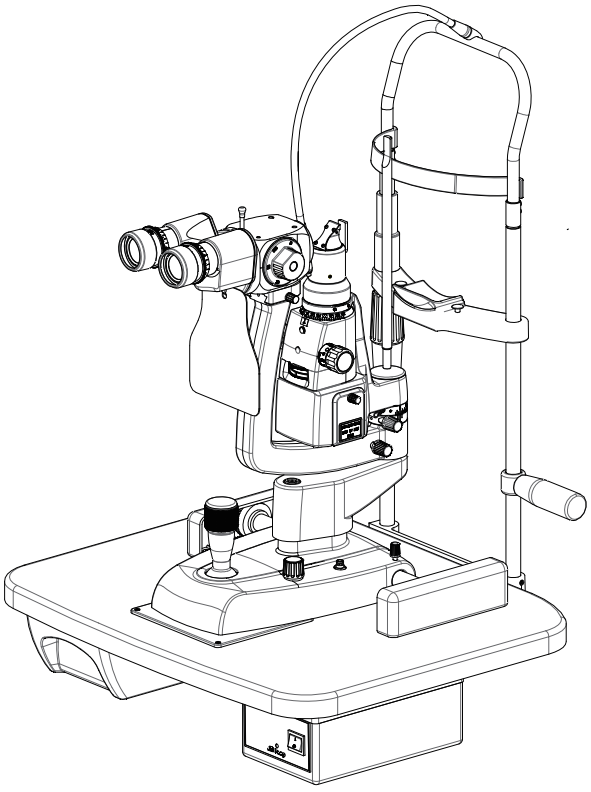
NIDEK

SLIT LAMP

SL-1800

OPERATOR'S MANUAL



Original instructions

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Contents

The SL-1800 Slit Lamp is a high-performance instrument. In order to use it efficiently and in maximum safety, we recommend reading this instruction manual carefully before beginning installation. Respect all the warnings contained herein and marked on the outside of the equipment.

GENERAL SAFETY PRECAUTIONS

WARNING

- If any serious device-related incident occurs, report it to Nidek and the competent authority in the country where the user or patient, or both reside.

CAUTION

- Do not perform servicing or maintenance on the device during use.
- Check that line voltage is that indicated on the instrument data plate.

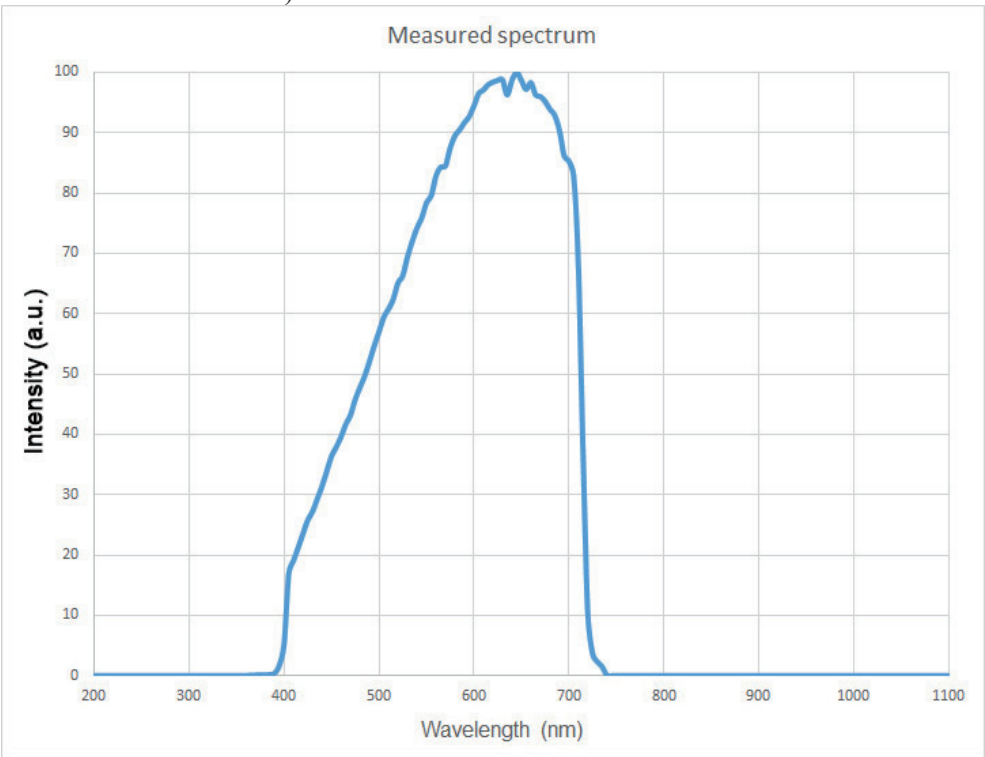
Should line voltage be different, set the voltage selector on the instrument power socket to the correct voltage (See INSTALLATION). The entire electrical system must comply with CEI or IEC standards for electrical systems on medical premises. In case of doubt consult your electrical installation or maintenance specialist.

- Never use multiple sockets or extension cords between the plug of the instrument power cord and the line socket.
- When disconnecting the instrument from electrical supply, always grasp the plug of the power cord, never the cord itself; never pull the cord to disconnect the plug.
- Never touch the power cord with wet hands; do not step on the cord or place weights on it; do not knot the cord.
- A damaged power cord can cause fires and electrical shocks and therefore must be inspected frequently. Should the power cord supplied with the instrument need to be replaced, contact your supplier.
- Do not attempt to perform any type of technical work on the instrument or the electrical system other than those specifically mentioned herein.
- Do not use the instrument near water; take care not to spill liquids on any part of the instrument. Avoid installing the instrument where it will be subjected to high humidity, dust, or rapid changes in temperature and/or humidity.
- Disconnect the instrument from the line socket before cleaning or disinfecting.
- " Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (<400nm) and, whenever possible, filters that eliminate short- wavelength blue light (<420nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for slit lamps, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also increase if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography".

-“CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 2.5 minutes" (Maximum examination times according to ISO 15004-2 and ISO 10939)



PRODUCT OUTLINE

The SL-1800 Slit Lamp is a high-performance instrument. In order to use it efficiently and in maximum safety, we recommend reading this instruction manual carefully before beginning installation. Respect all the warnings contained herein and marked on the outside of the equipment.

The slit lamps incorporate the latest technology to provide a product that will meet your most demanding requirements.

Product features include:
Multilayered antireflection coatings to improve light transmission.
Halogen illumination for more consistent lighting.
Three dimensional joystick for ease of alignment
Variable slit aperture (0 – 14mm) to provide exam flexibility
Complete selection of filters and accessories

Thank you for choosing the SL-1800

Indication for use Statement

An AC- powered slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Intended patient population

Age: Adults / Children / Infants
Health condition: Low vision
Conditions - Visual function: One eye or both eyes are normal or diseased
Eyes with no vision are excluded.

Intended user profile

Ophthalmologist, nurse, clinical laboratory technician /OD

Intended use environment

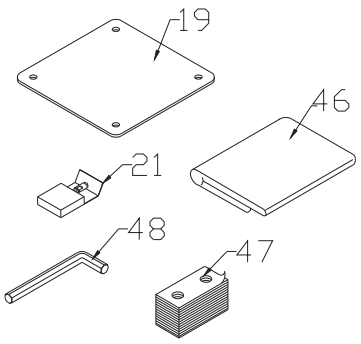
Medical facility or optical store

CAUTION

- If the device is used outside the specified use location, intended performance and security level cannot be maintained.

Standard Equipment

On receipt of the instrument, remove it from its packing and check that all the components listed below are included.



The packaging contains:

One slit lamp complete with optical microscope, including fluorescein filter system (52), with magnification power selector (28), with voltage selector (14) on the base,

One chin-rest with jointed fixation point.

This instruction manual.

A set of accessories, composed of:

- one calibration stick (43);
- one protective cover (46);
- one socket wrench (48);
- one spare lamp 6V 20W halogen PG22 ;
- two packets of chin-rest papers (47);
- one breath shield (5).
- One power cord;

One tabletop unit (38x50) on which are assembled:

one transformer box (15) with main switch (13), socket for the fixation point (38), and power socket (35) with incorporated voltage selector and fuses (34);

two right-angle movement guides for the base (17);

two wheel guide guards (18);

one slide plate for the positioning device (19);

one accessories drawer (16).

In case of split prism head slit lamp the packaging contains:

One slit lamp complete with optical microscope with magnification power selector (28), with voltage selector (14) on the base.

One chin-rest with jointed fixation point.

This instruction manual.

A set of accessories, composed of:

- one calibration stick (43);
- Instrument cover (46);
- one socket wrench (48);
- one spare lamp 6V 20W halogen PG22 ;
- two packets of chin-rest papers (47);
- one breath shield (5).
- One power cord;
- one transformer box(15) lighted main switch(13), fixation point connector (38), and line power socket(35) with incorporated voltage selector and fuses holder(34);
- two toothed guides (17);

- two wheel guards (18);
- one Teflon slide plate (19);
-

Ambient Conditions

As long as the slit lamp remains in its original packing it may be exposed to the environmental conditions listed below, for a maximum of 15 weeks during shipping and warehousing, without suffering damage.

Temperature between -10°C and +60°C,
atmospheric pressure between 500 hPa and 1060 hPa, and
relative humidity between 10% and 90%.
Ambient conditions for operation are, instead:
Temperature between +15°C and +30°C;
atmospheric pressure between 700 hPa and 1060 hPa, and
relative humidity between 30% and 75%.

Accessories

The accessories listed below are available as optional equipment.

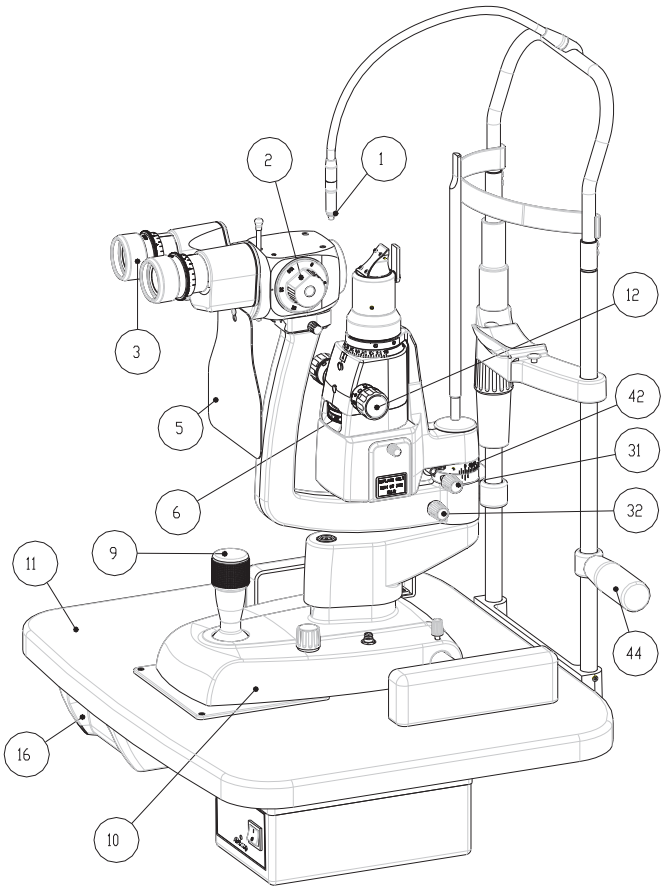
- Millimeter eyepiece,
- Beam splitter zeiss compatibility for microcamera,
- "C"-mount ½ CCD Adapter,
- Photocamera Adapter,
- Second observer Tube,
- Beam splitter zeiss compatibility double exit,
- Tonometer Z 800
- Hruby Lens
- Beam splitter Zeiss Compatibility one exit.
- Bearing plate.
- Digital camera system.
- Back light for digital camera.
- Foot switch for digital camera.
- Base & Joystick for digital camera.

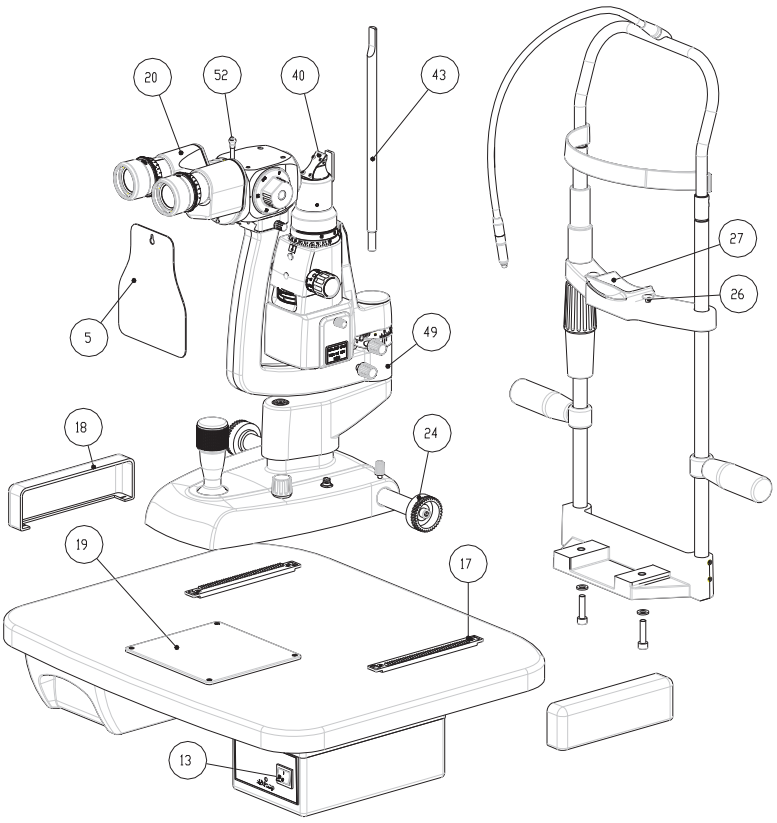
CAUTION

- In advance of an observation of each patient, wipe the foreheadrest and chinrest with a clean cloth. Moreover, remove one chinrest paper for each patient if a bunch of the chinrest papers is fixed on the chinrest. If necessary, wipe the foreheadrest and chinrest using a cloth dampened with rubbing alcohol.
- Set the light intensity as low as possible. The light intensity depends on the slit lamp settings such as voltage of illumination lamp, slit length, slit angle, selection of the filters and illumination time. High light intensity may cause thermal and photochemical damages onto the patient's retina.
- If your slit lamp was not supplied with a transformer (Part No.: 34530-M703), make sure that the power connection is compatible with the specifications in this manual and is connected by a qualified technician to an available and suitable power supply. See page 15.

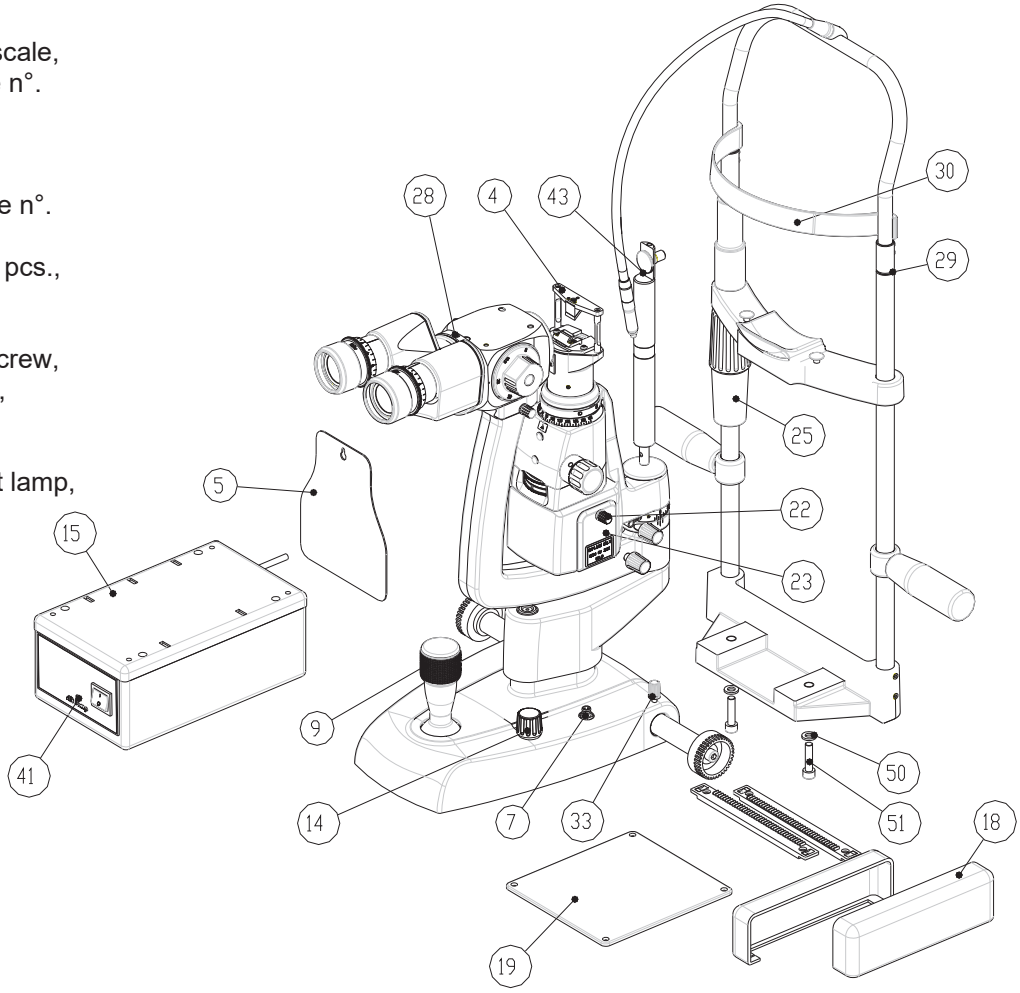
LEGEND

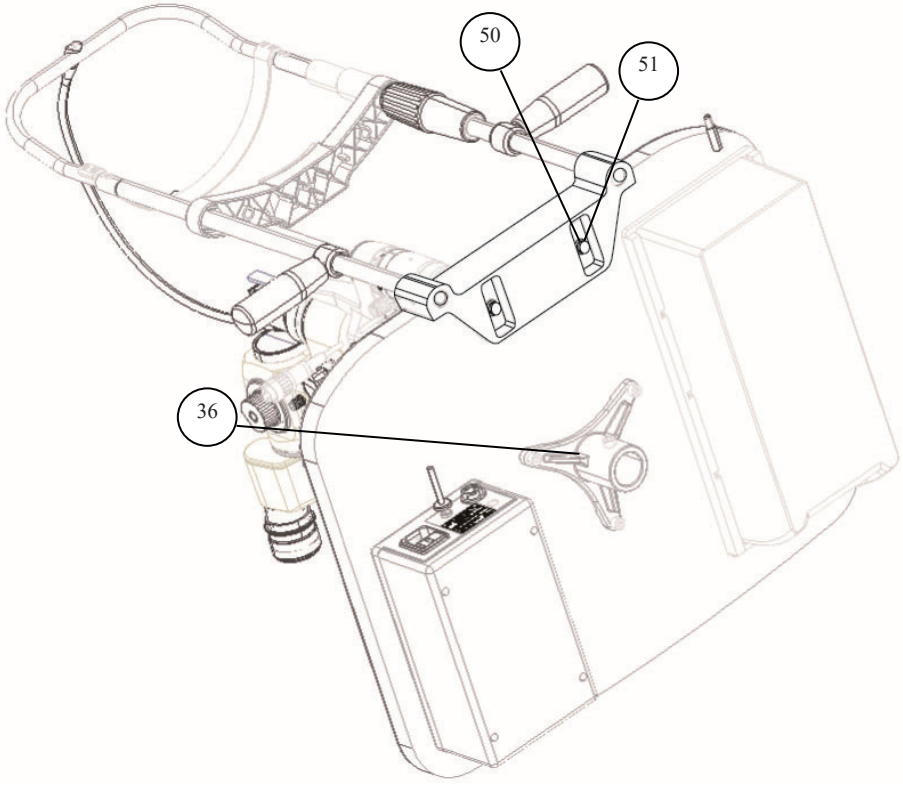
1) Fixation point,
2) Magnification power selector knob,
3) Extractable eyepieces,
4) Split prism head,
5) Breath shield, code no. 10.02.12.641,
6) Filter/diaphragm rotation ring,
7) Plug to connect transformer
8) Bulb's block springs,
9) Joystick for side-to-side, back-and-forth, and, up-and-down movements (x,y,z),
10) Base featuring right-angle movements,
11) Profiled tabletop, code n°. 10.07.02-10, 41x50 cm,
12) Slit width adjustment knobs,
13) Lighted main switch,
14) Light intensity selector,
15) Transformer box, code n°. 10.02.23.900, 6V,
16) Accessories drawer, with guides, code n°. 10.02.55.820,
17) Toothed guides, code n°. 10.02.10.415,
18) Wheel guards, code n°. 10.01.01.135,
19) Teflon slide plate, code n°. 10.01.01.136,
20) Binocular unit, code n°. 10.02.26.601,
21) Halogen lamp, 6V 20W PG22, code n°. 3008010620C,
22) Lamp door opening knob,
23) Door of halogen lamp compartment,
24) Toothed wheel, code n°. 10.02.10.414,
25) Chin-rest height adjustment knob,
26) Placement pins for chin-rest paper,
27) Chin-rest,
28) Microscope binocular eyepiece separation screw,
29) Eye position scale,
30) Headrest,
31) Projector slit set knob,
32) Microscope arm set knob,
33) Instrument base slide set knob,
34) Voltage selector and fuse-holder,
35) Line power socket,
36) Bearing to connect tables,
37) Transformer data plate,
38) Fixation point connector,

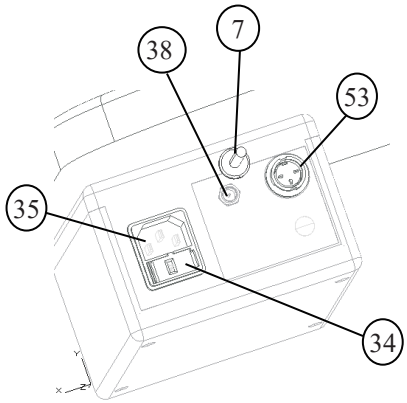




39) Lamp socket PG 22
40) Prism Head assembly,
41) LED signal for “transformer card trouble ”,
42) Projector positioning scale,
43) Calibration stick, code n°. 10.02.02.090,
44) Hand-rest knob,
45) Beam Splitter
46) Instrument cover, code n°. 4013090,
47) Chin-rest papers, 100 pcs., code n°. 4014010,
48) Socket wrench,
49) Lampholder unit set screw,
50) Chin-rest set washers,
51) Chin-rest set screws,
52) Filter Insertion rod,
53) Connection plug to slit lamp,







INSTALLATION

The instrument is supplied packed in such a manner as to best withstand standard shipping and warehousing conditions. Should defects attributable to shipping be discovered upon unpacking, please contact your installation specialist.

Follow the steps outlined below to assemble the instrument.

1)Put the table top on a very stable support (as a Electric stand or what ever stand you want). Then proceed in this way:

2)Unscrew the two hexagonal socket-head screws (51) recessed underneath the chin-rest. Position the chin-rest and align the holes in it with those of the top. Use the wrench supplied with the instrument (48) to tighten the screws.

3)Position the SL-1800 lamp, meshing the toothed wheels (24) on the base with the guides (17) in the upper part of the instrument-holder top. Also check alignment of the wheels and then lock in place by tightening the knob (33) on the right-hand side of the base over the wheel axle.

4)Attach the wheel guards (18) to the sides of the guides by sliding the tabs into the respective notches.

5)Position the rear part of the microscope (20): loosen the screw (28), position the microscope, and retighten the knob.

6)Hook the breath shield (5) to the support for that purpose on the binocular (20).

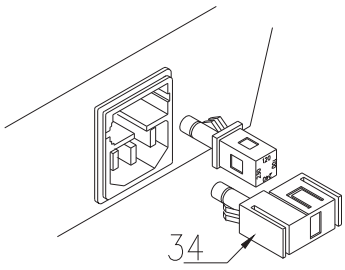
7)Insert the plug of the projector power cord into the socket (53) on the rear of the transformer

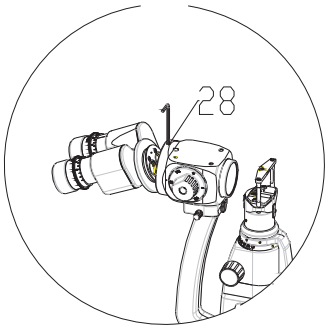
8)Insert the jack of the power cord of the chin-rest fixation point in the socket on the rear of the transformer (38).

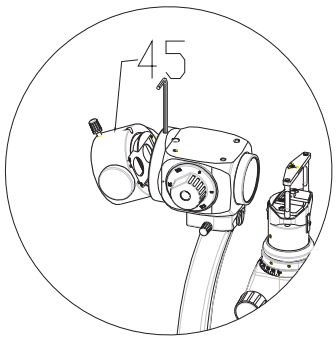
9) Check that the voltage selectors (34) on the transformer line power socket (35) is set to the voltage at which the instrument is to be used. If necessary, extract the relative slides and turn until the correct voltage value appears in the window.

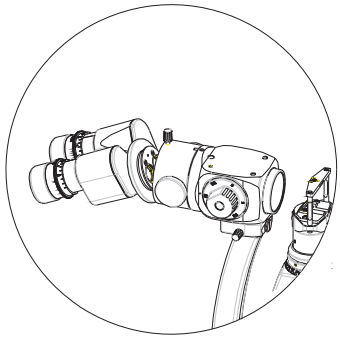
10) Insert the power cord into the socket (35).

11) Use the optional kit specified for NIDEK to connect with the general diagnostic table.









Installing the camera/videocamera mount

Loosen the screw (28) with the wrench key. Remove the binocular unit (20) of the microscope and insert the beam splitter (45); now reassemble the binocular unit on the beam splitter. If the image has shifted after assembly of the camera/videocamera, adjust the three screws on the elbow of the mount, in correspondence to the mirror, to center the image.

TRIAL OPERATIONS

a) Seat the patient in a comfortable position, with the chin on the chin-rest and the forehead on the forehead-rest.

b) Adjust the sleeve (25) to raise and lower the chin-rest until the patient's eyes are aligned with the marks on the chin-rest (29).

c) Switch the instrument ON; the switch (13) will light.

d) Use the selector (14) to adjust light intensity to the desired value.

e) Use the joystick (9) to frame and focus on the eye to be examined.

MAINS FEATURES

The SL-1800 Slit Lamp is the result of lengthy research conducted with the what of accredited professionals, in order to ensure the highest correspondence of state-of-the-art technology, quality, and design.

NIDEK is confident that the SL-1800 represents the best quality and technology currently available.

Important operational features of the instrument include:

- Fatigue-free observation and rapid magnification changeover.

- Base featuring stoppable right-angle movement in three planes, all controlled by a single joystick (x,y).

- Microscopic stereo observation of the eye in the light from the slit, at 5x-8x-12.5x-20x-32x magnification powers, and also including the possibility of fluorescin filter. Examination of the eye and evaluation of contact lens positioning by fluorescence.

- Microscopic examination of the posterior wall and the posterior vitreous body with the auxiliary Hruby lens or contact optics (Goldman lens).(option)

- Measurement of the diameters of the cornea and of the contact lenses.(option)

- Video record of the eye examination. (option)

LIGHT INTENSITY SELECTOR

The light intensity selector (14) is used to adjust the intensity of the illumination light of the slit lamp continuously from the minimum to the maximum in the range of the intensity level indication.

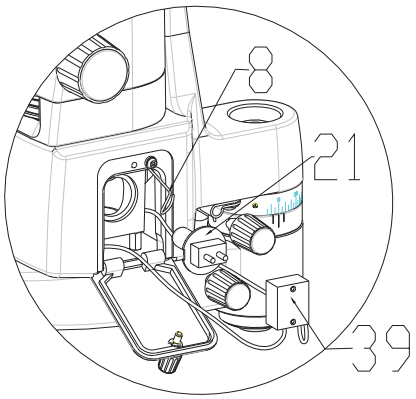
CAUTION

- Do not set the light intensity higher than necessary.
- Do not attempt to turn the knob beyond the range of the intensity level indication.

ROUTINE MAINTENANCE

The repairs illustrated below must all be performed only with the power cord disconnected from the line socket. For any type of breakdown requiring repairs different from those described below, contact your installation service.

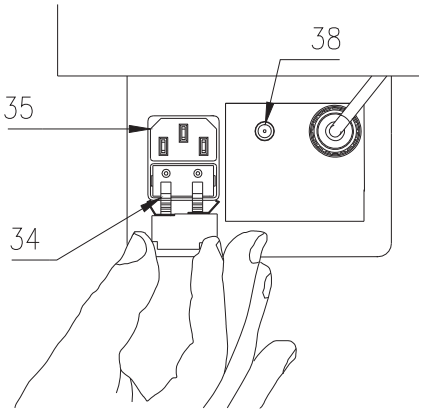
Replacing the projector lamp



To replace the lamp:
- Disconnect the power cord from the line socket.
- Turn the knurled knob (22) and open the lamp door (23);
- Turn the bulb's block springs (8) and take off the lamp socket (39);
- Remove the unserviceable lamp (21).
  Attention: the lamp could be very hot.
- Insert the replacement lamp (6V 20W halogen) taking care not to touch the bulb with bare hands.
- Check that the lamp is securely seated in the socket, block turning the spring.
- Insert the lamp socket. Close the lamp door and screw down the knurled knob (22);
- Reconnect the power cord plug to the line socket.

Replacing the fixation point lamp

To replace the fixation point lamps:
- Disconnect power by unplugging the plug (38) from its socket on the transformer.
- Unscrew the white fixation point cap.
- Replace the lamp with one of those supplied with the instrument, taking care that the pins be fully inserted in the socket.
- Screw on the cover.
- Reconnect the plug to the transformer socket.



Replacing the line fuses.

To replace the line fuses:
* The line fuses are located on the rear of the transformer inside the socket/voltage selector unit (34). Before proceeding with replacement, disconnect power by unplugging the instrument power cord from the line socket.

- Extract the voltage selector and remove the unserviceable fuses.
- Replace the fuses with new fuses compatible with the line voltage supply as reported on the transformer data plate (37)
- Replace the voltage selector
- Reconnect the plug to the line socket.

Meaning of LED blinking of transformer card Trouble (41)

Type of LED Blinking	PCB Legend : LED Indicator	State of Slit lamp's bulb	Suggestion
LED off	Input voltage in the right range	*Lamp On*	No action require
LED On:	Line synchronization failure and/or Internal over temperature :	*Lamp Off*	Call assistance
LED Intermittent Slow (1Hz):	Input voltage to PCB is low (under 5.9Vac, until 5.3Vac)	*Lamp On*	Check input voltage – Voltage selector
	Input voltage to PCB is too low (under 5.3Vac)	*Lamp Off*	Check input voltage – Voltage selector
LED Intermittent Fast (5Hz):	Input voltage to PCB is high (over 14 Vac)	*Lamp Off*	Check input voltage – Voltage selector
LED Intermittent (Double Flash):	Output current to the bulb is high (approximately 4A)	*Lamp Off*	Check bulb - Call assistance
LED Intermittent (Triple Flash):	Output voltage regulation is inconsistent Analog Error .- ADC saturation; The lamp it's switched in the transparent mode (not regulated).	*Lamp On*	Call assistance
The light intensity automatically falls down to prevent from heating as safety function when the illumination is continuously lit up at maximum level. *In this case, light intensity can be returned to the initial level by the illumination adjusting knob.			

Protecting the instrument from dust

When the instrument is not in use, it should be covered with the plastic cover supplied as standard equipment to protect it from dust. Any dust that may accumulate on the eyepiece and on the sight glasses during use should be periodically removed by means of a very soft cloth or a rubber ball air blower.

Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.
When disposing packing materials, sort them by the materials and follow local governing ordinances and recycling plans.

Others

When the instruments is sent back to NIDEK for repair or maintenance, wipe the surface (especially, the area where the patient's skin contacts) of the instrument with a clean cloth immersed in ethyl alcohol for disinfections.

END-OF-LIFE DISPOSAL INFORMATION

The symbol (barred waste can)) shown in the figure and found on the exterior of the instrument indicates that the electrical and electronic parts of the end-of-life instrument must be **separated and disposed of as special waste**.

(for EU)

in accordance with Art. 13 of Leg. Decree No. 151 of 25 July 2005 implementing Directives 2002/95/EC, 2002/96/EC, and 2003/108/EC concerning reduction of use of dangerous substances in electrical and electronic equipment and disposal of electrical and electronic waste.

The instrument you have purchased is made using particular materials and substances. It may also contain substances having potentially dangerous effects on the environment and human health if released into the environment by improper disposal.
To avoid releasing dangerous substances into the environment and in order to promote conservation of natural resources, and should the user decide to dispose of an end-of-life instrument, the manufacturer will facilitate re-use and recovery and recycling of the materials it contains.
Government agencies have adopted measures obliging users, distributors, and manufacturers to contribute to collection of waste electrical and electronic equipment (WEEE) and prescribes that such equipment find re-use or be recovered or recycled.

When disposing of the instrument, remember that disposal is regulated by precise European and national laws and regulations that prescribe the following:
- Do not dispose of as ordinary municipal waste. For separate disposal contact a company specialized in disposal of waste electrical and electronic equipment or your local waste disposal agency for information
- If a new instrument is purchased from the same manufacturer to replace an end-of-life instrument put on the market before 13 August 2005, of an equivalent type and performing the same functions as the new device, the distributor or manufacturer is required by law to take back the end-of-life device.
- If the user intends to dispose of a used device put on the market after 13 August 2005, the distributor or manufacturer is required by law to take back the device.
- The manufacturer is responsible for transporting, treating, and recovering and/or recycling any used equipment collected and for all relevant expenses.
- Never forget that dangerous substances present in waste electrical and electronic equipment and/or improper use of same or parts of same can have potentially adverse effects on the environment and human health. The instrument described in this manual contains metal and plastic mechanical parts, electrical components, and electronic circuit cards. The manufacturer is at user's complete disposition for any information requested regarding the dangerous substances contained in the instrument and recovery and recycling procedures and/or the possibility of re-using the end-of-life instrument.
Current legislation provides severe sanctions in the case of failure to respect disposal laws and regulations in force.

TECHNICAL DESCRIPTION

Slit lamp general features	SL-1800 prism tower	SL-1800 split mirror tower
Slit projection scale:	*1.16X*	*1.01 X*
Slit width (stepless setting): (mm)	*0 – 14 Continuously Variable*	*0 – 12 Continuously Variable*
Slit length (stepless setting): (mm)	*1.8 – 13 Continuously Variable*	*1.5 – 11 Continuously Variable*
Maximum slit length: (mm)	*14*	*12*
Aperture diameter : (mm)	*14 , 9, 5.5, 0.2*	*12, 8, 5, 0.3*
Filters:	*Blue, Red Free, Heat absorbing*	*Blue, Red Free, Heat absorbing*
Slit rotation angle:	*± 90°Continuous on Tabo scale*	*± 90°Continuous on Tabo scale*
Angle of incidence:	*0° horizontal*	*0° horizontal*
Free Working distance (exit prism/patient's eye distance):	*68 mm*	*68 mm*

Chin rest features	SL-1800 prism tower	SL-1800 split mirror tower
Fixation point:	*White, luminous, jointed*	*White, luminous, jointed*
Chin-rest height adjustment:	*76 ± 1 mm*	*76 ± 1 mm*
Fixation point lamp:	*Micro lamp 12 V 60 mA*	*Micro lamp 12 V 60 mA*

Dimensions of the top:	*410 x 500 mm*	*Not in use*
Supply voltage:	*100 V/120 V/230 V/240 V ac ±10% 50/60 Hz*	*100 V/120 V/230 V/240 V ac ±10% 50/60 Hz*
Fuses: 5x20 mm	*100-120 Vac --- 400 mA T* *230-240 Vac --- 200 mA T*	*100-120 Vac --- 400 mA T* *230-240 Vac --- 200 mA T*
Maximum Electric Power Consumption:	*40 VA*	*40 VA*
Instrument operating voltage:	*6 Vac*	*6 Vac*
Halogen lamp:	*6 V 20 W PG 22*	*6 V 20 W PG 22*

Microscope Features	SL-1800 prism tower					SL-1800 5x split mirror tower				
Type:	Galileian Converging Binocular					Galileian Converging Binocular				
Magnification power selection system:	5-position rotating drum					5-position rotating drum				
Eyepieces:	12.5x					12.5x				
Diopter adjustment	± 8 D					± 8 D				
Magnification powers (32X version) :	5x	8x	12.5x	20x	32X	5x	8x	12.5x	20x	32X
True visual field (mm)	46	29.5	18.4	11.5	7.5	46	29.5	18.4	11.5	7.5
Interpupillary adjustment	50-75 mm					50-75 mm				
Stereoscopical Angle	6°					6°				
Yellow filter included	Yes					No				
Magnification powers (40X Version) :	6.5x	10x	16x	26x	40x	-	-	-	-	-
True visual field (mm) (40X Version)	38,2	25,0	15,3	9,6	6,3					

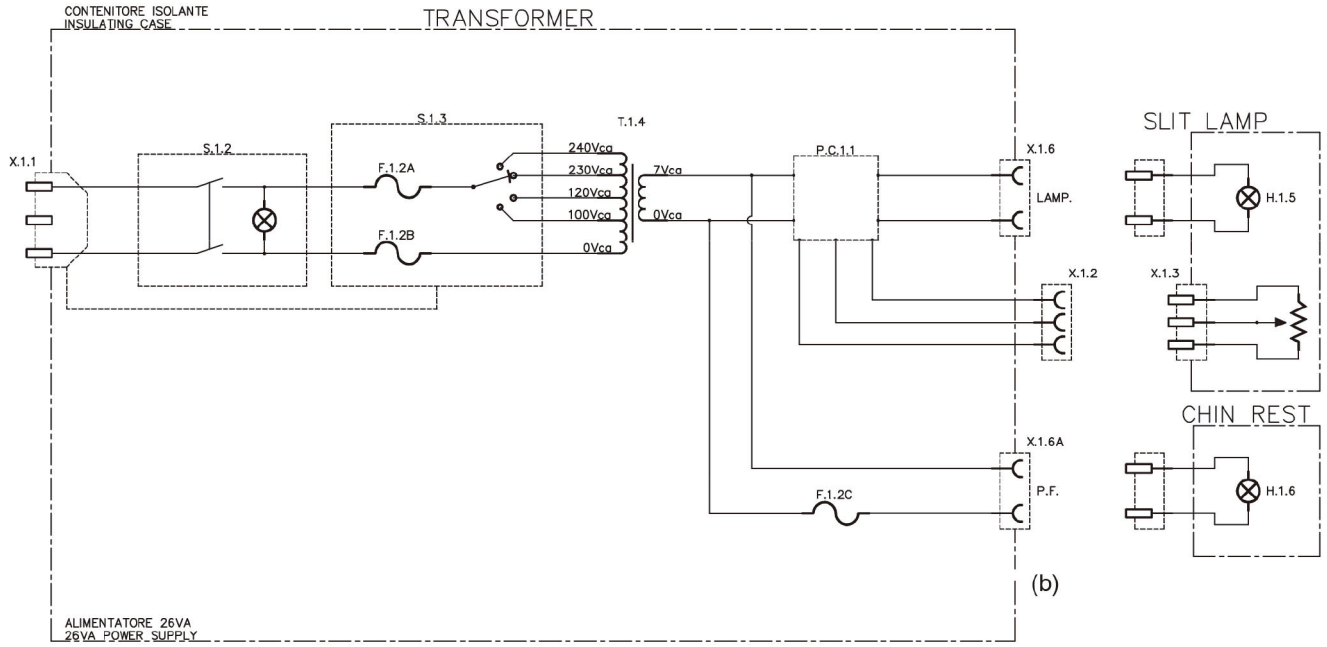
Right-angle movement base with single joystick control (x,y,z)

Side-to-side or lateral movement (x):	107 ±1 mm
Back-and-forth or depth movement (y):	113 ±1 mm
Up-and-down or vertical movement (z):	36 ±1 mm
Horizontal fine movement (x,y):	14 ±1 mm

Power supply		
Power supply input	Switch mode, [100/120/230/240 V~]+/-10%	Transformer box Part No.: 34530-M703 (Code No.10.02.23.900)
Power supply output	6 V~, 20 W / Slit illumination 6 V~, 1 W / Fixation light	
Complies with	IEC 60601-1, IEC 60601-1-2, ISO 15004-1, ISO 15004-2	

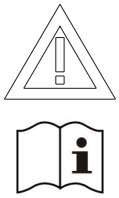
Function Block Diagram

On request, the manufacturer will supply diagrams, components lists, and detailed technical instructions for maintenance and calibration, for use only by authorized personnel with prior training. NIDEK hereby declares that all the components making up its instruments are covered by insurance and fully guaranteed for 12 (twelve) months.



F.1.2A/B	30060101T02	2	FUSE 0.2A@230–240V 5x20 T
F.1.2A/B	30060101T04	2	FUSE 0.4A@100–120V 5x20 T
X.1.6	3002063F010	1	EXIT CONNECTOR
X.1.1	300203020	1	POWER IN SOCKET SCHURTER KEA 4301–2044
T.1.4	301304160	1	TRANSFORMER 100–120–230–240/7V 26VA 50–60Hz
S.1.2	30120102020	1	POWER ON SWITCH WITH LAMP INCLUDED
-	-	-	(b)
F.1.2C	30060101T0125	1	FUSE 0.125A T
P.C.1.1	12.02.12.950	1	ELECTRONIC CONTROL BOARD RC57
X.1.6A	30020404020	1	FIXATION POINT PLUG
X.1.2	300409040	1	PLUG LUMBERG RKMWV3–101/0.8P
X.1.3	300409050	1	PLUG LUMBERG RSMF3/0.2M
H.1.5	3008010620C	1	BULB 6V–20W
H.1.6	300805M12	1	BULB OL1089 12V

Data Plate Symbols



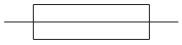
Read the instructions carefully.

Class II protection against direct and indirect electrical shocks.

Type B protection against direct and indirect electrical shocks.

MD

Medical device



Fuse.

EC REP

EU Authorized Representative

SN

Serial number

Classification according to EN60601- 1:2006 Standard (SL-1800 split mirror tower and prism head)

Protection against electrical shock:	Class II ME EQUIPMENT Type B applied parts
Protection against harmful ingress of water:	IPX0
Method of sterilization:	Disinfections of equipment
Level of protection in proximity to inflammable anesthetics and/or detergents:	No protection
Use conditions:	Temporary operating – Intermittent Operation Cycle power on: 10 min. – Cycle power off: 15 min.
Level of electrical connection between instrument and patient :	Devices with an applied part, not specifically designed for application of electrically conducting parts connected to patient.

ELECTROMAGNETIC COMPATIBILITY

The device is suitable for use in hospitals except for near active HF surgical equipment and RF shielded rooms with an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

⚠ WARNING

- Use of accessories, cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result improper operation.
- Do not use the device near, on, or under other electronic equipment. Otherwise, it could result in improper operation. If such use is necessary, the device and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including the specified or provided cables.
  Otherwise, degradation of the performance of this equipment could result.

Specified cables

Part name	Connector shielded	Cable shielded	Ferrite core	Length (m)
Power cord	No	No	No	2.5m

Essential performance

- Illumination function for the patient eye

The illumination may be turned off by electromagnetic disturbance. In this case, turn off the device, and remove the suspected cause of the electromagnetic disturbance as described in the warnings above. Then, turn on the device again.

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	*1	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	*2	

*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Dips: 0% U_T in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T in 1 cycle and 70% U_T in 25/30 cycles in single phase (at 0°) Short interruptions: 0% U_T in 250/300 cycle	Dips: 0% U_T in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T in 1 cycle and 70% U_T in 25/30 cycles in single phase (at 0°) Short interruptions: 0% U_T in 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the device, including cables.[a]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	
Proximity field from RF wireless communications equipment IEC 61000-4-3	See "Test specifications for enclosure port immunity to RF wireless communications equipment".	See "Test specifications for enclosure port immunity to RF wireless communications equipment".	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.			

Test specifications for enclosure port immunity to RF wireless communications equipment					
Test frequency (MHz)	**Band[a] (MHz)**	**Service[a]**	**Maximum power (W)**	**Distance (m)**	**Immunity test level (V/m)**
385	380 - 390	TETRA 400	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	0.3	28
1,720 1,845 1,970	1,700 - 1,990	GSM 1800, CDMA 1900, GSM 1900, DECT; LTE Band 1, 3, 4, 25: UMTS	2	0.3	28
2,450	2,400 - 2,570	Bluetooth, WLAN, 802.11: b/g/n, RFID 2450, LTE Band 7	2	0.3	28
5,240 5,500 5,785	5,100 - 5,800	WLAN 802.11 a/n	0.2	0.3	9
NOTE: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the ME equipment or ME system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.					
[a] For some services, only the uplink frequencies are included.					