4.3	The device is exposed to pathogens, allergens, and other	Contamination due to spillage / exposure to toxins	Moderate	Low	Minor	Users are instructed how to hand the batteries at the official collection point for recycling.	(3)	III	Inspection of Operator Manual

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		Battery leak	Major	Low	Moderate	Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.	(1)	IV	EN 60601-1 9012313978 Test report. Safety test
4.4.4	Inadequate material according to environment directives	Concentration of substances that are SVHC in REACH - regulation	Moderate	Low	Minor	The SILK'N FX™ substances was tested by a certified laboratory to compliance with REACH	(2)	III	Passed

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4.5 Electrical Hazards

Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
	Item / Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
4.5.1	Overheating which corresponding risk to health: electrical Shock in normal use.	Not connecting to a certified safety ground	Major	Medium	Major	Grounding of the accessible metallic parts. Mains Voltage isolation.	(1)(2)	II	EN 60601-1 Test report. 9012313978
4.5.2	Leakage current too high which corresponding risk to health: electrical Shock in normal use.	Short circuit	Major	Low	Moderate	Leakage current complies in accordance with EN60601-1 section 8.7	(2)(1)	IV	EN 60601-1 Test report. 9012313978
4.5.3	BOM	Use of non-safety approved components	Major	Low	Moderate	All insulation materials and connections are in accordance with EN60601-1. Use of safety approved components.	(2)(1)	IV	BOM Control
4.5.4	Manufacturing hazards	Human error during assembly	Modera te	Medium	Moderate	Production Ground continuation test	(2)	III	Working instruction and SILK'N

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
									FX™ ATP
		Applicator is not connected	Minor	Medium	Minor	Maximum voltage at the applicator not connected 8.4 V	(3)	IV	Inspection of Operation manual
4.5.5	Electrostatic phenomena (Electrostatic charge build-up)	Improper materials and grounding	Major	Low	Moderate	Intrinsic safe design. Certification to IEC60601-1-2	(1)(2)	III	EN 60601-1-2 9012313993 Test report.
4.5.6	Hazards in normal use	Unstable electrical supply	Minor	Low	Negligible	Self-test is done after power electronics is initiated. Power on does not turned on automatically, system is turned on in Stand By mode Pooling of electrical parameters every 100[ms]	(1)	IV	SILK'N FX™ System and Software V&V
		Abnormal charging	Major	Low	Moderate	Designed conforming to EN60601-1 and certified.	(2)(1)	IV	EN 60601-1 Test report. 9012313978
4.5.7	Heat	Due electrical short	Major	Low	Moderate	The treatment surface temperature is monitored and limited by hardware to 41°C	(2)(1)	IV	EN 60601-1 9012313978

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Hazard Identification			Initial risk estimation			Risk Reduction Method	Final Risk Evaluation		V&V
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)		Risk Control method	Risk Acceptability	
						and by software to 40°C			Test report.
	electrical short	Mechanical force	Moderate	Low	Minor	Electrical short by mechanical force are avoided and minimized by construction and production testing in accordance with EN60601-1, good engineering and good manufacturing practices	(2)	III	EN 60601-1 9012313978 Test report. Safety test
4.5.8	Electrostatic phenomena (Electrostatic charge build-up)	Improper design of electrostatic discharge requirements	Moderate	Low	Minor	SILK'N FX™ device is complies with electrostatic discharge requirements of EN 60601-1-2 Standard	(1)	IV	EN 60601-1 9012313978

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4.6 Radiation and Electromagnetic Hazards

Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.6.1	Hazards of interaction with external medical devices due to Electromagnetic interference.	Interruption of functionality of external medical devices	Minor	Medium	Minor	The System is designed, built and tested to conform to IEC 60601-1-2 , tested to conform to: EN 60601-1-2	(1)	IV	EN 60601-1-2 9012313993 test report
4.6.2		Susceptibility to electromagnetic interference	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: EN 61000-4-2 (ESD) IEC 61010-1 EN 61000-4-4 (Radiated Susceptibility) EN 61000-4-4 (Electrical fast Transients) EN 61000-4-5 (Surge) EN 61000-4-5 (Conducted RF) EN 61000-4-8 (Power frequency Magnetic Field)	(2)(1)	IV	SILK'N FX™ Safety Certification report

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
						EN 61000-4-11 (Voltage dips and interrupts)			
4.6.3	Unwanted and excessive optical radiation in normal use	Improper design of disabling the release of optical radiation in the absence of target tissue	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: IEC 60601-1	(2)(1)	IV	SILK'N FX™ Safety Certification report
		Failure of controls and protection against hazards	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: IEC 60601-1	(2)(1)	IV	SILK'N FX™ Safety Certification report
4.6.4	Unwanted and excessive optical radiation in single fault condition	Improper design that a single fault condition does not result in an increase of output	Moderate	Medium	Moderate	The device is designed, built and tested to conform to: IEC 60601-1	(2)(1)	IV	SILK'N FX™ Safety Certification report

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4.7 Human factors Hazards

Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.7.1	User does not understand how to initiate device operation.	User interface design is confusing. User confused by device operation, IFU insufficient or lacking.	Moderate	Medium	Moderate	Considerable thought has been devoted to making the interface natural and simple. The read-out device is a set of LEDs, with good brightness. In addition, an audible emission tone alerts the user of an emission in process. All Human-machine requirements of EN60601-1-6 have been met.	(3)(2)(1)	IV	EN 60601-1-2 9012313993 test report Inspection of user manual
4.7.2	User/Device - Operation violates the intended use and instruction how to use	Intended use, indication for use and instruction how to use are not clear or ambiguous	Moderate	Low	Minor	User manual will instruct for safe operation and include section on "Safety with.Silk'n FX"	(3)	III	Inspection of User manual
4.7.3	Device stopped prematurely	User is unaware of battery	Minor	Medium	Minor	User manual include maintenance instruction for	(3)	III	User manual

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		capacity				safe operation.			
4.7.4	The user fails to detect or understand device notifications	Background noise cause user to fail to detect or to ignore them	Minor	Medium	Minor	User manual include maintenance instruction for safe operation and labeling satisfies 21 CFR Part 801 (maximum light intensity, peak wavelength, warnings about optical radiation and thermal hazards)	(3)	III	User manual

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4.8 Thermal and Treatment Hazards

Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.8.1	Hazards because of the longest exposure times	Human errors, Violation of operation instructions	Minor	Medium	Minor	Warnings in operation manual	(1)(3)	III	Inspection of SILK'N FX™ operation manual.
4.8.2	Hazards from insufficient Output from Applicator in single fault condition.	Violation of design	Moderate	Medium	Moderate	The System is designed, built and tested to conform to IEC 60601-1, tested to conform freedom of unacceptable risk under single fault condition	(2)(1)	IV	EN 60601-1 9012313978 Test report. Safety test
4.8.3	[redacted]								

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Hazard Identification		Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
[redacted]						(1)(2)	III	EN 60601-1 9012313978 Test report. Safety test
						(1)(2)	III	test report Silk'n FX™ Software V&V Test 9.4.1 test ID OPRN2
		Fan failure	Moderate	Low	Minor	Design verification & validation. Compliance with standards	(1)(2)	III	Silk'n FX™ System verification and Software V&V Silk'n FX™ Software

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
									V&V Test 9.4.6 test ID EINT41
4.8.5	Ocular injury	Device use is in consistent with users's instruction	Major	Low	Moderate	The System is designed, built and tested to conform to IEC 60601-1, tested to conform freedom of unacceptable risk under single fault condition Warning in operation manual	(3)(2)	III	EN 60601-1 9012313978 Test report. Safety test Operation manual

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4.9 Software Hazards

Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.9.1	Device failed to Initialize	Firmware Code corruption (total code corruption). RAM failure	Moderate	Low	Minor	MCU load firmware software; but watchdog reset the MCU.	(1)	IV	Silk'n FX™ Software V&V Test id: 9.1.1
		Firmware Code corruption (errors in a few bytes)	Moderate	Low	Minor	MCU load firmware but software checks CRC and error led turn on.	(1)	IV	Silk'n FX™ Software V&V Test id: 9.1.1
		Omission – the system produce no flow at a time when one would be expected	Moderate	Low	Minor	Hardware watchdog expires, the watchdog de-energizes the system.	(1)	IV	Silk'n FX™ System V&V
		Commission – the	Moderate	Low	Minor	Watchdog uses logical	(1)	IV	Silk'n

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
		system produces a flow when a perfect system would not have				program flow monitoring, the watchdog de-energizes the system.			FX™ Software V&V Test id: 9.4.3 ID CNST15
4.9.2	Error in downloading the software	Defective MCU is not identified Watchdog hardware defective Communication cable damage	Moderate	Low	Minor	1) Verification test in production 2) QC inspection for complete download before operates. 3) During Download the SW calculates the algorithm check sum versus the MCU and receives feedback to the parameters (CRC#). Noise during the download will cause failure of the download process.	(1)(2)	III	Silk'n FX™ System acceptance test
4.9.3	On /Off Button are not functioning	Improper man machine interface design	Moderate	Low	Minor	Design reviews and production test	(1)(2)	III	Silk'n FX™ System

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item	Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
									acceptance test
		Buttons decoding algorithm failure (users presses down on a key or press and release)	Moderate	Low	Minor	Design reviews and production test	(1)(2)	III	Silk'n FX™ System acceptance test
		Communication failure	Moderate	Medium	Moderate	Design reviews and production test	(3)(2)(1)	IV	Silk'n FX™ System acceptance test
4.9.4	User Confusion on the status of the system	Improper software error handling design	Moderate	Low	Minor	Error indication shall have explanation in the operation manual.	(3)	III	Refer to operation manual trouble shooting page 11
4.9.5	The software allow light energy before skin	SW Failure of safety constraints	Major	Low	Moderate	Operation will ignite if: 1) Touch sensor detects	(3)(2)(1)	IV	Silk'n FX™ Software

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
	Item / Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
	attachment					skin touch. 2) Temperature stabilizer 3) Battery monitor Warning in operation manual			V&V Test id: 9.4.1 Refer to operation manual
	[redacted]								EN 60601-1 test report

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4.10 Battery Hazards

Hazard Identification		Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description	Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
4.10.1	Maintenance failure for rechargeable batteries	The instruction for use does not ensure adequate maintenance	Moderate	Low	Minor	The instruction for use shall contain instructions to ensure adequate maintenance.	(3)	III	EN 60601-1 9012313978 Test report. Safety test
4.10.2	Leakage of liquid	Liquid that might escape in a single fault condition	Major	Low	Moderate	Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.	(1)	IV	EN 60601-1 9012313978 Test report. Safety test
4.10.3	Noxious gas	Gases escape during charging or discharging – leaked whilst deployed at water or salt water	Major	Low	Moderate	Hardware designed to prevent on-board continues charging of the device, including battery overheat.	(1)(2)	III	EN 60601-1 9012313978 Test report. Safety test
4.10.4	Explosion and burning	Overcharging of battery could result in an unacceptable risk	Major	Low	Moderate	Hardware designed to prevent on-board continues charging of the device.	(1)	IV	EN 60601-1 9012313978 Test report. Safety test

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Hazard Identification			Initial risk estimation				Final Risk Evaluation		
Item / Hazard Description		Cause(s) of the Hazard	Severity	Occurrence	Level of Concern (Risk Index)	Risk Reduction Method	Risk Control method	Risk Acceptability	V&V
		Overheating	Major	Low	Moderate	Hardware designed to prevent battery overheating during charging and normal operation	(2)(1)	IV	EN 60601-1 9012313978 Test report. Safety test
4.10.5		Short circuit	Major	Low	Moderate	The battery pack contains battery protection circuit for avoiding short circuit.	(1)	IV	EN 60601-1 9012313978 Test report. Safety test

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5 Risk Estimation of Hazards Associated to the SILK'N FX™ device

Through hazard analysis, we determined that electric and battery hazards, thermal hazards, biological hazards and system used in contraindicated cases are the four significant hazards present with the Device. Neither of the hazards identified has been determined to be unacceptably high.

6 Conclusion of overall residual risk evaluation

The risks from all identified hazards have been evaluated and decided to be acceptable

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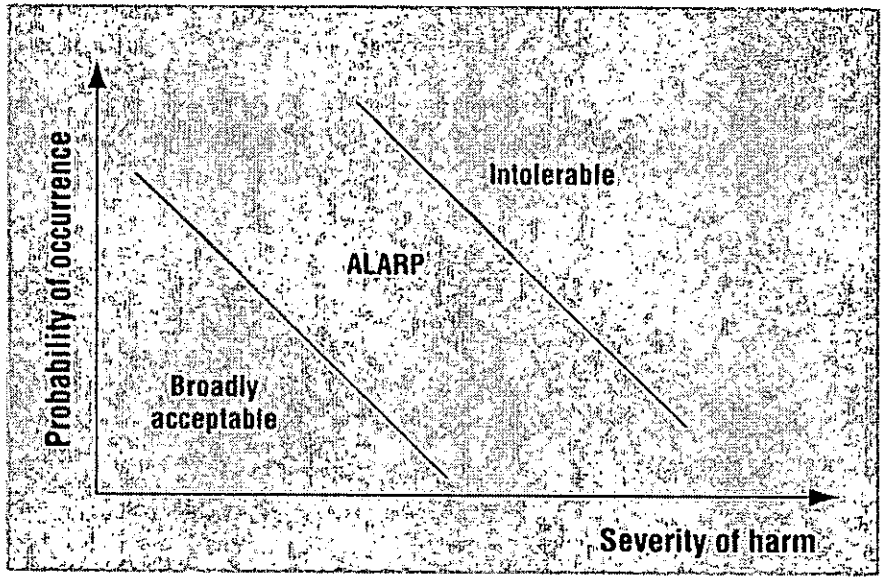
Appendix



- Figure 1.0 - Use an as low-as reasonably practicable approach,

Classification	Action required	Correlated risk region
Minor Risk	None	Broadly acceptable
Moderate Risk	Justification	ALARP
High Risk	Further risk reduction	Intolerable

Table 1.0

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