

**Reprocessing of flexible endoscopes
and endoscopic accessories.**



FUJIFILM
Value from Innovation

For perfect hygiene in endoscopy.

As one of the leading manufacturers of flexible endoscopes, we are very conscious of our responsibility towards you and your patients. For this reason we would like to support you in all the important aspects regarding the perfect reprocessing of endoscopes and endoscopic accessories.

Hygiene is the number one priority in hospitals and doctors' practices. It provides protection against the transmission of germs and prevents infections in patients, doctors and nursing staff. With this brochure, Fujifilm provides you with a useful guide to the simple and reliable cleaning and disinfecting of your endoscope, making your everyday working life easier.

The hygiene brochure is divided chronologically. It takes you step by step through the individual procedures: from preliminary cleaning through to final rinsing. Each individual action is therefore easy to understand, using photographs for illustration. In addition, the brochure provides you with important product summaries and helpful practical tips.

It goes without saying that all the procedures described here comply with the guidelines of the Robert Koch Institute (RKI) entitled "Hygiene requirements in the reprocessing of flexible endoscopes and additional endoscopic equipment". Together with the high-quality products from Fujifilm, you can thus ensure the optimum conditions for reliable diagnoses and treatments.

Manual reprocess	3-8
Machine reprocess	9-10
Reprocess and sterilisation of the accessories	11
Current cleaning brushes and adapters	12-13
General information for reprocess	14

Manual reprocess

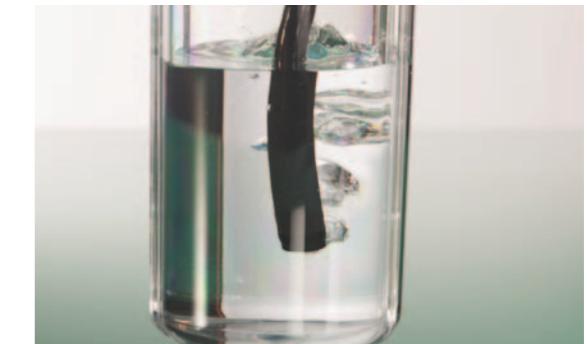
1. Step: Preliminary cleaning

1.1 The preliminary cleaning is carried out immediately following the examination.

1.2 Wipe the outer surface of the endoscope with a disposable cloth or damp compress (cleaning solution).



- Activate the air/water valve and pay attention to the escaping jet of water and bubbles.



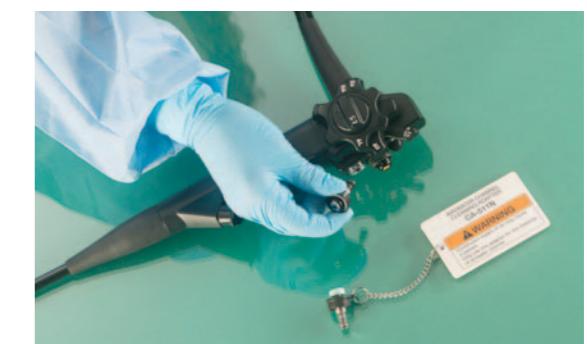
1.3 Hold the distal end of the endoscope in a container with cleaning solution.

1.4 Thoroughly rinse the channels:

- Activate the suction valve until the solution is clear.
- Alternate drawing in cleaning solution and air.



Stop the air insufflation at the processor and replace the air-water-valve to the bedside cleaning valve CA-511N. Switch on the air insufflation again and activate this valve.



⚠ With the duodenoscope and ultrasound endoscope with Albaran lever, the lever must be moved several times during preliminary cleaning.

1.5 Take the distal end out of the cleaning solution and thoroughly suction the channels.

- Suction the outlet channel with air until empty.
- Separate the water tank from the endoscope.
- Place a finger on the water tank attachment and activate the air/water valve until the flow of water stops.
- Disconnect the device from the processor/light source with a cloth.

Manual reprocess

- 1.6 Attach the protective cap for electronic plugs with video endoscopes.



- 1.7 Place the endoscope in a closed transporting bowl.

⚠ Take care that the effect of heat from the optical light-guide connector will not damage the endoscope!

- 1.8 Take the endoscope to the reprocess room.



Contaminated endoscope

2. Step: Leak test

- 2.1 Remove all valves (air/water and suction valves, as well as the distal cap and jet channel closing cap) and place in the solution. The disposable biopsy valve must be properly disposed of after each use.



- 2.2 Check all adapter, adapter points and tube of the leak tester. Make sure, that all is moisturefree.



- 2.3 Connect the leak tester, pump up to 150mmHg or 20kPa for 60 seconds and watch out a pressure decrease, while activating the bending wheels.

- 2.4 If the pressure decreases within 60 seconds, the endoscope doesn't pass the leak test.

⚠ If it is clear there is perforation, do not proceed further with reprocessing the endoscope.

- 2.5 Wipe the outer surface with disinfecting solution. Wrap the endoscope in a protective foil cover, pack in the despatch case, mark with „leaking, not disinfected“ and a description of the fault and send to the maintenance and repair shop.

⚠ After repair, carry out a leak test and clean and disinfect the endoscope.

3. Step: Manual cleaning with a brush

- 3.1 Wear disposable coats, disposable gloves, safety glasses and carry out all cleaning procedures under the surface of the detergent.



- 3.2 Clean the surface of the endoscope with a lint-free cloth.



Manual reprocess

- 3.3 Using the cleaning set (choose the right set according to page 13), fill all channels with cleaning solution, bubblefree!



CA-503A / CA-01T / WA-501 / AJ-500L



CA-503A

- 3.4 Activate air/water valves and suction valves while cleaning with a soft teeth brush. Optional use an ultrasonic bath afterwards.

⚠ Use cleaningsets according to instructions.

- 3.5 In the case of duodenoscopes, move the Albaran lever to the middle position and clean from all sides with a suitable brush. In case of the G8 duodenoscopes, the air/water channel can also be cleaned with a brush, the WA-501 (guide for the cleaning brush) is needed for this.



- 3.6 Clean all openings (valves-openings, forceps-channel-opening and suction connector) with a short suitable valve-brush. Clean all brushable endoscopic channels with the suitable endoscope brush at the minimum three times or until the brushes can be pushed through free of contaminants.



- 3.7 In the case of channels which are not be cleaned with brushes, e.g. the air/water channel, jet channel, balloon air feed channel with the double balloon endoscope (DBE) and balloon water feed channel with the ultrasound endoscope EG-530UR, connect to device-specific adapters and rinse thoroughly with solution. The CJ-500 is the cleaning adapter for the jet channel with the G5 endoscopes and the balloon water feed channel with the ultrasound endoscopes. The CA-300N and CA-500N are cleaning adapters for the air/water channel.

⚠ In case of the G8 duodenoscopes, the air/water channel can also be cleaned with a brush. With the EG-530UT ultrasound endoscope, the balloon water feed channel can also be cleaned with a brush.

⚠ Steps 1 to 3 are identical with manual, semi-automatic machine and machine reprocess.

4. Step: Intermediate rinsing

- 4.1 Place the endoscope and valves in a basin with microbiologically clean drinking water or sterile water in order to remove residues of chemicals, blood, protein and medication.

- 4.2 Using the suitable cleaning set, thoroughly rinse all channels and then remove all remaining water with air. Always rinse separately the jet channel and balloon air feed channel and balloon water feed channel and likewise remove remaining water.

5. Step: Disinfection

- 5.1 Place the cleaned endoscope and valves in the disinfection solution. Connect the suitable cleaning set and fill until there are no bubbles coming out of the channels.

- 5.2 Connect the jet channel and air and water supply channels to device specific adapters and fill with disinfection fluid with syringes until there are no bubbles coming out. Use the CJ-500 or AJ-500L cleaning adapter for the jet channel and the balloon water feed channel. In the case of the duo-denosope and ultrasound endoscope move the Albaran lever to the middle position.



Suction/entry supports and distal end (red coding)

- 5.3 Ensure concentration and residence time complies with the manufacturer's instructions.

- 5.4 For reasons of personal safety, close the bowl tightly with the cover.

- 5.5 At the end of the disinfection time, fill the channels with air to remove the disinfectant.

- 5.6 Using new disposable gloves, remove the endoscope from the disinfectant solution.

6. Step: Final rinsing

- 6.1 Place the endoscope and valves in a disinfected bowl with microbiologically clean drinking water or sterile water.

⚠ Fresh water should be used for each device.

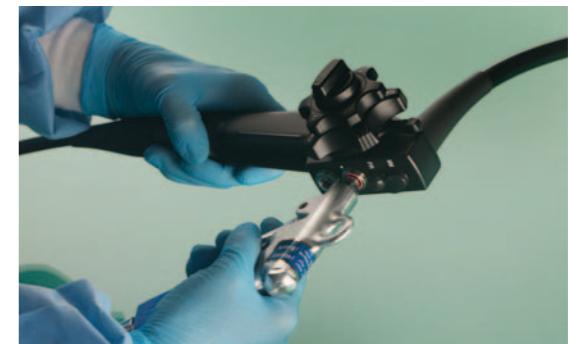
- 6.2 Rinse out the outer endoscope surface and valves.

- 6.3 Thoroughly rinse all the channels with the suitable cleaning set and device-specific adapters or a water gun with sterile filter.

7. Step: Drying and storage

- 7.1 Remove the endoscope and valves with disinfected hands or wearing new disposable gloves.

- 7.2 With a lint-free cloth, remove any water remaining on endoscope surface, operating section and valves.



7.3 Air the electrical contacts and channels with a compressed air gun or, using a connector set, connect the endoscope to a compressor for approx. 20 minutes (maximum pressure 0.7 bar).

⚠ The following is important with the double balloon endoscope: the water in the balloon air feed channel must be completely removed because this channel must be completely dry.



7.4 The preferred method of storing the endoscope is hanging up in a special endoscope cabinet in a dry environment protected from dust and with suitable fasteners.



7.5 During storage of the endoscope, the valves and protective cap for the electronic plug must be removed and stored separately.

7.6 Double balloon endoscopes should be perfectly stored in a smooth s-shape with suitable holders, so that the distal end doesn't rest on the ground, and residual moisture can dry completely.

7.7 In case of using a drying cabinet, make sure that all adaptors are connected in the right way.

8. Step: Reprocessing of work materials

- 8.1 The date the disinfectant solution was prepared must be documented.
- 8.2 Label on the bowl: date, concentration, residence time, service life of the disinfectant solution.
- 8.3 The disinfectant solution must be replaced in accordance with the manufacturer's instructions.
- 8.4 Ensure concentration and residence time comply with the manufacturer's instructions.
- 8.5 When replacing the cleaning solution (manual cleaning with a brush), the bowl must be thoroughly cleaned and disinfected mechanically.
- 8.6 Used brushes must be cleaned in an ultrasound bath, rinsed, disinfected, final rinsed and dried after each use.
- 8.7 The use of disposable brushes is recommended.
- 8.8 See page 11 for reprocess of accessories.

Machine reprocess

⚠ The following steps must also be carried out in advance of machine reprocess in an AWD (Automatic Washer Disinfector for endoscopes):

1. Step: Preliminary cleaning

2. Step: Leak test

3. Step: Manual cleaning with a brush

Steps 1 to 3 are identical with manual reprocess. See pages 3 to 6.

4. Step: Intermediate rinsing/rinsing of the cleaning solution

4.1 Place the endoscope and valves in a basin with microbiologically clean drinking water or sterile water in order to remove residues of chemicals, blood, protein and medication.

4.2 Rinse all channels using the suitable cleaning set or with a water gun.

⚠ Please note that in accordance with AWD manufacturer instructions the intermediate rinsing can be replaced by the machine preliminary cleaning phase.

⚠ Caution: insufficient intermediate rinsing can cause interactions when at the same time using aldehyde-free chemicals in the preliminary cleaning/manual cleaning with a brush steps and chemicals containing aldehyde in the machine.

5. Step: Disinfection

5.1 In accordance with the machine manufacturer's instructions, place the cleaned endoscope and valves in the Automatic Washer Disinfector for endoscopes (AWD).

5.2 Connect the appropriate connector set and leak tester.

⚠ Please make sure that all connecting points are moisturefree before connecting the leak tester.



5.3 Select the appropriate programme, preferably the standard programme.

5.4 Start the programme.



6. Step: Drying and storage

- 6.1 Remove the endoscope and valves from the AWD with disinfected hands or wearing new disposable gloves.
- 6.2 With a lint-free cloth, remove any water remaining on the outer surface, actuator and valves.



- 6.3 Air the electrical contacts and channels with a compressed air gun or, using a connector set, connect the endoscope to a compressor for approx. 20 minutes (maximum pressure 0.7 bar).



7. Step: Reprocess of work materials

- 7.1 A self-disinfecting cycle is recommended before using the AWD each day.
- 7.2 The containers for the cleaning and disinfecting agents must be marked with the date of opening.
- 7.3 Replace the water filters and air filters in accordance with the manufacturer's instructions.
- 7.4 Carry out a disinfecting and decalcification cycle for the AWD in accordance with the manufacturer's instructions.
- 7.5 When replacing the cleaning solution (manual cleaning with a brush), the bowl must be thoroughly cleaned and mechanically disinfected.
- 7.6 Used brushes must be cleaned in an ultrasound bath, rinsed, disinfected, rinsed and dried after each use.
- 7.7 Only disinfect accessories (biopsy forceps, brushes etc.) in the AWD in accordance with the manufacturer's instructions.
- 7.8 Accessories decontamination page 11.

- 6.4 The preferred method of storing the endoscope is hanging up in a special endoscope cabinet in a dry environment protected from dust and with suitable fasteners.



- 6.5 During storage of the endoscope, the valves and protective cap for the electronic plug must be removed and stored separately.

- 6.6 Double balloon endoscopes should be perfectly stored in a smooth s-shape with suitable holders, to ensure the run-off of the residual moisture.

Reprocess of accessories

Manual reprocessing steps for multi-use medical appliances such as biopsy forceps, polypectomy slings, papillotome/ERCP catheters, foreign body alligator forceps, water tank etc.

1. Step: Cleaning

- 1.1 Clean accessories with soft cloth/brush, disassemble, and use a non-foaming cleaning solution. Change the solution daily or more frequently if visibly contaminated. Clean all cavities and channels under water.

- 1.2 Cleaning the water tank WT-2 and WT-4.



WT-4

2. Step: Ultrasound bath

- 2.1 The ultrasound bath should be sufficiently large and deep to ensure complete immersion. Avoid dead space and do not overload.

- 2.2 A cleaning solution and a temperature of approx. 30°C should be used in the ultrasound bath (residence time: 5-10 minutes). At higher temperatures there is the risk of protein coagulation/protein fixing.

- 2.3 Fix the biopsy forceps and polypectomy slings with a clip in accordance with the manufacturer's instructions and in addition hold open the branch of the biopsy forceps with another clip. When rolled up the instruments should not exceed a diameter of approx. 30 cm. Fill all the channels and cavities with solution.

- 2.4 Clean for 5-15 minutes at 40 kHz in the ultrasound bath.

⚠ Comply with the manufacturer's instructions.

3. Step: Rinsing

- 3.1 Rinse all channels and cavities with water and blow through with a compressed air gun.

4. Step: Disinfection

- 4.1 Disinfection options for the accessories in accordance with RKI guidelines:
 - chemically with a virucidal product
 - thermo-chemically in the AWD with a virucidal product at a temperature of 35°C - 59°C
 - thermally in the AWD (Automatic Washer Disinfector) with an A0 value of 3000, i.e. at 90°C and a residence time of 5 minutes.

5. Step: Neutralisation

- 5.1 Neutralisation/clear rinsing to remove residues of the disinfecting agent.

6. Step: Drying

- 6.1 Drying of all channels with compressed air gun and functional test.

7. Step: Sterilisation

- 7.1 Steam sterilisation

- 7.2 Sterilisation in sterile goods packaging in a class B autoclave with fractionated pre-vacuum process.

- 7.3 Dwell time:

- Gentle programme 15 minutes at 121°C and 1 bar (just for FTS accessories).
- Universal programme 5 minutes at 134°C and 2 bar.
- Prion programme 60 minutes at 134°C and 2 bar.

⚠ Comply with the manufacturer's instructions.

8. Step: Storage

- 8.1 Store dry, in the dark and with air circulation.

9. Step: Function test

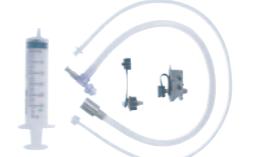
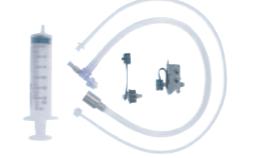
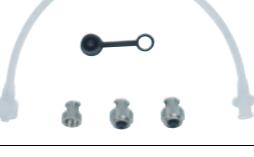
- 9.1 Test the function again before using with a patient.
- 9.2 If the accessories haven't been in use for a longer time, a new disinfection cycle must be carried out.

Cleaning brushes and Adapters

Cleaning brushes

Item Number	Type	Description
Reusable brushes		
1 F5RDPK1950230F		Double cleaning brush for channels with a diameter from 2.3 mm Colonoscope
2 F5RKP1950230F		Cleaning brush for channels with a diameter from 2.3 mm Colonoscope
3 F5RDPK1950180F		Double cleaning brush for channels with a diameter from 2.3 mm Gastroscope/duodenoscope
4 F5RKP1950180F		Cleaning brush for channels with a diameter from 2.3 mm Gastroscope/duodenoscope
5 F5RDPK1630120F F5RDPK1630180F F5RDPK1630230F	 	Double cleaning brush for channels with a diameter up to 2.2 mm Length: 120/180/230 cm Endoscopes with thin diameter
6 F5RKP1630120F F5RKP1630180F F5RKP1630230F		Cleaning brush for channels with a diameter up to 2.2 mm Length: 120/180/230 cm Endoscopes with thin diameter
7 F5RKP1020180F F5RKP1020230F		Cleaning brush for channels with a diameter up to 1.2 mm Length: 180/230 cm ED-450XT8, ED-530XT8, EG-530UT, UT2, UR2
8 F5VDPK0812007		Double valve cleaning brush Valve brush for suction and air/water valves and valve supports in series G5/G8
9 F5VPKP1245012		Valve brush Valve brush for suction and air/water valve supports in series type 3 and G5/G8
10 F5VPKP1620013		Valve brush Valve brush for biopsy channel inlet supports in series type 3
Disposable brushes		
11 KTE-004		Brush set Channels with a diameter from 1.8 mm up to 2.2 mm
12 DEC-18250	 	Double cleaning brush Channels with a diameter from 2.8 mm up to 4.2 mm
13 BNO-18230		Cleaning brush Channels with a diameter from 2.8 mm up to 4.2 mm
14 DEC-17250	 	Double cleaning brush Channels with a diameter from 2.0 mm up to 2.6 mm
15 BLP-10040		Valve brush All endoscopes
16 BNO-17100		Cleaning brush Channels with a diameter from 2.0 mm up to 2.6 mm

Adapters

Item Number	Type	Description
17 CA-503A		Channel cleaning set (incl. adapter CA-503B/C, CA-503S/A, CA-503W/T) Manual reprocess for series type 3/G5/G8
18 CA-500B		Channel cleaning set (incl. adapter 68A1042092) Manual reprocess for bronchoscopes EB-470, EB-270 and FB-120S/T/P
19 CA-500C		Channel cleaning set (incl. adapter 68A12238750) Manual reprocess for bronchoscopes EB-450, EB-250 and EB-530
20 CA-500D		Channel cleaning set (incl. adapter 2x CA-503B/C, 1x CA-503S/A, 1x CA-503W/T) Manual reprocess for series G5/G8 double-channel endoscopes
21 CA-601		Channel cleaning set (incl. adapter WA-005, CA-503B/C, CA-503W/T) Manual reprocess for EG-530UT2 and UR2
22 CA-300N/CA-500N		Cleaning adapter Series type 3 and series G5/G8 air/water channel
23 CA-511N		Flushing valve Series G5/G8 air/water channel
24 WA-501		Guide for cleaning brush Air/water channel
25 CA-01T		Cleaning adapter For WT-2, WT-4 and for water tank WT-01G
26 CJ-500		Cleaning adapter Series G5/G8 jet channel
27 AJ-500		Adapter with return valve Series G5/G8 jet channel
28 AJ-500L		Cleaning adapter Series G5/G8 jet channel
29 JET-500		Jet channel adapter set Series G5/G8 jet channel

Cleaning brushes and Adapters

General information regarding reprocess

The market for the reprocess of endoscopes provides a number of semi-automatic machine solutions in addition to machine solutions. However, to list each individual process at this point would go beyond the scope of this brochure. Fujifilm would be happy to provide you with comprehensive and individually-tailored advice.

Various products have proved their worth for cleaning and disinfection. Please obtain from your chemicals manufacturer the corresponding product liability declaration.

In general, products based on different active ingredients are not to be used in a reprocess cycle. This is because insufficient intermediate rinsing can result in chemical reactions such as discolouration of the outer surface or to closure of the endoscope channels.

Frequently changing the active ingredient can also have a disadvantageous effect on material compatibility. Increased wear and tear of the materials would be the result.

When changing chemicals from aldehyde to aldehyde-free products, or vice versa, ensure there is a sufficient cleaning and rinsing phase of 1-3 hours.

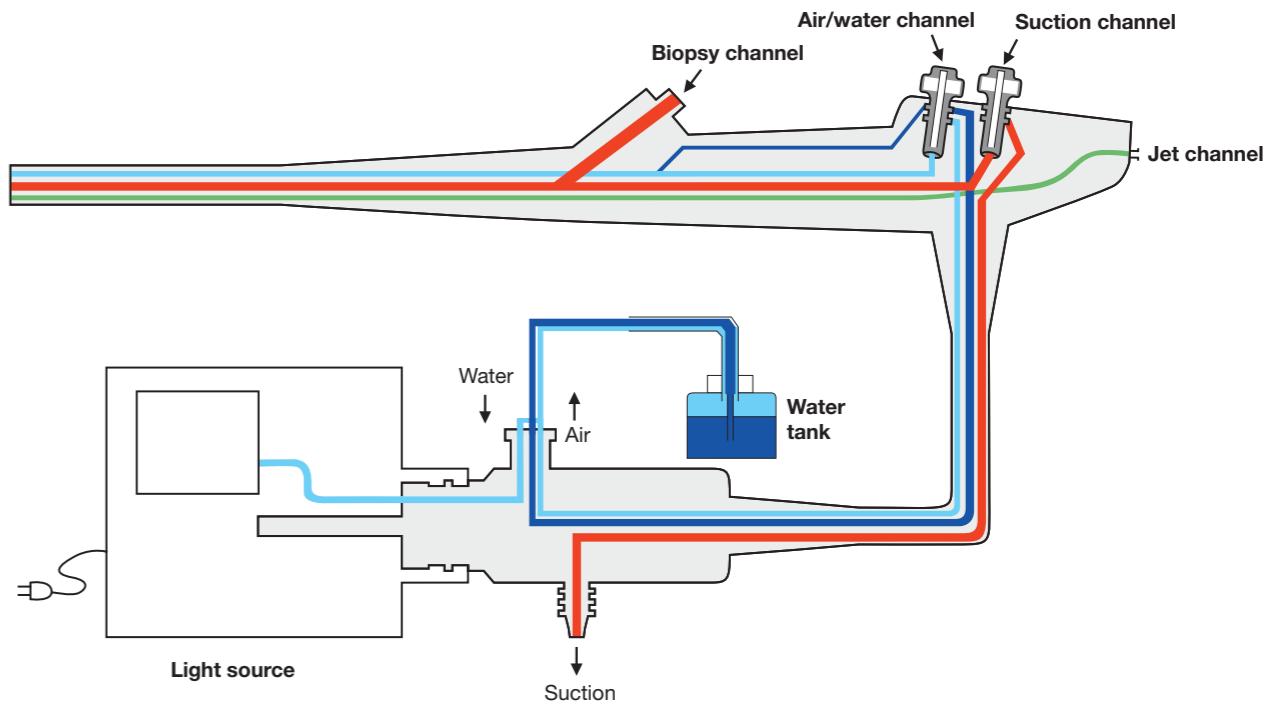
Compatible products create optimum conditions for manual and machine reprocess. The ideal situation would be that all products come from one manufacturer, i.e. products for preliminary cleaning in the examination room, manual cleaning of brushes, manual and machine disinfection of the endoscopes and also in the ultrasound bath for the accessories.

Examples:

- For manual preliminary cleaning/brush cleaning, use an aldehyde-free product, for example glucoprotamine. For manual/machine disinfection, use a product based on glutaraldehyde. Result: insufficient intermediate rinsing can lead to chemical reactions.
- In the ultrasound bath, use an aldehyde-free product to clean and disinfect and in the AWD use glutaraldehyde. If the different solutions enter the same escape tube at the same time, this can lead to chemical reactions and to closure of this escape tube.

Reprocess of flexible endoscopes in practice

Series G5/G8 channel diagram



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