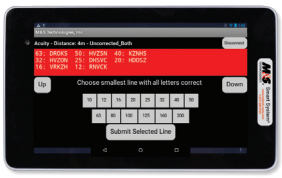
CTS
Clinical Trial Suite

VISUAL ACUITY

M&S | Clinical Trial Suite CTS

DVA-5000 Standardized Automated ETDRS

ACCEPTED BY THE FDA FOR USE IN ALL PHASES OF CLINICAL TRIALS



Tablet Controller

Test Results
Letter Score: 81
Equivalent Acuity: 20/25
Log: 0.12

Sample Test Result

FEATURES

- Computerized Automated ETDRS quickly and accurately guides technicians through the testing algorithm eliminating technician bias, and errors
- Standardized, calibrated background luminance is set to 85 cd/m2 as recommended by the FDA/ISO and can be customized to fit any luminance levels required
- Strictly adheres to ANSI Z80.21-2010 (R2015), ISO 8596:2017 and ISO 10938 standards
- Subject results are automatically calculated thereby eliminating erroneous test results and calculation errors
- Clinical Trial testing with consistent, repeatable results from site-to-site and visit-to-visit
- Pre-programmed testing protocols by visit. Customized per sponsor specifications
- Participant memorization effect is eliminated with randomized letter, number, and symbol presentations, ensuring more accurate result
- Test results can be automatically exported in an XML or CSV format to any EDC or Reading Center providing immediate access for statistical analysis
- Result output in letter score, logMAR, decimal score, and Snellen equivalent
- Accepted by the US FDA as an acceptable method in visual acuity testing in all phases of clinical trials
- CE/MDR approved for distribution to the European Union
- Product of choice by major Pharmaceutical Companies and Research Institutions
- Published & validated to existing ETDRS standards by *Southern College of Optometry, Published Optometry and Visual Performance*. Volume 6, April 2018

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