Hill-RBF Calculator Instructions for Use

Version: V1.0
Issuing Date: May, 2016
HS-Doc. no. 1500.7020037.04010 / 2016 – 05

Preface
Thank you for choosing the Hill-RBF Calculator for IOL power selection prior to cataract surgery. Provided you carefully follow these instructions for use, the use of the calculator should be reliable and trouble-free.

**WARNING!**
Please read the instruction manual carefully before using this calculator. It contains important safety information for both the patient and the surgeon.

Intended use
The Hill-RBF Calculator is designed to assist the user in selecting the appropriate IOL power for cataract surgery when optical biometry is used to calculate the power of a biconvex intraocular lens (IOL).

Safety

**WARNING!**
These signs must be strictly adhered to, to ensure safe operation of the instrument and to avoid endangering users and patients.

Patient population
The Hill-RBF Calculator is an advanced, self-validating method for IOL power selection employing pattern recognition and a sophisticated form of data interpolation. This method of IOL power selection performs for short, normal and long eyes. Based in artificial intelligence, this methodology is entirely data driven and free of calculation bias. This approach also employs a validating boundary model, indicating to the user when it is performing within a defined area of accuracy.

IOL models and biometry devices supported
The Hill-RBF Calculator is meant to serve as an adjunct tool to assist physicians in selecting the appropriate IOL power for a particular patient. It is intended to be used in conjunction with a comprehensive ophthalmic examination and the appropriate diagnostic tests and measurements necessary for cataract surgery candidates. It was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF IOL. It performs best with this combination of biometry device and IOL. It may also be used with other biconvex IOL models within the power range of +6.00 to +30.00 dioptres.

**WARNING!**
Using other data sources or IOL models other than the SN60WF, may reduce the overall performance of the calculator. The Hill-RBF Calculator can only be used with biconvex IOL designs. For example, anterior chamber IOls are often based on a convex-plano design.

Disclaimer
The results obtained by the Hill-RBF Calculator are not intended to serve as medical or surgical instruction, or be definitive; nor can it be guaranteed that the results will be accurate for every
Physicians who use the calculator must arrive at their own independent determinations regarding the proper treatment of their patients and are solely responsible for the final post-operative refractive outcome. By using the Hill-RBF Calculator, the user agrees to waive all claims against and hold Warren E. Hill and Haag-Streit AG harmless from any claims arising out of your use of this tool.

Data safety
The use of this Calculator may involve the entry of certain confidential patient data, which may be deemed “protected health information” ("PHI") under the Health Insurance Portability and Accountability Act of 1996 and Standards for Privacy of Individually Identifiable Health Information, 45 CFR Parts 160 & 164 ("HIPAA") as amended, or supplemented by additional legislation or regulations from time to time. All information during transfer of the data from the original computer and the server is encrypted. The data provided is stored for the purpose of improving the performance of the Calculator and for on-going research. All PHI data is encrypted using technology customary to the industry. Haag-Streit, as the provider of the Hill-RBF Calculator service, uses reasonable efforts to avoid unauthorized disclosure of data.

Supported web browsers
The Hill-RBF Calculator was tested on the following web browsers:
Internet Explorer V. 11 (Microsoft)
Edge (Microsoft) V. 25
Firefox (Mozilla) V. 44
Chrome (Google) V. 50
Safari (Apple) V. 9
Introduction

User interface

This chapter describes the use of the Hill-RBF Calculator step by step.

Patient data entry

As a first step, patient data must be entered. This area allows the user to identify the patient for which the calculation is to be carried out.

The fields for ID and patient’s name (family name) are mandatory entries. The patient’s first name and date of birth are optional entries. Clicking on the calendar icon next to the date of birth field opens a calendar tool that allows for the easy selection of the correct date of birth.

Surgeon data entry

With the current release, all fields in the surgeon data entry section are optional.

Data entered in the surgeon entry section will be visible on the printout and this area allows for easy identification of the surgeon.

In a future release, this data will be used to remind the user to provide stable post-operative refraction data for a respective patient. This information is anonymized and will be used as part of an ongoing process to improve the performance of the Hill-RBF Calculator.

Operation

This chapter describes the use of the Hill-RBF Calculator step by step.

Patient data entry

Row to select the target refraction for the right (OD) and the left (OS) eye.

In the current release of the Hill-RBF Calculator, this value is fixed to 0.00 D, targeting emetropia with a range of other values also displayed.

Clicking on the “?” opens the on-line help file.

Surgeon data entry

Data entered in the surgeon entry section will be visible on the printout and this area allows for easy identification of the surgeon.

In a future release, this data will be used to remind the user to provide stable post-operative refraction data for a respective patient. This information is anonymized and will be used as part of an ongoing process to improve the performance of the Hill-RBF Calculator.
Biometry data entry

Entering biometry data is divided into two steps. First, the user selects the biometry device used to acquire the measurement data. Afterwards, the following biometry values are entered: Axial length (AL), anterior chamber depth (ACD) and keratometry (flat (K1) and steep (K2) keratometry values and their corresponding meridians in degrees). All other fields are optional with the current release.

Even though only the above mentioned fields are necessary to calculate IOL power with the current release of the Hill-RBF Calculator, it is recommended that all data available be entered to allow for improved accuracy of the calculator in future releases.

WARNING!
The Hill-RBF Calculator was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF IOL. It performs best with this combination of biometry device and IOL. Using other types of biometry, or IOL models, may reduce the overall performance of the calculator.

IOL data entry

Enter the IOL manufacturer’s name as well as the specific model name in their respective entry fields. Then add the A-constant for the SRK/T formula optimised for optical biometry in the A-Constant field.

Even though only the A-Constant field is mandatory, entering all data will help to improve the performance of the calculator.

WARNING!
The Hill-RBF Calculator was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF IOL. It performs best with this combination of biometry device and IOL. Using other IOL models, may reduce the overall performance of the calculator. The Hill-RBF Calculator can only be used with biconvex IOL designs.

Performing the IOL calculation

After all mandatory data is entered, the calculation button at the bottom is enabled. Clicking on this button will display the IOL calculation result. The Hill-RBF calculator is self-validating, which means that an IOL power will be displayed only if the pre-operative data is within the calculator boundary model. If the pre-operative data is outside the calculator boundary model, a warning message will be displayed instead of an IOL calculation result. If a warning message appears, it is recommended to instead use latest generation IOL calculation formulas, such as the Barrett Universal II formula, or the Olsen formula.

Printing the calculation result

To print the calculation, click on the printer icon as described in the introduction. A 2nd browser window will open, providing a PDF printout of the results for documentation purposes.
Terms of Use, License Agreement and Privacy Policy

PLEASE READ THESE TERMS OF USE, LICENSE AGREEMENT AND PRIVACY POLICY (“AGREEMENT”) IN FULL. THIS IS A LEGALLY BINDING CONTRACT BETWEEN YOU (“USER”) AND WARREN E. HILL AS THE AUTHOR AND HAAG-STREIT AG AS THE SERVICE PROVIDER OF THIS CALCULATOR AND GOVERNS ALL ASPECTS OF USER’S ACCESS TO AND USE OF THE HILL-RBF CALCULATOR. BY CLICKING ON THE “I AGREE” BUTTON AT THE BOTTOM OF THIS AGREEMENT, USER AGREES TO ALL TERMS AND CONDITIONS SET FORTH BELOW AS WELL AS THE TERMS OF USE AND PRIVACY POLICY.

Introduction

The Hill-RBF Calculator is an advanced, self-validating method for IOL power selection employing pattern recognition and a sophisticated form of data interpolation. It has been optimized for use with biometry data from the Haag-Streit LENSTAR LS 900 optical biometer in combination with the Alcon SN60WF biconvex intraocular lens (IOL). The Hill-RBF on-line calculator may also be used with data from other optical biometers, which provide clinically equivalent biometry data as compared to the LENSTAR LS 900. It may also be used with other biconvex IOL models in the power range of +6.00 to +30.00D. WARNING: Using other data sources, or IOL models other than the original ones used to develop the Hill-RBF Calculator, may reduce the overall performance of the calculator.

Disclaimer

The Hill-RBF Calculator is meant to serve as an adjunct tool to assist physicians in selecting the appropriate IOL power for a particular patient. It is intended to be used in conjunction with a comprehensive ophthalmic examination and the appropriate diagnostic tests and measurements necessary for cataract surgery candidates. It was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF IOL. It performs best with this combination of biometry device and IOL. It may also be used with other biconvex IOL models in the power range of +6.00 to +30.00D. WARNING: Using other data sources or IOL models than the original ones the model was derived on, may reduce the overall performance of the calculator. The Hill-RBF Calculator may only be used with biconvex IOL designs. The results obtained by the calculator are not intended to serve as medical or surgical instruction, or be definitive; nor can it be guaranteed that the results will be accurate in every case. Physicians who use the calculator must arrive at their own independent determinations regarding the proper treatment for their patients and are solely responsible for the refractive outcome. By using the Hill-RBF Calculator, the user agrees to waive all claims against and hold Warren E. Hill and Haag-Streit AG harmless from any claims arising out of your use of this tool.

Ownership

The Hill-RBF Calculator is based on intellectual property of Dr. Warren E. Hill. It is provided to the user by Haag-Streit AG, for educational and internal business, including the user’s clinical operations and purposes only. The user may not reverse engineer, decompile, or disassemble the Hill-RBF Calculator. The user may not adapt or modify, create derivative works, operate a service bureau, or act as a Software as a Service (SaaS) provider based upon the Hill-RBF Calculator. The License below defines the extent of Licensee’s rights with respect to the Hill-RBF Calculator.

Non-exclusive, Limited License

This agreement gives the user the right to access the Hill-RBF Calculator and to use it for the limited purpose of performing IOL power calculations for user’s internal business, including user’s clinical operations and purposes only. Said license rights are not transferable or sublicense able, nor may the Hill-RBF Calculator be reproduced, or modified without the express prior written consent of Dr. Warren E. Hill and Haag-Streit AG. Licensee agrees to use all reasonable efforts to prevent unauthorized use, distribution, disclosure or publication of the Calculator or any data generated using the Calculator.
By this license, the user acquires no ownership right, title or interest in the Hill-RBF Calculator, or in any applicable patents, trademarks, copyrights, trade secrets and other intellectual property rights which may be embodied or contained therein.

**Use and entry of patient, biometry and IOL information; cookies**

Use of this Calculator may involve the entry of certain patient data, which may be deemed “protected health information” (“PHI”) under the Health Insurance Portability and Accountability Act of 1996 and Standards for Privacy of Individually Identifiable Health Information, 45 CFR Parts 160 & 164 (“HIPAA”) as amended or supplemented by additional legislation or regulations from time to time. All data is encrypted during transfer of the data from the original computer and the server. The data provided is stored for the purpose of improving the performance of the Calculator and research. All PHI data is encrypted using technology customary in the industry Haag-Streit as provider of the Hill-RBF Calculator service uses reasonable efforts to avoid unauthorized disclosure of data. The Calculator site uses cookies to facilitate easier navigation within the site and provide a higher level of convenience for the visitor. A cookie is a small piece of information about an Internet session that may be created when a visitor accesses a web site. The cookies used by the Calculator site are not written to the visitor’s hard drive, exist only until the browser is shut down, do not contain any personal information regarding the visitor, and do not retrieve any information from the visitor’s personal computer.

**No warranties**


TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, AND IN ALL STATES AND JURISDICTIONS WHERE SUCH DISCLAIMERS ARE PERMITTED BY LAW, WARREN E. HILL AND HAAG-STREIT AG EXPRESSLY DISCLAIM ALL REPRESENTATIONS AND WARRANTIES REGARDING THE CALCULATOR, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

WARREN E. HILL AS WELL AS HAAG-STREIT AG EXPRESSLY DISCLAIMS ANY WARRANTY, EITHER EXPRESS OR IMPLIED, REGARDING SYSTEM AND/OR CALCULATOR AVAILABILITY, ACCESSIBILITY, OR PERFORMANCE. BY ACCEPTING THESE TERMS, THE USER HEREBY ACKNOWLEDGES THAT, AT ANY GIVEN TIME, THE HILL-RBF CALCULATOR MAY NOT BE AVAILABLE OR MAY BECOME UNAVAILABLE DUE TO ONE OR MORE OF THE FOLLOWING: PERIODIC SYSTEM MAINTENANCE, TECHNICAL FAILURE OF THE HILL-RBF CALCULATOR, TELECOMMUNICATIONS INFRASTRUCTURE, OR DELAY OR DISRUPTION ATTRIBUTABLE TO VIRUSES, DENIAL OF SERVICE, INCREASED OR FLUCTUATING DEMAND, ACTS OR OMISSIONS OF THIRD PARTIES, ACTS OF GOD, OR ANY OTHER CAUSE REASONABLY BEYOND THE CONTROL OF WARREN E. HILL AS WELL AS HAAG-STREIT AG.

**Limitations on liability**

THE USER HEREBY EXPRESSLY ASSUMES THE ENTIRE COST OF ANY DAMAGE RESULTING FROM THE USER’S USE OF THE HILL-RBF CALCULATOR AND THE INFORMATION CONTAINED IN OR COMPILED BY THE CALCULATOR AND SHALL
INDEMNIFY AND HOLD WARREN E. HILL AND HAAG-STREIT AG HARMLESS FROM AND AGAINST ALL LOSS, COST, CLAIMS OR DAMAGES ARISING OUT OF THE USER’S USE OF THE HILL-RBF CALCULATOR AND THE INFORMATION CONTAINED IN OR COMPILED BY THE CALCULATOR.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, AND IN ALL STATES AND JURISDICTIONS WHERE SUCH LIMITATIONS AND EXCLUSIONS ARE PERMITTED, IN NO EVENT WILL WARREN E. HILL AS WELL AS HAAG-STREIT AG BE LIABLE FOR ANY DAMAGES WHATSOEVER (INCLUDING, WITHOUT LIMITATION, DIRECT, INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE OR INCIDENTAL DAMAGES) ARISING OUT OF THE USE OF OR INABILITY TO USE THE CALCULATOR, EVEN IF WARREN E. HILL AND/OR HAAG-STREIT AG HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Terms and conditions

Upon acceptance of the terms of this Agreement by clicking “I agree” below, the user will be bound by the terms of this Agreement. Warren E. Hill and Haag-Streit AG reserve the right to change this policy at any time. This Agreement cannot be modified except by Warren E. Hill and Haag-Streit AG.

This Agreement shall be governed by and interpreted in accordance with the laws of Switzerland, without giving effect to its conflict of law provisions. Exclusive place of jurisdiction shall be Koeniz (Switzerland).

This Agreement may be terminated by Warren E. Hill or Haag-Streit AG at any time for a violation of its terms; any failure by Warren E. Hill or Haag-Streit AG to immediately address or enforce any aspect of this Agreement shall not be considered a general or continuing waiver of such right of termination. Warren E. Hill and Haag-Streit AG may discontinue temporarily or permanently the Hill-RBF Calculator and the availability of the Hill-RBF Calculator to the user or to others at any time, in their sole discretion.

Alcon is a registered trademark of Novartis AG, Basel, CH-4002, Switzerland
LENSTAR and 900 are registered trademarks to Haag-Streit Holding AG, Gartenstadtstrasse 10, 3098 Koeniz, Switzerland

(C) 2016 Warren E. Hill and Haag-Streit AG

Warren E. Hill, MD
East Valley Ophthalmology
5620 East Broadway Road
Mesa, Arizona, 85206 USA

Haag-Streit AG
Gartenstadtstrasse 10
CH-3098 Koeniz, Switzerland
Should you have any further questions, please contact HAAG-STREIT at:
https://www.haag-streit.com/haag-streit-diagnostics/contact/