

Manual

Solo (*Easy-light*)

Manual as of 2012
Update: January 2016
Subject to modifications and amendments!

Block Optic Ltd.
Semerteichstr. 60 Phone: +49(0) 231 / 10 87 78 50
D- 44141 Dortmund Fax: +49(0) 231 / 17 63 065 email: info@block-optic.com

Index

1 Device Specifications.....	3
2 Important information for assembly, use, maintenance and repair.....	6
2.1 Required space and connection requirements.....	6
3 Packaging.....	7
4 Scope of supply.....	8
4.1 System components of the basic equipment.....	8
4.2 Accessories (Optional).....	8
5 Appliance description	10
5.1 Basic concept.....	10
5.2 Phoropter rail with Phoropter arm (optional).....	10
5.3 Storage of small instruments.....	11
6 Safety precautions.....	12
7 Maintenance, cleaning, care and disposal.....	13
8 Technical Data.....	15
9 E.G.-Declaration of Conformity.....	16

Thank you very much for your confidence which you expressed by purchasing this examination unit. With our *Solo* you have chosen a modern fully developed product which has been produced and tested according to strict quality criteria. Continuous research and development might lead to changes in version and scope of supply. The figures in this instruction manual might therefore be slightly different in some cases. The right-hand version is displayed. The setting is mirrored accordingly in the left-hand setting. If you have any questions or need further information regarding the unit, please don't hesitate to call us or send a fax. Our service team will be glad to help you.

1 Device Specifications

Device Type: Solo Examination Unit

Manufacturer: Block Optic Ltd.
Semerteichstr. 60
44141 Dortmund
Germany

Intended

Applications : Solo is a universal examination unit for integration of ophthalmologic and optical devices. Depending of its use the devices can be positioned in front of the test subject. The examination unit Solo is used for optometry and ophthalmology.

Unintended

Applications: Other applications as those described above are prohibited. Unpredictable hazard can come up during unintended use. The motor (optional) is not intended for permanent up and down movements with the vertical adjustment. After continuous operation of 1.5 minutes it must be cooled down for at least 8.5 minutes. A continuous operation of the vertical adjustment for more than 1.5 minutes can lead to a defect of the vertical adjustment. During routine operation the required cooling period is achieved automatically.

Scope of supply: Solo can be delivered with various equipment. The actual scope of supply is listed in detail in the delivery note.

Safety Remarks :

- a) Please read the instruction manual carefully and make yourself acquainted with all functions before you start to operate the device.
- b) Don't change anything at the unit by yourself as this might impact the safety and leads to the expiry of the warranty.
- c) This unit is not intended for use in areas with risk of explosions.
- d) Do not operate the unit if you observe visible damages. Breakdowns which have impact on the safety need to be repaired immediately. In this case, please contact an authorized service technician at Block Optic
- e) Only use original accessory parts for the Solo.

f) Accessories which will be connected with the electric supply of the examination unit need to be proven to comply with the appropriate DIN EN or IEC specifications. Furthermore all configurations have to comply with the requirements of the system standard DIN EN 60601-1-1 (IEC 601-1-1) and its modifications. Coupling of non-medical devices (e.g. data processing devices) to a medical electronically system such as the examination unit must not lead to a safety degree for patient, user, and the environment which is beyond DIN EN 60601-1-1 (IEC 601-1-1) and its modifications. If the admissible leakage current is exceeded by the coupling, protective measures according to the system standard DIN EN 60601-1-1 (IEC 601-1-1) and its modifications need to be provided. After installation or later modifications the system must not put any risk to the patient, the user or the environment.

**Liability of
Manufacturer :**

The device has been manufactured according to the latest technical development and acknowledged technical safety directives. Block Optic considers itself responsible for any impact on safety, reliability and performance of the device only if:

- Mounting, extensions, readjustments, modifications or repairs are carried out by authorized persons,
- the electric installation of the concerned room complies with the requirements of VDE 0100-710 and
- the device is used according to the instruction manual.

**Responsibility of
User:**

The user is responsible for:

- Compliance with standards for prevention of accidents and the directives for establishment, operation and application of medical devices (Medical Device Operating Directive)
- Operation,
- Maintenance,
- Duly and safe condition of the product and
- Storage of the instruction manual and the technical appendix at the usage site.

Warranty : The General Terms and Conditions of Block Optic are effective as the basic principle.

Text Accentuation: Important parts of the text in the instruction manual are marked by accentuations and key words. The following accentuations are used in the actual instruction manual:

Caution!

Indicates a potentially hazardous situation. Please note such precaution measures to prevent any damage from patients or objects.

Important!

Indicates important information. Please read this information to maintain the high safety and function level of the device.

Special note!

Indicates information for proper usage. Please read this information to avoid any misuse.

2 Important information for assembly, use, maintenance and repair

The examination unit *Solo* should only be setted up and mounted by the company Block Optic Ltd. or by authorized technicians of Block Optic!

Repair and maintenance work may only be carried out by the company Block Optic Ltd. or by trained service technicians. Repair work practicable by yourself is described in chapter 7: Maintenance, cleaning, care and disposal.

2.1 Required space and connection requirements

The examination unit *Solo* with an swivel table can be mounted directly on the wall together with its main base. The minimum amount of desk-top space required is 650 mm x 780 mm, the size of the swivel table is 1100 mm x 780 mm (see Illustration 8.1).

The column holding the chart projector ends 1965 mm \pm 10 mm above floor level. To install the instrument column the height of the room has to be at least 2050 mm, this must be considered mainly at rooms with slanted walls.

The examination unit with its wall-mounted terminal box unit shall be connected to the mains and the electrical installation in the surgery (e.g. room lighting, curtain control, etc.). The mains voltage must be 230 V, 50-60 Hz with a rating of at least 6.3 A (1500 VA).

3 Packaging

The *Solo* examination unit can if necessary be supplied packaged in a special transportation box:

Dimensions (L/W/H): variable, depending on extra equipment.

Weight: variable, depending on extra equipment,
approx. 85 kg without Swivel- table,
approx. 135 kg with Swivel- table.

When the packaging boxes are delivered, please check for external damage and observe the enclosed freight information!

Special note!

Please ensure that you remove all component parts belonging to the unit!

To set up the examination unit you only need the tools of a service technicians. No special tools are required.

4 Scope of supply

4.1 System components of the basic equipment

The *Solo* examination unit (right-hand or left-hand version) for holding phoropter rail and instrument column comprises:

- electrical equipment:
 - Transformer 230 V primary;
 - keyboard;
 - safety switch-off for upward movement of the electromotive patient chair;
 - *Easy-light* main module;
- Headrest bar for adapting various types of headrests;
- Installation accessories Block-box (hex driver, screwdriver, fuses, blocking device for the telescopic table during transportation, electrical plugs for the table-top and small instruments, manual).

4.2 Accessories (Optional)

Additional to the basic design the unit *Solo* can be provided with instruments and devices as well as electrical and electronic accessories, mechanical spare parts and wooden fittings.

Following instruments and devices are optional available:

1. Phoropter rail including support lugs, various versions;
2. Phoropter arm, various versions, including support;
3. Instrument column including adapter fitting;
4. Swivel-table;
5. Mounting of a trial lens drawer behind the chair;
6. Desk section of the various styles and sizes and
7. Container with 4 drawer for accessories.

Following electrical and electronic accessories are optional available:

1. Swan neck reading light, mounted on the phoropter arm;

2. The modern reading light „*Tolomeo Micro*“, mounted on the phoropter rail;
3. Undulated tray for a hand-held ophthalmologic unit with its own built-in on/off switch;
4. Undulated tray for a hand-held ophthalmologic unit with micro-switch, control over readout-potentiometer;
5. Twin charging unit, built into the unit, including support frame and dust cover;
6. Support for indirect/ head-worn Ophthalmoscope;

Following mechanical spare parts are optional available:

1. Headrest bar for adapting various types of headrests;
2. Cable tubing support for Slit Lamps ;
3. Adapter for the various reading lamps on the rectangular instrument column;
4. Various types of projector adapters;
5. Support for a proximity meter;
6. Support for the twin charging unit;
7. Tilting device for all block phoropter arms;
8. Various phoropter adapter versions, depending on the type of phoropter used.

5 Appliance description

5.1 Basic concept

The *Solo* examination unit is a refraction and examination unit. The modular design allows it to form a workplace which can be extended with various modules. With its minimal required space the examination unit can be used in small refraction rooms.

The phoropter is attached to the phoropter arm (various designs) and is either moved manually or is motor-driven in front of the patient by means of the phoropter rail. The stable projector column serves to support the optotype projector. If necessary, a reading lamp is attached directly onto the phoropter arm or onto the projector column.

Connection and storage facilities are available for various hand-held instruments. The hand-held instruments have their place in the built-in charging unit and in the undulated tray of the small instruments module.

The examination unit is available as a right-hand or a left-hand unit (definition of direction: from the practitioner's point of view to which direction the instrument table moves forwards, look at illustration 5.1), as well as in various colour combinations or surface coatings in veneer wood or plastic.

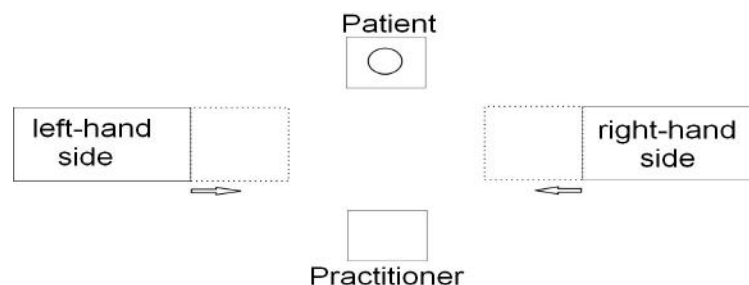


Illustration 5.1: Definition of direction

5.2 Phoropter rail with Phoropter arm (optional)

Various phoropter arms can be mounted on the phoropter rail of the *Solo* examination unit (either driven manually or by motor). The phoropter rail is fitted on a precision guide which makes it possible to move the phoropter arm with the attached phoropter in front of the patient without great effort. The phoropter arm moves through the manual operation of the release button into the physiological correct reading position and fulfils the optimal conditions for a close reading test.

All phoropter arms can be fitted with reading lamps with flexible arms for the optimum lighting of the sample text for the close reading test if required.

5.3 Storage of small instruments

A special space is provided at the front of the unit for positioning a small instruments module. It is possible to choose between various possibilities for storage from the accessories on offer:

1. Undulated tray with micro-switch for one up to two ophthalmological hand-held instrument, with transformer, controlled via rheostat.
2. Twin charging unit built into the unit including support frame and cover screen. The charging unit is mounted securely in a special support with a cover on the front of the unit. For the plug-in power supply unit of the charging unit, a separate two-pole-and-earth socket outlet is available in the unit.
3. Close testing instruments and indirect/ head-worn ophthalmoscope: Special hook-shaped supports can be attached and power is supplied via PLD – or *Easy-Electronic*.

6 Safety precautions

Please keep in mind that during each height adjustment, chair rotation as well as table movement the patient is not exposed to hazard. Especially when raising the chair, the seat displacement and the footrest present a source of danger. Therefore make sure that the patient's feet are always positioned on the footrest.

Caution!

Please make sure while adjusting the chair's height that the patient's feet rest comfortably on the footrest of the patient chair. **Crushing hazard!!**

7 Maintenance, cleaning, care and disposal

For maintenance and care of the installed examination devices/ supply products please follow the directions of the concerning instruction manual.

Repair work practicable by yourself:

Before exchanging a fuse the unit must be separated from the power supply, therefore switch off both main switches (wall connection box and keyboard). Use only the prescribed fuse types and ratings. For more information, see technical appendix.

Maintenance and Safety Inspections (STK):

To ensure the high safety standard and high quality of the examination unit Solo we recommend a regular maintenance. Please contact an authorized Block service technician.

For the examination unit Solo we keep up to 10 years after the date of purchase spare parts on stock. After this period maintenance and repair work can be conducted contingently with original part.

Following maintenance should be conducted half yearly:

- Cleaning of the actuation-toothed belt, the phorofter rail and the telescopic-table rail with silicon-free lubricant (WD40), do not use any abrasive or water!

Following maintenance should be conducted yearly through authorized Block service technician:

- Inspection of the slipping clutch,
- Inspection of the sliding contact with checking of foreign particle,
- Checking the condition of every external connecting wire (Inspection for isolation damage),
- Check up of the effective operation of the shut down function,
- General check up of proper function,

Following maintenance must be conducted every 2 years by a specialist :

- STK

Depending on the usage frequency the user should do maintenance work every ½ year .

**Cleaning and greasing of the phoropter and telescop table rail.
Following specifications for the cleanser and grease are required:**

**silicon and acid free
not resinifying
no usage of abrasive or water**

Maintenance and care:

Important!

Turn off both main switches even when cleaning with a damp cloth. Leave the appliance to dry out completely before using again.

We recommend cleaning the coated surfaces with a cloth moistened (never dripping wet). Please do not use any abrasive or aggressive cleaning supplies. Make sure that no moisture gets in between the keyboard keys. Chair Cleaning: Simply clean with lukewarm water and a micro-fibre rag. Please do not use solvents, chlorides, abrasives, chemical cleaning agents or wax polishes. Please remove ink stains immediately. Do not use care agents containing oil or fat.

It is advisable to protect the unit against dust with a protective hood at the end of each working day, simply because open measuring and examining instruments are inherently sensitive to dust.

Waste disposal:

The examination unit *Solo* contains devices, which cannot be disposed in domestic waste. Please authorise for this purpose a waste management enterprise.

8 Technical Data

Required Space (with Block patient chair and desk combination as suggested in the prospectus):

LxW: look at Illustration 8.1.

Please give attention to the required projecting distance of 5 m. A set of tilted mirrors is necessary with small rooms; order no. 30 00 0110.

Gross Weight: variable, depending on equipment, approx. 85-135 kg

Mains Voltage: Please look at type label! 230 V 50/60 Hz

Power Consumption: 1500 VA plus all the external consumers connected up
Connection

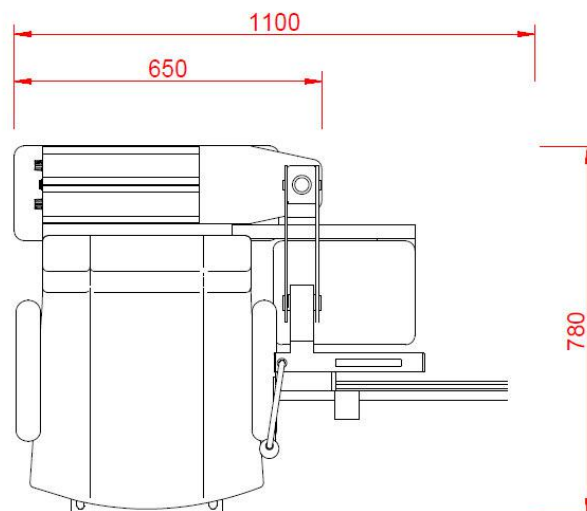
Requirements: 230 V wall-mounted terminal box with provisions for connecting room lighting, curtain control, reading lights, fixation lights and Maddox cross.

Operating conditions: Temperature of the environment between +10 °C and +40 °C
Relative humidity between 30 % and 75 %
Air pressure between 700 hPa and 1060 hPa

Height adjustment of the chair:

Not intended for permanent operation!

Continuous up and down movements must not exceed 1.5 minutes. Cool down device for at least 8.5 minutes.



Grundriss Solo 1:10

Illustration 8.1: Dimensions of the unit "Solo"

9 E.G.-Declaration of Conformity

For the following named products examination units by Block Optic Ltd.

INNOVARIO[®], DUOLINE^{2010®}, CT, IDEO, SOLO

it is confirmed that the products meet the requirements as determined by the European Community:

89/336/EWG electromagnetic compatibility,
93/42/EWG medical products.

Evaluation of the products complies with the standards listed below:

EN 60601-1:2006 Medical electrical equipment,
EN 55011 Emission of electromagnetic interference,
IEC 801 Immunity from electromagnetic interference.

This declaration in responsibility for the manufacturer:

Block Optic Ltd.
Semerteichstr. 60
44141 Dortmund
Germany

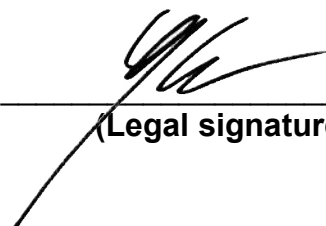
The examination units are labelled with:



Is submitted by:
J. Grawunder, Manager

Dortmund, 1. January 2016

(Place, Date)



(Legal signature)

CERTIFICATE



Block Optic Ltd.

www.block-optic.com

ISO 9001:2015

DEKRA Certification GmbH hereby certifies that the company

Block Optic Limited

Scope of certification:

Development and production of ophthalmic and optical examination units and chairs

Certified location:

D-44141 Dortmund, Semerteichstraße 60
D-46342 Velen, Industriestraße 6

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. A15170393.

This certificate is valid from 2016-07-02 to 2019-07-01

Certificate registration no.: 50716344


Lothar Weimofen
DEKRA Certification GmbH Stuttgart; 2016-07-02

