COLLEGE OF SCIENCES AND TECHNOLOGIES OF COIMBRA UNIVERSITY

COIMBRA UNIVERSITY HOSPITAL

COIMBRA SURGICAL CENTRE

BlueWorks

DIGITAL IMAGE ACQUISITION FOR OPHTHALMOSCOPE

THESIS PROJECT

MASTERS IN BIOMEDICAL ENGINEERING

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COIMBRA UNIVERSITY HOSPITAL

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DIGITAL IMAGE ACQUISITION

FOR OPHTHALMOSCOPE

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Version 1.0

Coimbra, September 2011

I dedicate my final project to my parents and sister.

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“Os fracos tentam, os cobardes desistem, só os fortes conseguem.”

(desconhecido)

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ABSTRACT

This project was performed in order to satisfy a need – to provide an ophthalmoscope with digital data acquisition. In fact, most ophthalmoscopes do not contain the data recording ability. Therefore, the main advantages of a digital ophthalmoscope are, among others, better quality data sharing, the possibility of exam's reassessment and improved medical teaching. Moreover, this work and the concept of a possible solution were the product of on-going discussion between BlueWorks and clinical staff working at Coimbra University Hospital.

Once the challenge was presented, several prototype's technical drawings were idealized in AutoCAD® 2011 environment and a number of experiments in optics laboratory were accomplished as well. In the end, the prototype developed contains a camera inside and it fits into the Panoptic™ ophthalmoscope. In order to verify its capacity to record retinal images, the prototype has been clinically tested and its outcomes have been markedly positive.

Usually, a technical solution by itself does not mean success. In fact, its performance must create impact in order to be considered essential. In this particular case, ocular fundus pathologies should be detected and data should be acquired with best possible quality, this being ultimately the purpose of this scientific project.

Taking into account its growing impact in medical community, the prototype is now being recommended in daily clinical practice.

CHAPTER 1 INTRODUTION

1. 1 HUMAN EYE

Certainly, the most well-known optical system is the eye. Commonly, the human being is considerate as a visual animal due to its reactions to the light. In reality, the eyes allow the photons to be detected and be converted to electro-chemical signals in the neurons. The connection between the eye and the brain is made by the optic nerve.

1.1.1 STRUCTURE AND PHYSIOLOGY OF THE HUMAN EYE

The human eye is normally referred as a double positive lens and a globe. In more detail, the ‘Figure 1’ illustrates its anatomical sections.

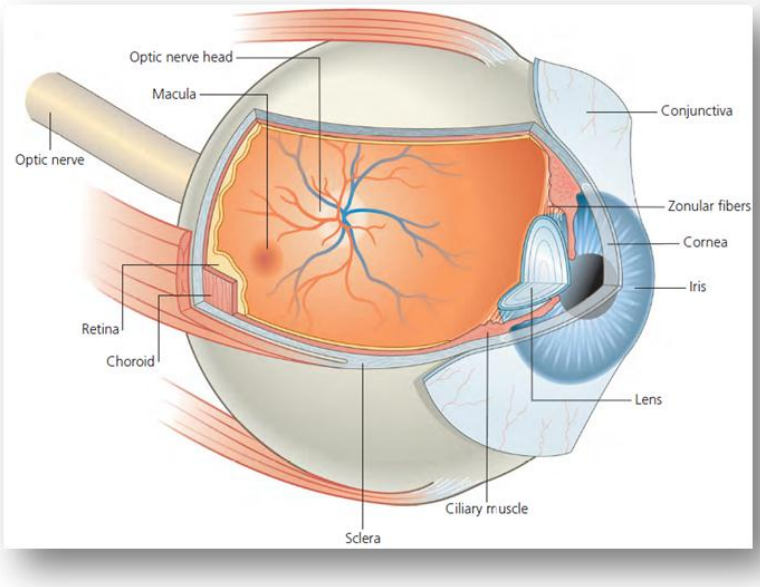


Figure 1 - Anatomy of the eye. This cutaway division allows to observe the most relevant structures [1].

In next subdivisions, only the topics related to the retina and optic disc will be approached, due to Project purpose.

1.1.2 RETINA

From Latin *rete* which means net, the retina is the innermost layer and the only one with photosensitivity. So, when a ray of light is focused on the retina, a several electrical and chemical reactions are initiated [2].

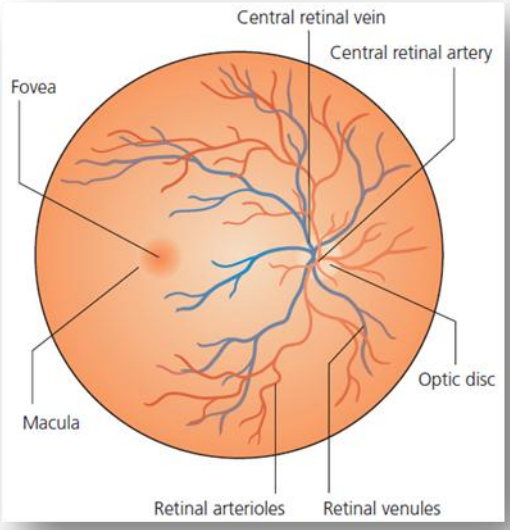


Figure 2- Normal Retina. Also known as fundus, the retina is an extension of the nervous system [1].

The retina has two types of photoreceptor cells: the rods and the cones. The primary function of these 125 million cells is to convert the photons into electro-chemical signals and to send them to the brain. Their density across the retina is not regular and more features about these cells are presented below [1]:

1.1.3 OPTIC NERVE

The optic nerve is, approximately, constituted by 1 million axons of the ganglion cells and its only visible part is the optic disc [1].

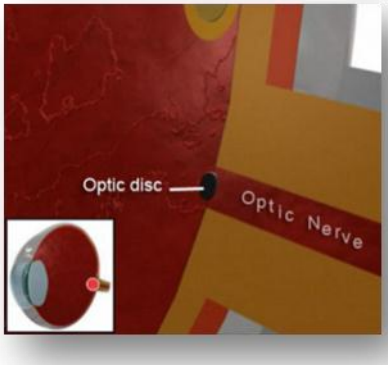


Figure 3 - The optic nerve and the optic disc. Through this structures, the information travels from retina to the brain [3].

The main role of the optic nerve is to transmit the information from the retina to the brain. The retinal arterioles and veins which leave the surface of optic disc, pretends to nourish the inner one-third. During the eye examination, it appears as a white and circular structure and since there are no photoreceptors, its position matches the blind spot of the eye [1, 3].

1.1.4 RETINAL EVALUATION

Several systemic and neurologic diseases have its first symptoms by modifications of the eye. For that reason, the ophthalmology is partially associated with other specialties, assigning a crucial importance of retinal assessment [19]. So, in order to evaluate the retina, the medical procedures are grouped in the following table [4]:

Table I – List of exams to assess the retina

✓ Refraction; ✓ Ophthalmoscopy; ✓ Visual fields; ✓ Colour vision valuation; ✓ Fundus photography;	✓ Dark adaptation tests; ✓ Electroretinography; ✓ Ultrasound; ✓ Fluorescein angiography.

To respect the main purpose of this project, the retinal exam which will be profoundly studied is the ophthalmoscopy.

1.2 OPHTHALMOSCOPY AND STATE OF THE ART

At the end of subchapter 1.1.2, the “Table I” provides the list of exams that evaluate the retina, however according to the aims of this project, solely one of these exams will be studied. Accordingly, this chapter will focus on the ophthalmoscopy, branching out in the following items:

- Diagnostic ophthalmic device which is used in ophthalmoscopy – the ophthalmoscope;
- State of the art: a brief view of the market related with the ophthalmoscopy.

1.2.1 OPHTHALMOSCOPY AND CLINICAL APPROACH

During an exam of ophthalmoscopy, the main assessed structures are: retina, optic disc, choroid and blood vessels [5]. In addition, the ophthalmoscopy can be performed in three methods: ophthalmoscopy with slit lamp, indirect

ophthalmoscopy and direct ophthalmoscopy. Since this project comprehends the ophthalmoscope as the object of study, the selected methods to be approached are the indirect and direct ophthalmoscopy. The reliability of ophthalmoscopy is about 90-95%, providing information not only about eyes' diseases but also the cardiovascular system, central nervous system and the eye effect caused by diabetes as well. Commonly, ophthalmoscopy is accomplished in dim room to avoid the contraction of the pupil (miosis). Nevertheless, the mydriatic drugs are applied to dilate the pupil, allowing a better inspection of the fundus [5].

1.2.1.1 MYDRIASIS

The target of mydriatic drugs is the iris' muscles which are under control of the autonomic nervous system. Depending on the muscle affected by the drug, some receptors are blocked whereas others are stimulated. Thus, mydriasis is due to the response of that receptors [6]. For better comprehension of this issue, the "Figure 4" allows a brief visualization of possible paths responsible for the mydriasis.

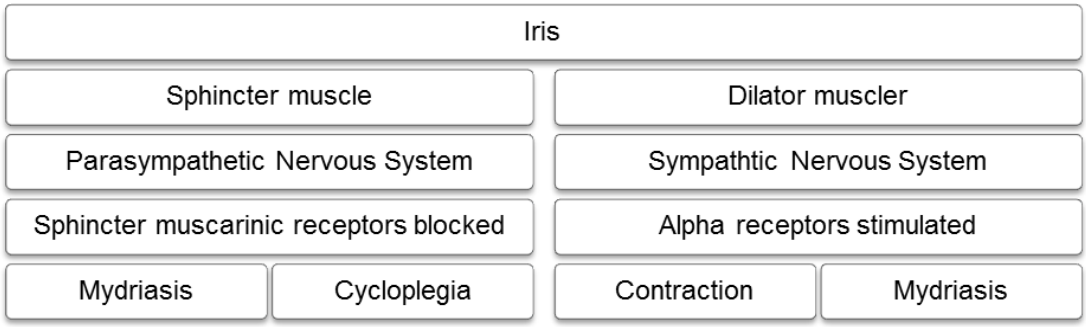


Figure 4 - Diagram of mechanism behind of mydriasis. Mydriasis is accomplished either through blockade or activation of certain receptors.

Table II- Some examples of side-effects and contra-indications related to mydriatic agents [6]

Side-effects	Contra-indications
✓ Decreasing of vision performance	✓ Heart disease
✓ Tachycardia	✓ Hypertension
✓ Headache	✓ Glaucoma
✓ Arrhythmia	✓ Unconscious patient

Table III - Mydriatic agents. Regarding the Phenylephrine, the 2.5% concentration is most used due to best potential performance effects [7].

Drug	Trade name	Concentration	Action Time	Target Muscle
Phenylephrine	Mydfrin® Neo-Synephrine®	2,5% 10%	3min-2h	Dilator
Cyclopentolate	Cyclogyl®	0,5% 1% 2%	6h-24h	Sphincter
Tropicamide	Mydriacyl®	0.5% 1%	4h-6h	Sphincter

1.2.1.2 EXAM PROCEDURES

Figure 5- Direct ophthalmoscopy examination [5]. One or two mydriatic drops are applied with an interval of 5 minutes, in each eye. Nearly 15-20 minutes after, the exam begins with the visualization of the optic disc – for purposes of orientation - succeeding the vessels, macula and finally the remainder retina [8].

Figure 6- Indirect ophthalmoscopy examination [9]. The exam may occur for 5 to 10 minutes, under mydriatic drug effect, and the devices used are the indirect ophthalmoscope and a convex lens with 20D or 30D. After the exam, the patient must protect his/her eyes from excessive sun exposure caused by pupillary dilatation. This is the reason for which the use of sun glasses is indicated [5].

1.2.2 OPHTHALMOSCOPE

Undoubtedly, the invention of ophthalmoscope was a great advance in understanding and investigating the causes and treatment of diseases related to blindness [9].

1.2.2.1 THE ORIGIN OF THE OPHTHALMOSCOPE

In 1847, a young student was standing in the auditorium of the university, when Ernest Brücke - a Viennese physiologist – observed a reflected red light from the student's eye in direction to his eye. Afterward and during four years, Hermann von Helmholtz – a German physiologist - studied the Brücke's observations and worked on them until inventing the direct ophthalmoscope, in 1851 [9].

Figure 7 - Helmholtz's ophthalmoscope. The model of 1851 was made in Austria [10].

However, and as is customary, there was a controversy about who invented it firstly. In fact, Charles Babbage – an English mathematician – built an instrument which allowed the visualization of the interior of the eye. However, he only published his invention in 1854 [11]. In 1863, the first atlas of ophthalmology was published by Richard Liebreich who was a physician and designer. In that publication, he wrote about the fact of being associated to Helmholtz and also mentioned gratitude to this. It explains the reason why Helmholtz is even more recognized than Babbage [12]. Regarding the indirect ophthalmoscope, this optical device was developed by Dr CJT Rooter in 1852, in other words, one year after the invention of the direct ophthalmoscope [9].

1.2.2.2 OPHTHALMOSCOPE AND ITS DIFFERENT DESIGNS

The ophthalmoscope was invented in order to exam the internal structure of the eye. Once the quantity of light reflected from the patient's eye is insignificant, a light source is essential to illuminate the inner eye. Therefore ophthalmoscopes are constituted by two leading mechanisms: a viewing system containing a scheme of lenses for light focusing and an illuminating system [13].

This chapter will follow the issues hierarchically presented in the diagram below:

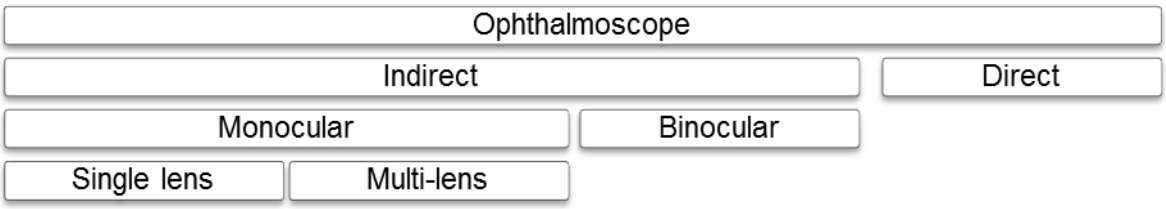


Figure 8 – Summary diagram of the different designs of ophthalmoscope.

Depending on the viewing system, the different designs of the ophthalmoscope are collected in two sets [13]:

- Direct Ophthalmoscopes – the retina is seen directly;
- Indirect Ophthalmoscopes – an image of the retina is observed.

In case the image is observed with either one eye or both eyes, the indirect ophthalmoscope may be classified as [13]: monocular indirect ophthalmoscope and binocular indirect ophthalmoscope. Finally, and according with the optical complexity, the monocular indirect ophthalmoscope is grouped into two sets [13]: monocular indirect ophthalmoscope with single lens; and monocular indirect ophthalmoscope with multi-lens.

1.2.2.2.1 DIRECT OPHTHALMOSCOPE

The direct ophthalmoscope is recommended since it's easy to use when the pupils are small or undilated. In addition, its size allows for a better usability [9].

VIEWING SYSTEM

According to the viewing system, the main point is to achieve the largest area of the subject's retina as possible. Thus, the field-of-view θ, depends upon: distance between the pupils of the subject and the observer, d; diameter of the subject's pupil, D_s; diameter of the observer's pupil, D_o [13]. The equation (2) is valid in these cases: the subject's eye is emmetropic and the beam of light is collimated [13].

$$\theta = \frac{(Ds+Do)}{2d} \quad (rad) \qquad \text{Equation (2)}$$

Once known the value of angular radius of the field-of-view, the following stage is the calculation of size of the retina field,η, which is given by subsequent equation [13]:

$$\eta = \frac{-\Theta}{Fs} \quad (metres) \qquad \text{Equation (3)}$$

The power of the subject's eye is represented as F_s, and its value is roughly 58.6 m^{-1}. Therefore, the equation (3) permits to relate the size of an image with the angular size of a distant object [13].

Analysing both equations and the role of dilatory drugs, the main conclusion is that the value of D_s increases after administration of mydriatic agents, and consequently the field-of-view increasses as well. The limitation of the field-of-view is specially due to the value of distance, d [13].

Commonly, the direct ophthalmoscope is known as a result of its great magnification of 15x. In fact, the succeeding equation explains why [13]

$$M_d = \frac{Fs}{4} = \frac{58.6}{4} \approx 15$$ Equation (4)

However, the equation (4) is not valid in case of ametropy. Thus, the magnification depends on the refractive error, K, and the distance between the eye and ophthalmocope, d, as well [10]:

$$M_d = \frac{Fs + K}{4\,(1+dK)}$$ Equation (5)

Focusing on the refractive errors, the direct ophthalmoscope contains spherical lenses which support the observer to focus. The range of refactive power of these lenses is commonly between -30D and +30D [14].

The refractive power of the lens, P, is determined by: distance between the patient's eye and the ophthalmoscope, d; refractive error of the patient, K; refractive error of the observer, K_o. Thus, the global equation which is valid for both cases – emmetropy and ametropy – is [13]:

$$P = K_o + \frac{K}{(1+dK)}$$ Equation (6)

However, there are no cylindrical lenses in its constitution. Subsequently, this optical advice does not allow to compensate an astigmatic error of refraction. [9]

ILLUMINATION SYSTEM

To understand the importance of some of these optical structures, a brief approach is made as follows:

Table IV– Aperture Disks used in ophthalmoscopy. The apertures remain optically combined with the interior of the patient's eye.

APERTURE DISKS	DESCRIPTION
Smaller	Recommended for small pupils [9]. Decreasing of corneal reflex [14]. Best performance in terms of observing the macula [14].
Larger	Increasing of coneal reflex [14]. Increasing of the amount of light onto the retina [14].
Slit illumination	Used for focal high-intensity illumination [9]. Permits the estimation of the level of the regions of the fundus [9].

Occasionally, the ophthalmoscopes also contain a grid for which the patient may look at, allowing for a better viewing of the macular area [7].

Table V- Filters used in ophthalmoscopy [9].

FILTER SYSTEM	DESCRIPTION
Green (Red-free light)	Retinal blood vessels appear dark. Retinal nerve fibers stand out more. Used for detection of hemorrhages, holes and degenrations of the macula.
Red light	Less contrast between the retinal blood vessels and the retina. High absorption of red rays by melanin pigment which contrast with red fundus. Used for detection of tumors which contain melanin and it is indicated in differentiating hemorrhage.
Cobalt-blue	Used for fluorescein assessment of the retina. The ophthalmoscopes which use this type of filters must have an illumination system with advanced control and great intensity.
Polarizing	The two polarizing filters allow for the reduction of the noisy reflections from the patient's cornea. In order to compensate the filtering effect, the illumination must have a greater intensity.

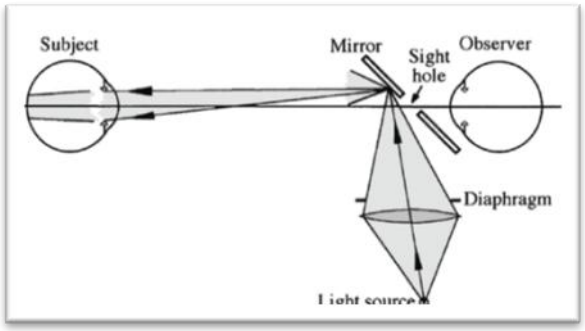


Figure 9 - Scheme of illumination system of the direct ophthalmoscope.

The mechanism which begins with the light source. Then, the beam enters into the eye since it is reflected by the mirror. To control the diameter of the beam, there is also a adaptable diaphragm[13].

1.2.2.2.2 INDIRECT OPHTHALMOSCOPE

Due to the greater illumination, wide field of view, depth perception and the possibility of using it at a distance, the clinical cases for which this device is acclaimed are, for example: detection of retinal detachments; during retinal detachment surgery; recognition of malignancies when the subretinal fluid is abundant [15].

MONOCULAR INDIRECT OPHTHALMOSCOPE WITH SINGLE LENS

In consequence, the indirect ophthalmoscope with single lens aims to increase the area of the retina which can be observed by placing additional lenses of suitable power between th subject's and observer's eyes [13].

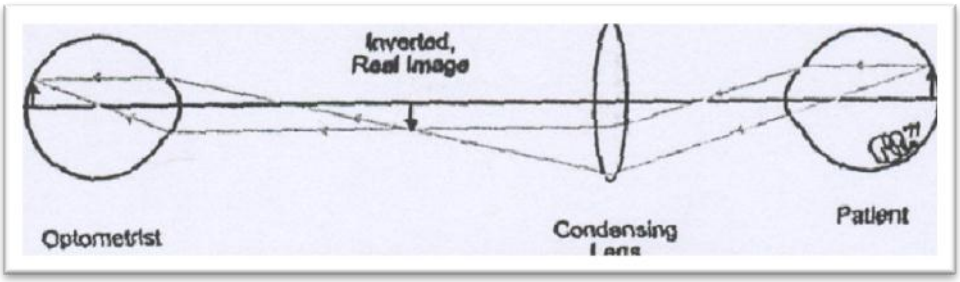


Figure 10 - Monocular indirect ophthalmoscope with single lens. This optical system provides a greater field-of-view than the direct ophthalmoscope, however the magnification is smaller and the image is inverted [14].

To calculate the magnification of the image, demonstrating that the magnification is smaller than that of the direct ophthalmoscope's, the following figure and equations are established below [15]:

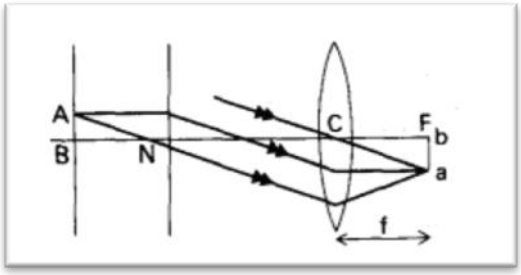


Figure 11 - Linear Magnification of indirect ophthalmocope with condensing lens. Increasing the field-of-view implies the decreasing of magnification [15].

According to the 'Figure 11', the definition of linear magnification is the following:

$$\text{Linear Magnification} = \frac{ab}{AB} \qquad \text{Equation (7)}$$

As the segments Ca and AN are parallel, thus the aCF angle is equal to the ANB angle:

$$\tan aCF = \frac{ab}{CF} = \tan ANB = \frac{AB}{BN} \qquad \text{Equation (8)}$$

Reorganizing the equations (6) and (7):

$$\frac{ab}{CF} = \frac{AB}{BN} \ll=\gg \frac{ab}{AB} = \frac{CF}{BN} \qquad \text{Equation (8)}$$

Where the segment CF is the focal length of the condensing lens and the segment BN is the distance between the nodal point and the retina of the patient's eye. In emmetropic eye, the segment BN measures 15 milimeters. The common power of the condensing lens used are +20D and +13D. Applying the equation (1), the focal length for lens +20D and +13D are 50 milimeters and 75 milimeters, respectly [15].

Subsequently, the respective magnification for each lens is the following:

Table VI – The magnification in indirect ophthalmoscopy.

Power of the condensing lens	Calculation	Magnification
+20 D	$\frac{CF}{BN} = \frac{50}{15} = 3$	**3x**
+13D	$\frac{CF}{BN} = \frac{75}{15} = 5$	**5x**

MONOCULAR INDIRECT OPHTHALMOSCOPE WITH MULTI- LENS

Instead of the previous example which had only one lens, the following optical scheme comprehends a complex optical system with multi-lens:

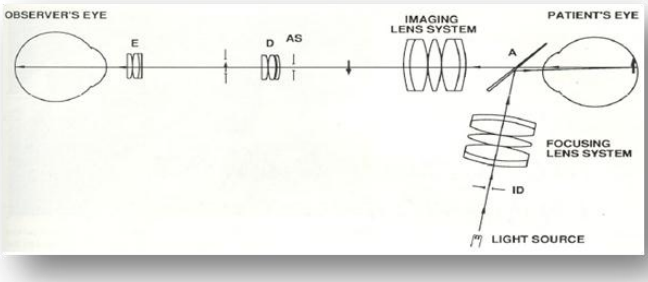


Figure 12 - Monocular indirect ophthalmoscope multi-lens designed in laboratoy.

In comparison with “Figure 9”, this one contains a architecture more similar to the direct ophthalmoscope design [14].

BINOCULAR INDIRECT OPHTHALMOSCOPE

This type of ophthalmoscope contains the peculiarity of having eyepieces or macroscopes which confer an erect retinal image (only Galilean or Keplerian types). Owing to the binocular system, the image is stereoscopic and the field-of-view is wider [13].

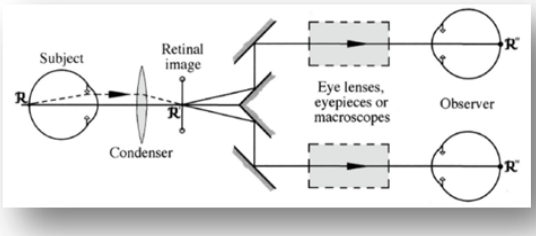
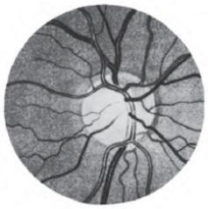
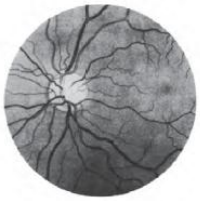


Figure 13 - Binocular indirect ophthalmoscope. The symbols R, R’ and R’’ mean retinal conjugate points [13].

Since all important subjects were approached , the succeding procedure is to recapitulate the main aspects of direct and indirect ophthalmoscope.

Table VII – Summary of the leading features related to direct and indirect ophthalmoscope.

Features	Direct	Indirect
Image		
	Erect [9]	Inverted [9]
Field of view	Smal (8º - 12º)	Greater (≈ 60º)
Magnification	15x	3x-5x
Stereopsis	No	Yes
Optical system	Simple	Complex
Usability	Easy	Requires practice
Cost	Low	High

1.2.3 COMPANIES RELATED TO OPHTHALMOSCOPES

When researching for ophthalmoscopes, the main companies which appear associated to these optical devices are: Welch Allyn®, Heine and Keeler Ltd.

CHAPTER 2 PANOPTIC™ OPHTHALMOSCOPE

The Panoptic ™ ophthalmoscope is the main optical device in focus on this project.

Figure 14 - Panoptic™ ophthalmoscope. This optical instrument is the core subject of study [16].

In order to understand its impact in clinical context, this chapter will meet the leading features associated to this instrument and, briefly, it will take into account the comparison between Panoptic™ and standard ophthalmoscopes, as well.

2.1 WELCH ALLYN® AND ORIGIN OF PANOPTIC™ OPHTHALMOSCOPE

Welch Allyn® is a company established in New York. Their mission is to provide technological healthcare solutions on a worldwide level, and they stood out due to the development of the world's first hand-held and direct-illuminating ophthalmoscope, in

1915. The company's designation is owing to the founders's name: Francis Welch and Noah Allyn [17, 18].

Since 2000, the Panoptic™ ophthalmoscope has been a trade product from Welch Allyn ® company and, only two years after; this device is recognized as technologically significant, contributing to the *Global R&D 100 Award* [18].

2.2 PANOPTIC™ MODELS

The available model configurations of this instrument are presented below. In this project, the Panoptic™ considered was the 11820 model.

Table VIII – Panoptic™ models [19].

11810 Model	11820 Model	11800-V Model
• Panoptic™ Ophthalmoscope	• Panoptic™ Ophthalmoscope • Cobalt Blue Filter • Corneal Viewing lens	• Veterinary Panoptic Ophthalmoscope • Three spot sizes: micro, small and large • Add-on magnifying lenses.

The difference between 11810 and 11820 models is related to the type of apertures and filters inside of the ophthalmoscope. Thus, the 11820 model is considered as a better and more expensive offer [20].

Table IX – Difference between 11810 and 11820 Models [21].

11810 Model	11820 Model	Aperture
✓	✓	• Three spot sizes: micro, small, large.
✖	✓	• Add-on magnifying lenses; Cobalt Blue Filter; Corneal Viewing lens
✓	✓	• Slit aperture
✓	✓	• Red-free Filter
✓	✖	• Half-moon aperture

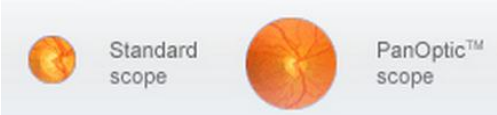
2.3 PANOPTIC™ FEATURES AND ADVANTAGES

Wherever the model considered, Panoptic™ contains a special feature patented - axial point source optics - which permits to focus the light into an axial point of the cornea. Thus, the visualization of the fundus is performed without any administration of mydriatic drugs since the pupillary dilatation is not necessary [22].

Table X– The main features of Panoptic™ [23].

Axial PointSource™ Optics	3.5 Volts Power Source	Patient Eyecup Functions	Focusing Wheel
Easy light entering;	Rechargeable battery	Proper viewing distance.	Focusing range: [-20D +20D]
Provides a larger field-of-view;	Wall transformers	Prevents environment light entering	
Increases the magnification.			

Table XI – The main advantages of Panoptic ™. The large field-of-view and great magnification allows the detection of delicate conditions such as: papilledema, hypertension and diabetic retinopathy [24, 25].

✓ No need of pupillary dilatation. ✓ Field of view 5X larger than a standard ophthalmoscope. 	✓ The magnification is roughly 26% over a traditional de ophthalmoscope. ✓ Suitable Working distance between patient and observer. ✓ Erect image.

2.4 OPTICAL SCHEME OF PANOPTIC™

The Panoptic™ is optically classified as a monocular indirect ophthalmoscope; however its providers and manufacturers describe it as a direct ophthalmoscope since the image is erect. In fact, the relay lenses located at the front of 'Practitioner's Eye' reinverts the initially inverted image [26].

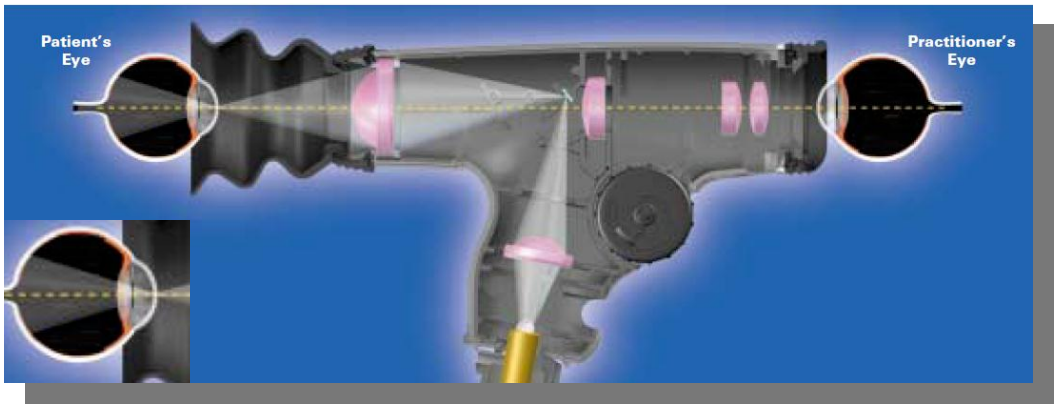


Figure 15 – Optical scheme of Panoptic™ ophthalmoscope [27]. In detail, this scheme presents the axial point that is located at the cornea. The beam converges on this point and subsequently it diverges along the retina.

CHAPTER 3 PROJECT CHALLANGE

At present, the majority of ophthalmoscopes have no mechanisms for capturing images or videos during the eye examination. Since the ophthalmoscopes are an extremely important and useful tool for ophthalmologists and neurologists, they have been noticing the need for digital image acquisition.

3.1 IDEA

Dr. João Lemos, Neurologist at Coimbra University Hospital (HUC), was the first entity to expose the need for digital funduscopy and, consequently, he is the major responsible for the innovative idea of building a device which fits into the ophthalmoscope and registers the exam by the whole. More so, this device should allow the image acquisition while the physician is examining the patient's eye.

3.2 ADVANTAGES OF DIGITAL FUNDUSCOPY FROM OPHTHALMOSCOPE

The advantages are obvious since in other medical specialities, for example – radiology, ophthalmology, and cardiology - the clinical information has been accomplished in digital format. Definitely, the capturing of a digital image of the eye's fundus from the ophthalmoscope would revolutionize the clinical practice of neurologists and ophthalmologists and would strengthen the

professional relationships between them. Additionally, the neuro-ophthalmology speciality would enhance as well, with the increase of available records to support the diagnosis process and the clinical assessment. The leading gains related to digital image acquisition in ophthalmoscopy are presented, briefly, as follows:

Table XII– Advantages of digital image acquisition in ophthalmoscopy

- ✓ **Objective documentation** - instead of existing just a visual inspection and some text notes, an image is available:
  - Neurologists and ophthalmologists may share between them a greater number of the eye's fundus, allowing a higher quality on the exam description. In addition, the image records the moment (date and time) when it was capture.
  - The patient can realize in a better way his or her clinical situation looking at the image of own's eye.
- ✓ **Reassessment**: the clinician may request a review of an examination (image/video). In this manner, a periodic control of patient's clinical status is performed and the respective longitudinal analysis is assessed as well.
- ✓ **Better teaching**:
  - Medical students can easily understand how to use the ophthalmoscope because they may watch the resulting image in real-time, depending upon the tool position.
  - The divulgation of the eye's fundus images as being a valid reference and the achievement of the first atlas of neurology would certainly enrich the knowledge in this medical area.

3.3 PROJECT AIM

Hereupon, the project "**Digital Image Acquisition for Ophthalmoscope**" was introduced in order to develop a technological solution which will record the eye's fundus. Thus, and concerning the medical requisites, a prototype was created and tested in clinical context at Coimbra University Hospital.

3.4 INSTRUMENT OF STUDY: PANOPTIC™

The most promising device to which imaging could be added was the Panoptic™ ophthalmoscope due to its great image quality. Since Dr. João Lemos owned one of these devices, this was the main tool. In this way, the referred prototype is only compatible with this ophthalmoscope.

3. 5 TEAM PROJECT

The project was developed by a biomedical engineering student - Taíssa Pereira – in order to obtain her master's grade. The coordinators and institutes inherent to this project are presented in "Table XIV".

Table XIII – Entities responsible for this Project

Coordinators	Institutes
Dr. João Lemos, Neurologist	Coimbra University Hospital.
Eng.º Paulo Barbeiro	BlueWorks – Medical Expert Diagnosis, Lda.
Prof. Dr. Miguel Morgado	Physics Department, Coimbra University.
Prof. Dr. Eduardo Silva, Ophthalmologist	Coimbra Surgical Centre, Coimbra University Hospital.

3.6 WORK PLACE AND FINANCY

Regarding the work place, the project was executed in the installations of the company BlueWorks – Medical Expert Diagnosis, Lda, in Coimbra, Portugal.

3.7 SIMILAR IDEAS

During the research for digital ophthalmoscopes, two companies from different countries were found – OPTOMED and GrancIInfo - which commercialize a product with a similar idea [28, 29]. Plus, it was also published a patent, in April 2011, that is valid only in the United States of America [30, 31]. This information warrants, in a certain way, the possibility of success of this project since it offers evidence of the potential of this idea.

3.8 WELCH ALLYN AND DIGITAL OPHTHALMOSCOPE POSSIBILITY

As the Panoptic™ ophthalmoscope is a product of Welch Allyn, it was imperative to know if this company will produce or commercialize a similar product with image acquisition any time soon. Thus, the kick-off task was to contact the distributers of Welch Allyn in Portugal, in order to clarify this issue. Fortunately, their answer contributed favourably to this project because, at the moment, Welch Allyn is not producing this type of device and has no plans associated to it.

CHAPTER 4 PROJECT METHODOLOGY

When the challenge was exposed, there was no oficial plan containing all actions to fulfill. In addition, the Welch Allyn 's distributors did not provide any documents or information regarding the optical system of the Panoptic™ ophthalmoscope – for example, the lenses' optic power. Hence, the knowledge associated to possible optical behavior will not be predictable through mathematical procedures.

Consequently, the work progress depended soleley on the output obtained in laboratory, during the experimentations' phase. As a result, this project implemented an add-on methodology. In additon, the optics laboratory of the Institute of Biomedical Research in Light and Image – IBILI - were the main place of the experimentations. Finally, the procedures which describe the work evolution may be resumed in four phases. Observing the following scheme, the mentioned work phases are:

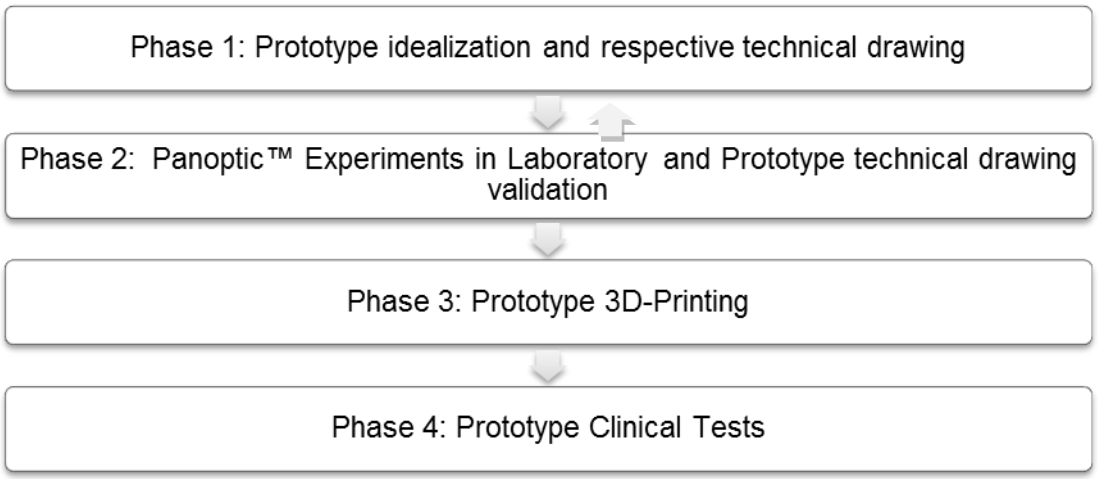


Figure 16 – Project Process Diagram.

Briefly, it is important to refer the connection between the first and second phases which is indicated in the scheme through the pair of arrows. In fact, these major stages were developed at the same period. Firstly, because the conclusions of laboratorial tests influenced the prototype technical drawing; and secondly, because new experiments were required in order to confirm if the modified prototype was valid according to the clinical requirements.

Thus, this circle drawing-testing was, unquestionably, the main nucleus of this project that finished when the final prototype drawing was chosen to 3D printing – corresponding to the following project phase. Before of the description relative to the mentioned project phases, it is also a priority to reveal the clinical requirements which are organized and presented below:

Table XIV – Clinical requirements

✓ **Erect image.**	✓ **Magnified image.**
✓ **Image/video recording while the physician is examining the patient's eye with own's eye.**	✓ **Great usability.**

Following the brief introduction to this chapter, the following topics will detail the procedures inherent to the prototype development.

4.1 FIRST DRAWINGS AND FIRST TEST

According to the medical requisites, the physician should observe the patient's eye at the same time as the image sensor – or camera – is capturing the exam. Thus, a part of the light should go on to the doctor's eye, and another

part to the sensor. In order to solve this requisite, a beam-splitter (45 degrees type) was considered to be the best option.

Since we do not know how the rays which leave the ophthalmoscope behave, a convergent lens would be necessary in way to converge the beam to the sensor. Relatively to its optical power or the focal length, the experimentations should respond to this issue afterwards. For comfort purposes, it was also introduced a window at the observer's side.

The software used to draw this initial prototype was the 2D- Draft IT.

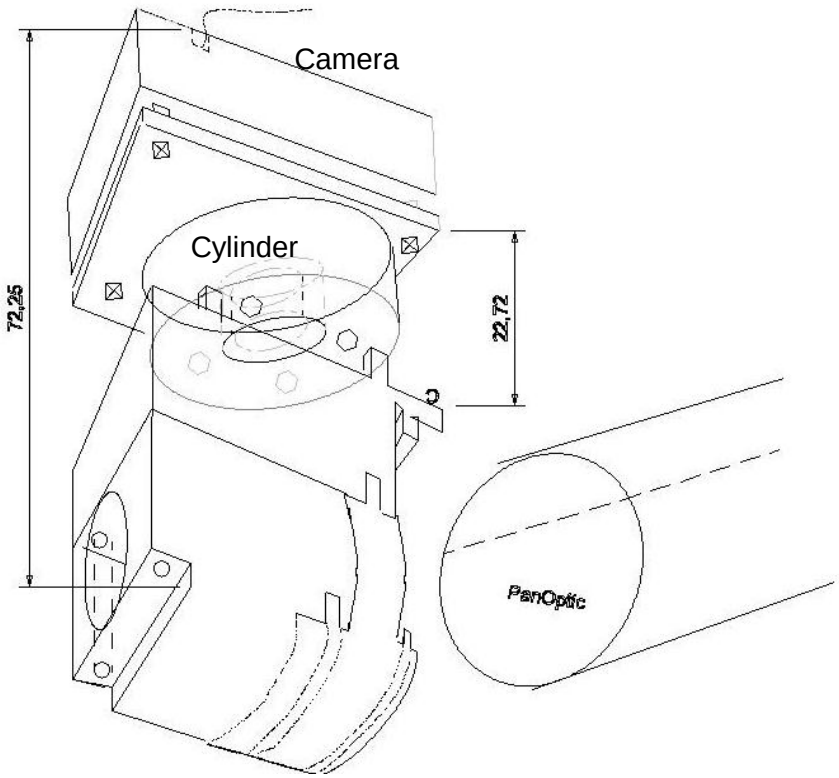


Figure 17 – The first prototype drawn with Draft-IT software. Initially, the position of the camera was controlled by the rotation of the cylinder, in order to allow a better focused image.

The following table describes briefly the components inside of this prototype.

Table XV – Constituents of the first prototype

✓ **Sensor: 1.3 Mega Pixel, Plug&Play Webcam from Genius [32].**
✓ **One Convergent Lens.**
✓ **Cubic Beam-splitter - 50%R/50%T.**
✓ **Window.**

Before testing this possibility, it was concluded that the used software did not provide an acceptable drawing quality, according to the high potential of this project. This way, the greatest solution was to work in AutoCAD® 2011 environment, due to the fact that there was already previous experience from the Blueworks team in using this tool.

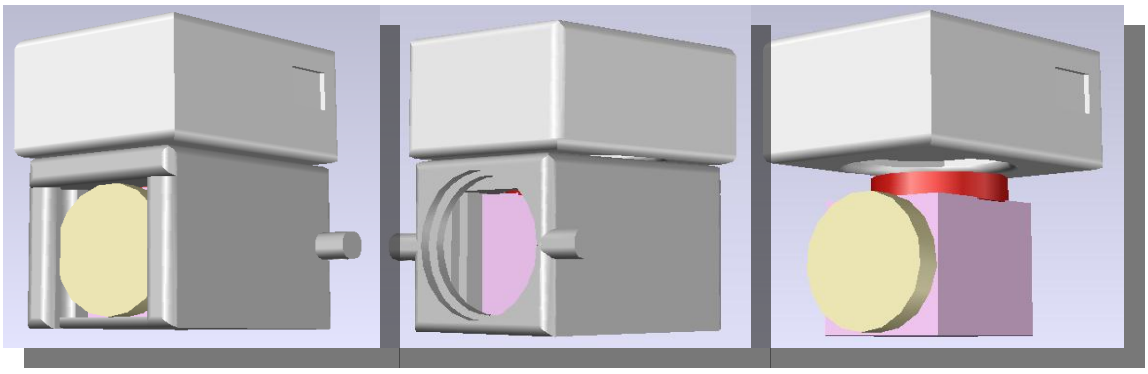


Figure 18 – The first 3D- prototype drawn in AutoCAD® 2011 software. The window is the yellow component, the lens is illustrated in red colour, the beam-splitter is the pink object and, at the top, it was introduced the camera.

Other change was regarding the existence of the cylinder which allowed changing the camera position. In AutoCAD® drawing, there is no cylinder and thus the sensor has a fixed position. Actually, it was assumed that the absence of automatic focusing system would not influence the image quality, significantly.

The first test in laboratory was performed in order to assess the camera's image quality. Contrary to what was previously assumed, the sensor must have automatic focusing system and so the camera chosen was considered not valid for this prototype. Thus, another camera was bought in way to solve this question.

4.2 SECOND DRAW AND SECOND TEST

The second drawing consists in improving the first one, in consequence of the first test results.

Relatively to the components inside, the camera with auto-focus [49] was the new major acquisition. In addition, this prototype presents also two available compartments – one at the patient's position (arrow 1) and other at the physician's location (arrow 2)- in order to introduce at maximum 2 lenses, eventually needed, instead of only one. In case of being necessary another lens to converge the beam to the sensor, there is also another small and discrete section for that.

The Panoptic™ ophthalmoscope possesses an external ring of rubber which fits into the device and provides improved comfort to the physician's eye

touching the device. By removing this rubber ring, and attach in its place the developed device, it was also created a structure (arrow 3) in the prototype opposite side in order to allow for this rubber ring to be repositioned, and therefore maintain user comfort.

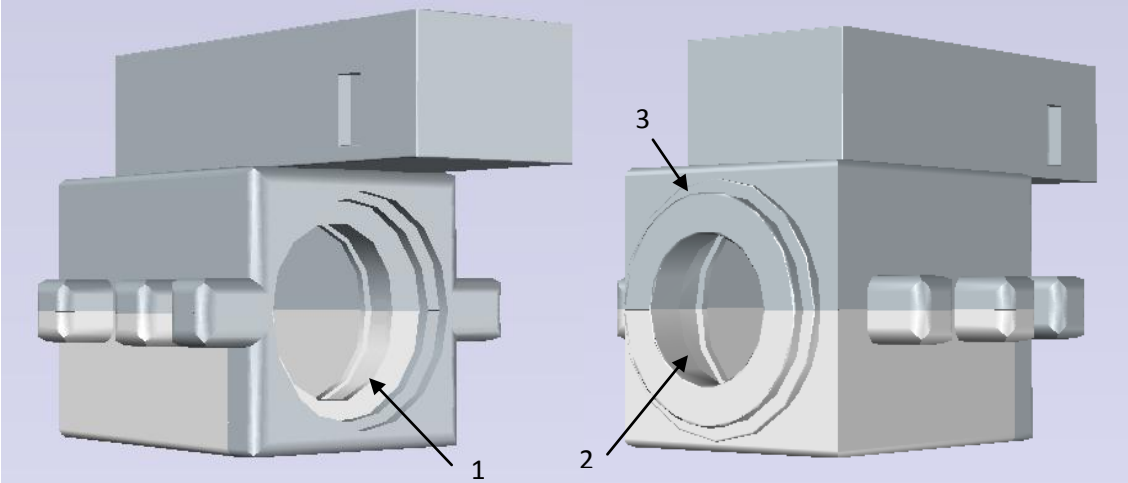


Figure 19 – The second 3D- prototype drawn in AutoCAD® 2011 software.

This prototype is more complex and larger than the first one.

The components inside of the second prototype are resumed in the next table.

Table XVI – Constituents of the second prototype

- ✓ Sensor: Logitech HD Webcam C270 [33].
- ✓ Two Convergent Lenses.
- ✓ Cubic Beam-splitter.

The aims of the second test were to evaluate the prototype's measurement and also the performance of the new camera.

Relatively to the new image sensor, no more complications were exposed. Actually, the image presented a great quality and the auto-focusing mechanism improved the results, as expected. However, the prototype's major axis measured almost six centimetres and this detail was responsible for a new possibly problem:

- At 6 centimetres from ophthalmoscope, is the image focused onto the clinician's eye without loss of magnification and field-of-view?

Well, to response to this question it was necessary to use an improvised tube with the same length of the prototype in question.

Figure 20– Experimental set-up to verify the image formed at 6 centimetres from ophthalmoscope.

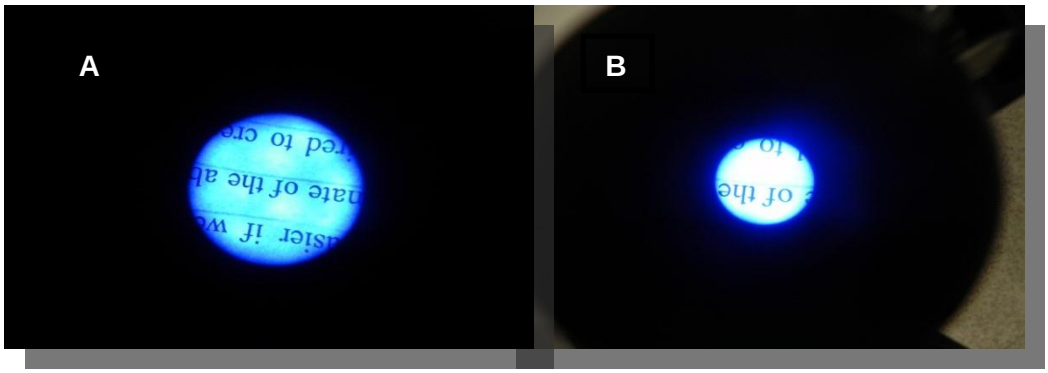


Figure 21 – The comparison of the image formed at about 24 millimetres (A) and at 6 centimetres (B) from the ophthalmoscope. The main conclusion is the obvious loss of field-of-view of the image.

Regarding the initial question, the answer is absolutely “No”. Actually, the field-of-view decreased drastically but the image quality was maintained.

Thus, the possible solutions were:

1. Testing the best lenses to use since they were already predicted in the technical drawing, although not dimensioned;
2. Adding a commercially available eyepiece in order to increase the field-of-view.

The first option was rejected because it was almost impossible to discover the best length distance without the optical knowledge of the ophthalmoscope, taking into account the time constrains for this project. In addition, it would be indispensable to have a perfect alignment and to not have

any kind of movement, and the used experimental setups did not provide such ideal conditions.

As a result, the main conclusion was that the absence of information regarding the lenses' optic power, which would be introduced in the prototype, would lead to the invalidation of the second 3D-prototype drawing. Regarding the second option, after testing several eyepieces, using one with 16 times magnification, it was possible to re-establish the field-of-view, as required, however the image appeared inverted. Hereupon, the clinical requirements were not respected, and so the project entered a critical phase.

Figure 22 – The experimental set-up using the eyepiece (white arrow) at 6 centimetres from Panoptic™. The great field-of-view is re-established; however the image is not erect.

4.3 CRITICAL PHASE

Given this new scenario – the image obtained is inverted - which did not met the initial clinical requirements, other options had to be studied. Three

alternatives to resolve this issue were identified. The next chapters address these and explain the advantages and disadvantages of each option.

4.3.1 ALTERNATIVE DESCRIPTION

The following table contains the main aspects about the three possible alternatives.

Table XVII – The alternatives description.

Option	Description
1	**Lens and eyepiece optical system**: an erect image and a large filed-of-view are achieved. Keeping the three options, this one is the most complex and its prototype has the greatest dimensions.
2	**Hybrid approach – eyepiece and image software**: although the digital image is erect, the clinician observes a larger but inverted image.
3	**Simplistic vision – sensor charge-coupled device (or CCD)**: prototype with a single component, a simple camera or sensor CCD. The clinician has to choose between recording the images and watch them on monitor or examining the patient's retina with his or her own eye. This option offers the smallest and more least expensive prototype.

4.3.1.1 OPTION 1: LENS AND EYEPIECE OPTICAL SYSTEM

In this approach, the main idea was to develop an optical system. As the eyepiece reverses the image and provides a great field-of-view, a lens is required in way to reverse the initial erect image. The idea is clearly represented through the following scheme:

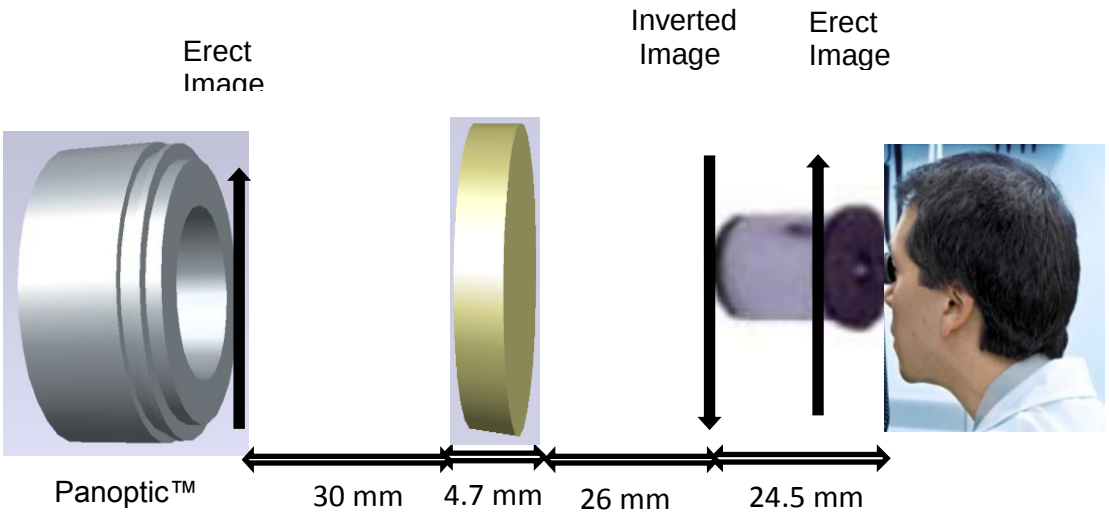


Figure 23 – Scheme of the first alternative. The lens is about 30 millimetres from the ophthalmoscope because the second technical drawing contains the compartment for the lens at this distance. The values 4.7 and 26 millimetres were obtained by the optical CAD software used.

Table XVIII – Features related to the first option components

Lens – LB1092 [34]	**Eyepiece - "Huygenian Eyepiece"** [35]
Focal length: + 15 mm Thickness: 4.7 mm Price: 18.50 €	Length : 24.5 mm Magnification: 15 x Price: 55 €

The lens' characteristics – focal distance and expectable image quality - were achieved thanks to the optical CAD software: OSLO.

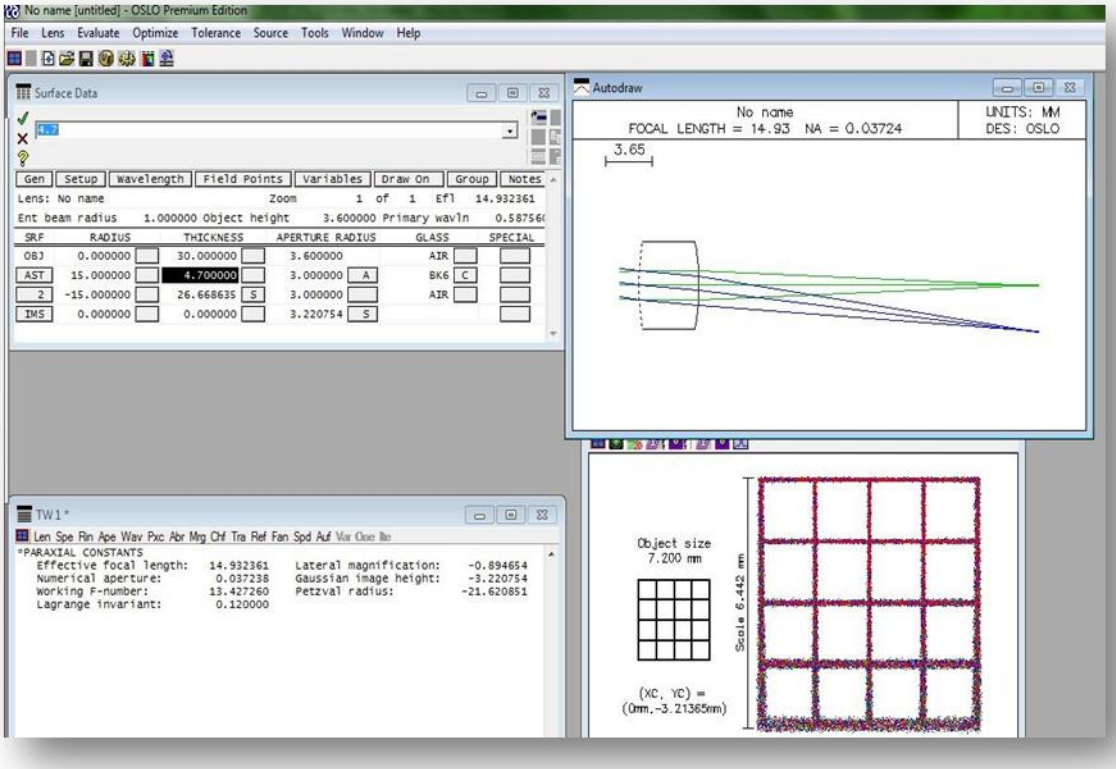


Figure 24 – The print screen of the OSLO results. The grid demonstrates the image quality and the values inside the boxes express the several features relative to the lens.

Table XIX – Advantages of the first option.

Advantages
✓ Erect and magnified image.
✓ Image with quality (conclusion based on the software's results).
✓ According to the clinical requirements.

Table XX – Disadvantages of the first option.

Disadvantages
✖ Prototype lenght: 80.5 mm (at minimum).
✖ Weight (high number of components).
✖ Price.
✖ High probability of breakage in the fitting area.
✖ Usability.

4.3.1.2 OPTION 2: HYBRID APPROACH – EYEPIECE AND IMAGE SOFTWARE

In this second alternative if the image registered by the sensor is erect, then it's not critical if the image observed by the physician is inverted.

Table XXI – Components of the second alternative.

Components
✓ Eyepiece: Inverted and magnified image.
✓ Beamspliter
✓ Software to reverse the image acquired.

Table XXII – Disadvantages of the second alternative.

Disadvantages
➢ May need to add a lens.
➢ Dimension/ Weight.
➢ Price.

4.3.1.3 OPTION 3: SIMPLISTIC VISION – SENSOR CCD

The last alternative presents a prototype constituted by just one component: the image sensor. The exam viewing (image or video) is performed merely by observing the monitor. In case of not needing image or video acquisition, the physician may remove or raise the prototype, since it possesses a hinge at the top.

Table XXIII – Advantages of the third alternative.

Advantages
✓ Economic. ✓ Not heavy. ✓ Mobile.

4.3.2 COST ESTIMATION

Table XXIV – Cost Estimation. The third alternative is the most economic and the simplest.

Option	Optical Components (€)	3D-Printing (€)	Total (€)
1	Beamsplitter: [100-160] [36,37] Eyepiece: 55[35] Lens LB 1092: 18.50[34]	500	673.50
2	Beamsplitter: 100[36,37] Eyepiece and additional lenses: ≈ 100[35]	300	500
3	Camera: ≈ 30 [38]	200	230

4.3.3 ALTERNATIVES ANALYSIS

Before choosing the better solution, it was necessary to analyse and classify the most important characteristics that the prototype should have. The next table presents the classification for each alternative:

Table XXV – The alternative analysis.

Option	Dimension Weight	Experimental Viability	Usability	Price	Image/video Record	See image through the eyepiece *	Erect Image
1							
2							
3							

* Simultaneously with image/video capture

Legend:

 High

 With restrictions

 Approved

 Impossibility

The trade-off between these requirements was analysed in by the whole Project Team, resulting in a consensus towards option number 3.

4.4 THE FINAL PROTOTYPE

After redesigning the prototype, the final result was the following:

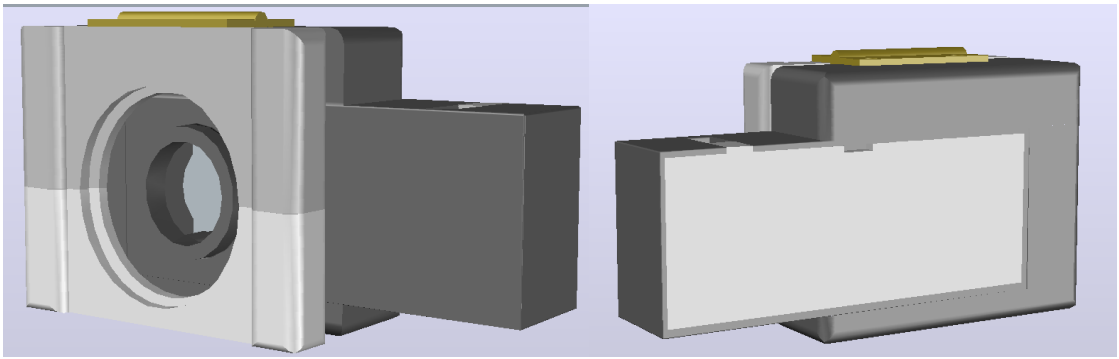


Figure 25– The third 3-D prototype technical drawing. Smaller, cheaper and more versatile are only some of the advantages. If the clinician wants to observe the patient's eye, he just has to rise up the sensor, which has a rotation axis (arrow points to the hinge) of 180 degrees. If he wants to record images/video, the sensor must be as the representation shows.

4.5 THE 3D-PRINTING

According to the 'Diagram V' which resumes the project progress, the following theme regards the phase number 3. Before the technical drawing is printed at the factory, it was necessary to redesign the third prototype in order to decrease the distance between the sensor and the ophthalmoscope. Such is notorious by observing the lateral view of the drawing.

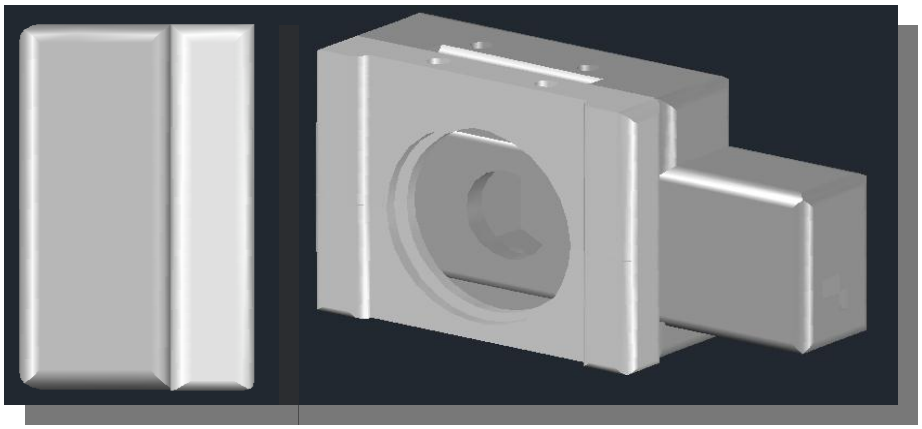


Figure 26 – The prototype to 3D- printing. In this drawing, the hinge is not present because it is an accessory and the factory only receives the pieces that are really to print.

The 3D – printing process lasted almost one week, and when the physic prototype arrived from the factory, the hinge chosen was no longer available in stock. This new problem was resolved through buying two smaller hinges, instead of one.

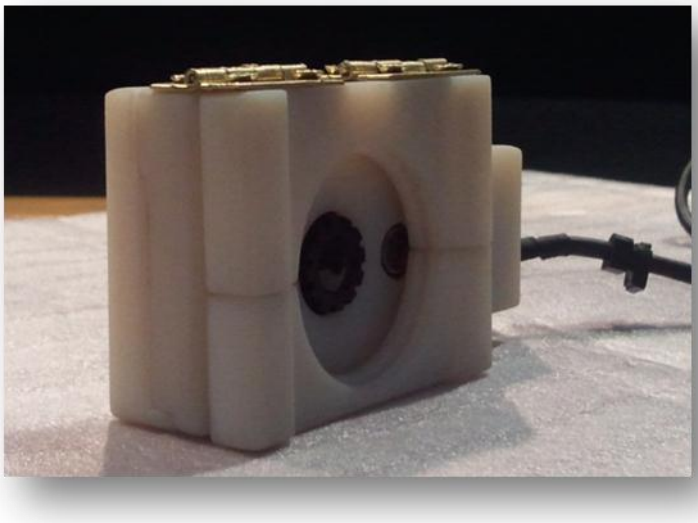


Figure 27 – The physic prototype with the camera inside. Given the circumstances, it contains two hinges, instead of one.

Figure 28 – The prototype fits into the Panoptic™.

Figure 29 – The hinges performance.

The subsequent phase consists in the prototype clinical tests. During the clinical practice, the main point to refer is:

- ✓ When the sensor was raised, it hit in the forehead's doctor. Consequently, the hinges had to be removed and small magnets were introduced in order to join the sensor's piece with the double semi-

circular pieces which contacts directly to the ophthalmoscope. In this way, removing the sensor is much easier and faster.

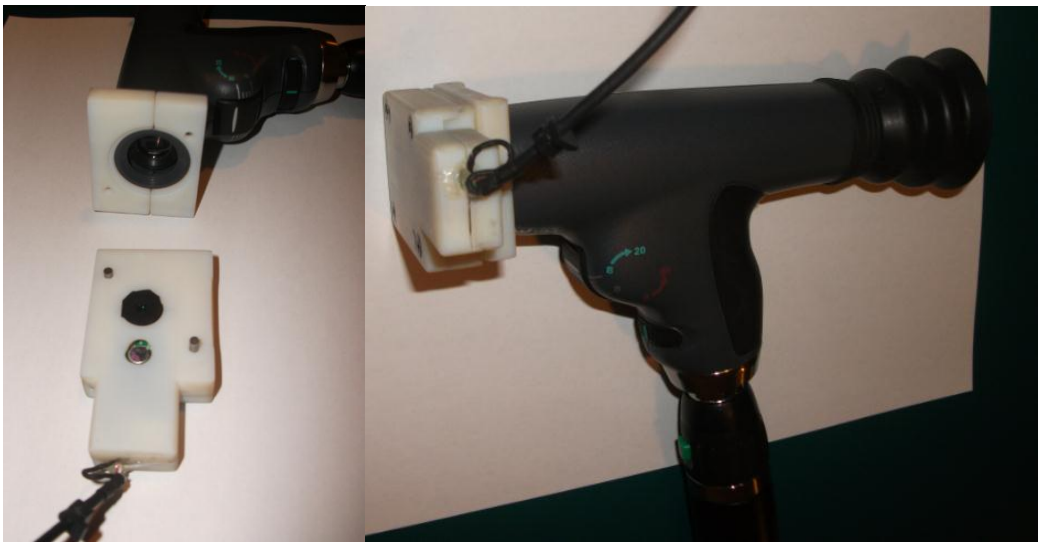


Figure 30 – Current status of prototype.

CHAPTER 5 PROTOTYPE CLINICAL RESULTS

After the 3D-printing, the physic prototype had to be tested clinically at Neurology Service of Coimbra Hospital University.

At the moment, the initial feedback has been positive since this technical solution has had a positive impact in clinical practice. In fact, the prototype has detected several pathological clinical cases, proving the scientific meaning of this project.

Thus, this chapter will address the clinical cases acquired and also the ideas for future work that arose during the project.

5.1 CLINICAL CASES DETECTED

Solely one month was enough to demonstrate the effective potential of the development of the referred idea. In fact, several retinal fundus were recorded, several patients being oriented afterwards. However in this thesis only three of these will be addressed.

The mentioned medical cases represent pathological conditions which are identified and documented with the respective image.

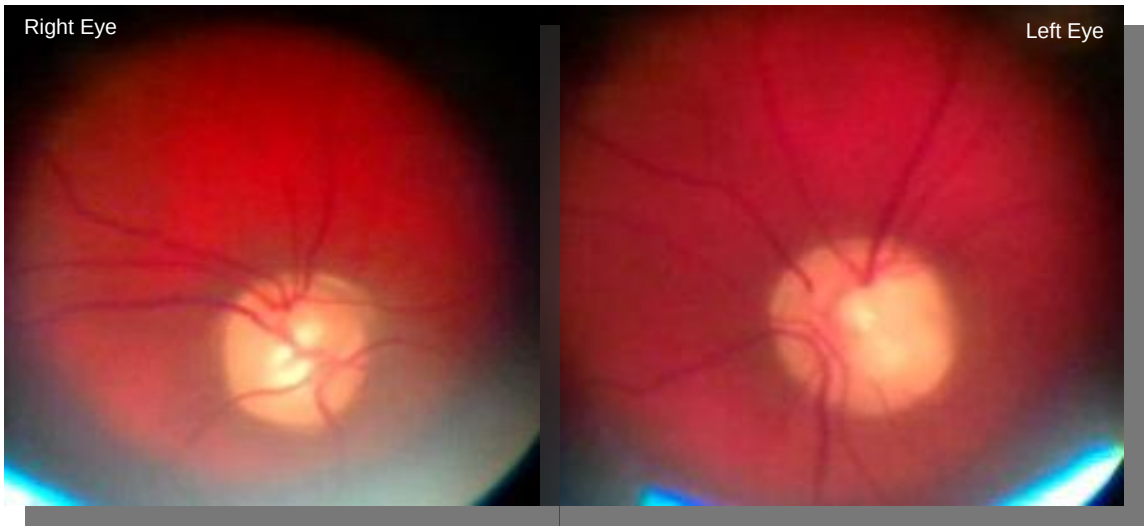


Figure 31- Right optic neuropathy. This patient has a history of surgery to low-grade glioma and was submitted to radiotherapy. Comparing these two images, the optic disc of right eye is whiter and ipsilateral arteriolar narrowing is more evident, representing a right post-radiotherapy optic neuropathy.

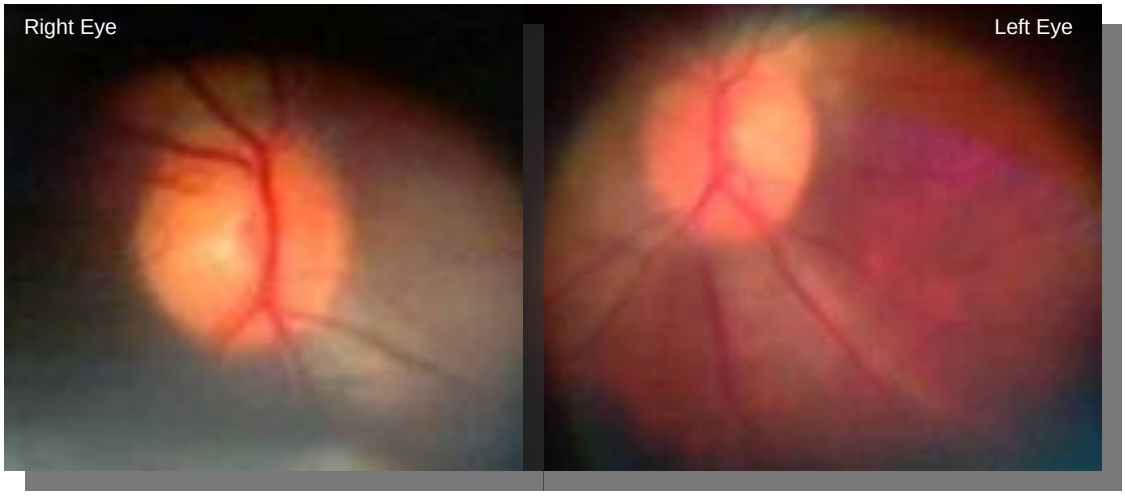


Figure 32 - Left posterior optic neuritis, steroid-dependent. Both eyes reveal a normal fundus, which corroborates the retrobulbar inflammatory component on the left eye.

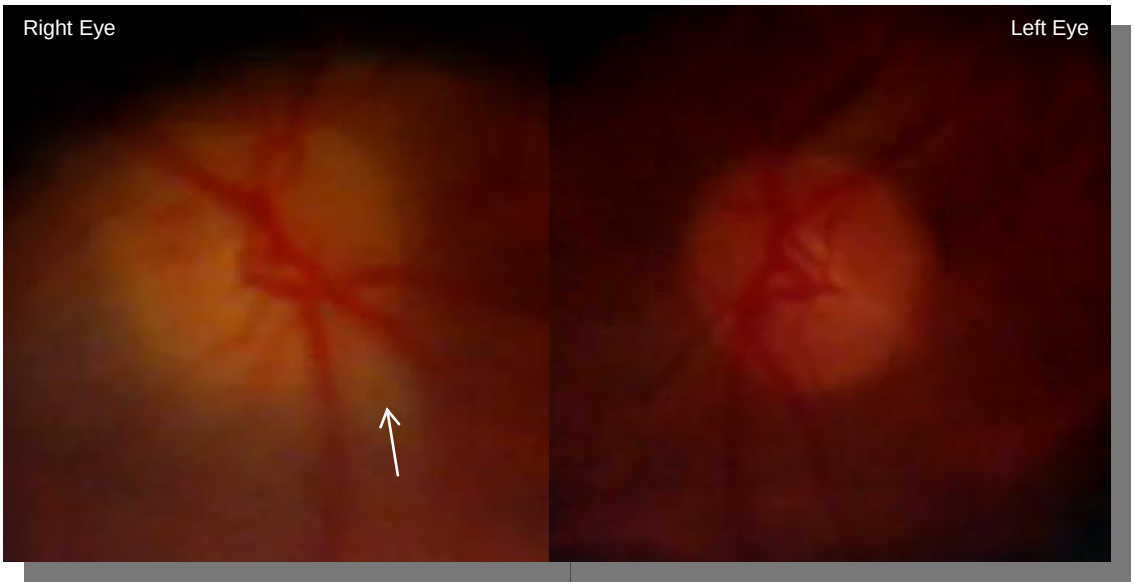


Figure 33- Anterior ischemic optic neuropathy. The white arrow, in the right eye image, points to the pale edema. The left eye presents a normal optic disc.

As a video format, it was also recorded a clinical case of torsional pendular nystagmus, in a case of subtle oculopalatal tremor and progressive ataxia, the video in this case being truly important, since it has captured a clinical sign (pendular nystagmus) sign, that would be otherwise very difficult to notice by naked eye only.

5.2 NEW IDEAS AND FUTURE WORK

Among several ideas, one is to improve the image quality. This possibility may be pursued by chosing a better image sensor. Consequently, a new prototype should be constructed according to the sensor’s measurements.

The images and videos recorded have been saved with the purpose of being shared afterwards. Thus, it has been developed a layer of software in order to integrate these information into the existent data base at Ophthalmology Service named *OphthalSuite*. In additon, there is a proposal which consists in creating a friendly-user software, that will allow for quick image acquisition of both eyes ocular fundi, overllapping images side by side

Other idea would be standardized this procedure among medical community that uses direct ophthalmoscopy in a daily basis, since the physicians have seen its potential with only one user; several users will even justify more the use of this technique.

CHAPTER 6 CONCLUSION

This project is an example of what biomedical engineering can achieve. As a matter of fact, the application of this potential technical solution in the health area was verified with success.

Although the initial idea – image acquisition while the physician is examining the eye – was not attained due to the expected high dimensions of the prototype and its difficult usability, the main goal was achieved. Even with the several problems during the experimentation phase, the constructed prototype allows to record video and image in a Panoptic™ ophthalmoscope.

During the first month of the prototype clinical tests, the digital ophthalmoscope has had a great acceptation, since it allows to document in an objective way the ocular fundus, which previously was only observed and textually described. Therefore, a solid idea would be to further divulgate this work in order to, eventually, commercialize this prototype.

Finally, this project has contributed to evidence that both ideas as well as needs should never cease to be communicated between physicians and engineers, because there must always exist enough motivation and initiative to improve and to construct better technology.

CHAPTER 7 REFERENCES

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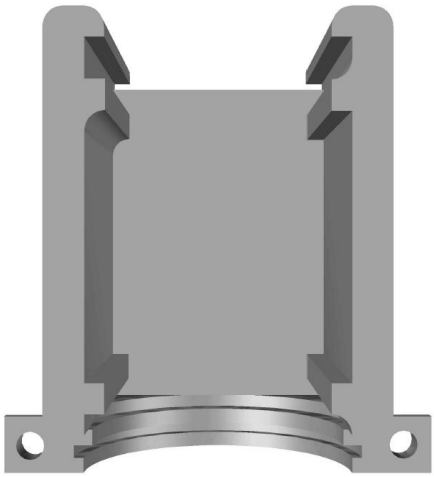
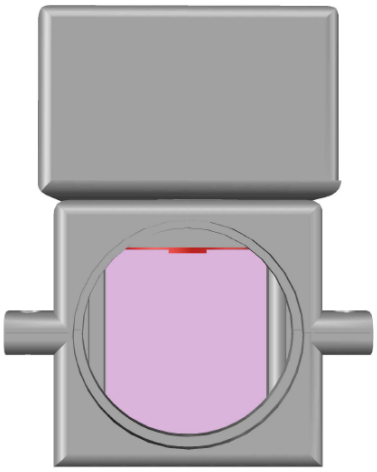
ATTACHMENT I: FIRST 3D-PROTOTYPE

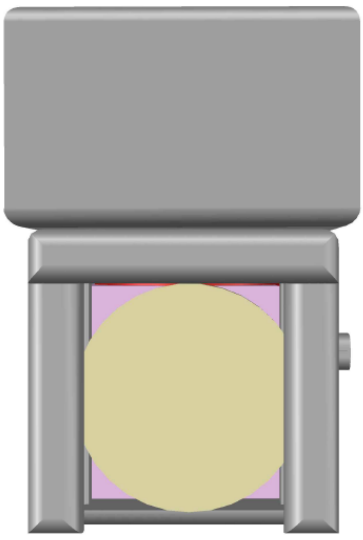
Superior View



Frontal View

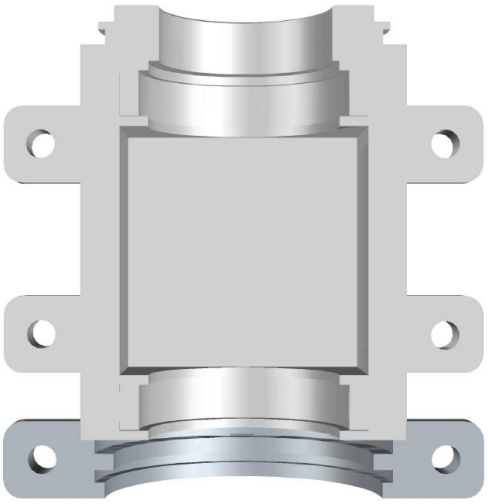


Posterior View

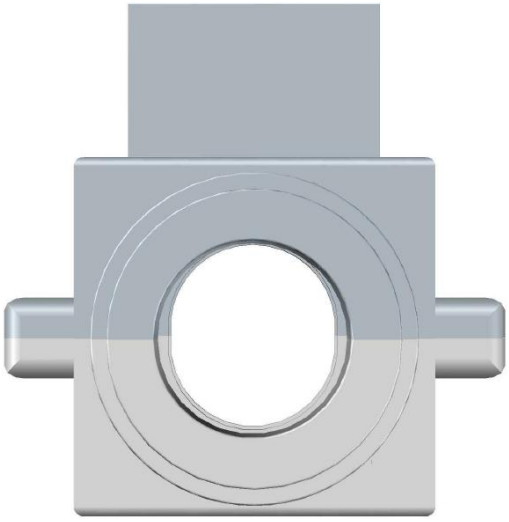


ATTACHMENT II: SECOND 3D- PROTOTYPE

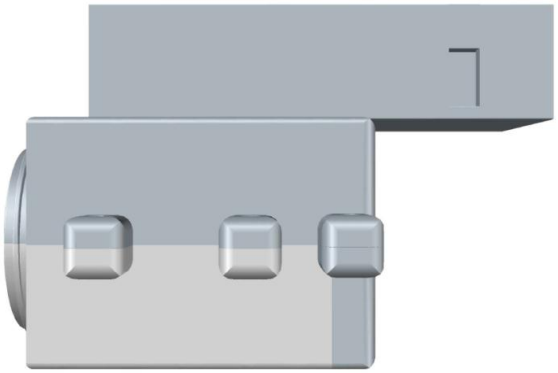
Superior View



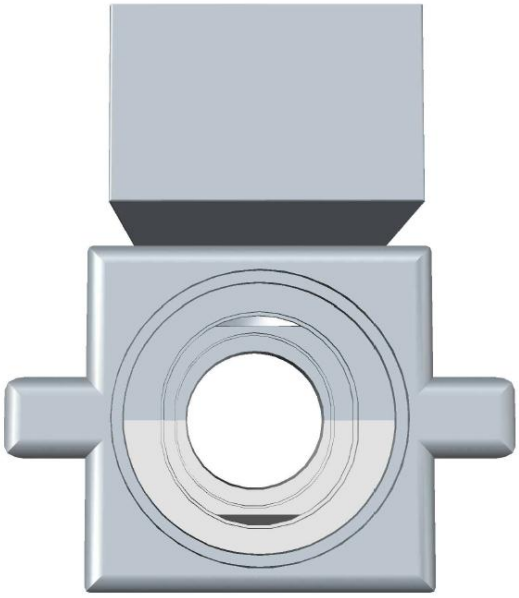
Frontal View



Lateral View

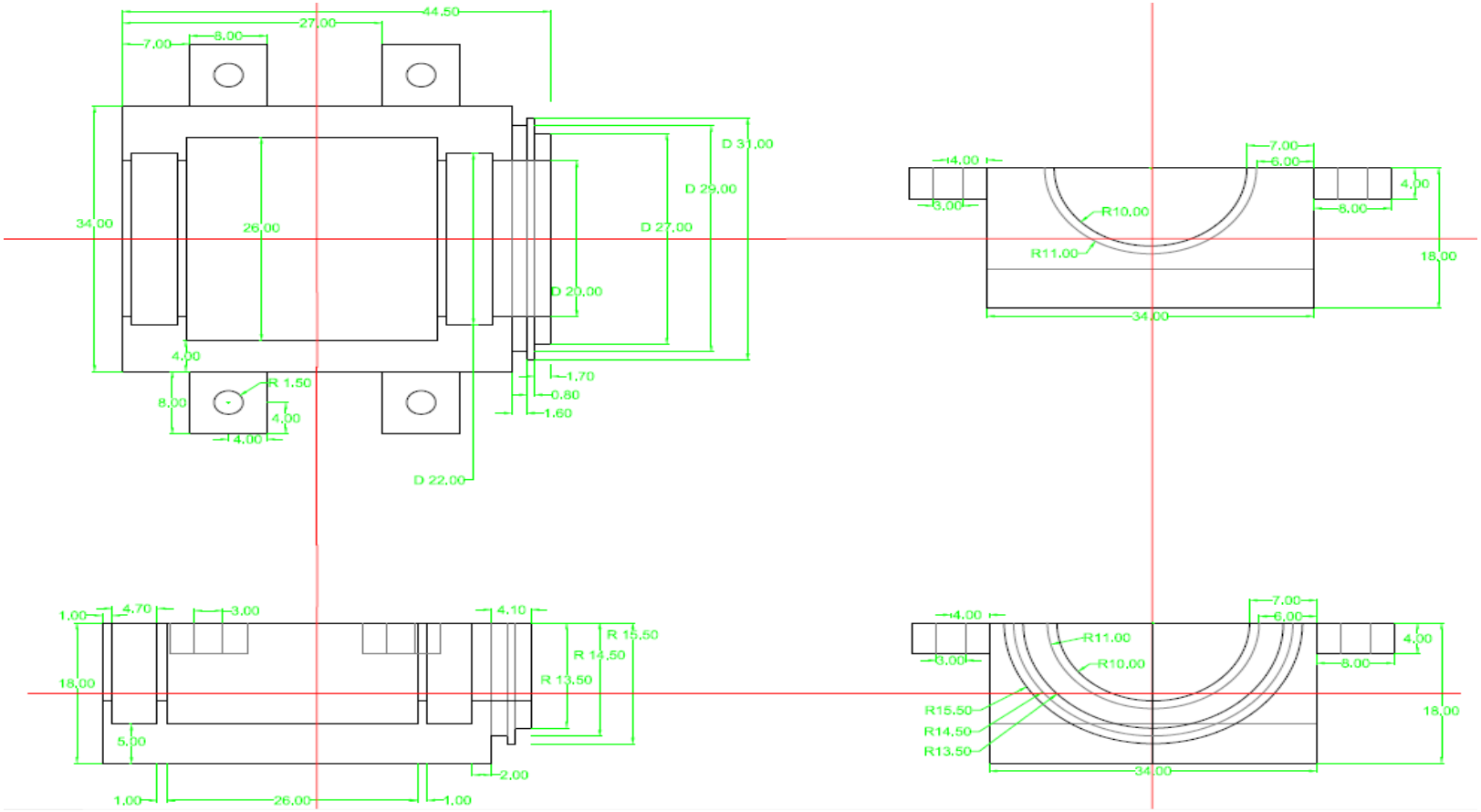


Posterior View

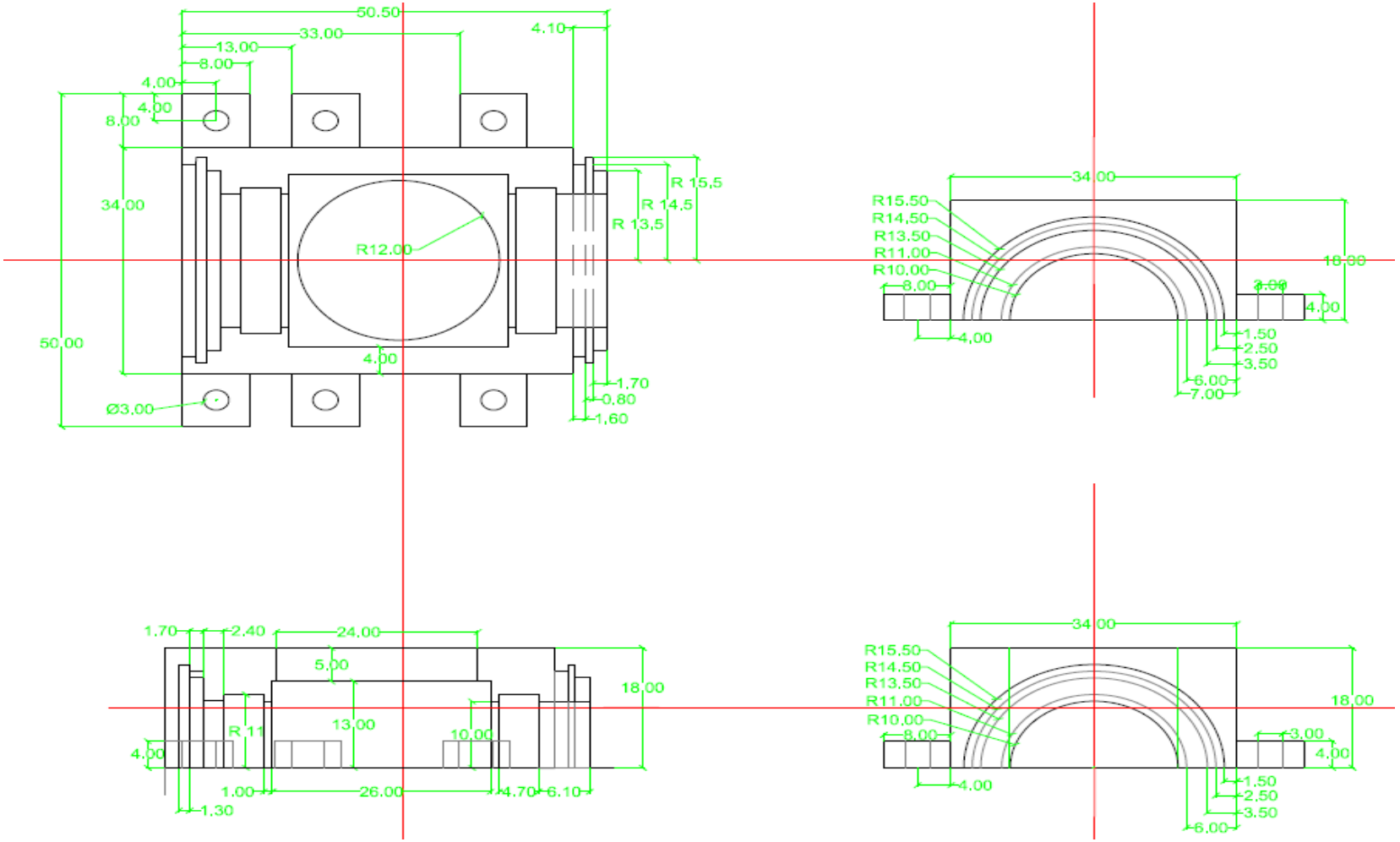


ATTACHMENT III: SECOND 2D-PROTOTYPE

Optical system suport



Covering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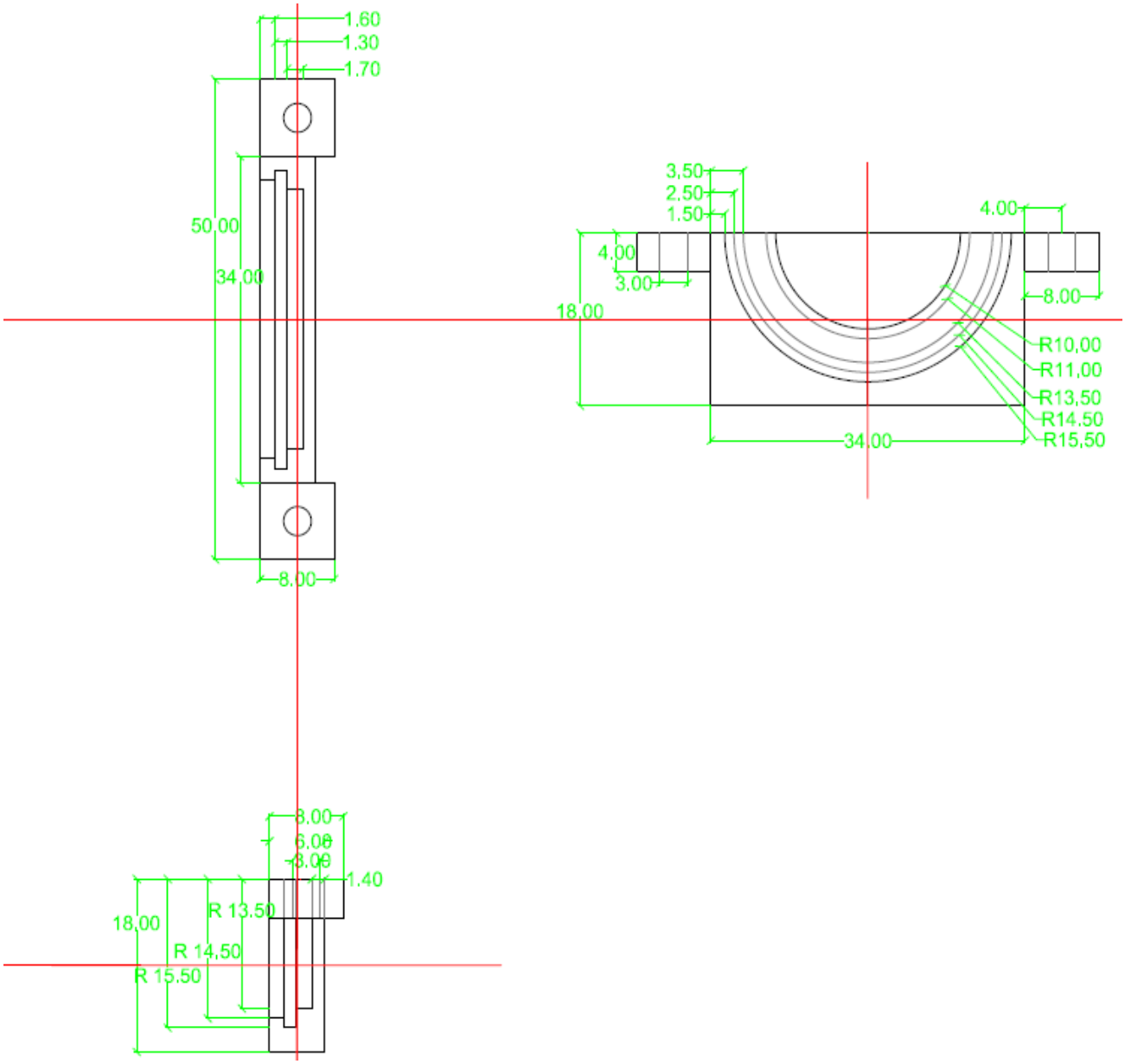
33.00
13.00
8.00
4.00
4.00
8.00
4.10
34.00
R12.00
R 15,5
R 14,5
R 13,5
50.00
4.00
Ø3.00
1,70
0,80
1,60
34.00
R15.50
R14,50
R13.50
R11.00
R10.00
8.00
4.00
18.00
4.00
1.50
2.50
3.50
6.00
7.00
1.70
2.40
24.00
5.00
18.00
R 11
13.00
10.00
4.00
1.00
26.00
4.70
6.10
1.30
34.00
R15.50
R14.50
R13.50
R11.00
R10.00
8.00
4.00
18.00
3.00
4.00
1.50
2.50
3.50
6.00

Fitting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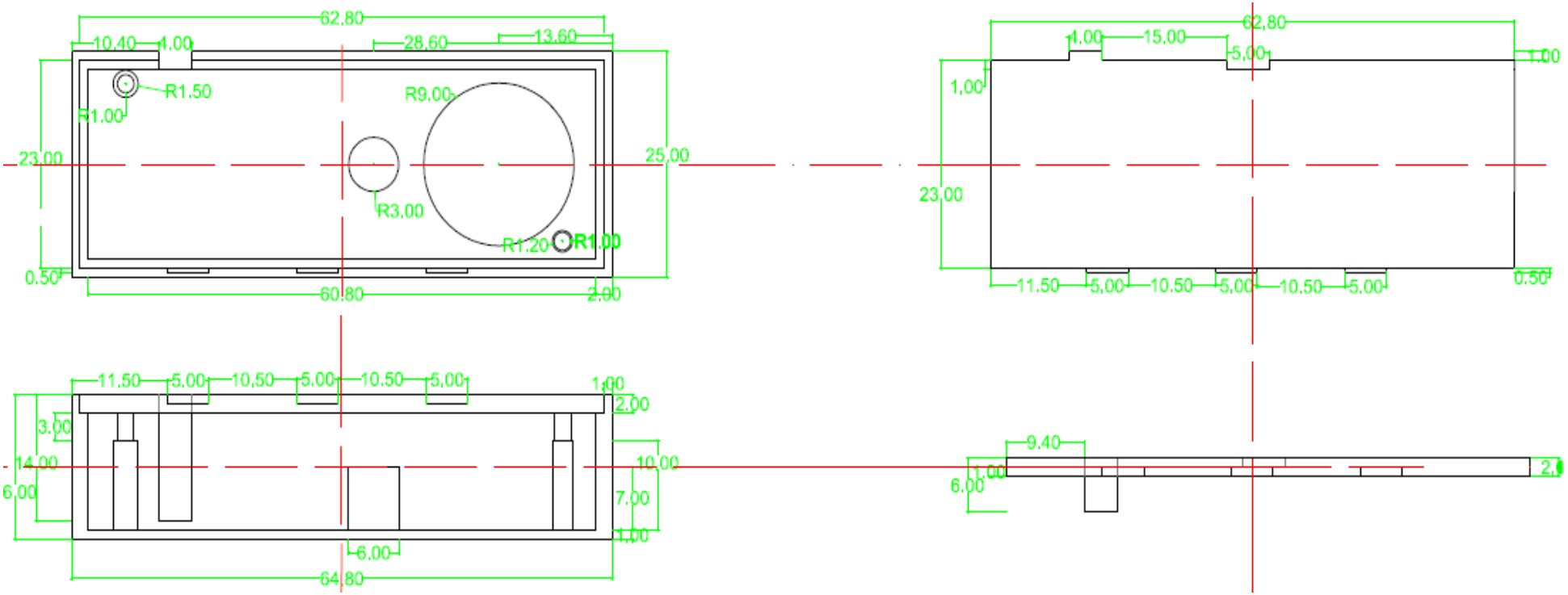
1.30
1.70
50.00
34.00
8.00
3,50
2.50
1.50
4.00
4.00
3.00
18.00
8.00
R10,00
R11,00
R13,50
R14.50
R15,50
34.00
8.00
6.00
3.00
1.40
18,00
R 13.50
R 14,50
R 15.50

Camera’s box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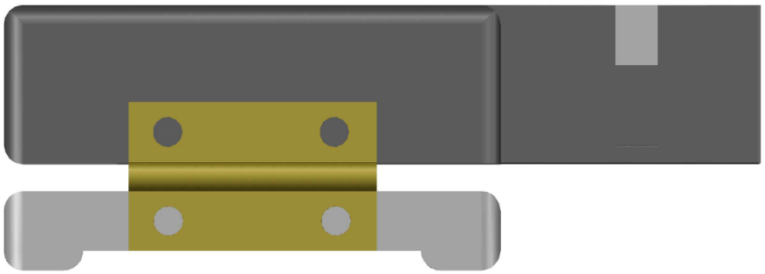
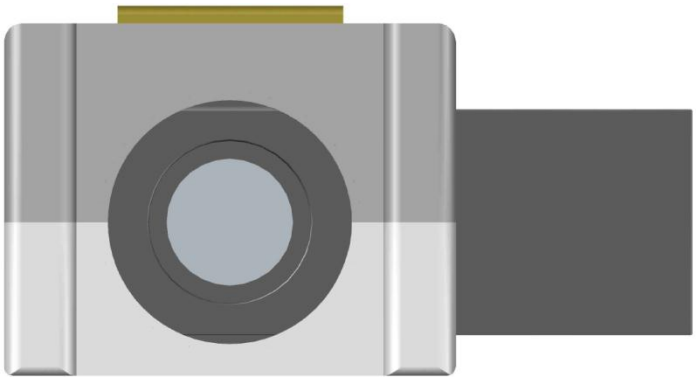
10.40
4.00
28.60
13.60
R1.50
R1.00
R9.00
23.00
25.00
R3.00
R1.20
R1.00
0.50
60.80
2.00
62.80
1.00
15.00
5.00
1.00
1.00
23.00
11.50
5.00
10.50
5.00
10.50
5.00
0.50
11.50
5.00
10.50
5.00
10.50
5.00
1.00
2.00
3.00
14.00
6.00
10.00
7.00
1.00
6.00
64.80
9.40
1.00
6.00
2.0

ATTACHMENT IV: THIRD 3D-PROTOTYPE

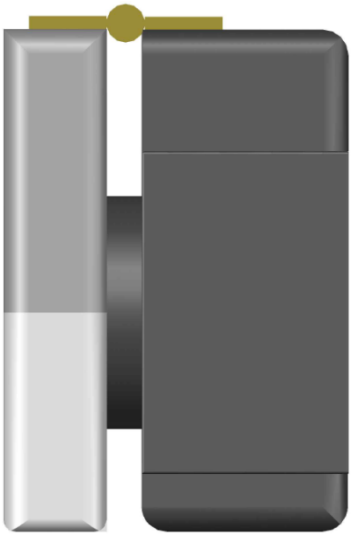
Superior View



Frontal View

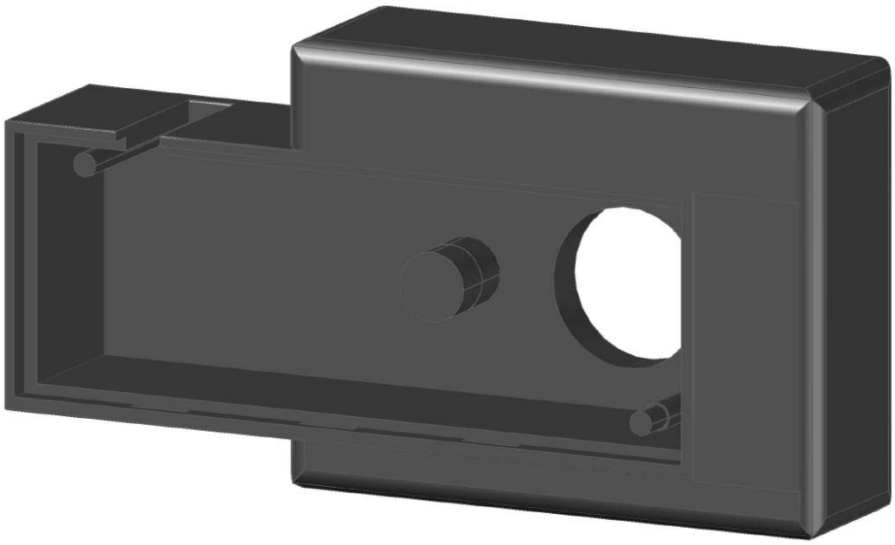


Lateral View



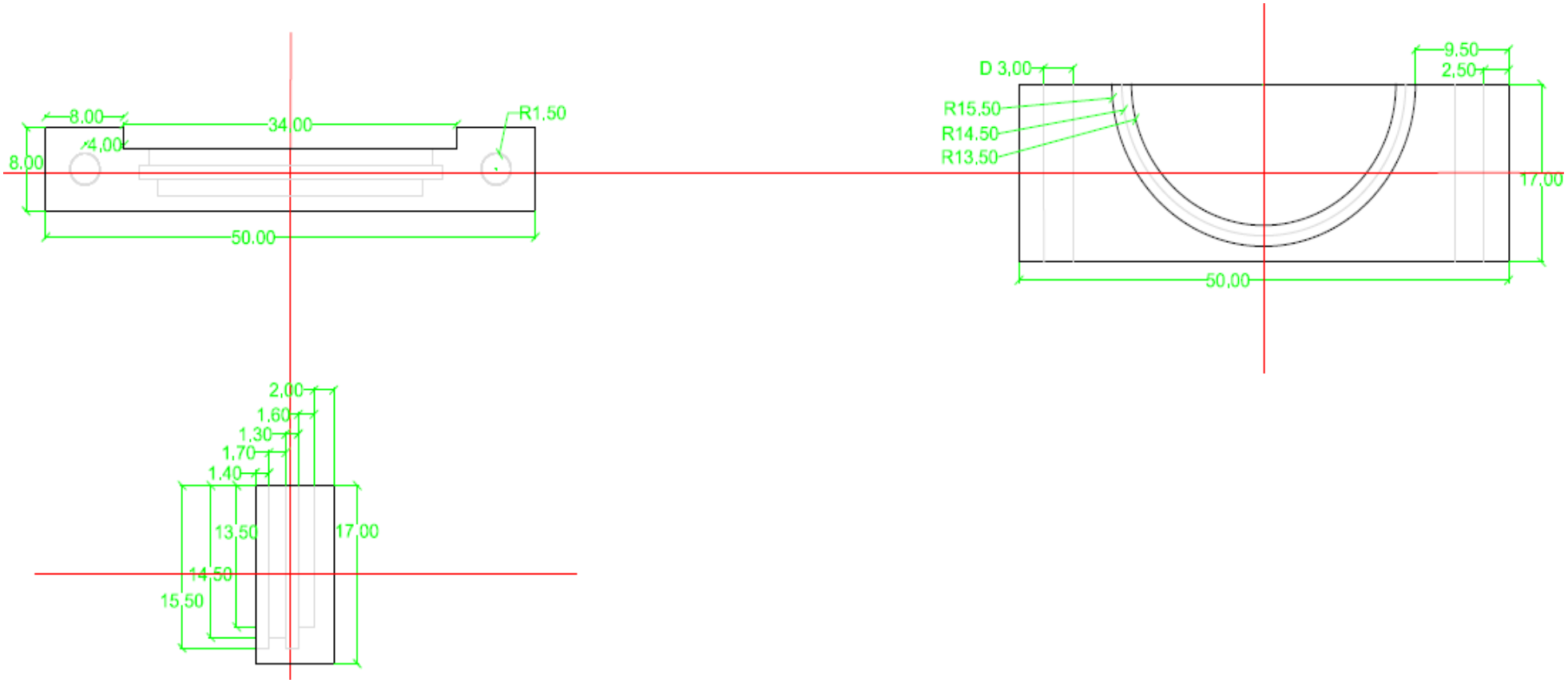
Posterior View - I

Posterior View – II

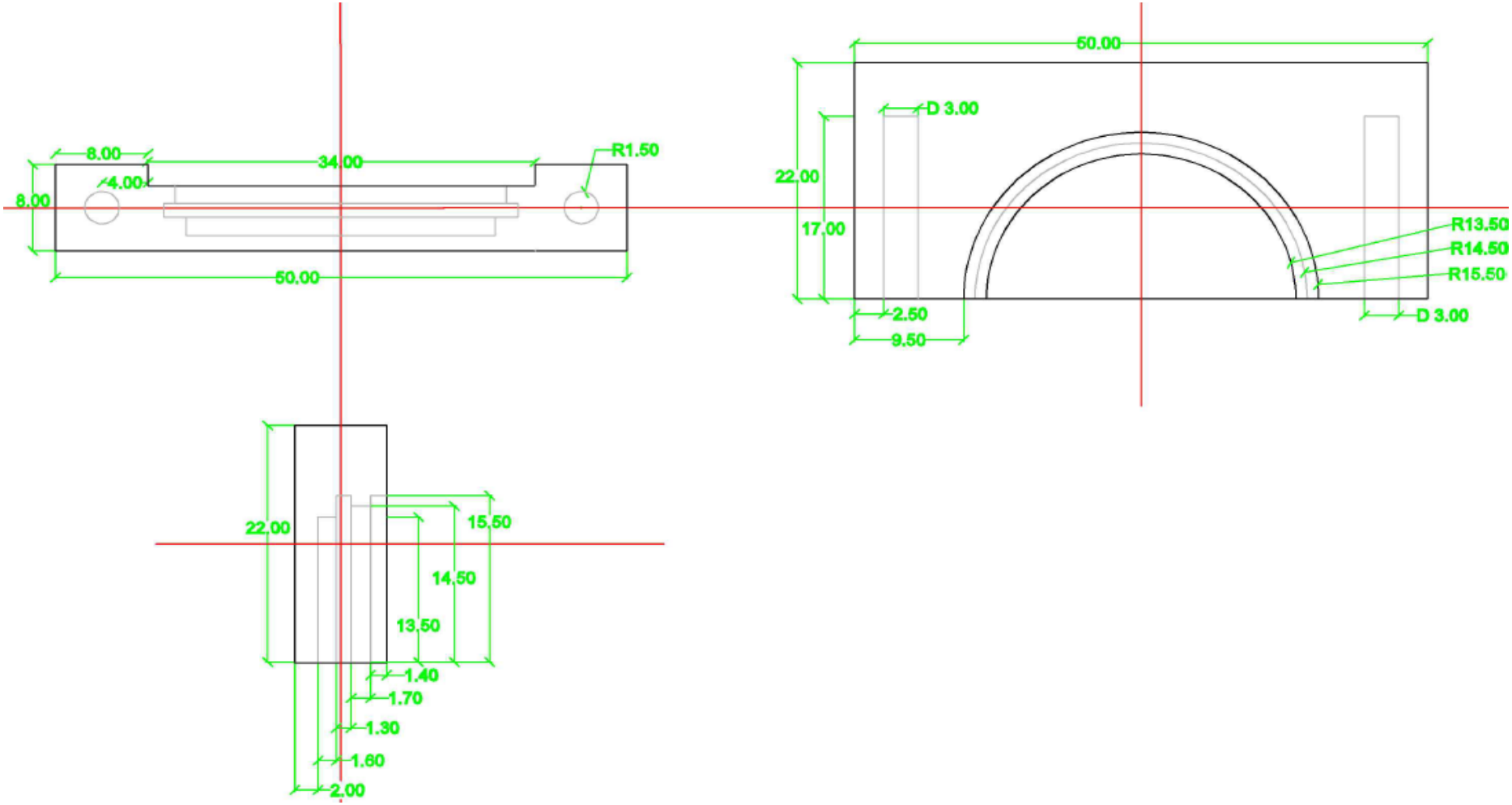


ATTACHMENT V: THIRD 2D-PROTOTYPE

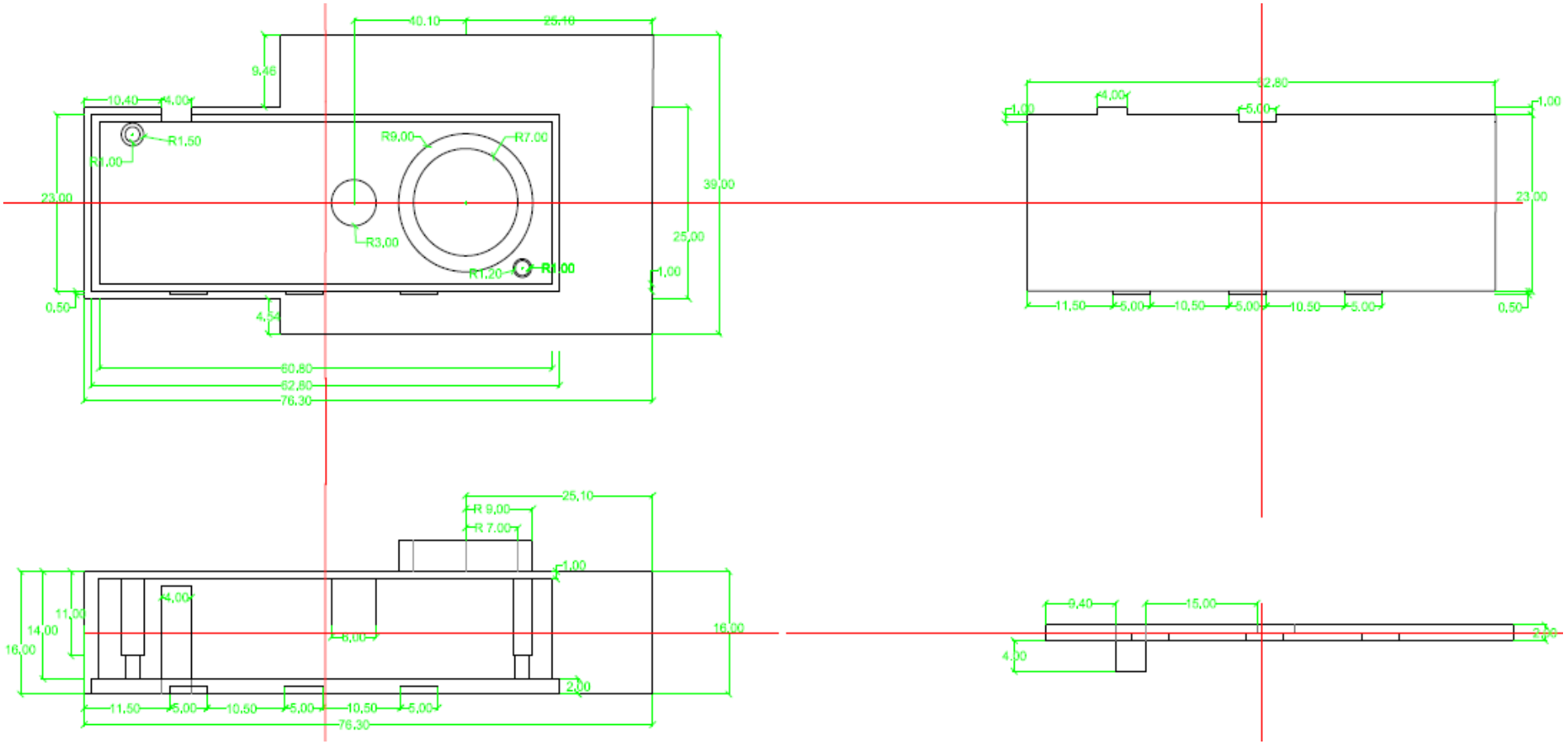
Inferior fitting



Superior fitting



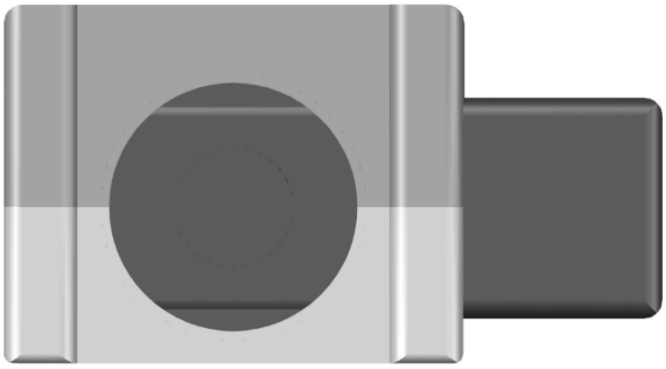
Camera box


10,10
25,18
9,46
10,40
4,00
R1,50
R1,00
R9,00
R7,00
23,00
39,00
25,00
R3,00
R1,20
1,00
0,50
4,54
60,80
62,80
76,30
12,80
4,00
1,00
5,00
1,00
23,00
11,50
5,00
10,50
5,00
10,50
5,00
0,50
25,10
R 9,00
R 7,00
1,00
4,00
11,00
14,00
16,00
6,00
16,00
2,00
11,50
5,00
10,50
5,00
10,50
5,00
76,30
9,40
15,00
2,00
4,00

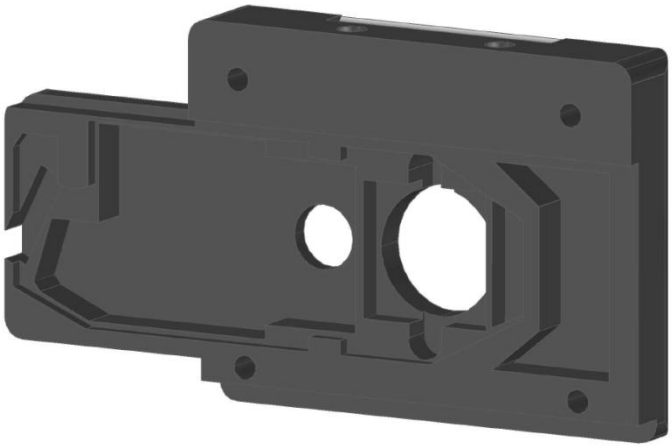
ATTACHMENT VI: 3D-PROTOTYPE TO 3D-PRINTING

Superior View

Frontal View

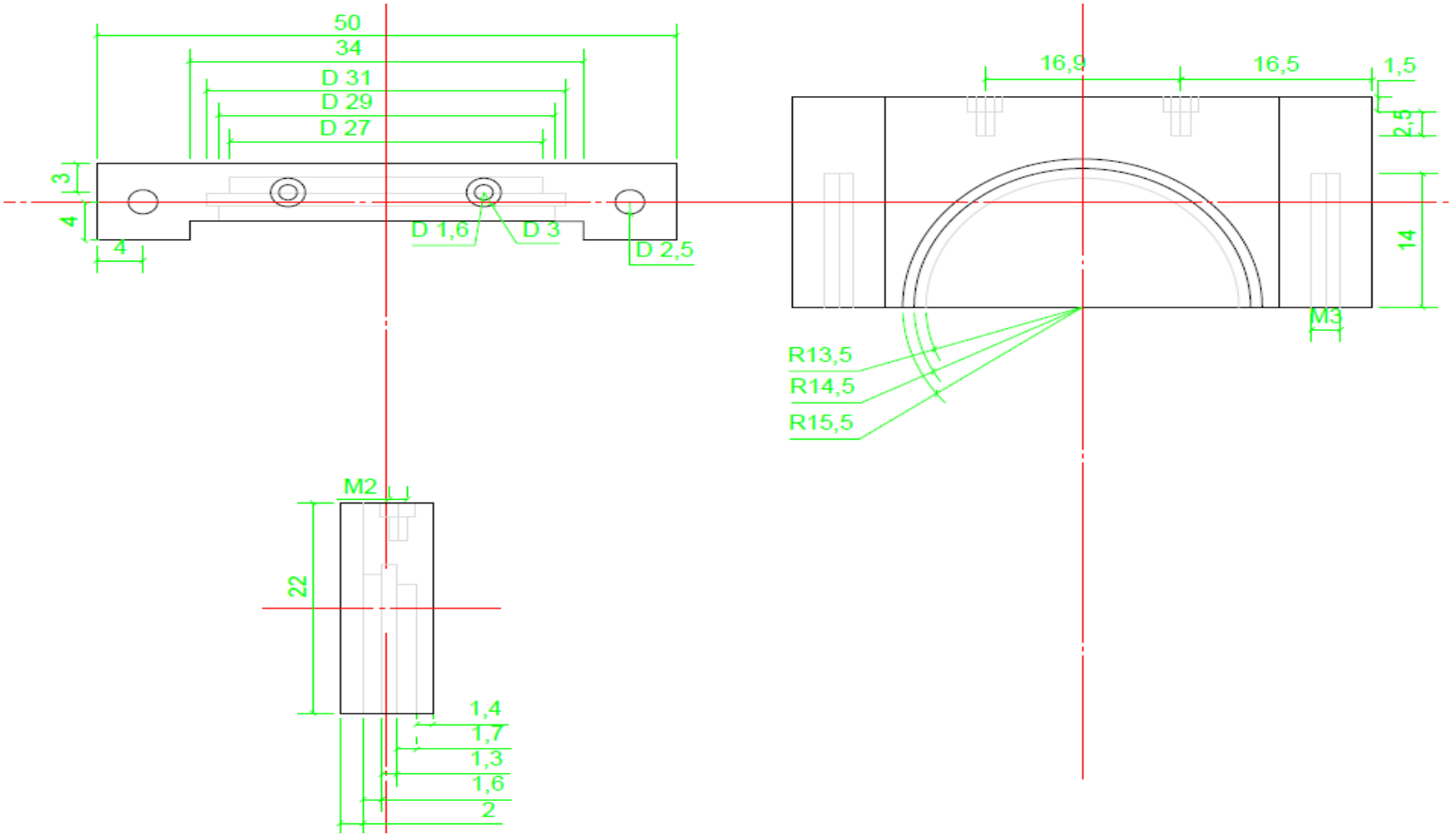


Posterior View

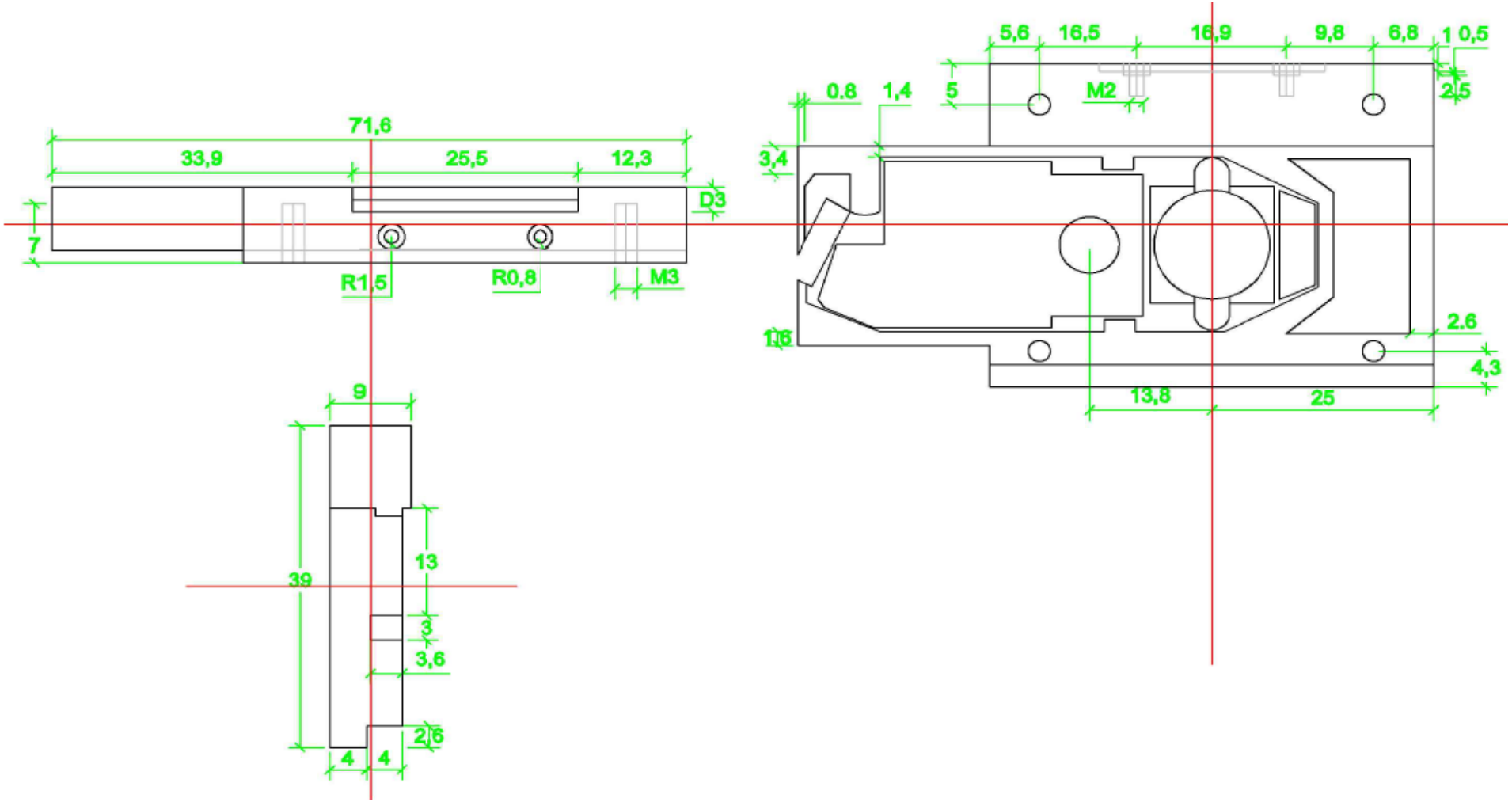


ATTACHMENT VII: 2D- PROTOTYPE TO 3D-PRINTING

Superior fitting



Camera’s box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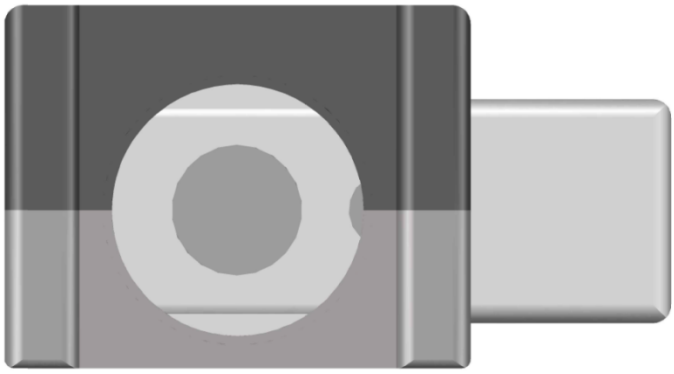
33,9
25,5
12,3
D3
7
R1,5
R0,8
M3
9
39
13
3
3,6
2,6
4
4
5,6
16,5
16,9
9,8
6,8
1
0,5
2,5
0.8
1,4
5
M2
3,4
1,6
2.6
4,3
13,8
25

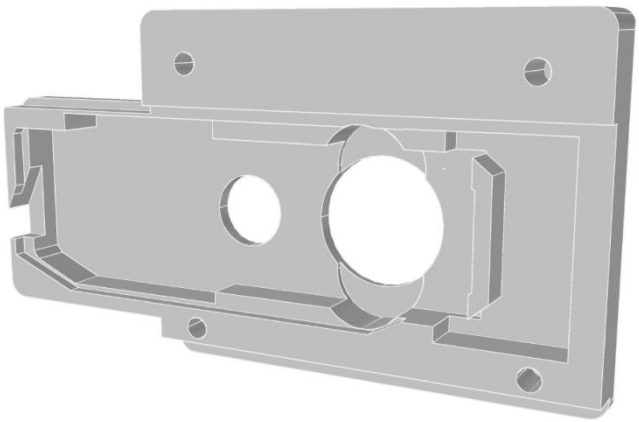
ATTACHMENT VIII: THIRD 3D-PROTOTYPE MODIFIED

Superior View

Frontal View

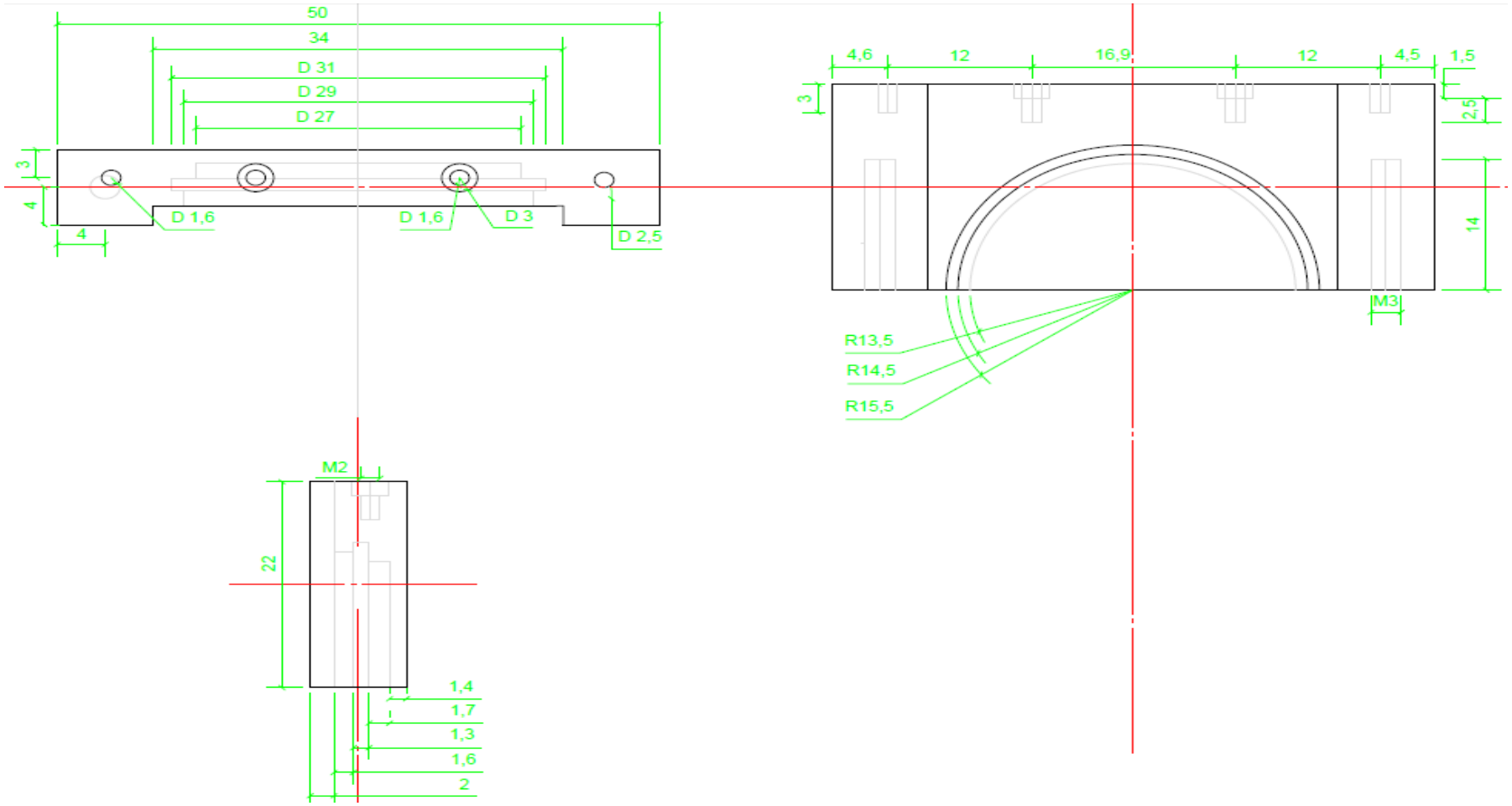


Posterior View

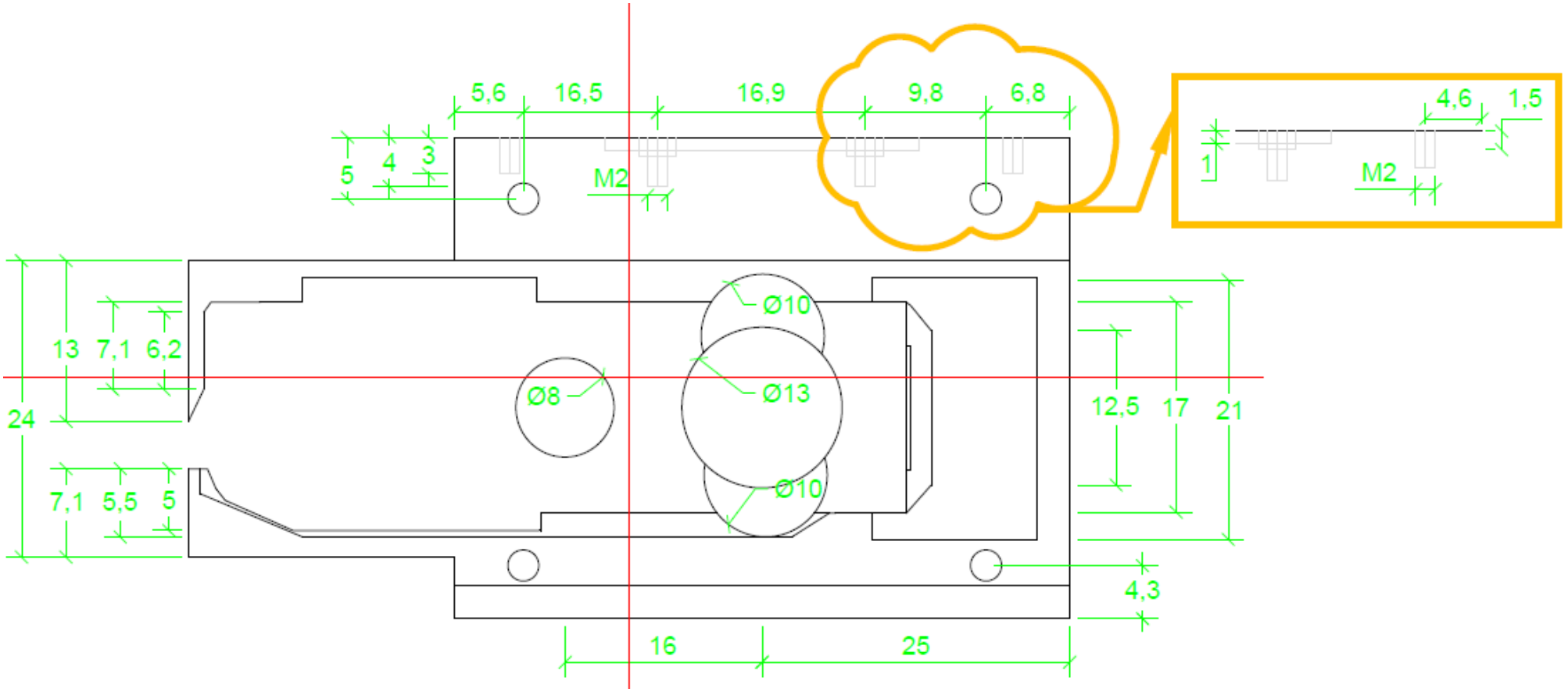


ACHMENT XIX: THIRD 2D-PROTOTYE MODIFIED

Superior fitting



Camera’s box


5,6
16,5
16,9
9,8
6,8
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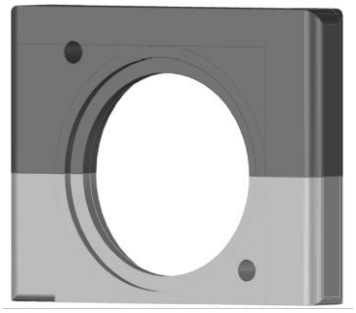
4
3
M2
4,6
1,5
1
M2
Ø10
Ø8
Ø13
Ø10
13
7,1
6,2
24
7,1
5,5
5
12,5
17
21
4,3
16
25

ATTACHMENT XX: CURRENT STATUS OF PROTOTYPE

Fitting



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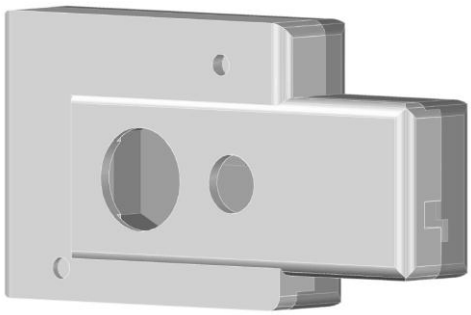
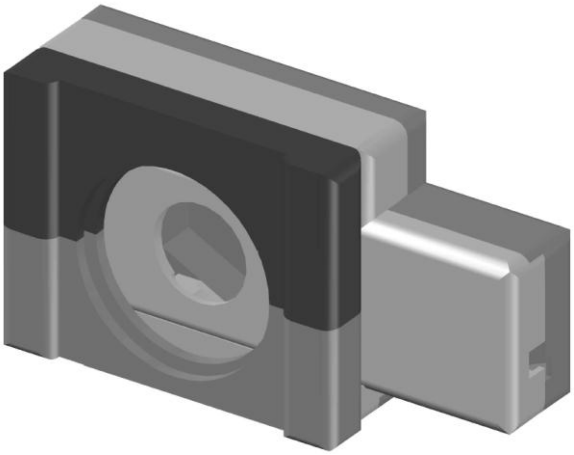


Superior View



ATTACHMENT XXI: Project Tasks.

ID	Task Name	Duration	Start	Finish
1	Kick-off Meeting	0 days	Mon 14-02-11	Mon 14-02-11
2	Research and contacts	5 days	Tue 15-02-11	Tue 22-02-11
3	Working on the 1st prototype in Draft-It	10 days	Tue 22-02-11	Mon 07-03-11
4	Working on the 1st prototype in AutoCad® 2011	12 days	Thu 10-03-11	Fri 25-03-11
5	Experimentation phase	48 days	Thu 10-03-11	Mon 16-05-11
6	Working on the 2nd prototype in AutoCad® 2011	19 days	Mon 28-03-11	Thu 21-04-11
7	Working on the 3th prototype in AutoCad® 2011	23 days	Fri 22-04-11	Tue 24-05-11
8	Working on the prototype to 3D-printing in AutoCad® 2011	21 days	Thu 26-05-11	Thu 23-06-11
9	Prototype 3D-printing at factory	3 days	Fri 24-06-11	Tue 28-06-11
10	Preparation of the prototype for clinical tests	3 days	Wed 29-06-11	Fri 01-07-11
11	Prototype went to Coimbra University Hospital	0 days	Tue 05-07-11	Tue 05-07-11
12	Working on the prototype modified in AutoCad® 2011	7 days	Tue 05-07-11	Wed 13-07-11
13	Prototype Clinical Tests and Writing the thesis	36 days	Thu 14-07-11	Thu 01-09-11

ATTACHMENT XXI: Gantt Diagram.