

OPERATING MANUAL
PHARMA TEST Suppository Disintegration Tester
Typ: PTS 3E



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1. Suppository Disintegration Testing

Several international pharmacopoeias describe disintegration testing of suppositories, like the European Pharmacopoeia EP5.x, BP etc.

A sample is placed into a perforated basket assembly and a container. A suitable water bath having a minimum volume of 4 ltr. For each sample is heated up to 37°C, the samples are immersed into the bath and turned for 180° each 10 minutes. A sample is disintegrated if no solid rest is left within the basket. A test of three samples is recommended and should be done preferably in one instrument.

The PTS-3 allows the test of 3 samples at the same time under constant conditions. The instrument is equipped with a adjustable thermostat to heat the water of the bath within a range of 30° to 45°C, a timer which allows the setting of maximum testing time, a suitable water bath for 12 ltr. of water, the basket assembly for three samples, a DC motor to turn the instrument for 180° at a programmable time interval.

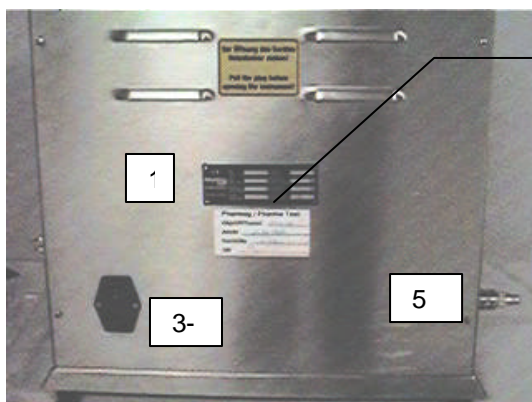
The unit is assembled and equipped according to the current DAB specifications and supplied in a ready to use condition.

The standard apparatus comprises:

1 built-in thermostat with circulation pump and heater, 1 LED display for the water-temperature, 1 timer to program a maximum testing time, 1 water bath of 12ltr. volume, 1 basket-assembly for 3 samples and a handle, 3 stainless steel basket assemblies, 3 glass-plates to cover the baskets, 1 glass rod, 1 control thermometer, 1 rubber mat.

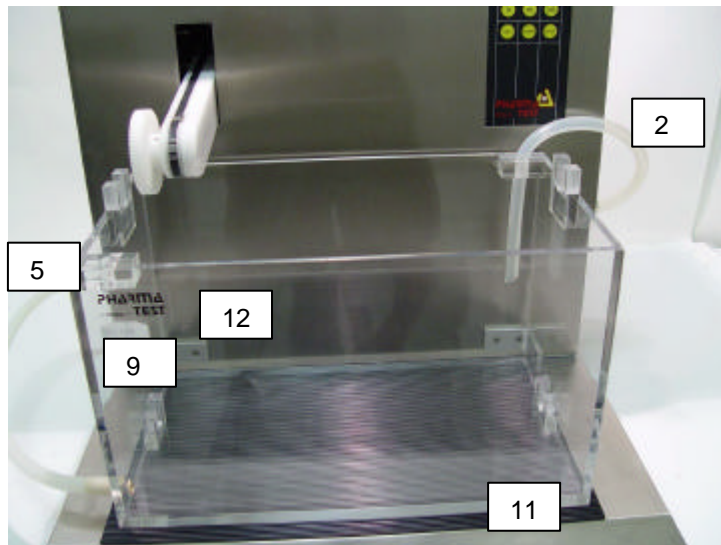
2. Setting up the instrument

After unpacking please check the completeness of the delivery scope in accordance to the attached delivery note and your order documents. At the same time, the current voltage characteristics shown on the identification plate should be compared with the mains voltage available.



- 1 Identification plate
- 3 Mains-switch
- 4 Mains-socket and fuse holder
- 5 Fast coupling

Place the instrument in the work place provided, while the rear wall of the unit should be in a distance of 10cm to the laboratory wall. Connect the supplied mains cable with the instruments (3) and the local mains.



Place the rubber mat (11) with the smooth surface below onto the frame housing and place the water bath (12) container on it. Attach the silicone tubing of the water bath with the fast coupling (5) of the frame support. Connect the circulation tubing (2) with the water bath. Fill the bath with 12l demineralised or distilled water to the Max.-Level indicator (9).

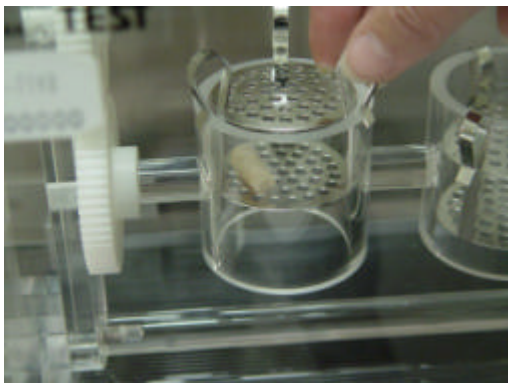
3. Pump and heating

As soon as the mains switch (3) is turned on the pump and heater start working. Make sure that the system is primed up as the pump is *not self priming*.

Attention: *The pump is not self priming, when starting the system the \hat{t} . time having water in the bath make sure that the pump is primed. Dry running will damage the pump.*

The heating system is calibrated at factory. Before starting a test you need to control the bath temperature. Probably you need to rise it as the wide open area will drop down the bath temperature. To control you need an accurate mercury thermometer. Correct the temperature at the thermostat (6) pushing the "SET°C" key and push up or down marked key to adjust. The heater is working as soon as the mains switch (3) is turned on.

Place into the 3 stainless steel baskets (10) each one sample and put them into the Perspex holders. Now place the complete holder with its handle into the bath, while you lift the drive axis (7) upwards. Fix the holder inside the bath at its holders. Use the gear-wheel to turn the baskets into an upright position.



Place basket back into support



Adjust the supports inside the bath previous to test start

5. Setting the testing time



The keyboard includes the timer display , the time setting keys and start/stop key.

Select the maximum testing time as follows:

Max.Time = 30 minutes

Press key “m” and hold until display shows

0030

now release key. As long as you push the key the figures will change, so you may select any testing time.

After time has been selected, press “START” key to begin the test. Automatically within a 10 minutes (setting INT = 0) interval the motor will turn the baskets for 180°. The timer display will always show the elapsed time. You can select interval times from 1 to 10 minutes. Press key “INT” display shows : 1=1 min. 2=2 min. 3=3 min. ...0 = 10 min.

6. Additional functions

- REC** The “REC” marked key can be used while a test is running to display the maximum testing time you had programmed (recall)
- STOP** Press the “STOP” key twice to abort a test, the display will thereafter show your programmed maximum time again, which is memorized.
- START** Press the “START” key to start a test after the total time has been set.

7. Maintenance

A daily cleaning of the bath and circulation system is recommended. Increase the temperature of the bath and use clean distilled water, which is pumped through the system. As any oily phase is floating on top of the water level, near to no product will arrive inside the heating system.

Don't clean the Perspex parts in water which is heated up to more than 45°C, otherwise you will damage the parts. Don't use any aggressive solvent for cleaning.

Check every month the flow-rate of the pump and compare with the one mentioned in the QC report supplied with the instrument. Is the measured rate more than 20% less the mentioned one, the circulation system needs to be controlled.

No further maintenance is required.

8. Spare parts and consumables

| Description | Part – No. | Units built-in |
|--|------------|----------------|
| PTS 3E Plexiglas-Water bath complete | 391-7140 | 1 |
| PTS 3E POM toothed gear | 391-2601 | 4 |
| PTS 3E spring | 391-1148 | 1 |
| POM Plexiglass drive arm and basket support complete | 391-1142 | 1 |
| Stainless steel basket for suppository | 391-7352 | 3 |
| Glass cover plate to test vaginal ovals | 391-3002 | 3 |
| Glass test rod | 391-3003 | 1 |
| Thermometer 1HN11 -10/+50°C | 105-0800 | 1 |
| PTS 3E toothed belt 6x500 | 391-2600 | 1 |
| CPU N 540.. | 391-0850 | 1 |
| PTS 3E Tastaturfolie | 391-0852 | 1 |
| Mains Transformer 48 VA 12V/4A | 101-1129 | 1 |
| 24V DC Motor 402.866 | 101-3020 | 1 |
| MD6Z Pump 220/240V | 101-1120 | 1 |
| MD6Z Pump 115V | 101-1121 | 1 |
| 230V heating tube | 302-3006 | 1 |
| 115V heating tube | 302-3005 | 1 |
| Thermo-Fuse 98° | 101-4438 | 1 |
| Thermo-Switch 16A -90° | 101-4450 | 1 |
| PTS 3E Temperature Control Thermostat "Störk" complete | 391-7111 | 1 |
| DAB cleaning oil, 100ml. | 10-60010 | 1 |
| ALGEX 250 ml, | 106-0331 | 1 |
| IEC/EUR mains cable - 250V/16A | 34-08500 | 1 |
| US mains cable – 125V/6A | 34-08511 | 1 |

Installation and Adjustment Information
PTS 3E – PTZ – PT-DDS
Control Thermostat, Typ STORK ST70-31.10
Art.-No. 391-7111

Part no.: 391-7111

Part label: Störk (tronic) temperature controller (ST70-31.10)

Function: control the heating of the system

Placement: connect heating element, temperature sensor and 12-24Volt power supply

Description:

STÖRK TRONIC

MICROPROCESSOR BASED TEMPERATURE CONTROLLER **ST70-31.10**

General Data

The ST 70-31.10 microprocessor-based regulator is a versatile temperature controller with high accuracy. The instrument is provided with software enabling the user to set up a variety of different control configurations. Versions of the controller are available for resistance thermometer, thermocouple, current and voltage in-puts. The control set point and the following parameters are adjusted by a three button membrane keypad on the front of the instrument.

- *Set point
- *Switch hysteresis
- *Control range limitation - minimum value
- *Control range limitation – maximum value
- *Actual value correction
- *Keypad lock

Other device characteristics such as the function of the output relay and the monitoring and control characteristics are factory preset but can be varied.

Technical Data

Measuring Input:

| | | |
|-----------------------------|----------------------|---------------|
| For resistance thermometers | Pt100: | -99... +600°C |
| | PTC: | -50... +150°C |
| Thermocouples Type J | (Fe-CuNi) | -99... +700°C |
| Type K | (NiCrNi) | -99... +999°C |
| Current input 4-20mA: | Parameters A10 + A11 | |

Indication:

One 3-digit super-red LED digital display, 13mm high.

Installation Data:

Front panel: 72 x 36mm
Panel cut-out 68 x 28mm
Installation depth: approx. 70mm including terminals

Enclosure :

Protection category to the front IP50, IP 63 on request

Ambient Conditions:

Storage temperature: -20...+70°C
Operating temperature : 0... +55°C
Relative humidity : 75% maximum without dew

PARAMETERING ST46...142**CUSTOMER SETTING OPTIONS**

Adjustment of the regulator, the so-called parameter takes place on three operating levels. The Set point Level, the P-Parameter Level and the A-Parameter Level.

SET-POINT ADJUSTMENT

The controller is normally at the Set point Level. Under normal working conditions the display shows the actual value of the process temperature. The control temperature (Set point 1) is displayed by pressing the SET button. If the SET button is pressed with either the UP or DOWN button Set point 1 is increased or decreased.

When the desired setting has been reached, the UP or DOWN button is released before releasing the SET button. The SET value is retained in memory even if there is a power failure.

SETTING OF P-PARAMETERS

In order to prevent accidental or unauthorised changes to the preset parameter values, access to the Parameter Level has been made difficult. Simultaneously pressing the UP and DOWN button for about 3 seconds switches the controller to the Parameters. The display now shows P1. To display and adjust the value of P1, press the SET button and the existing value of P1 is displayed. By simultaneously pressing the SET button and either the UP or DOWN button this value can be increased or decreased as required. Release the UP or DOWN button before releasing the SET button and the new value is saved into the non-volatile memory. The display will again show P1. Use the UP or DOWN button to select the remaining P-parameters, and this can be adjusted in a similar manner.

To return to the operating mode: Simultaneously press the UP and DOWN button for approx. 3 seconds and the display will again show the process temperature. In any case if no adjustment of the parameters is made for 30 seconds, the controller will automatically return to the operating mode.

Factory programming of the controller (A-Parameters)

This level contains the safety relevant characteristics which are pre-set by factory.

In order to prevent accidental or unauthorised changes to the preset parameter values, access to the A-parameter level has been made difficult.

WARNING

Unauthorised entry and adjustment of these parameters is normally prohibited, as this could result in dangerous changes to the function of the regulator. We only provide this information to customers when they:

1. Subsequently demand this information
2. Ensure that this information is not generally made available to their customers.
3. Accept full responsibility for any subsequent damage or claims which may result from incorrect or dangerous A-parameter settings.

It is on this understanding that we pass this information to you.

To enter the A-parameter level

Simultaneously press the UP and DOWN button for about 3 seconds and 'P1' appears in the display. Press the UP button until the highest p number is displayed. Keep the UP button pressed for a further 15 seconds and the display will change to 'PA'. Simultaneously press the UP and DOWN button until 'A1' is displayed.

The controller is now in the A-Level, and the parameters can be adjusted using the same method as in the P-Level.

P6 = use for calibration, adjust to "-" when temperature too high and to "+" when too low.

Software ST XX-XX.10 Second operating level (P-Parameters)

| Para-meter | Function | Adjustable range | Standard Setting | Customer Setting |
|------------|---|----------------------------|------------------|------------------|
| P2 | Hysteresis K1 | 0,1...99,9K | 0,1K | |
| P4 | Control range limitation minimum Setpoint | -99°C...P5 | -99°C | |
| P5 | Control range limitation minimum Setpoint | P4...999°C | 999°C | |
| P6 | Actual value correction | -10...+10K | 0,0K | |
| P19 | Keyboard lock | 0: not locked 1: locked | 0 | |

*The standard Setting of the control range limitation depends on type of sensor

Software ST XX-XX.10 Third operating level (A-Parameters)

| Para-meter | Function | Adjustable range | Standard Setting | Customer Setting |
|------------|------------------------|--|-----------------------|------------------|
| A1 | Switch mode K1 | 0: heating contact 1: cooling contact | 0 | |
| A3 | Sensor error K1 | 0: failure switch off 1: failure switch on | 0 | |
| A8 | Display mode | 0: without decimal point, without leading zeros 1: with decimal point, without leading zeros 2: without decimal point, with leading zeros 3: with decimal point, with leading zeros | 1 | |
| A10 | Voltage input Tu | -99...999 | 0,0 | |
| A11 | Voltage input To | -99...999 | 100 | |
| A40 | Hysteresis mode K1 | 0: Symmetrical 1: One side of Setpoint | 0 | |
| A50 | Minimum action time | 0,0...999 sec. | 0,0 sec | |
| A60 | Sensor selecting | 0: Thermocouple type J 1: Thermocouple type K 2: Pt100 (3-wire) 3: Pt100 (2-wire) 4: KTY 81-121 (2-wire) 5: 2-10V or 4-20 mA 6: 0-10V or 0-20 mA | Dependent on hardware | |
| A70 | Software time constant | 0: 0,0 sec. 1: 0,8 sec. 2: 2,4 sec. 3: 6,0 sec. 4: 16,0 sec. 5: 38,6 sec. 6: 96,0 sec. | 3:6,0 sec. | |
| A80 | Temperature scala | 0: Fahrenheit 1: Celsius | 1 | |

*only active when voltage or current input is provided

Chemical Behaviour

PLEXIGLAS GS PLEXIGLAS XT

The stated behaviour was established for the grades PLEXIGLAS GS 215, 218, 221, 222, 224, 231, 233, 237, 240, 245, and 2458 as well as for PLEXIGLAS XT. The extruded materials are, however, attacked more easily by solvents.

For greater chemical resistance, grade PLEXIGLAS GS 209 is recommended. The data given revert to a test temperature of 23°C and presuppose stress free installation.

The behaviour of the material in practice depends largely on the temperature in use. In case of doubt, we advise you to consult us as to the chemical resistance for particular applications.

The results obtained for all products, especially the branded ones, refer to the production batch tested in each case.

Fertilisers

+ NITROPHOSKA, various grades

Fats, oils, waxes

+ Animal
+ Mineral
+ Silicone oil
+ Vegetable

Gases and vapours

+ Ammonia
o Bromine vapours, dry
+ Carbon dioxide
+ Carbon monoxide
+ City gas
o Chlorine vapours, dry
+ Exhaust gases containing HCl
+ Exhaust gases containing HF
+ Exhaust gases containing H₂SO₄
+ Hydrogen sulphide
+ Methane
+ Nitrogen dioxide
+ Nitrogen monoxide
+ Oxygen
+ Ozone
+ Sulphur dioxide, dry

Beverages, etc.

+ Beer, wine
+ Camomile extract
+ Chocolate

+ Fruit juice, milk, coffee
o Spirits, up to 30%
+ Vinegar
+ Water, mineral water

Adhesives and sealants

- Acrylate sealing compound
o All-purpose adhesive
+ Insulating tape
o PATTEX special-purpose glue
+ PERBUNAN
o PLEXISOL adhesive
o PLEXIT
+ PLEXTOL adhesive
- Polyurethane sealing compound
+ Sealing strips (EGO-FERM, TEROSTAT 81/86)
o Silicone
- Thiokol rubber (one-and-two component)

Cosmetics, etc.

- Camphor
+ DIPLONA hair oil
+ Face tonic
+ Glycerine
+ Hair setting lotion (PRIMAWELL)
- Nail varnishes
- Nail varnish removers
+ Ointments
+ Peat water

+ POLYCOLOR

+ Seawater
+ Soaps
o Sprays

Plastics

+ Foam plastics
- Foam plastics, plasticised
+ Polyamide
+ Polyethylene
+ PVC
- PVC, plasticised
+ Rubber
- Rubber, plasticised

Foods and spices

+ Aniseed, bay leaf, nutmeg
- Cloves
+ Common salt
+ Honey, pure
+ Ice cream
+ Meat, fish
+ Pepper, cinnamon, onions
+..Pickles

Cleaning agents

a) General

Acids, see under chemicals
- Alcohol, concentrated
o Alcohol, up to 30%
Alkalis, see under chemicals
+ Ammonia solution

- Benzine, mixture, containing aromatics
- + Benzine, non-aromatic
- + Bleach
- Carbon tetrachloride
- Methylated spirits
- Perchloroethylene
- + Petroleum
- + Petroleum ether
- + Soap solution
- + Soda water
- Stain remover
- Trichloroethylene
- + Turpentine
- + Turpentine substitute

b) Branded products

- + AJAX
- + Antistatischer KUNSTSTOFFREINIGER und Pfleger
- + BFK cleanser
- o BOLIMENT
- + BÖTTCHERIN
- + BURMAT
- + BURNUS
- + CILLIT-GRÜN
- + DOR
- + DOSYL
- + DOSYLAN
- + FAKO Polish
- + FAKO Polishing Paste
- + FEWA
- + FRAPPIN
- + FÜLLBOX
- + LAVAPLEX
- + NULL-NULL
- + PERSIL
- + PLEXIKLAR
- + PRIL
- + REI
- + SEIFIX
- SIDOLIN
- SPECTROL
- + SPÜLI
- + WC-00

c) Cleaning agents for pipes and tanks

- + CALGONIT D, DA, S
- + NEOMOSCAN M, M powder
- + Niroklar GR liquid
- + Niroklar GR powder
- + P3
- o P3 basic cleaner
- + P3-dix

Pesticides

- Sprays (applied directly)
- o Sprays (applied in the air)

- o Pesticides in aqu. Solutions
- + NEXION stable spray
- + RABOND stable spray

Protective coatings (strippable)

- + DIEGEL liquid film 23922
- + KOPPERSCHMIDT covering paste
- o SPRAYLAT

Other substances

- + Urine
- Fuel for petrol engines
- o Fuel for diesel engines

The symbol signify:

- = not resistant
- o = limited resistance
- + = resistance

Paints, etc.

- o Acrylic paints and lacquers
- + Non-aromatic benzines
- Nitrocellulose lacquers
- + Oil paint, pure
- Thinners in general

Antistatics

- + HB 155
- + Antistatic fluid and cleaning agent

Technical bath

- + Electroplating bath
- + Photochemical bath

Building materials and protectives

- Bitumen emulsion
- + Cement
- + Gypsum
- o Hot bitumen
- + Mortar
- + Red lead

Chemicals, solvents, etc.

a) General

- Acetic acid, concentrated
- o Acetic acid, up to 25%
- Acetone
- + Alum
- + Aluminium chloride
- + Aluminium oxalate
- + Aluminium sulphate
- Ammonia water
- + Ammonium sulphate
- Amyl acetate
- Aniline
- + Arsenic
- + Arsenic acid
- + Battery acid
- Benzaldehyde

- Benzene
- + Benzine, pur
- Bromine
- 1-Butanol
- Butyl lactate
- + Butyric acid, up to 5%
- + Calcium chloride
- + Calcium hypochlorite
- Carbon disulphide
- Carbon tetrachloride
- Chlorinated hydrocarbons
- Chlorine, liquid
- o Chlorine water
- Chloroethyl ether
- Chlorophenol
- o Chromic acid
- + Citric acid, up to 20%
- + Copper sulphate
- Cresol
- + Cyclohexane
- Diacetone alcohol
- o Diamyl phthalate
- Dibutyl phthalate
- + Diethylene glycol
- Dioxane
- Ether
- Ethyl acetate
- Ethanol, concentrated
- o Ethanol, up to 30%
- Ethyl bromide
- Ethyl butyrate
- Ethylene bromide
- + Ferric chloride
- + Ferrous chloride
- + Ferrous sulphate
- + Formic acid, up to 2%
- o Formic acid, up to 40%
- + Glycerol
- + Glycol
- + Heptane
- + Hexane
- + Hydrochloric acid
- + Hydrofluoric acid, up to 20%
- + Hydrogen peroxid, up to 30%
- + Iodine, metallic
- + Lactic acid, up to 20%
- + Magnesium chloride
- + Magnesium sulphate
- + Manganese sulphate
- + Mercuri
- Methanol, concentrated
- o Methanol, up to 30%
- Methyl ethyl ketone
- Methylated spirits
- + Milk of lime
- + Monobromonaphthalene
- + Nickel sulphate
- + Nitric acid, up to 40%
- Nitric acid, over 40%
- + Oxalic acid

- Perchloroethylene
- + Petroleum
- + Petroleum ether
- Phenols
- + Phosphoric acid, up to 50%
- Phosphorus trichloride
- Phosphorus, white
- + Picric acid, 1% in water
- + Potassium bichromate
- + Potassium carbonate
- + Potassium chloride
- + Potassium cyanide
- + Potassium hydroxid solution
- + Potassium nitrate
- + Potassium permanganate
- o 2-Propanol
- + Propylene
- Pyridine
- Silicon tetrachloride
- + Silver nitrate
- + Soap solution
- + Soda
- + Sodium bisulphite
- + Sodium carbonate
- + Sodium chlorate
- + Sodium chloride
- + Sodium hydroxide sol. 30%
- + Sodium hypochlorite
- + Sodium sulphate
- + Sodium sulphide
- + Stannous chloride
- + Stearic acid
- + Sulphur
- Sulphur dioxide, liquid
- + Sulphuric acid, up to 30%
- o Sulphurous acid, conc.
- + Sulphurous acid, up to 5%
- + Sulphuryl chloride
- + Tartaric acid, up to 50%
- Thionyl chloride
- Toluene
- + Triethylamine
- Trichloroacetic acid
- + Turpentine
- + Turpentine substitute
- + Urea, up to 20%
- Xylene
- + Zinc sulphate, aqueous
- + Zinc sulphate, solid
- b) Branded products**
- + CLOPHRN T 55,A 60
- o DEKALIN
- o FRIGEN A 12 (CF₂Cl₂)
- GLYBAL A
- + PALATINOL K
- o PALATINOL 0, BB new
- + SANGAJOL
- + TERAPIN

- TETRALIN
- Disinfectants**
- a) General**
- Carbolic acid
- + Chlor lime paste
- + Hydrogen perox., up to 40%
- o Hydrogen perox., over 40%
- Iodine tincture, 5%
- + Lugol solution
- Methylated spirits
- + Sublimate
- b) Branded products**
- o ÄTHROL, up to 5%
- BAKTOLAN, conc.
- + BAKTOLAN, up to 5%
- + CHINOSOL, up to 1%
- + CHLORAMIN, solution
- CHLORAMIN, suspension
- + ELMOCID GAMMA, up to 2%
- LYSOFORM
- + MEFAROL, up to 1%
- + MERCKOJOD, up to 1%
- + MERFEN
- + PERHYDROL
- + PERODIN
- + SAGROTAN, up to 2%
- o SAGROTAN, up to 5%
- o VALVANOL, up to 2%
- + ZEPHIROL, up to 5%