Holladay Automated Contrast Sensitivity Testing System
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Background
Jack T. Holladay, MD, MSEE, FACS and M&S Technologies Inc., are pleased to introduce the Holladay Automated Contrast Sensitivity System, a CSF System with rotationally symmetric targets and randomly presented optotypes providing a technician-free, computer-driven system that significantly reduces the time for testing to 10 minutes average per eye with a tighter standard deviation due to the design and presentation of the optotypes.

Features

- Standardized illumination with certification on brightness, contrast and color temperature.
- The system reduces the time of testing to an average of less than 5 minutes per eye with a tighter standard deviation due to software design and new optotypes.
- Automated, user-interactive testing mechanism eliminates technician bias.
- Testing protocol allows screen blanking for a pre-determined period of time to allow the retina to completely refresh between displays.
- System allows for maximum response time for all patient inputs, thereby eliminating the “focusing” effect.
- The testing logic has provides a test reliability index against which the validity of the results can be measured.
- Bullseye optotype eliminates biases from the patient with non-rotational symmetric optical aberrations such as residual astigmatism, coma, trefoil, etc.
- Replaces existing testing methods which are biased for with-the-rule aberrations such as vertical astigmatism and vertical coma and biased against aberrations such as against-the-rule astigmatism and horizontal coma.
- Automatic report printing, graphing and output to any media for data collection.
- Conforms to ANSI guidelines for CSF testing at (1.5, 3, 6, 12, 18) cycles per degree.
- The system tests at the ANSI specified light levels of 85 cd/m2 (photopic) and 3 cd/m2 (mesopic) and includes all of the options and parameters the agency requires for contrast testing.
Assembly, Installation and Calibration Instructions

1) General Installation
   a) Unpacking: Carefully unpack each of the components, the following is a list of components:
      1) 19" NEC Computer Monitor
      2) Dell Computer
      3) Microsoft Windows 7
      4) Keyboard & Mouse
      5) Contrast Keypad Controller
      6) Extended Keypad Cable (25’ grey Serial Cable)
      7) IR Detector
      8) DVI Monitor cable
      9) Speakers
      10) Mesopic Filter
      11) Printer (optional)
      12) Glare (optional)
      13) Power cables
   b) Locate the Monitor and Computer, Keyboard and Mouse to a permanent location within the exam room.
   c) Plug keyboard cable into an open USB port on the front or back of the computer. Plug mouse cable into an open USB port on the front or back of the computer.
   d) Plug keypad controller extension cable female end into the back of computer at serial port labeled IOIOI.
   e) Secure serial cable connector with small screwdriver.
   f) Plug keypad into male end of extension cable and secure.
   g) Plug computer power cord into the back of computer at location.
   h) Plug DVI monitor cable into the DVI Port on back of PC
   i) Plug in DVI cable into DVI-D port on monitor
   j) Plug in monitor power cable into the back of the monitor
   k) Plug in the IR detector in open USB port – system will not run without IR detector
   l) Plug in the speakers to an open USB port and the green audio-in on back of PC
Filter Installation

The Photopic filter decreases the luminance of the monitor so that it falls within the ANSI specifications for Photopic (~85 cd/m\(^2\)) vision testing. The Mesopic filter adds additional filtering to reduce the luminance to the ANSI specification for Mesopic testing (~3 cd/m\(^2\)).

To install the Photopic/Mesopic filter:

1. Carefully unpack the filter from its box
2. Using the enclosed Velcro, attach the filter to the monitor when doing Mesopic testing.
3. There is a selection in the patient information screen to select Photopic/Mesopic

Data Storage

The test data is stored in the following folder:

C:\Program Files\MSTec\Sinusoidal\User

The Year folder contains the individual raw test results by month and by day and by patient

The CSV folder contains a Comma-delimited file with all of the test results that can easily be imported into common spreadsheet programs for analysis.

Viewing Saved Results

To view prior exam results click the Open Saved Results button on the main configuration. Select the Date/Patient from the list and click Open. The result can then be analyzed or re-printed.
Initialize and Calibrate Equipment

A. The unit comes precalibrated to a distance of 13.13 feet (4 meters)
B. Upon completing all the connections, turn on the computer and monitor
C. **Note:** It is required that the monitor warm up for 30 minutes to 1 hour for proper luminance
D. To Launch Smart System for Visual Acuity Testing, use the M&S Smart System 2012 icon
E. To Launch HACSS, double click the HACSS Icon
F. At first use, click **Screen Settings**
G. Calibrate by measuring from the patient to the monitor and setting the “Distance from the Screen in Feet” to this number. E.g. 14.5 **Important Note** - The calibration distance is recorded in Feet and entered in the Calibration Distance box as such.
Entering a distance in meters will result in a miscalibrated system. 3 meters = 9.84 feet, 4 meters = 13.12 feet, 5 meters = 16.4 feet.

H. Measure the 10 cm x 10 cm box and verify that it is accurate, adjusting the Pixels Wide and Pixels High if needed.

I. Click Save.

J. After changing calibration the system will require an image update – click the Update button on the main screen before testing. It will take several minutes to update the images used for testing.

K. To begin testing, click New Test.
Contrast definitions

Cycles per degree – The Holladay Automated Contrast Sensitivity Testing System uses sine gratings both linear and in a bulls-eye pattern. The number of cycles per degree is the number of cycles of the sine wave that fit in one degree of arc at the given calibration distance and gives a representation of the spatial frequency. For instance in the illustration below, 3 cycles per degree would indicate that there are 3 cycles of the sine wave in the area that subtends 1 degree of arc at the calibration distance. Higher numbers such as 30 and 60 cycles per degree indicate a high spatial frequency while low number such as 1.5 and 3 indicate a low spatial frequency.

Percent Contrast – Indicates the difference between the peak of the sine wave and the white background as a percentage. For instance, in the illustration above there is a 50% difference between the peak of the sine wave which is a dark gray and the white background. The white would measure 85 cd/m² while the gray would measure 42.5 cd/m².

Candelas per Meter Squared (cd/m²) - A measure of the light radiating from a light source onto a one-meter-square surface. This measurement is taken with a photometer using a specialized probe to measure the light output. For instance a common office computer monitor displaying a white screen may measure 180 cd/m²

Photopic – Human color vision under normal daytime conditions. For contrast testing the ANSI recommends testing Photopic vision at 85 cd/m²

Mesopic – Human vision in low but not fully dark conditions, and generally tested near 3 cd/m²

High Frequency Cut-off – The highest spatial frequency a patient can resolve.
Using the *Holladay Automated Contrast Sensitivity Testing System*

The *Holladay Automated Contrast Sensitivity Testing System* is controlled using the wired keypad.

<table>
<thead>
<tr>
<th>Test Selection Buttons</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>End Test</strong> – Ends the test</td>
</tr>
<tr>
<td><strong>End Demo</strong> – Ends the training</td>
</tr>
<tr>
<td><strong>Bullseye</strong> – During manual testing shows a bullseye</td>
</tr>
<tr>
<td><strong>Blank Disk</strong> – During manual testing shows a blank disk</td>
</tr>
<tr>
<td>The Following are used in the manual test and control spatial frequency and contrast percentage</td>
</tr>
<tr>
<td>SF</td>
</tr>
<tr>
<td>▲</td>
</tr>
<tr>
<td>● The Bullseye and Blank Disk are used during the patient exam</td>
</tr>
</tbody>
</table>

**Test Input Buttons**
The two large keys are used to choose the correct answers for each of the test types. Once a test is being conducted only these buttons respond to input.
Contrast Testing

There are a number of test protocols included with the Holladay Automated Contrast Sensitivity Testing System.

<table>
<thead>
<tr>
<th>TESTS</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each test available for Left or Right eye or both eyes</td>
<td>Test uses sinusoidal bulls-eyes ranging from 18 cycles per degree to 1.5 cycles per degree in decreasing contrast levels.</td>
</tr>
<tr>
<td>Bulls-eye Sine</td>
<td>Mesopic version of the Bulls-eye Sine test. Use the filter for this test.</td>
</tr>
</tbody>
</table>

These tests follow the ANSI guidelines for CSF testing, proving 1.5, 3, 6, 12, 18 cycles per degree and both Photopic (85 cd/m²) and Mesopic (3 cd/m²) levels. A filter is used to reduce the illumination to the Mesopic level.

**Note:** For the Mesopic tests, always place the Mesopic Filter over the monitor.

Running a Test

1. Using the Keyboard, press the **New Test** button.

2. The menu will appear
3. Fill out the patient information

4. Select the test by pressing the **Light Level** drop-down

5. Select the eye by pressing the **Eye Testing** drop-down

6. Select **Modify Test** if there are certain tests that do not need to be conducted, e.g. Visual Acuity, 18 CPD, etc.

7. Run the test by pressing the **OK** button.

8. The test is started.

9. First a training is conducted to familiarize the patient with the test so that they know the Bulls-eye and Blank disk or the linear gratings.

10. When an optotype is presented, the system will beep to let the patient know that a target has been presented.

11. Next the high-frequency cut-off is determined (equivalent Visual Acuity). The patient uses the keypad to either choose Bulls-eye/Blank-Disk or the appropriate angle of the linear grating. This is a measure of acuity. The equivalent 20/X acuity is shown at the conclusion of the test with the results.

12. Finally the contrast test begins and the patient then uses the appropriate input keys to record their response – Bulls-eye or Blank-disk

13. At the conclusion of the exam a report as printed. This report is shown later in these procedures.
Running a Manual Test

1. Using the Keyboard, press the Run Manual Test button.

2. A Bullseye will appear and spatial frequency and contrast log will be shown.

3. Use the SF up/down and % up/down to change the Spatial Frequencies and Contrast Percentages.

4. If a Blank Disk is desired, press Blank Disk button. To return to Bullseye Target press Bullseye button.
Running a Test on a previous patient

1. Using the Keyboard, press the **New Test** button.

![Image of the HACSS interface](image)

2. The menu will appear

![Image of the menu](image)

3. Click **Prev Patient**

4. Fill out the **Subject ID** and click **Find**

5. Patient information will be populated

6. Test will commence 3/10 log units above the previous values for the patient

7. Select the test by pressing the **Light Level** drop-down
Testing Notes

While performing tests with the Bulls-eye gratings, blank disks are interspersed throughout the course of the exam. By including these disks at the same contrast level as being tested, the patient cannot cheat by indicating they see contrast levels they cannot actually see. The test report includes a Patient Reliability Index that shows the number of Blank-Disk Targets presented and the number the patient accurately responded to. If the patient scores low, you may wish to retest this patient.

During the course of all available tests between presentations of the gratings the screen goes blank to allow the retina to refresh.

Test Protocol Description

1. A training phase is conducted to familiarize the patient with the targets. In the case of the Bulls-eye gratings, a grating and blank disk are alternately displayed so that the patient learns to differentiate these targets.

2. The High-Frequency cut-off is determined. This will provide an equivalent acuity at the end of the exam. Starting at 18 cycles per degree at 99% contrast, the patient is presented with increasingly higher spatial frequency targets (e.g. 24, 30, 38 cpd) until they record an incorrect answer. The last correct spatial frequency is then verified.

3. For 18, 12, 6, 3, and 1.5 cycles per degree contrast testing begins at 0.3 log units above the normative results. If this is not visible, it moves to 0.3 log unit steps of contrast. With the first correct answer the test moves down 0.3 log units until an incorrect response is recorded. The test then moves up 0.2 log units and works back down in 0.1 log unit steps if correct and goes up another 0.2 if incorrect. It continues reducing contrast in 0.1 log steps until a miss or repeat of the best answer. The system averages the two best at next incorrect – or reports the final answer if correct twice on same log unit of contrast.

4. Throughout the exam randomly interspersed blank disks are shown to prevent guessing. At the conclusion of the exam the report will include a Reliability Index that shows the number of blank disks presented and number the patient identified and provides a percentage. A low score may indicate the need to educate the patient and have them retake the exam.

5. The exam beeps, adding a beep at each spatial frequency so that the clinician can “hear” that the patient is still progressing. At the completion the Windows ‘Ta Da’ is played to let the clinician know that the test is completed.
6. The report will provide the raw data as well as a percentage of normal based on normative values. It also provides an elapsed time and reliability index. For each cycles/degree, the percent of contrast and its corresponding log units are printed.

7. Finally the report present the high-frequency cut-off and its equivalent acuity level

**Stopping a Test in Progress**

To Stop a test while in progress press **Exit Test** while the system is displaying a target
Example Report

Test Rel. Index – The number of random gray disks correctly identified as gray disks. If the patient has a low reliability, they may have been trying to cheat or didn’t properly understand the test directions.

End Date/Time – The completion of the test.

Area Under Curve – An indication using all tested spatial frequencies of the patient compared to the normative values expressed as a percentage – may be higher than 100% if patient above norm.

Elapsed time – the time the test took the patient to complete.

Cut-off Freq – If testing acuity using sine bulls-eyes, the highest spatial frequency the patient could resolve.


Test No Answers – The number of times the patient did not answer within the time limit over total number of presentations.

Spatial Frequency = % / Log Contrast / Standard Deviation.

Select Results – allows tracking of multiple tests.

Close – Return to main menu.

Preview – Print Preview.

Print – If optional printer attached, prints the results.
Shutting down the System

It is strongly recommended that the system be shut down at the end of every day of use. To exit perform the following steps:

1. From the Main Screen

2. Press **Exit Program**

3. The system will exit to Microsoft Windows

4. Press the power switch on the front of the computer

5. The computer will shut down

6. **Note** – The monitor should be left on. It will automatically switch to power-saving mode and will automatically come on when the computer is turned on in the morning.
License Agreements

M&S® Technologies, Inc. ("MST")
End User Limited Hardware Warranty

Computer hardware products and related accessories purchased new from M&S Technologies, Inc., or on behalf of M&S through its Authorized Representatives, come with a 1-year limited hardware warranty. Refurbished computer hardware products and related accessories purchased from M&S Technologies, Inc., or on behalf of M&S through its Authorized Representatives, come with a 30-day limited hardware warranty.

This limited hardware warranty covers defects in M&S Technologies, Inc. materials and workmanship relating to purchased hardware and accessory product purchases by M&S end-users customers.

This limited hardware warranty does not cover:

- Software, including the operating system and software added to the M&S-purchased hardware products. (See the M&S Software License Agreement and related Limited Lifetime Warranty for any M&S-developed software.)
- Hardware products and accessories not purchased through M&S Technologies, Inc. or its Authorized Representatives
- Problems that result from:
  - External causes such as accident, abuse, misuse, or problems with electrical power
  - Servicing not authorized by M&S Technologies, Inc.
  - Usage that is not in accordance with product instructions
  - Failure to follow the product instructions or failure to perform preventive maintenance
  - Problems caused by using accessories, parts, or components not supplied by M&S

- Products with missing or altered Service Tags or serial numbers
- Products for which M&S has not received payment
- Expendable and/or consumable parts
- Normal wear and tear

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state (or jurisdiction to jurisdiction). M&S’ responsibility for malfunctions and defects in hardware is limited to troubleshooting with the end user, repair and/or replacement as set forth in this warranty statement. All express and implied warranties for the product, including but not limited to any implied warranties and conditions of merchantability and fitness for a particular purpose, are limited in time to the term of the 1-year limited warranty period or the 30-day limited warranty period. No warranties, whether express or implied, will apply after the limited warranty period has expired.

M&S does not accept liability beyond the remedies provided for in this limited hardware warranty or for consequential or incidental damages, including, without limitation, any liability for third-party claims against you for damages, for products not being available for use, or for lost data or lost software. Our liability will be no more than the amount you paid for the product that is the subject of a claim. This is the maximum amount for which we are responsible.
A small percentage of users may experience epileptic seizures when exposed to certain light patterns or backgrounds on a computer screen or while using the hardware. Certain conditions may induce previously undetected epileptic symptoms even in users who have no history of prior seizures or epilepsy. If you, or anyone in your family, have an epileptic condition, consult your physician prior to using the hardware. Immediately discontinue use of the hardware and consult your physician if you experience any of the following symptoms while using the hardware: dizziness, altered vision or muscle twitches, loss of awareness, disorientation, any involuntary movement, convulsions, or any unusual behavior or condition.

The limited hardware warranty on all M&S-purchased hardware products begins on the earliest date of the packing slip, invoice, or receipt. The warranty period is not extended if we repair or replace a warranted product or any parts. M&S may change the availability of limited hardware warranties, at its discretion, but any changes will not be retroactive.

M&S warrants that the Products that you purchased from us, or on behalf of M&S through our Authorized Representatives, are free from defects in materials or workmanship under normal use during the Limited Warranty Period. You are entitled to warranty service according to the terms and conditions of this document if a repair to your Product is required within the Limited Warranty period. This Limited Warranty extends to the original end user purchaser and is not transferable. Warranty service availability and response times may vary.

Before the warranty expires, please contact M&S Technical Support at 847-763-0500 or our Authorized Representatives. Please also have your hardware Service Tag or invoice number available.

During the 30 days of the 30-day limited refurbished hardware warranty and the first year of all other limited hardware warranties, M&S or its authorized representative will provide telephone support, repair or replace any M&S-purchased hardware products that prove to be defective in materials or workmanship. If M&S or its authorized representative is not able to troubleshoot the problem with the end user or repair the product, we will replace it with a comparable product that is new or refurbished. M&S may also provide loaner hardware in circumstances whereby a repair or replacement is required. It is at the full discretion of M&S, as to the best approach for providing warranty service.

As part of warranty repairs or replacement, M&S or its Authorized Representatives may require the system software/firmware be brought up-to-date.

During the Limited Warranty Period, M&S will troubleshoot and correct the issue with the end user, repair or replace any defective component. This is your exclusive remedy for defective products. M&S reserves the right to elect, at its sole discretion, to give you a refund of your purchase price instead of a

All warranty service calls handled directly by M&S will be assigned a Technical Support tracking number.

When your warranty service requires you to return hardware to the M&S Technologies, Inc. Illinois warehouse, M&S will provide a loaner and a return label to ship your M&S-purchased product for repair. You must return the defective products to us in their original or equivalent packaging, or accept the risk if the product is lost or damaged in shipment. M&S will return the repaired or replacement products to you. M&S will pay to ship the repaired or replaced products to you if you use an address in the United States (excluding Puerto Rico and U.S. possessions and territories). Otherwise, M&S will ship the product to you freight collect. If the failed M&S-purchased hardware is not received by us within twenty-one (21) business days from the date that the loaner was dispatched to customer, or the unit is not returned in the specific packaging, the Customer will be invoiced at list price for the replacement unit. Upon receipt of the repaired or replaced hardware, you must ship any loaned hardware to the M&S Technologies, Inc. Illinois warehouse using the prepaid freight provided.
If M&S determines that the problem is not covered under this warranty, we will notify you and inform you of service alternatives that are available to you on a fee basis. Products returned will not be accepted if there is damage due to external causes, including accident, abuse, misuse, natural and unnatural disasters, acts of God, problems with electrical power, servicing not authorized by the M&S, usage not in accordance with product instructions, failure to perform required preventative maintenance, problems caused by use of parts and components not supplied by M&S, and damage incurred during shipment of defective parts to M&S for repair. If damage is evident from these causes, the CUSTOMER will be invoiced at list price for the replacement parts. Servicing fees may also be applied at the sole discretion of M&S. Although M&S is not under any obligation to provide warranty service for Product damaged in any of the ways mentioned herein, M&S may, at its sole discretion, agree to provide additional service for such Products if, after inspection by M&S, we determine that the Product is still in acceptable operating condition.

If warranty service is provided by an M&S authorized representative, depending on circumstances, you may be required to return M&S-purchased hardware to the authorized representative via prepaid freight.

NOTE: Before you ship the product(s) to us, make sure to back up the data on the hard drive(s) and any other storage device(s) in the product(s). Remove any confidential, proprietary, or personal information and removable media such as floppy disks, CDs, or PC Cards. We are not responsible for any of your confidential, proprietary, or personal information; lost or corrupted data; or damaged or lost removable media.

M&S is not responsible for the preservation of any data or the protection of any confidential, proprietary or personal data contained in any product, nor is M&S responsible for the restoration or reinstallation of any programs or data other than software written and installed by M&S or its authorized representatives when the product was provided to the end user by M&S or on behalf of M&S by its authorized representative.

Upon the expiration of the limited hardware warranty, you will be offered an option to purchase an extended service contract. Hardware service will be provided to you under the terms of the service agreement. Please refer to that contract for details on how to obtain service.

We use new and refurbished parts made by various manufacturers in performing warranty repairs and in building replacement parts and systems. Refurbished parts and systems are parts or systems that have been returned to M&S, some of which were never used by a customer. All systems are inspected and tested for quality. Replacement parts and systems are covered for the remaining period of the limited hardware warranty for the product you bought. M&S owns all parts removed from repaired products.

This limited hardware warranty coverage terminates if you sell or otherwise transfer this product to another party.
This Limited Warranty is made as of the date of shipment of the Products to the Customer (the "Effective Date") by and between M&S Technologies, Inc., its subsidiaries and affiliates, with offices at 5557 W. Howard Street, Skokie, Illinois 60077 ("collectively the Company").

1. Definitions.

In addition to the terms defined elsewhere in this Agreement, the following terms whenever used in this Agreement shall have the following meanings:

"Customer" means the end user of the Products.

"Hardware" means the hardware purchased from M&S, along with any end user manuals supplied by M&S. This includes M&S Products purchased through M&S authorized representatives.

"Maintenance Releases" means any update, upgrade, revision, patch, bug fix or an improved, upgraded or enhanced version of the Products released by M&S to which Customer is rightfully entitled by way of a valid maintenance agreement, warranty, or other M&S offering. Third Party Products are excluded and subject to their own terms and conditions.

"Object Code" means computer programs assembled, compiled, or converted to magnetic or electronic binary form on software or hardware media, which are readable and usable by computer equipment, but not generally readable by humans without reverse assembly, reverse compiling, reverse conversion, reverse engineering and/or any other disassembly or decompilation.

"Product(s)" means, collectively, the Hardware and Software which may be supplied to Customer.

"Software" means all components of M&S vision testing industry software and related documentation made generally available by M&S from time to time, which is accompanied by its own license agreement. The term "Software" shall include any and all software, scripts, firmware, and microcode running on Hardware or any computer system, including all Maintenance Releases supplied in accordance with this Agreement. The Software shall be provided in Object Code form only. No source code will be provided.

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