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1 Introduction

1.1 Document owner

<table>
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<tr>
<th>Job Title</th>
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<td>Principal Vision Scientist</td>
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1.2 Referenced documents

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1.3 Scope

This manual applies to all MF01 MRIFocus kits.

1.4 Purpose

This document describes how to fit the MRIFocus lens holder and lenses, how to clean these parts and use them appropriately.

2 Description and intended use

The MF01 MRIFocus kit consists of MR safe prescription lenses and mounts suitable for use with Siemens 20, 32 and 64 channel MRI head coils. The individually inscribed left and right push-fit ophthalmic lenses have been designed to substitute the wearer's usual prescription glasses only for the duration of the MRI scan. Please note the frame and lenses are designed for use with average adult heads and inter-pupillary distances so may not be suitable for some wearers. The lenses have a spherical correction only, so will not be suitable for wearers with significant astigmatism. If you intend to scan an individual participant many times, or scan a population with a specific ophthalmic condition, custom fit lenses can be provided that are tailored to their ophthalmic prescription. Contact us for further information.

Also note that due to mechanical constraints, when the lenses are mounted onto the lens holder the distance between the lenses and the eyes is greater than the distance obtained when wearing prescription glasses. This means that to obtain the same level of ophthalmic correction provided by the prescription glasses, the MRIFocus lenses often need to have a greater ophthalmic correction. To minimise the discrepancy, try to position the wearer's head closer to the lens holder when setting up the head in the head coil.

The MF01 MRIFocus kit includes two lens holders: one suitable for Siemens 32 channel MRI head coil (Figure 1) and the other suitable for Siemens 20 and 64 channel MRI head coils (Figure 2).
Figure 1. Lens holder for Siemens 32 channel MRI head coil.

Figure 2. Lens holder for Siemens 20 and 64 channel MRI head coils.
The kit also includes a vision test chart, lens cleaning liquid and microfibre cleaning cloth, all packaged in a compact case to facilitate storage and handling (Figure 3). No previous optical knowledge is necessary for clear, quick, and safe vision correction.

Figure 3. MF01 MRIFocus kit.

3 Parts list

The MF01 MRIFocus kit consists of:

1. One or two lens holders
2. User manual (this document).
3. Set of interchangeable ophthalmic lenses
4. Pocket Snellen acuity chart
5. Lens cleaning kit
6. Storage case

The lens set offers a wide range of optical powers. The lenses are inscribed with the lens power. Negative powered lenses correct myopia. Positive powered lenses correct presbyopia.
The lens set includes twenty-six pairs of -6 to +6 dioptre lenses in 0.5 dioptre increments (+6.0, +5.5, +5.0, +4.5, +4.0, +3.5, +3.0, +2.5, +2.0, +1.5, +1.0, 0.5, 0.0 planar, opaque/blackout, -0.5, -1.0, -1.5, -2.0, -2.5, -3.0, -3.5, -4.0, -4.5, -5.0, -5.5, -6.0).

4 How to fit the lens holder and lenses

Where possible in advance, inform the patient/volunteer they will need to bring their ophthalmic prescription to the MRI preparation area. This can be used to guide which lenses to use. Otherwise, use the pocket Snellen acuity chart to assess their vision monocularly: select the lens for each eye which allows them to comfortably read the 20/20 (6/6) row at a distance of 6 feet (1.82 meters).

1. To fit the lens holder, clip on to the head coil mirror mount rail.
2. To fit the lenses, place the lenses into the lens holder (Figure 4).

![Figure 4. Lens fitted into the lens holder.](image)

Instruct the patient/volunteer that if they notice that they cannot see clearly, or experience vision disturbance like double vision, or start to get a headache, they should notify the MRI scanner operator immediately. In these cases, check if the ophthalmic lens correction is appropriate for the wearer. Discontinue use until the problem is resolved.
5 Product hygiene

- Product is wipeable
- Between uses, disinfectant wipe clean, then allow to dry
- Only use the provided lens cleaning kit for cleaning lenses. When necessary, replenish with spectacle lens cleaner and a clean, lint-free cloth

6 Product warnings

MF01 MRIFocus should only be used under supervision of a healthcare professional in an MRI environment.

- Do not use MF01 MRIFocus for a purpose for which it is not intended
- Do not attempt to sterilise any part of this equipment
- Do not expose to heat, ionising radiation, chemicals, or harmful energies
- MF01 MRIFocus lens do not protect the eye from any electromagnetic radiation sources
- Discontinue use if the wearer reports headaches or disturbed vision
- Do not use if any part of system is broken or damaged
- Not suitable for prolonged use. Intended for short-term use only during the MRI scan
- Not to be used as a permanent substitute for individually prescribed glasses

7 Cleaning

⚠️

Clean lens holder between uses. Do not sterilise in an autoclave.

8 Servicing

⚠️

If any of the parts become worn or damaged, stop use and contact to Cambridge Research Systems to discuss service options.

9 Life support applications

MF01 MRIFocus should NOT be used in situations where failure of the device would constitute a hazard.
10 Revision history

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