# User-Centered Design and Usability Report (Extract)

## Electronic Health Record (EHR) Usability Standards

## Fort Lauderdale, FL October 2013

# 1. Preamble

The ifa Premium V6 EHR system was developed based on more than 20 years of experience with software applications for eye clinics and eye care offices (see history). The system was developed together with clinical specialists, ergonomic experts and IT professionals.

# 2. Definition and Standards

## 2.1 Definitions

Usability of software is defined as the ease of use and learnability. That includes methods of measuring the usability, e.g. analysis of user needs and the study of “state of the art” health IT applications.

## 2.2. International standards

The Premium EMR was developed following international guidelines and standards. The processes have been structured according to the following three ISO standards:

- ISO 9241-210
- ISO 9241-11
- ISO 9001:2008

The relevant outcome of implementing the standards has been documented during the production and testing processes.

### 2.2.1 ISO 9241-210

The ISO standard 9241-210 has been implemented dedicated to the process of the software development with the following main topics:

- Analysis of the user environment and user tasks
- Involvement of users and clinical professionals in the design process
- Continuous improvement management (fine tuning)

### 2.2.2 ISO 9241-11

The components of ISO 9241-11 have been integrated into the process of designing the user interface and the corresponding display and data entry components, mainly:

- Part 3: Visual display requirements
- Part 5: Workstation layouts
- Part 8: Requirements for displayed colors
- Part 9: Requirements for non-keyboard input

- Part 17: Form filling dialogues

#### 2.2.3 ISO 9001:2008

For the entire process management ISO 9001:2008 (quality management) was deployed:

- Identification of context of use
- Selection of usability measures
- Evaluation of usability (test management)
- Continuous redesign of software components (PDCA)

# 3. History of the software development

The software development of the Premium V6 ifa EMR is based on a long history of software engineering in the area of health IT. The ifa company started developing health IT software in 1984. The wkomma GmbH, solution provider for clinical product management, has a history of also more than 20 years represented by the responsible management.

## 3.1 Previous generations

The first EMR generation was developed in cooperation with the Mayo Clinic in Jacksonville; FL. Ophthalmic specialists of the Mayo Eye clinic together with experts of the American Academy of Ophthalmology (AAO) did study the requirements for the paperless eye institute in the US. The first results have been published in 1996 (Why computerize the eye clinic, J.Bolling, MD – see attachment). The EMR system is since then used in the US and in more than 20 countries by approximately 13,000 eye care professionals, ophthalmic surgeons, technicians, nurses and administrators every day.

In 2007 the Premium application was developed following guidelines for usability of health IT applications. In 2009/2010 the relevant components have been redesigned according to the ONC requirements.

## 3.2 Existing user base

The existing users did play an important role in the improvement and update processes of the Premium V6 software. The ifa team organized regular training and work sessions (TWS) in Fort Lauderdale, FL and New York City, NY. The TWS concept combined several usability test processes with established users and “new comers” without experience with EHR systems.

The results of the TWS tests processes have been factored into the customization and redesign processes of the EMR system which is dedicated to ophthalmology.

# 4. Definition of user groups and qualifications

According to ISO 9241-210 the analysis of the user environment and the needs and qualification play an important role for a successful design process.

The Premium EMR system is typically used by three specific user groups:

- Physicians / providers for several subspecialties of eye care environments
- Specialized ophthalmic technicians
- Administrators and members of the management

## 4.1 Clinical user groups

The clinical user groups use the system when a patient are with them in an exam or treatment area. The clinical user groups typically enter all medical data such as medical history, general exam (vital signs, HPI etc.) and eye exam.

These users (can) follow clinical pathways which they can implement together with the ifa product specialists within the customization process. In this context scribes who join the physician during the exam and enter the data into the EMR system are defined as clinical users.

The clinical users have to concentrate on the communication with the patients and therefore the software has been developed for easy and intuitive use so that the main focus can be on the patient.

## 4.2 Non-clinical user groups

All other team members in an eye care environment who are not defined as clinical users are seen as non-clinical users. They enter e.g. billing codes, generate reports and letters, run statistics and queries for several needs defined by regulatory requirements or individual management needs.

Non-clinical user groups can focus more on the efficiency of the outcome and the meaningful use e.g. in the area of communication with referring physicians, patient education etc.

# 5. Definition of user requirements

The user requirements depend on the tasks the user groups have to perform with the software. Therefore the development of the user interface and the test processes follow different concepts.

## 5.1 Easy to learn

The introduction of an EMR /EHR system means change management for the entire clinical and non-clinical team. The team members are different in age and have different qualifications and experience with using a software system. The “easy to learn” principle defines the learning process with a maximum of four to eight hours for dedicated tasks (e.g. for technicians who enter medical history and pre-exam data into the system).

### 5.2 Easy and fast to use

The electronic system competes with the traditional paper record which allows quick and simple data entry without following any standards and structured processes for meaningful use. In the eye care environment a lot of numerical and text based data have to be entered to complete a comprehensive eye care patient chart.
The following components are identified for a fast and easy to use system:

- Clinical pathways with structured exam templates dedicated to the encounter type of the patient
- Intelligent pick lists which represent the most common data codes and descriptions for the corresponding chart area (observation class)
- Data macro pools to bundle data which are often used together to describe an ophthalmic patient case
- Chart monitor functionality which reminds the user to enter important data which has been forgotten

The data entry process for the EMR system has to be faster than the data documentation process with the paper charts. In this context the customization of the system plays an important role.

## 6. User context and environment

The user environments vary from private offices to academic institutes. The human resource capacity has to be considered (e.g. a scribe is entering the data instead of the provider himself).

### 6.1 Interaction with scribes

If a scribe is entering data which are dictated by the physician the user interface has to be synchronized between the two actors. Free text should be avoided by the physician as these are not counted as “meaningful use” of data. The provider has to know and understand the system with clinical workflows and the relevant pick lists so that the scribe can follow the dictation without delay. For this scenario it is important that different users can define different templates and can customize the system by themselves. That allows individual layouts corresponding with the users experience and documentation routines.

### 6.2 Interaction with patients

The acceptance tests did demonstrate that the patients tolerate or even prefer electronic chart systems if there is a clear benefit for them. With predefined exam routines the physician can be much faster and can pay more attention to the patients compared with the traditional paper chart.

The professional EMR system must also offer patient education elements for an attractive interaction with the patient:

- Fundus images" before and after"
- IOP charts with target IOP values
- Dashboards with combination of graphical and images based information
- Context integrated patient education with images and videos

### 6.3 Data entry devices

The system has to be designed for a fast data entry with all types of data entry devices:

- Keyboard with also using function keys
- Mouse for specific user movements (short distances between related data entry areas)
- Templates for touch screens and mobile devices

The PREMIUM EMR allows all kind of input devices, also parallel for the different preferences of larger user groups. The user interfaces can be customized dedicated to the preferred input device.

### 6.4 Data output

In ophthalmology the images and graphical objects are extremely important for all medical decision processes. Therefore the software has to support comprehensive viewing concepts such as:

- Split screen layouts for large monitor systems
- Dual monitors for parallel viewing and data entering processes

The screen layout is customizable for the entire range of monitors and mobile devices so that in heterogeneous user groups the ideal visual data output component can be chosen.

## 7. Consistency and usability

According to ISO 9241-11 the visual display, colors and the dialogs for filling templates and forms have a high priority. The ifa Premium EMR was developed strictly according to the principals of the ISO standard.

### 7.1 Global screen layout

The global screen layout is based on the experience withprevious EMR generations and corresponding with user tests for data entry efficiency and data display quality. In addition to V5 the Premium V6 offers an additional template set which makes the data entry process easy and intuitive. The following components represent the “backbone” of the user interface:

- Main Menu
- Sub Menu
- Pick list templates

All three components are static and allow fast data entry with a minimum of mouse clicks or button touches.

The templates based user interface has been compared with traditional “pull down” menus. The template based data entry processes are significantly faster than “pull down” menus with comparable sets of information.

Similar features are always positioned in the same area of the screen. That allows the user to enter data quickly without searching or “thinking”. This is very important especially for the clinical user groups. Physicians or technicians can concentrate on the communication with the patients because the eye movements are always the same and independent from the area or data capturing.

## 7.2 Reading curve (eye movements) and data entry flow

The team had researched the eye movements of the users when they follow a new screen display. The so called “reading curve” is compliant with standards proposed by the 3W committee (guidelines for intuitive user interfaces for web applications).

The reading curve has been fine-tuned during the post-market testing procedures and followes today the highest performance test results (see power point presentation for Premium architecture).

## 7.3 Templates and fonts

The templates have been designed for standard screen resolution of 1280 x 800 minimum. This combination allows a template design with easy to use buttons for touch screens and mouse clicks. The fonts are defined with a size of 12 (Main Menu) and 10 (Sub Menus and Pick Lists).

## 7.4 Color schemes

The color schemes have been developed according to ISO 9241-11 part 8 (requirement for displayed colors). The palette (see attachment) represents a harmonic combination with easy to read contrast combinations. The final color scheme has been chosen based on user tests.

The different colors of the scheme represent also corresponding functionalities. The button colors of the sub menu are identical with the corresponding pick lists. That allows the user to unconsciously remember the area of data capturing.

# 8. Quality management

The entire processes of system analysis, development, testing and documentation etc. strictly follow quality management principles.

## 8.1 Processes according to ISO 9001

The ISO 9001:2008 standard was chosen for the following areas:

- Identification of context of use for the dedicated user groups (clinical and non-clinical users). The specific needs of an eye care environment have been factored into the analysis process.
- The selection of usability measures have been defined in structured processes in cooperation with established users and non-users.
- The usability has been evaluated with professional test studies following the specific criteria for EMR use in eye institutes and ophthalmic offices (specific combination of numerical data, text components and images)
- According to the ISO 9001 principles a continuous process for updates and redesigns is established

## 8.2 User manual “How-to” documents

Even for an easy to learn application comprehensive user documentation is required. Because of the complexity and the high numbers of functions and features a structured documentation concept has been chosen. So called “How-to” documents describe single features. According to specific guidelines for these documents they are compact and easy to read with a maximum of three pages US-letter (see SOP for the development of “How-to” documents).

The user documentation is integral part of the user interface. The “How-to” documents can be chosen through an integrated “information center” which offers the directory of all feature descriptions. For more complex features the “How-to” documents can be context sensitive and implemented into the corresponding sub menu or pick list.

# 9. Customization potential and processes

For the usability of a digital system the customization potential is critical. If the system can be adapted to the context of the user the usability is is more efficinet compared with an inflexible system.

## 9.1 General adaptation to user specialties

In eye care environments the subspecialty defines the user context:

- Ophthalmologists who manage chronic diseases need less complex data entry routines but wish comprehensive display features for the interpretation of trends and progressions (e.g. glaucoma and retina specialists).
- Ophthalmic surgeons (cataract and refractive surgery) need specific data macros for the pre-and post-surgery documentation without long term data interpretation.

The PREMIUM EMR therefore offers subspecialty versions which are developed with ophthalmic experts representing all important subspecialties in eye care such as retina, glaucoma, cataract and refractive surgery, pediatric ophthalmology, oculoplastics and optometric services incl. contact lens management.

According to the usability tests with ophthalmic subspecialists the goals for ease of use and efficiency depend strongly on the level of customization.
For the adaptation of the ifa PREMIUM EMR/EHR consistent customization guidelines are implemented according to quality management principles. These SOPs (Standard Operation Procedures) ensure the compliance with the design concept of the PREMIUM EMR/EHR.

The areas of customization (independent from vendor input):

- Codes and terminologies
- Clinical pathways with data entry routines
- Clinical Decision Support System
- Pick lists with frequently used documentation components
- Macros for data batch processing
- Reviews and reports
- Chart monitor to check the completeness of important data entries

The customization potential is documented with structured SOPs which are viewable within the user interface (integrated “information center”).

## 9.2 Language and terminologies

The system can be adapted to the local clinical language and terminology. The user can chose from SNOMED compatible codes and descriptions and modify the descriptions according to the user context (ISO 9241-11).
For the consistency (high priority for the usability) coding guidelines are provided (see attachments).

## 9.3 Clinical pathways

Clinical pathways are essential for the realization of “Evidence based Medicine” (EbM) which support the clinical decision process. The user can define and preset exam and therapy routines following clinical guidelines. The ifa PREMIUM EMR is preset with the “Preferred Practice Patterns” (PPPs) published by the American Academy of Ophthalmology (AAO).
The customized exam forms support the usability of the system according to the dedicated user tests.

## 9.4 Work flow management

In addition to the clinical pathways the users can manage the organizational work flows with the integrated WFM tool (WFM = Work Flow Management). The WFM application can coordinate all relevant tasks such as:

- Prescription management
- Physician order management
- Patient education
- Support of the patient portal etc.

Like all the other customization features the WFM can be adapted independently from ifa.

## 10. Test management

The usability of the system is verified with structured test processes according to ISO 9001:2008 SOPs.

10.1 Pre-market tests

During the development process the usability was tested by experts who are familiar with the user context in professional eye care environments. The different user groups have been represented in the documented testing procedures.

10.2 Post- market tests

According to standard test guidelines the post-market tests have been performed with test users representing the specific user groups for eye care EMR systems:

- Established users
- Potential or new users (without previous experience

All test results have been documented and integrated into the improvement management (see separate test study documentation).

## 11. Conclusion

The usability of the ifa PREMIUM is based on standardized system analysis, development, test and improvement processes. The relevant international standards (ISO 9241, ISO 9001 etc) have been used to ensure a high level of quality and ease of use of the system.

## 12. Attachments

- Samples “How to…” documents
- Coding guidelines clinical terminology
- SOP Customization
- ifa Architecture PPT
- Customization potential PPT
- Subspecialty versions PPT

# Attachments

# How to use the ifa EMR software?

The ifa system provides comprehensive documentation on how to use the software as efficient as possible. Please us these support tools:

## Glossary and Quick Guide

For the global overview the Glossary and Quick Guide offers explanations about terms and functions.

Choose: Patient Manager/Information Center/Glossary

## “How to … “ documents

For all relevant tasks and functions so called “How to… “ documents describe step by step the routines and work flows (e.g. “How to generate a digital chart review” or “How to print an individualized letter automatically”).

Choose Patient Manager/Information Center/How to… documents

## More useful information

The Information Center (Choose: Patient Manager (EMR)/Patient Menu on the left side of the screen > Information Center) provides all kind of structured support documents:

- PowerPoints with EMR presentations (Navigation, Data Model etc.)
- Clinical pathways according to the AAO Preferred Practice Patterns (PPP)
- Hot Keys (Keyboard Function List)
- Customization Checklist etc.

***Enjoy using the leading EMR system for ophthalmologists worldwide***

# SOP: Coding Guidelines for clinical codes (observation classes) of the EMR system

**Procedure**: Change or add codes within observation classes and diagnosis etc.

## Purpose

To ensure compliance with the standards for clinical documentation and ensure comprehensive outcome (“meaningful use” of digital data).

## Scope

This SOP applies to the EHR/EMR customization in the area of observation classes for all ifa versions and entities and partners worldwide

## Responsibility

- Clinical product management for the market (country)

- Product management ifa (approval)

- Project management (documentation)

## Importance of compliance

In new projects it can be required to add or to change clinical codes within the standard

database. These modifications are critical for the consistency of the clinical

documentation system. The process has to follow documentation concepts to ensure

compatibility with:

- Search routines for codes
- Define and print reports
- Use clinical decision support (CDSS)
- Perfomance of  statistics and queries
- Exchange information with registries and research projects

## General guidelines

The coding is essential for the use of the health IT  applications (like CDSS, registries etc.) in the future and to reach the goals of the implementation of comprehensive EMR systems. The main guidelines:

- The coding should follow international terminology concepts which are adapted in the country (such as SNOMED, LOINC, ICD country modifications).

That means that the structure should be following the global SNOMED concept:
    - Observation class (area of observation e.g. “lens”)
    - Code of finding/observation (5 digits)
    - Description of finding (text)
    - Laterality (R/L/B)
    - Modifier 1-2-3
    - Individual specifications as free text (comment)
- All clinical relevant information shall be covered by the finding code and never by the modifiers. These modifiers shall only carry individual information for the specific case.
- Example: The grading of a cataract should be coded in the main code and not with modifiers
    - Correct: CatG2 **Cataract G2** as finding
    - Wrong: Cat **Cataract** as finding and modifier **G2**

**Standard processes**

If codes and descriptions shall be added or changed the processes shall follow standard guidelines according to quality management (e.g. ISO 9001 or JCI/Joint Commission International):

- Identification of needs or gaps for the documentation
- Check the existing codes (if existing what are the changes, if not existing what are the codes and descriptions)
- Check the guidelines for the coding
- Choose the corresponding observation class
- Provide the changes with an EXCEL sheet
- Let the changes and additions be approved (define approval process)
- Make the changes in the master system after approval
- Document the changes for the team (users) and provide information when and how to use

**Verification**

The ifa EMR system provides the function to create and print a change log for all observation classes. This documentation shall be used for the approval and communication process by all team members.

**Related documentation**

- Checklist for coding guidelines

- Rules for coding diagnosis as sample

# Script for customization „kick-off“ session no.01

Introduction (10 min.)

- Who is the remote coach?
- Who are the participating users (roles in the team)?
- Who are the members of the ifa project work group?
- What is the ifa infrastructure (remote customization process)?

Basics about the EMR user interface (20 min.)

- The first screen (important areas)
- The patient chart (patient manager)
- The main UI components
    - The ergonomics of the “reading curve” (w3c standard)
    - The main menu(no changes possible)
    - The sub menu (window 11)
    - The pick lists
    - The data entry area
    - The info part
    - The control bars and their functionality

The data entry process (2 demo patients) (10 min)

- Import or entry of patient demographics
- Chief complaints/encounters
- Medical history
- General exam with refraction and VA data etc.
- Anterior exam
- Posterior exam
- Special exam

The areas of customization (part 1:clinical) (10 min.)

- Encounter types
- Review of findings
- Treatment plan
- Drug prescriptions
- Other related features

Questions and answers (10 min.)

What to do next?

The next sessions

**Script for customization „kick-off“ session no.02**

Introduction (5 min.)

- Who is the remote coach?
- Who are the participating users of the session (roles in the team)?

Feed back from the users (10 min.)

- Evaluation of work packages
- Questions and answers (referring to the last session)

The output process (10 min.)

- Printing letters
- Printing prescriptions for glasses and contact lenses
- Treatment plan work flows

The areas of customization (part 2: administration) (25 min.)

- Clinic basic data
- Team data
- Letters and forms
- Prescriptions for glasses and contact lenses
- Treatment plan data
- Other related features

Questions and answers (10 min.)

What to do next?

The next sessions

# Primary Customization Guidelines
# PREMIUM + SMART Version international (all languages)
Version 01/ 01012010

- The screen resolution has to be 1280x800 or higher and the setting has to follow the standard layout (all buttons at the bottom have to be displayed).

- The template- and button sizes and their positions are fixed.

- The color schemes are binding (depending on version: Premium/Smart and sub specialties)

- The labels of the main menu (left template) are fixed. All other labels can be customized according to the defined requirements.

- A change of codes (findings) shall be always within the same observation class (category)

- If additional observation classes are chosen (categories of findings) all corresponding reviews and reports have to be modified.

- Within one project only the same observation classes shall be used for the same findings (as otherwise users can not use the same reviews and reports).

- All changes have to be documented in a detailed customization document which becomes part of the project documentation (for support purposes).

- Conceptual questions (e.g. how to integrate sub specialty templates or individual user requirements) have to be reflected before the customization process specialties and to avoid double work.

- General proposals for changes of master versions have to be provided to the product management work group for a structured consensus process.

- General customization information are provided with separate documents (e.g. PP customization and preparation packages 1+2)