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Health informatics — Ophthalmic examination device data

Part 2: Specular microscope

bsi.

National foreword

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Foreword

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Introduction

Ophthalmic devices are used in hospitals and clinics to examine patients. The primary devices used in these ophthalmic examinations provide the measurement of refraction, corneal curvature, intraocular pressure, lens power, and visual acuity. Almost all patients who consult for a diagnosis in ophthalmology undergo these examinations.

Besides such general ophthalmic devices, specular microscopes are often used to capture and analyze an image of the corneal endothelium, which dehydrates the corneal stroma and maintains the cornea's clarity. Thus, measuring the cell density of the corneal endothelium is one of the most crucial and reliable methods to determine its condition. The analysis results of the specular microscope are indispensable for not only patients experiencing trouble in the cornea but also safe prescriptions for contact lenses.

Like other ophthalmic devices, various manufacturers supply specular microscopes. Thus, standardized procedures for mutually communicating analysis results are crucial between the specular microscope and ophthalmic information system (OIS).

However, the integration of this information is complex and potentially error-prone owing to variable data formats provided by specular microscopes from different manufacturers and the lack of interoperability. Thus, the integration of analysis results from various specular microscopes into an OIS or hospital information system (HIS) warrants significant individual effort for each manufacturer's specular microscope.

This document specifies the content and format for the analysis results of specular microscopes, identifying the information that could be included in the analysis results, as well as how it should be formatted when communicated to an OIS, HIS, or other similar systems.

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Health informatics — Ophthalmic examination device data —

Part 2: Specular microscope

1 Scope

This document specifies the data output formats for the specular microscope. The data are usually sent from the specular microscope to either an ophthalmic information system (OIS) or a hospital information system (HIS).

This document addresses text-based analysis reporting of the specular microscope measured and analysed data such as the central corneal thickness, the density of endothelial cells per 1 mm^2, the coefficient variant, and the ratio of endothelial cells with a hexagonal shape.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
corneal endothelium
monolayer of endothelial cells that constitutes the posterior corneal surface

Note 1 to entry: The corneal endothelium dehydrates the corneal stroma and maintains the cornea's clarity.

Note 2 to entry: Measuring the endothelial cell density provides valuable information about the cornea's condition.

3.2
endothelial cell density
CD
number indicating how many endothelial cells are present in one square millimeter (mm^2)

Note 1 to entry: This value is often referenced to determine the condition of the corneal endothelium. If the corneal endothelium is young and healthy, the value is high, and if the corneal endothelium is old and damaged, the value is low.

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