853 CO_2 Suppressor

Metrohm
Ion analysis

Manual

8.853.8001EN

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Although all the information given in these instructions has been checked with great care, errors cannot be entirely excluded. Should you notice any mistakes please inform the author at the address given above

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1 Introduction

1.1 Instrument description

The **853 CO_2 Suppressor** is used to remove CO_2 before detection takes place. CO_2 can enter the eluent flow from the sample itself, or is produced by the suppressor reaction (see below, *Reaction in the suppressor module «MSM II»*).

If the 853 CO_2 Suppressors is connected between the suppressor module «MSM II» and the detector block the CO_2 peak is effectively minimized. The principle is based on the permeability of the Teflon AF™ membrane in the degassing cell of the 853 CO_2 Suppressor to gases. The eluent (together with the injected sample) passes through a capillary with a Teflon AF™ membrane contained in the degassing cell, in which a vacuum has been created by a pump. At the same time the pump draws CO_2-free air (the CO_2 is removed by the CO_2 Absorber Cartridge) through the degassing cell. The lower CO_2 vapor pressure in the degassing cell compared with that in the capillary results in the diffusion of CO_2 from the eluent flow. The pump of the 853 CO_2 Suppressors is provided with electricity from an external power supply. The 853 CO_2 Suppressor is controlled by Remote commands.

Reaction in the suppressor module «MSM II»

If a carbonate eluent is used then the following reaction (among others) takes place in the suppressor module «MSM II»:

$$R\text{-}SO_3^-H^+ + NaHCO_3/Na_2CO_3 \rightarrow R\text{-}SO_3^-Na^+ + H_2O + \mathbf{CO_2}$$

1.2 Parts and controls

*In this section you will find the numbers and designations of the parts and controls of the 853 CO_2 Suppressor. The numbering applies throughout the instructions for use, i.e. bold numbers in the text (e.g. **3**) refer to the parts and controls illustrated here.*

1.2.1 Front view 853 CO_2 Suppressor

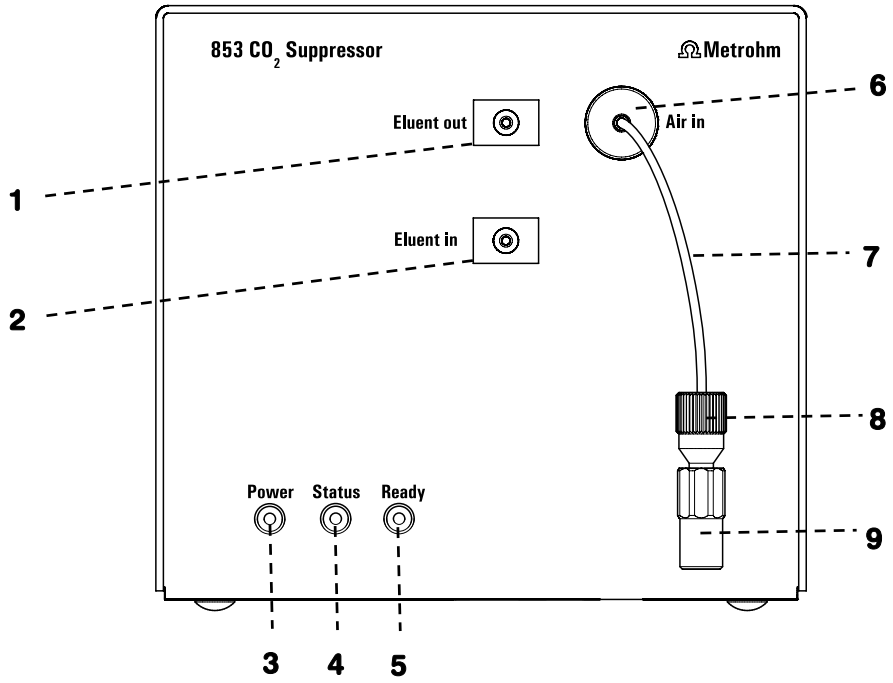


Figure 1: Front view 853 CO_2 Suppressor

1 Eluent flow outlet "Eluent out"

2 Eluent flow inlet "Eluent in"

3 LED "Power"
Lights up green when the pump is running.

4 LED "Status"
Lights up orange when the pump is running and the pressure in the vacuum chamber is too high or too low. After the pump has been switched on it takes a few seconds for the vacuum to be established.

5 LED "Ready"
Lights up green when the pump is running and the pressure in the vacuum chamber is within the ideal working range.

6 Aspiration opening "Air in"
Opening for drawing in CO_2-free air (through CO_2 Absorber Cartridge).

7 PEEK flow reduction capillary 6.1831.130
The length of the flow reduction capillary provides an optimal flow and should not be altered.

8 Pressure screw

9 Coupling

1.2.2 Rear view 853 CO_2 Suppressor

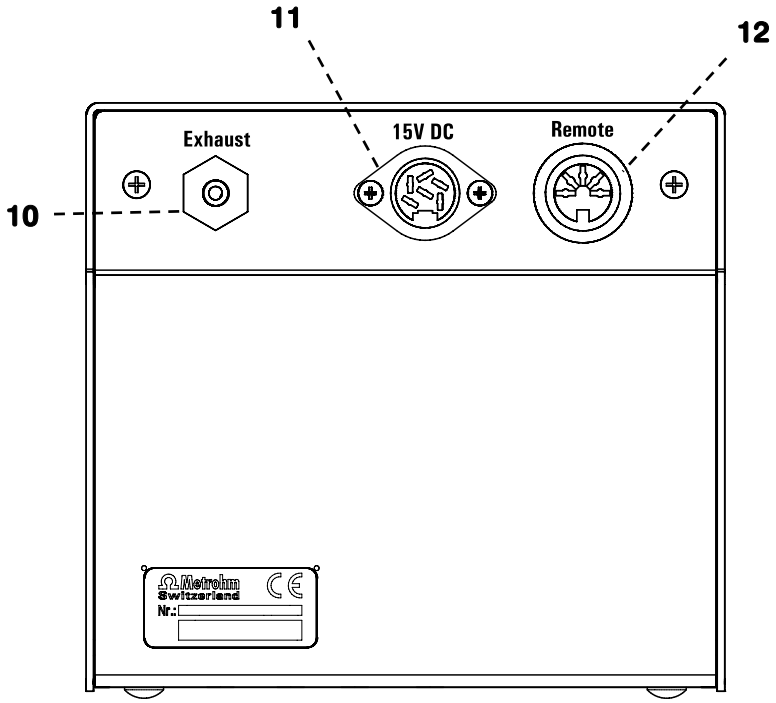


Figure 2: Rear view 853 CO_2 Suppressor

10 Exhaust opening "Exhaust"

Air is pumped out of the degassing cell through this opening.

11 15V Mains connection "15V DC"

12 Remote interface "Remote"

For remote control by external devices.

1.3 Information on the Instructions for Use

Please read through these Instructions for Use carefully before you put the 853 CO_2 Suppressor into operation. The Instructions for Use contain information and warnings to which the user must pay attention in order to assure safe operation of the instrument.

1.3.1 Organization

These **Instructions for Use 8.853.8001EN** for the 853 CO_2 Suppressor provide a comprehensive overview of installation, startup procedure, operation, fault rectification and technical specifications of this instrument. The Instructions for Use are organized as follows:

Section 1 Introduction
General description of instrument, parts and controls and safety notes

Section 2 Installation
Installation and connection of the instrument, of the accessories and of the software

Section 3 Operation
Introduction to the operation.

Section 4 Troubleshooting - Problems
Possible faults and their remedies.

Section 5 Appendix
Technical data, standard equipment, optional accessories, validation, warranty and declaration of conformity, index

In order to find the information you require about the 853 CO_2 Suppressor you should either use the **Contents** or the **Index**.

1.3.2 Notation and pictograms

The following notation and pictograms (symbols) are used in these Instructions:

10	Part or control
	**Danger/Warning** This symbol indicates a possible risk of death or injury to the user and possible damage to the instrument or its components by electric current.
	**Danger/Warning** This symbol indicates a possible risk of death or injury to the user and possible damage to the instrument or its components.
	**Attention** This symbol indicates important information that you should read before continuing.
	**Information** This symbol indicates additional information and tips which may be of particular use to you.

1.4 Safety information

1.4.1 Electrical safety

Electrical safety when handling the 853 CO_2 Suppressor is guaranteed within the scope of Standard IEC 1010-1 (protection class III, protection code IP20). The following points must be observed:

- **Mains connection**

*The **mains connection** must be made in accordance with the instructions given in Section 2.2.*

- **Opening the instrument**

The housing contains no components which could be set or adjusted by the user .

The instrument should only be opened by specialists from Metrohm. If the 853 CO_2 Suppressor is connected to the mains supply it should neither be opened nor should components be removed from it, as otherwise there is a risk of coming into contact with current-carrying components. Before opening the instrument always make sure that the plug has been pulled out!

- **Protection against electrostatic charges**

Electronic components are sensitive to electrostatic charges and can be destroyed by a discharge. Before you touch any electronic components of the 853 CO_2 Suppressor you should ground you and your tools by grasping a grounded object (e.g. the instrument housing or a radiator) in order to eliminate any electrostatic charges that may be present.

1.4.2 General safety rules

- **Solvent handling**

Check the pump tubing and inlet and outlet connections for leaks at regular intervals. Observe the relevant regulations when handling and disposing of flammable and/or toxic solutions.

2 Installation

2.1 Instrument setup

2.1.1 Packaging

The 853 CO_2 Suppressor and its separately packed accessories are supplied in very protective special packaging. Please store all this special packaging; it is the only way in which the safe transport of the instrument can be guaranteed.

2.1.2 Checks

Please check that the delivery is complete and undamaged immediately on receipt (compare with delivery note and list of accessories given in Section *5.2*). If transport damage is evident please refer to the information given in Section *5.5.1* "Warranty".

2.1.3 Arranging the instruments

Place the 853 CO_2 Suppressor next to the detector block in the Compact IC. With a modular system, place it in the Separation Center, likewise next to the detector block.

2.2 Mains connection

The 853 CO_2 Suppressor is provided with a 15 V power supply from an external power supply (6.2152.020).

1 Connection 853 – Power supply

- Connect the external power supply (6.2152.020) to the 15V connection "**15V DC**" of the 853 CO_2 Suppressor.

2 Mains connection

- Plug the mains cable into the connection on the external power supply (6.2152.020), and connect it to the mains supply (100-240 V).

Mains cable

The instrument is supplied with one of the following mains cables

- 6.2122.020 with SEV 12 plug (Switzerland, …)
- 6.2122.040 with CEE(7), VII plug (Germany, …)
- 6.2133.070 with NEMA 5-15 plug (USA, …)

which has three wires and is fitted with a plug with a grounding pin. If a different plug has to be used then the yellow/green wire (IEC standard) must be connected to the grounding pin (Protection class I).

Make sure that the power supply is always in a dry location. Protect it against direct contact with liquids.

2.3 Connection to the 861 Advanced Compact IC

The 853 CO_2 Suppressor is part of the version 2.861.0040 of the 861 Advanced Compact IC.

The electrical connections of the system, consisting of the 861 Advanced Compact IC and 853 CO_2 Suppressor, are shown in the following diagram:

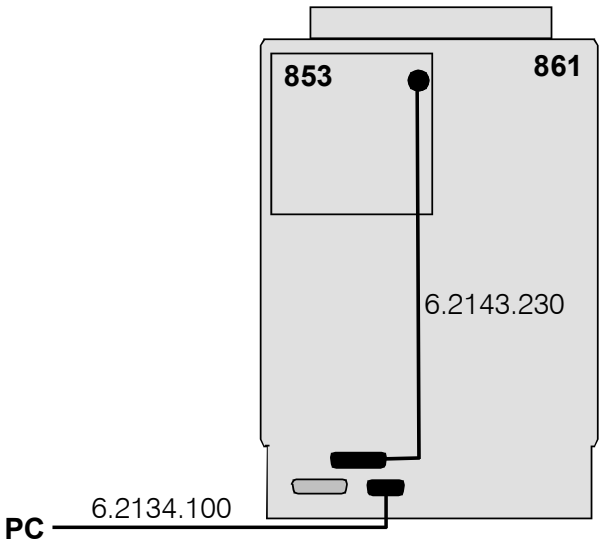


Figure 3: Connection between 853 CO_2 Suppressor and 861 Advanced Compact IC

The 853 CO_2 Suppressor can be controlled by the system driver of the 861 (Version 2.861.0040) in the PC program **«IC Net»** (from Version 2.3 SR2) (see *«IC Net» Instructions for Use, Section 6.27*).

2.4 Connection to 830 IC Interface

Connect an Event line of the 830 IC Interface to the remote interface **12** of the 853 CO_2 Suppressor using a cable 6.2128.180.

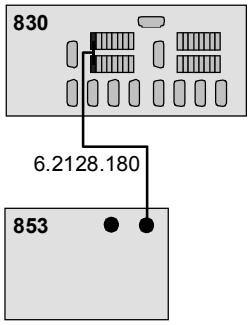


Figure 4: Connection between the 853 CO_2 Suppressor and 830 IC Interface

In the PC program **«IC Net»** the 853 CO_2 Suppressor does not have its own device driver. It can be controlled via the 830 IC Interface. This means that the 830 IC Interface must be included in your system and configured for controlling the 853 CO_2 Suppressor:

1 Open «IC Net» system

- In the PC program **«IC Net»** open the system in which the 830 IC Interface is to be included.

2 Include the 830 IC Interface in the system

- Use **Setup**/**New devices**/**Link to existing device** to select the 830 IC Interface (the 830 IC Interface must already have previously been added to the "Workplace", see *IC Net Instructions for Use, Section 5*). The device symbol for the 830 IC Interfaces is added to the system.

3 Open the "Events setup" tab

- Double-click on the device symbol of the 830 IC Interfaces to open its configuration menu and select the **Events setup** tab.

4 Set the control line for the 853 CO_2 Suppressor

- The value for the Event line used to control the 853 CO_2 Suppressor must be set to 1. In the example shown above this is Event Line 1, see *Figure 4*.

The 853 CO_2 Suppressor has now been included in your system and can be controlled by the PC program **«IC Net»**. It is started together with the other system hardware with **System**/**Control**/**Startup hardware** and closed down with **System**/**Control**/**Shutdown hardware**.

2.5 Connection of capillaries

The 853 CO_2 Suppressor is connected between the suppressor module «MSM II» and the detector block.

1 Suppressor module «MSM II» – 853 CO_2 Suppressor

- Connect the "Suppressor outlet capillary for eluent" (marked with "Detector") to the **"Eluent in"** inlet (**2**) of the 853 CO_2 Suppressor using a 6.2744.010 Pressure screw.

2 853 CO_2 Suppressor – Detector block

- Connect the "Inlet capillary to detector block" to the **"Eluent out"** outlet (**1**) of the 853 CO_2 Suppressor using a 6.2744.010 Pressure screw.

2.6 Cartridges

Effective CO_2 removal requires that the air pumped through the degassing cell should contain as little CO_2 as possible. This is achieved by drawing the air through a 6.2837.000 **CO_2 Absorber Cartridge**.

The **CO_2 Absorber Cartridge** can become blocked by moisture. This can be prevented by connecting a 6.2837.010 **H_2O Absorber Cartridge** in front of it.

The cartridges are installed as follows:

1 Remove caps

- Remove the sealing caps at the inlet and outlet of each cartridge.

2 Connect CO_2 Absorber Cartridge

- Insert the CO_2 Absorber Cartridge (3-layer filling, blue-brown-gray) in the coupling **9**.

3 Connect H_2O Cartridge – CO_2 Cartridge

- Insert the 6.1808.190 Adapter in the CO_2 Absorber Cartridge.
- Attach the 6.1801.140 PVC tubing to the 6.1808.190 Adapter.
- Insert the H_2O Absorber Cartridge (filled with orange drying beads) into the 6.1801.140 PVC tubing.

4 Attach the cartridges

- Attach the two cartridges to the left-hand mounting support of the 861 Advanced Compact IC or 820 IC Separation Center using two 6.2027.070 Holders.

3 Operation

3.1 General information

- The pump has two operating stages. The first stage is used to create the vacuum, the second stage to maintain it.
- The **Power** display lights up green when the pump is switched on.
- The **Status** display lights up orange when the pump is running and the pressure in the vacuum chamber is either too low or too high. After the pump has been switched on it takes a few seconds for the vacuum to become established.
- The **Ready** display lights up green when the pump is running and the pressure in the vacuum chamber is within the working range.

3.2 Control

The 853 CO_2 Suppressor is controlled by the PC program **«IC Net»**. It is not included in the software as a separate device driver, but is controlled from other devices via a Remote line.

3.2.1 Control via 861 Advanced Compact IC (2.861.0040)

The 853 CO_2 Suppressor is included in the device driver of Version 2.861.0040 of the 861 Advanced Compact IC. Detailed information is provided in the *«IC Net» Instructions for Use, Section 6.27*.

3.2.2 Control via 830 IC Interface

If the 853 CO_2 Suppressor is used together with a modular system then it can be controlled via a Remote line of the 830 IC Interface (see *Section 2.4*).

4 Troubleshooting - Problems

4.1 Remedying faults and problems

If difficulties occur during analyses with your IC system then it is best to search for their causes in the following sequence: **column → pump → eluent → IC system**. In the Instructions for Use of your Modular IC system or Compact IC you will find an overview of possible faults together with their causes and remedies.

In addition to these general problems, the following section covers those problems which could arise from the use of the 853 CO_2 Suppressor.

4.2 Chromatography problems

Problem	*Cause*	*Remedy*
Poor retention time reproducibility	• **Leak** in the instrument. • **Blockage** in flow path.	• Contact Metrohm Service. • Check the capillary connections and replace any compressed capillaries
Noisy or **unstable baseline**	• **Leak** in the instrument. • **Blockage** in flow path • CO_2 cartridge exhausted • Vacuum pump faulty	• Contact Metrohm Service. • Check the capillary connections and replace any compressed capillaries • Replace CO_2 cartridge (see Section *4.4.3*) • Contact Metrohm Service.
High **pressure** in the system	• **Pressure screws** tightened up too far. • A liquid-transporting component in the device is **blocked**.	• Loosen pressure screws slightly or replace connection (cut new capillary end) • Contact Metrohm Service.
Poor peak shape	• **Dead volume** in system	• Check capillaries

4.3 Instrument problems

Problem	*Cause*	*Remedy*
LED "Power" (**1**) does not light up when instrument is switched on.	• **Power supply** not connected	• Connect the 853 CO_2 Suppressor to the mains supply via the external power supply (see *Section 2.2*)
	• **6.2152.020 Power supply** faulty or **electronics** fault in 853 CO_2 Suppressor	• Contact Metrohm Service.
Neither **LED "Status"** (**2**) nor **LED "Ready"** (**3**) lights up when instrument is switched on (**LED "Power"** (**1**) lights up).	• **LED**s faulty	• Contact Metrohm Service.
Vacuum out of working range. **LED "Ready"** (**3**) does not light up after instrument has been switched on for at least 30 s.	• **Leak** in system (vacuum too weak)	• Contact Metrohm Service.
	• **H_2O Absorber Cartridge** blocked (vacuum too strong).	• Regenerate the **H_2O Absorber Cartridge** (see *Section 4.4.4* or 8.108.1046 Leaflet)

4.4 Care and maintenance

4.4.1 Care

The 853 CO_2 Suppressor requires adequate care. If it becomes excessively dirty then this could interfere with its functions and shorten the working life of its robust mechanism and electronics.

Spilt chemicals and solvents must be wiped up immediately. The electrical connections on the rear panel of the instrument (the mains connection in particular) should be protected against contamination.

Although constructive measures to a large extent prevent liquid penetration, if aggressive media should nevertheless penetrate the interior of the instrument then the mains plug of the external 6.2152.020 Power supply should be pulled out immediately to prevent serious damage to electronic components. If such damage should occur please contact Metrohm Service.

The instrument should only be opened by specialists from Metrohm.

4.4.2 Maintenance by Metrohm Service

It is advisable to carry out the maintenance of the 853 CO_2 Suppressor within the framework of an annual service visit by trained Metrohm technicians. If aggressive and corrosive chemicals are used then it may be necessary to reduce the service intervals.

The Metrohm Service Department will be pleased to provide you with competent advice about the care and maintenance of all Metrohm instruments at any time.

4.4.3 CO_2 Absorber Cartridge replacement

The 6.2837.000 CO_2 Absorber Cartridge requires replacement at regular intervals because of blockages or exhaustion.

Blockages

Moisture will block the CO_2 Absorber Cartridge. This is indicated by the cartridge material changing color (the blue layer turns violet). The air flow is reduced and the vacuum becomes too low – instead of the "**Ready**" LED (**3**) the "**Status**" LED (**2**) lights up. In order to protect the CO_2 Absorber Cartridge an H_2O Absorber Cartridge is included upstream from it. Regular regeneration (see *Section 4.4.4*) of the H_2O Absorber Cartridge increases the working life of the CO_2 Absorber Cartridge.

Exhaustion

The absorption capacity of the CO_2 Absorber Cartridge is limited. Depending on the working life and the laboratory surroundings the absorption capacity decreases with time. This is indicated by a rising baseline (as more CO_2 reaches the detector).

4.4.4 H_2O Absorber Cartridge regeneration

The purpose of the H_2O Absorber Cartridge is to protect the CO_2 Absorber Cartridge from moisture. The lifespan of the H_2O Absorber Cartridge depends on the humidity of the ambient air. Humidity exhausts the H_2O Absorber Cartridge. Exhaustion is indicated by a color change: before the color of the whole of the filling material has changed (from orange to colorless) the H_2O Absorber Cartridge must be regenerated (see 8.108.1046 Leaflet). Regeneration consists of replacing the filling material:

1. Heat the loose material (i.e. not in the cartridge) at 140 °C overnight and then refill it, or dispose of the old material and refill the cartridge with new material (Fluka # 94098).
2. Cover the packed material with absorbent cotton.

5 Appendix

5.1 Technical data

Provided that nothing to the contrary is mentioned, the published data represents typical values for the 853 CO_2 Suppressor at an ambient temperature of 25°C.

Vacuum

Pressure range	< 65 mm Hg
Establishment time after start	< 30 s

Flow range

Recommeded flow range	0.1…1.0 mL

Degassing capillary in 853 CO_2 Suppressor

Material	Teflon AF
Solvent resistance	Very good resistance to most solvents (exception: PFCs)

Ambient temperature

Nominal working range	+5...+45 °C (at max. 85% rel. humidity)
Storage	-40...+70 °C
Transport	-40...+70 °C

Power supply

Voltage	100...240 V (± 10%)
Frequency	50 / 60 Hz
Power consumption	15 W
Fuses	Overload protection

Safety specifications

Construction / Testing	EN/IEC/UL 61010-1, CSA-C22.2 No. 61010-1, Protection code IP20, Protection class III
Safety information	These Instructions for Use contain information and warnings that must be observed by the user in order to ensure the safe operation of the instrument.

Electromagnetic compatibility (EMC)

Emitted interference	Standards met: - EN/IEC 61326 - EN 55022 - CISPR 22
Immunity to interference	Standards met: - EN/IEC 61326 - EN/IEC 61000-4-2 - EN/IEC 61000-4-3 - EN/IEC 61000-4-4 - EN/IEC 61000-4-5 - EN/IEC 61000-4-6 - EN/IEC 61000-4-11 - EN/IEC 61000-4-14

Housing

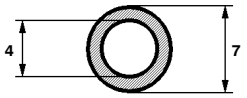
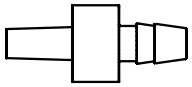
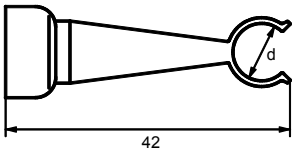
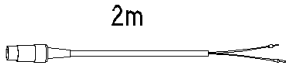
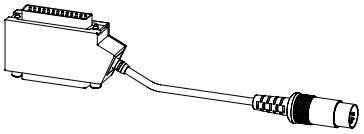
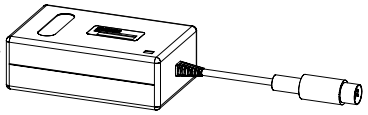
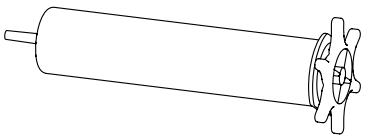
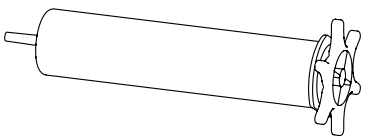
Housing material	Steel sheet, enameled
Width	130 mm
Height	120 mm
Depth	150 mm
Weight	
Device	2.2 kg
Power Supply	280 g

5.2 Standard equipment

Subject to changes!
All dimensions are given in mm.

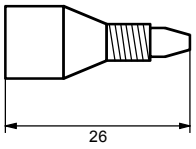
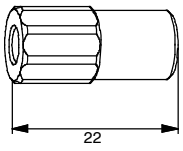
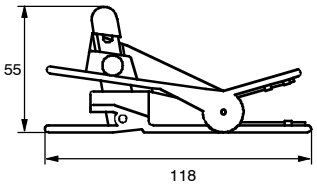
5.2.1 2.853.0010 CO_2 Suppressor

The 2.853.0010 CO_2 Suppressor includes the following accessories:

Number	Order no.	Description
1	1.853.0010	**CO_2 Suppressor**
1	6.1801.140	**PVC tubing** For connecting the CO_2 Absorber Cartridge and H_2O Absorber Cartridge. L = 110 mm, d1 = 4 mm, d2 = 7 mm 
1	6.1808.190	**Adapter tubing nozzle/Luer** For connecting the CO_2 Absorber Cartridge and H_2O Absorber Cartridge 
1	6.2027.070	**Cartridge holder** Holder for the CO_2/H_2O Absorber Cartridges, diameter d = 25.0 mm, 2 pieces 
1	6.2128.180	**Remote connection cable** Connection cable 830 IC Interface – 853 CO_2 Suppressor. 
1	6.2143.230	**Connection cable 861/761-853** 
1	6.2152.020	**Power supply** External power supply for electricity supply to 853 (100-240V / 15V). 
1	6.2837.000	**CO_2 Absorber Cartridge** 
2	6.2837.010	**H_2O Absorber Cartridge** One as spare while the other is being regenerated. 

Number	Order no.	Description
1	**8.853.8001 EN**	**Instructions for Use (English)** for 853 CO_2 Suppressor

5.3 Optional accessories

Order no.	Description	
6.2744.014	**PEEK pressure screw** Spare part. For connecting the CO_2 Absorber Cartridge.	
6.2744.120	**Coupling 1/16" – Luer** Spare part. Connection piece between 6.2744.010 PEEK pressure screw and CO_2 Absorber Cartridge.	
6.2621.080	**Capillary cutter for plastic capillaries** With 5 spare blades	

5.4 Validation / GLP

GLP (**G**ood **L**aboratory **P**ractice) requires, among other things, that the precision and correctness of analytical instruments is checked at regular intervals by using SOPs (**S**tandard **O**perating **P**rocedures, **SOP**). An example of such a standard operating procedure is available from Metrohm under the title **«Application Bulletin No. 277 – Validation of Metrohm Ion Chromatography Systems by using Standard Operating Procedures (SOP)»**. This SOP can be adapted for your ion chromatography system and used for its validation.

The 853 CO_2 Suppressor must be included as a part of the whole ion chromatography system, whose most important components include the pumps, separation columns, detector and evaluation system, in the all-embracing validation of the whole system.

Please contact your local Metrohm agency in order to receive support in validating your 853 CO_2 Suppressor. It can also provide you with validation documentation which will help you to carry out your installation qualification (IQ) and operational qualification (OQ).

Further information about QA, GLP and validation can also be found in the brochure «**Quality management with Metrohm**» which is also obtainable from your local Metrohm agency.

Checking the electronic and mechanical assemblies of Metrohm instruments can and should be undertaken within the framework of regular servicing by Metrohm technicians.

5.5 Warranty and Conformity

5.5.1 Warranty

The warranty on our products is limited to defects that are traceable to material, construction or manufacturing error which occur within 12 months from the day of delivery. In this case, the defects will be rectified in our workshops free of charge. Transport costs are to be paid by the customer.

For day and night operation, the warranty is limited to 6 months.

Glass breakage in the case of electrodes or other parts is not covered by the warranty. Checks which are not a result of material or manufacturing faults are also charged during the warranty period. For parts of outside manufacture insofar as these constitute an appreciable part of our instrument, the warranty stipulations of the manufacturer in question apply.

With the regard to the guarantee of accuracy, the technical specifications in the instruction manual are authoritative.

Concerning defects in material, construction or design as well as the absence of guaranteed features, the orderer has no rights or claims except those mentioned above.

If damage of the packaging is evident on receipt of a consignment or if the goods show signs of transport damage after unpacking, the carrier must be informed immediately and a written damage report demanded. lack of an official damage report releases Metrohm from any liability to pay compensation.

If any instruments and parts have to be returned, the original packaging should be used if at all possible. This applies above all to instruments, electrodes, burette cylinders and PTFE pistons. Before embedment in wood shavings or similar material, the parts must be packed in a dust-proof package (for instruments, use of a plastic bag is imperative). If open assemblies are enclosed in the scope of delivery that are sensitive to electromagnetic voltages (e.g. data interfaces etc.) these must be returned in the associated original protective packaging (e.g. conductive protective bag). (Exception: assemblies with built-in voltage source belong in a non-conductive protective packaging).

No warranty responsibility whatsoever will be accepted by Metrohm for damage which arises as a result of non-compliance with these instructions.

5.5.2 Declaration of Conformity

This is to certify the conformity to the standard specifications for electrical appliances and accessories, as well as to the standard specifications for security and to system validation issued by the manufacturing company.

Metrohm
Ion analysis
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Name of commodity	**853 CO_2 Suppressor**
Name of manufacturer	Metrohm Ltd., Herisau, Switzerland

Description The 853 CO_2 Suppressor is a device to remove CO_2. It is connected between suppressor module «MSM II» and detector.

This instrument has been built and has undergone final type testing according to the standards:

Electromagnetic compatibility: Emission
EN/IEC 61326, EN 55022 / CISPR 22

Electromagnetic compatibility: Immunity
EN/IEC 61326, EN/IEC 61000-4-2, EN/IEC 61000-4-3, EN/IEC 61000-4-4, EN/IEC 61000-4-5, EN/IEC 61000-4-6, EN/IEC 61000-4-8, EN/IEC 61000-4-11, EN/IEC 61000-4-14, Namur

Safety specifications
EN/IEC/UL 61010-1, EN/IEC 61010-2-081, CSA-C22.2 No. 61010-1

It has also been certified by ElectroSuisse, which is member of the International Certification Body (CB/IEC).

CE *The instrument meets the requirements of the CE mark as contained in the EU directives 89/336/EEC and 73/23/EEC and fulfils the following specifications:*

EN 61326 Electrical equipment for measurement, control and laboratory use – EMC requirements

EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use

Metrohm Ltd. is holder of the SQS-certificate of the quality system ISO 9001 for quality assurance in design/development, production, installation and servicing.

The system software, stored in Read Only Memories (ROMs) has been validated in connection with standard operating procedures in respect to functionality and performance.

The technical specifications are documented in the instruction manual.

Herisau, April 1, 2005

D. Strohm Vice President Head of R&D	Ch. Buchmann Vice President Head of Production Responsible for Quality Assurance

5.5.3 Quality Management Principles

Metrohm Ltd., CH-9101 Herisau, Switzerland

Metrohm
ion analysis
CH-9101 Herisau/Switzerland
E-Mail info@metrohm.com
Internet www.metrohm.com

Metrohm Ltd. holds the ISO 9001 Certificate, registration number 10872-02, issued by SQS (Swiss Association for Quality and Management Systems). Internal and external audits are carried out periodically to assure that the standards defined by Metrohm's QM Manual are maintained.

The steps involved in the design, manufacture and servicing of instruments are fully documented and the resulting reports are archived for ten years. The development of software for PCs and instruments is also duly documented and the documents and source codes are archived. Both remain the possession of Metrohm. A non-disclosure agreement may be asked to be provided by those requiring access to them.

The implementation of the ISO 9001 quality system is described in Metrohm's QM Manual, which comprises detailed instructions on the following fields of activity:

Instrument development

The organization of the instrument design, its planning and the intermediate controls are fully documented and traceable. Laboratory testing accompanies all phases of instrument development.

Software development

Software development occurs in terms of the software life cycle. Tests are performed to detect programming errors and to assess the program's functionality in a laboratory environment.

Components

All components used in the Metrohm instruments have to satisfy the quality standards that are defined and implemented for our products. Suppliers of components are audited by Metrohm as the need arises.

Manufacture

The measures put into practice in the production of our instruments guarantee a constant quality standard. Production planning and manufacturing procedures, maintenance of production means and testing of components, intermediate and finished products are prescribed.

Customer support and service

Customer support involves all phases of instrument acquisition and use by the customer, i.e. consulting to define the adequate equipment for the analytical problem at hand, delivery of the equipment, user manuals, training, after-sales service and processing of customer complaints. The Metrohm service organization is equipped to support customers in implementing standards such as GLP, GMP, ISO 900X, in performing Operational Qualification and Performance Verification of the system components or in carrying out the System Validation for the quantitative determination of a substance in a given matrix.

5.5.4 Index

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