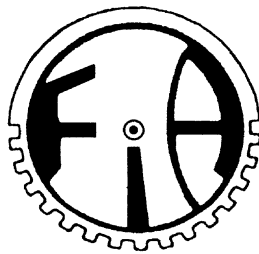


Qualification Document



Dissolution Testers for Chewing Gums DRT1 - DRT6 PTM



Document No.: IQ/OQ DRT1-6 PTM

Revision: 009

Created by: AB FIA

Valid from: 23.06.2009

Repl. Doc. from: 09.11.2008

SECTIONS:

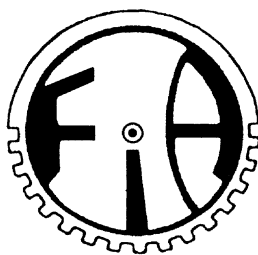
1	Master Plan <ul style="list-style-type: none">1.1 Qualification team1.2 Requirements and specification
2	Qualification Results Summary <ul style="list-style-type: none">2.1 Instrument Type2.2 Measuring Tools List
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1

Master Plan



Dissolution Testers for Chewing Gums DRT1 - DRT6 PTM



Document No.: IQ/OQ DRT1-6 PTM

Revision: 009

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1. Master Plan

1.1 Qualification Team

Instrument Type		Serial Number
DRT1- 6		
Circulation heater		
	Name	Signature
Tested by		
Approved by		



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1.2 Requirements and specification

The requirements and the specification for FIA Dissolution Tester DRT1-6, including the PTM-models incorporate the following features:

1.2.1 DQ

Design Qualification (DQ) is normally performed by the manufacturer during development of the instrument. The instruments are manufactured according to the technical requirements (ISO, CE).

1.2.2 IQ/OQ

The manufacturer performs Installation Qualification (IQ) and an extended operation qualification (OQ) prior to shipping.

A further installation qualification is required to check that the system has been correctly installed and set up prior to the customer using the system on his site. This may be carried out by the user or by a authorised FIA engineer.

Following successful on-site installation, the system should then be tested according to operation qualification OQ in which the critical functions of the system are checked according to the requirements and any additional specifications stipulated by the customer. This process may be carried out by the user or by an authorised FIA engineer.

1.2.3 PQ

Like OQ, the performance qualification (PQ) must be conducted at the customer's site according to the users requirements and is normally carried out by the user.



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1.2.4 Presentation of test results

Depending on the instrument type, not all tests listed in IQ/OQ protocols are possible to perform. Tests that are irrelevant for the instrument are commented with n.a. (not applicable). For example, it is not possible to test more than the only cell on a DRT1 chewing apparatus. The first row of test results for cells 2 - 6 is marked with **n.a.** and the rest of the table may be left unfilled.

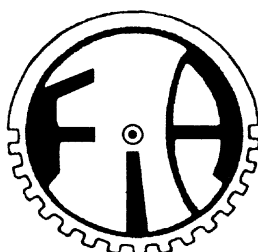
Qualification result summary, IQ summary and OQ summary are signed, but in the singular test protocols, only deviations like a failed test are signed. Corrections of figures or text in the protocols are also signed and dated.



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2

Qualification Results Summary



Dissolution Testers
for Chewing Gums
DRT1 - DRT6
PTM



Document No.: IQ/OQ DRT1-6 PTM

Revision: 009

Created by: AB FIA

Valid from: 23.06.2009

Repl. Doc. from: 09.11.2008

2.1. Results summary

The following instrument and components have been qualified. The Qualification has been performed according to the master plan and appropriate standard operation procedures. Test protocols have been filled in correctly and test results documented. The instrument can be released for the appropriate use.

Instrument Type			Serial Number	
DRT1- 6 PTM				
Circulation heater				
Qualification range	SOP	TP	passed	failed
IQ	F001	F001		
	F002	F002		
	F003	F003		
OQ	F004	F004		
	F005	F005		
	F006	F006		
	F007	F007		
	F008	F008		
	F009	F009		
	F010	F010		
Date:		Tested by:	Approved by:	



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2.2. Measuring Tools

Measuring instrument	Serial number	Meas.-range	Resolution	Certificate			
				Number	Provider	Valid from	Valid to
Thermometer							
Micrometer							
Calipers							
Timer							
Balance							

Due to ISO 9001 every company is engaged, to set the time of validity for its measuring instruments by themselves. The intervals for the certification have to be set in a way that any deviation is shown and to approve that only accurate and valid instruments are used. The intervals are also related to the use and frequency of use. It is the users responsibility that correct measuring instruments are used.

	Tested by:	Approved by:
Date:		



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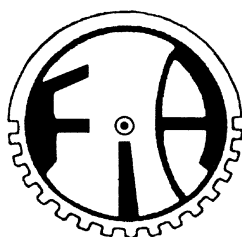
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3

Installation Qualification (IQ)



Dissolution Tester for Chewing Gums DRT1- 6 PTM



Document No.:	IQ/OQ DRT1-6 PTM
Revision:	009
Created by:	AB FIA
Valid from:	23.06.2009
Repl. Doc. from:	09.11.2008

3.1. Installation Qualification Summary

The following instruments and components have been qualified in accordance with the requirements of the Master Plan.

The Installation Qualification has been performed following the procedures in the master plan with the appropriate standard operation procedures. Test protocols have been filled in correctly and the test results documented.

The system can now be released for operational qualification (OQ).

Instrument Type			Serial Number	
DRT1 - 6				
Circulation heater				
Qualification Type	SOP	TP	passed	Failed
IQ	F001	F001		
	F002	F002		
	F003	F003		

	Tested by:	Approved by:
Date:		



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Revision:	009
Created by:	AB FIA
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Standard Operation Procedure SOP-No.: F001

3.2. Check for Completeness and Transport Damage

3.2.1 Aim

The purpose of this SOP is to check that the delivery is as stated on the packing note and that there has been no damage in transit.

3.2.2 Scope

This operation should be performed on initial installation of the system and thereafter whenever the system is moved.

3.2.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

3.2.4 Description and Execution

An essential element of the Installation Qualification is that all the system components ordered and/or appearing on the delivery note have (a) been received and (b) been received safely and in good working order.

- Please unpack the instrumentation carefully.
- If any units/parts are missing, please inform the manufacturer immediately.
- Similarly, if any damage has been sustained (even, if only to the outer packing), please advise (a) the manufacturer and (b) the carrier or forwarding agent immediately.
- Failure to do so may jeopardise and ensuing insurance claim.

3.2.5 Reference Documents

The appropriate protocol should be filled in before proceeding further.



Document No.: IQ/OQ DRT1-6 PTM

Revision: 009

Created by: AB FIA

Valid from: 23.06.2009

Repl. Doc. from: 09.11.2008

Test Protocol TP-No: F001

1 Packing Note Check

Packing Note Number	
---------------------	--

	passed	failed
Delivery is as stated on the packing note		
Any items on back order are as stated on the packing note		

2 Damage during transport

	passed	failed
No evidence of damage to the packing		
No evidence of damage to the system		

	Tested by:	Approved by:
Date:		



Document No.: IQ/OQ DRT1-6 PTM

Revision: 009

Created by: AB FIA

Valid from: 23.06.2009

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Standard Operation Procedure SOP-No: F002

3.3. Installation of the system

3.3.1 Aim

The purpose of this SOP is to describe the installation of the system such as to ensure its safe operation.

3.3.2 Scope

This operation should be performed on initial installation of the system and thereafter whenever the system is moved. The system should be checked for short deliveries and/or transit damage prior to undertaking this operation.

3.3.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

3.3.4 Description and Performance

Once unpacked, the system should be positioned on the floor in the vicinity of the required supplies and with the wheels locked on the carrier.

3.3.5 Dissolution Tester DRT1-3

Ensure that the supply is earthed and that the mains voltage and frequency are the same as that on the rear of the Circulation Heater but do not connect yet.

Ensure that the compressed air supply is set at 6 ± 0.5 bar (84 ± 7 psi) and connect it to the Dissolution tester.

3.3.6 Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.



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Test Protocol TP-No: F002

1. Checking the electrical supply

	passed	failed
The available Main Voltage and Frequency are identical to that specified on the instrument (230 V / 50 Hz or 115 V / 60 Hz)*		
An earthed mains socket available *		
There are no fluctuations in the main voltage and frequency that could effect the correct operation of the system*		

* It is the responsibility of the user to ensure that the electrical supply provided is compatible with that of the system.

2. Checking and connecting the compressed air supply

	passed	failed
Check that compressed air is set to a pressure of 6 bar (84 psi). Minimum supply of 25 l/min.		

	Tested by:	Approved by:
Date:		



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Standard Operation Procedure SOP-No: F003

3.4. Setting-up

3.4.1 Aim

The purpose of this SOP is to describe the set-up of the system such as to ensure its safe operation.

3.4.2 Scope

This operation should be performed on initial installation of the system and thereafter whenever the system is moved.

3.4.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

3.4.4 Description and Performance

On completion of the installation procedures, the instrument should be set up according to the following instructions. NOTE: It is essential that the water bath is filled with water before the Dissolution Tester is connected to the mains supply.

- Fill the Water Bath with de-ionised water up to the graduation mark (add an anti-algae inhibitor if desired). Please ensure that all connection tubes are intact.
- Ensure that the main switches located at the front panel of the Electronic Control Device and on the front panel of the Circulation Heater are in their zero (off) positions. Now connect the mains supply cables to the mains supply. NOTE :- Please ensure that the supply is earthed and that the mains voltage and frequency are the same as that on the instrument.
- Switch on the Circulation Heater and set the temperature according to the manual.
- Check all Water Bath, Thermostat and Connection Tubes for leaks.
- At the Electronic Control Device: ensure switches on top are set in down positions (lift and lower surface). Switch on "Main" (a green lamp indicates power on).
- A Safety Cupboard is mounted to cover the Chewing Module and to eliminate the clamping risk between the Jaws. The door of the cupboard must be closed before the instrument can operate. While the door is opened, the power is shut



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down and at the same time the supply of compressed air to all Pneumatic Cylinders is shut. The lamp is put out and a puffing sound is heard. The Pneumatic Cylinders are kept in their positions.

- An Emergency Stop is placed by the Control Device. While the emergency stop is pressed down, the power is shut down and at the same time the supply of compressed air to all pneumatic cylinders is shut. The lamp is put out and a puffing sound is heard. The Pneumatic Cylinders are kept in their positions.
- The Emergency Stop is reset by turning it Counter Clock Wise.

3.4.5 Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No.: F003

1. Setting up

	passed	failed
Fill Water Bath with deionised water		
Power on the Circulation Heater		
Water circulates		
Water Bath and all connections are leak free		
Power on the Electronic Control Device		
Press the Emergency Stop		
Power is cut to Control Device		
Compressed Air is cut		

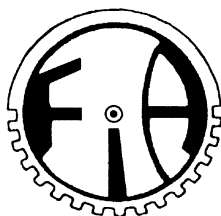
	Tested by:	Approved by:
Date:		



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4

Operation Qualification (OQ)



Dissolution Tester for Chewing Gums DRT1-6 PTM



Document No.: IQ/OQ DRT1-6 PTM

Revision: 009

Created by: AB FIA

Valid from: 23.06.2009

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4.1. Operation Qualifications Summary

The following instruments have been qualified in accordance with the requirements of the Master Plan.

The Operation Qualification has been performed with the appropriate standard operation procedures. Test protocols have been filled in correctly and the test results documented.

Instrument Type			Serial Number	
DRT1 - 6				
Circulation Heater				
Qualification Type	SOP	TP	passed	failed
OQ	F004	F004		
	F005	F005		
	F006	F006		
	F007	F007		
	F008	F008		
	F009	F009		
	F010	F010		

	Tested by:	Approved by:
Date:		



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Created by: AB FIA

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Standard Operation Procedure: SOP-No: F004

4.2. Check of Thermostating in Water bath

4.2.1 Aim

The purpose of this SOP is to ensure that the temperature in the Water Bath is within the accepted tolerances.

4.2.2 Scope

The performance of this check should be performed at least every six months.

4.2.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4.2.4 Description and Performance

Use a certified thermometer to perform this test.

- Fill the Water Bath with deionised water.
- Introduce the thermometer into the Water Bath. Set the temperature on
- 37.5 °C. Wait until the Water Bath temperature is stable.
- Note the value from the thermometer in the test protocol.
- Repeat the measurement 3 times at intervals of approx. 5 minutes.

The Water Bath should be of 37.5 ± 0.2 °C to be accepted. Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No: F004

1. Temperature in water bath

Measure- ment	Temperature in °C	Passed	Failed
	Water Bath 37.5±0.2		
1			
2			
3			

Please take measurements 3 times at 5 minute intervals.

Please ensure that any validation tools used in these tests are included in the measuring tools list.

	Tested by:	Approved by:
Date:		



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Standard Operation Procedure: SOP-No: F005

4.3. Check of Thermostating in Test Cell

4.3.1 Aim

The purpose of this SOP is to ensure that the temperature in the Water bath is within the accepted tolerances and that the temperature in the Test Cell (Cuvette) is reached after the specified time (method dependent) and is kept within the specified tolerances.

4.3.2 Scope

The performance of this check should be performed at least every six months.

4.3.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4.3.4 Description and Performance

Use a certified thermometer to perform this test.

- Fill the Water Bath with deionised water.
- Introduce the thermometer into the Water Bath. Set the temperature on
- 37.5 °C. Wait until the Water Bath temperature is stable.
- Note the value from the thermometer in the test protocol.
- Mount the test cells.
- Fill the Test Cell with 40 ml of de-ionised water.
- Introduce the thermometer into the Test Cells.
- Note the value from the thermometer in the test protocol.
- Repeat the measurements 10 times at intervals of 2 minutes.

The Test Cells should reach 37.0 ± 0.5 °C to be accepted.

4.3.5 Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No: F005

1. Temperature in test cell

Meas. nr	Test Cell $37.0 \pm 0.5^{\circ}\text{C}$			Passed			Failed		
	1	2	3	1	2	3	1	2	3
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

For DRT4-DRT6; continue with measurements in the table below.

Please take measurements 10 times at 2 minute intervals. NOTE: Test Cells cannot pass during the first measurements!

Please ensure that any validation tools used in the tests are included in the measuring tools list.



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Test Protocol: TP-No: F005 continued

Meas. nr	Test Cell 37.0±0.5°C			Passed			Failed		
	4	5	6	4	5	6	4	5	6
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

	Tested by:	Approved by:
Date:		



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Standard Operation Procedure: SOP-No: F006

4.4. Check of Gap between Jaws

4.4.1 Aim

The purpose of this SOP is to check that the Gap between Jaws is possible to set to an appropriate value. It includes also the measurement on the strokelength (amplitude) of the lower jaw.

4.4.2 Scope

The setting of the Gap between Jaws may differ between methods. The gap should be checked every time after a longer stand still or before changing method.

Comment: the strokelength of the jaw is of minor importance but it is checked here.

4.4.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4.4.4 Description and Performance

The factory setting is about 1.6 mm.

Comment: the value depends on the Method used for each type of Chewing gum.

1.6 mm is a good basic setting but must be checked and if needed, adjusted every time a new type of gum has to be tested.

The measurement is made by placing blank Jaws on the Upper Chewing Surface and on the Lower Chewing Surface. Check that the door(s) of the Safety Cupboard is closed.

On the Electronic Control Device: Turn the power on by pressing the button MAIN. A lamp indicates power on. LIFT **and** LOWER SURFACE is put to **UP** position, which means that the Lower Jaw is in its highest chewing position. Open the door(s) and measure the Gap between the Jaws with a thickness gauge (previously controlled with a certified micrometer). The Upper Jaw may be not completely parallell with the Lower. Therefore the Gap is checked at different positions around the periferial parts of the jaws. The gap should be 1.6 ± 0.05 in the basic setting.



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SOP-No: F006 continued

The distance may be set by loosening the Stop Screw on the metal body (Upper Jaw), hold around the body and screw the axis to correct distance. Then the Stop Screw is fastened (twisting moment 1 ± 0.2 Nm) with a hexagonal key.

The strokelength of the Lower Jaw is measured with thickness gauge and a caliper when the Lift is in its upper position and the Lower Chewing Surface (with Jaw) is in its lower position. The strokelength is thus equal to the distance between the surface of the Upper Jaw and the surface of the Lower Jaw with the Gap subtracted. The strokelength should be 5 (+2, -1) mm.

4.4.5 Reference Documents

Please study the Operating Manual carefully, it contains nomenclature and illustrations to the procedure above. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No.: F006

1. Gap between jaws

Checking /setting	passed			failed		
	1	2	3	1	2	3
Checking of Gap to 1.6 ± 0.05 mm						
Strokelenlength of Lower Jaw 5 (+2. -1) mm						

Checking /setting	passed			failed		
	4	5	6	4	5	6
Checking of Gap to 1.6 ± 0.05 mm						
Strokelenlength of Lower Jaw 5 (+2. -1) mm						

Please ensure that any validation tools used in the tests are included in the measuring tools list.

	Tested by:	Approved by:
Date:		



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Standard Operation Procedure: SOP-No: F007

4.5. Check on Angle of Rotation

4.5.1 Aim

The purpose of this SOP is to check the Angle of Rotation.

4.5.2 Scope

The Angle of Rotation normally not changed from the basic setting of 20 degrees.

4.5.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4.5.4 Description and Performance

The adjustment is made by placing blank Jaws on the Upper Chewing Surface and on the Lower Chewing Surface. Check that the door(s) of the Safety Cupboard is closed.

On the Electronic Control Device: Turn the power on by pressing the button MAIN. A lamp indicates power on **Lift and Lower Surface is put to UP position**, which means that the Lower Jaw is in its highest chewing position.

With a sharp marker, make a vertical line on the Upper Jaw and on the Lower Jaw (the mark on the Upper Jaw must be exactly above the mark on the Lower Jaw).

Put **Lower Surface is put to Down position and again to the UP position**. The Upper Jaw has now turned 20 degrees which equals to about 4.9 mm. Make sure that only one turn is made.

Measure the linear distance between the two marks with a caliper. It must be 5 ± 1 mm which will mean that the Rotation Angle is 20 ± 4 degrees.

Adjustments of the Angle is made as follows. Loosen the socket head cap screw with a hexagonal key. Set the Turning Angle. Move the Stop Knob to its stop. Tighten the Socket Head Cap Screw again, hard (3 Nm).

4.5.5 Reference Documents

Please study the Operating Manual carefully, it contains nomenclature of the different parts of the Dissolution Tester and illustrations to the procedure above. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No.: F007

1. Angle of rotation

Checking/Setting	passed			failed		
	1	2	3	1	2	3
Checking of Angle of Rotation to 20 ± 4 degrees						
Measured difference between marks in mm						

Checking/Setting	passed			failed		
	4	5	6	4	5	6
Checking of Angle of Rotation to 20 ± 4 degrees						
Measured difference between marks in mm						

Please ensure that any validation tools used in the tests are included in the measuring tools list.

	Tested by:	Approved by:
Date:		



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Standard Operation Procedure: SOP-No: F008

4.6. Checks on Frequency

4.6.1 Aim

The purpose of this SOP is to check the Frequency settings.

4.6.2 Scope

The Chewing Frequency may be adjusted using the knob on the Electronic Control Device. The obtained frequency may be read on a display.

Comment: the appropriate frequency depends on the Method used for each type of Chewing gum. The order in which the chewing motions appear (Press, Twist, Open and Regain) is locked by the electronic control and the order cannot be changed.

4.6.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check. The Chewing Frequency is set every time after a stand still or before changing method.

4.6.4 Description and Performance

The supplier has preset the maximum chewing frequency and locked it at approximately 66 strokes per minute (at a pressure of 6 ± 0.5 bar).

The obtained *chewing frequency* can be read during "Chewing" on a Frequency Counter, a display on the Control Device. The display is updated twice each minute. Average value is observed during some minutes to get a representative figure. To obtain a representative value on the display the apparatus must work for at least half a minute after adjustments.

Adjustments can be made in the range of about 20 to 62 strokes per minute. Acceptable differences in settings are -6/min on the lower and +6/min on the upper limit. A set value should not differ more than ± 2 / min during a period of 5 min.

Check that the door(s) of the Safety Cupboard is closed.

On the Control Device: Turn the power on by pressing the button MAIN. A lamp indicates power on.

WARMING UP PERIOD: Put the time to 0 min.
(For details see Operation Manual).

CHEWING TIME: Put the time to 30 min.



Document No.: IQ/OQ DRT1-6 PTM

Revision: 009

Created by: AB FIA

Valid from: 23.06.2009

Repl. Doc. from: 09.11.2008

SOP-No: F008 continued

On the Control Units put the switches:

LOWER SURFACE = **DOWN** ,

LIFT = **UP** .

Press START firmly once for about a second after which the *chewing motions* starts. Set the FREQUENCY to minimum with the knob and note the minimum value of the display during one minute.

Set the FREQUENCY to maximum with the knob and note the maximum value of the display during one minute.

Set the FREQUENCY to 40 strokes / min and adjust as well as possible during a minute or two. Note the observed minimum and maximum reading during one minute.

Watch the Lower Jaw, start a timer and count the number of strokes during exactly one minute. The value should be 40 ± 2 strokes / min to be accepted. The same measurements are made for all test cells.

4.6.5 Reference Documents

Please study the Operating Manual carefully. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No.: F008

1. Frequency settings

Setting / displayed frequency strokes per min	passed			failed		
	1	2	3	1	2	3
Minimum (lowest value)						
Maximum (highest value)						
Setting / displayed frequency strokes per min	passed			failed		
	4	5	6	4	5	6
Minimum (lowest value)						
Maximum (highest value)						

2. Frequency counting

Count at set value 40 strokes/min	passed			failed		
	1	2	3	1	2	3
Counted						
Count at set value 40 strokes/min	passed			failed		
	4	5	6	4	5	6
Counted						

	Tested by:	Approved by:
Date:		



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Standard Operation Procedure: SOP-No: F009

4.7. Check on Timer settings

4.7.1 Aim

The purpose of this SOP is to check the Timers of the Electronic Control Device.

4.7.2 Scope

There are two timers on the Control Device: WARMING UP PERIOD and CHEWING TIME. Warming up period is normally set to between 5 and 10 minutes for the preheating of the dissolution medium before the chewing is being started. Chewing time is the time to the next sampling point. After the first sampling is made, the Warming up period is always set to zero.

4.7.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4.7.4 Description and Performance

On the Control Device:

Check that the door(s) of the Safety Cupboard is closed.

Turn the power on by pressing the button MAIN. A lamp indicates power on.

WARMING UP PERIOD: Put the time to 5 min.

(Mode **A** on the timer is always chosen and the display 0-30 min).

CHEWING TIME: Put the time to 5 min.

(the letter **C** should be displayed on the left of the digits except for the PTM-models where an **A** is displayed and **m** on the right).

On the Control Units put the switches:

LIFT = **DOWN** , LOWER SURFACE = **DOWN** .

Have a stopwatch ready and start it simultaneously with the Timer (see below).

Press START firmly once for about a second and a green lamp on the timer for WARMING UP PERIOD flickers and indicates that its counting down the preset time after which the chewing motions starts.

Measure the time between the start and chewing. 5 min $\pm$ 30 sec is accepted.

The chewing stops automatically at the preset time for the first sampling.



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SOP-No: F009 continued

Reset the timers by pressing MAIN, thus turning off the power. Press MAIN again (power on). Put the WARMING UP PERIOD to zero. Start again and clock the time from the start of chewing until the end. Note that a "*counting down diagram*" is displayed on the Timer. 5 min $\pm$ 15 sec is accepted. Repeat for settings of 10 min.

4.7.5 Reference Documents

Please study the Operating Manual carefully. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No: F009

1. Timer settings

Measurem.	Time in min		Passed	failed
	NOMINAL	ACTUAL		
1. Warming up period	5.0		±0.5 min:	
2. Chewing time	5		±0.25 min:	
3. Warming up period	10.0		±1 min:	
4. Chewing time	10		±0.25 min:	

Please ensure that any validation tools used in the tests are included in the measuring tools list.

	Tested by:	Approved by:
Date:		



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Standard Operation Procedure: SOP-No: F010

4.8. Check of Pressure control and torque monitoring

4.8.1 Aim

The purpose of this SOP is to ensure that the pressure and torque values represent the actual values that are exposed by the DRT on any formulation like for example a chewing gum.

4.8.2 Scope

The performance of this check should be performed at least every six months.

4.8.3 Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4.8.4 Description and Performance

Use a weight, weighed on a certified balance and a calibrated dynamometric wrench to perform this test.

- Follow instructions in the "*Manual for Pressure and Torque Measurements*".
- Register the values that are monitored for pressure while the weight of known value is put on the Base Chamber surface for the lower jaws.
- Mount adapters for torque measurements on the base chambers.
- Register the values at a setting on the dynamometric wrench for about 100 Ncm.
- Check that when the preset pressure limit is exceeded, a "!" mark is displayed in the logg-data.

The monitored values should not deviate more than 20% from the applied pressure (weights) or torque. To increase accuracy in the measurements it is possible to set up calibration curves. That is beyond the scope of the OQ.

4.8.5 Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.



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Test Protocol: TP-No: F010

1. Pressure

Applied weight (N)			Monitored pressure (N)			Applied weight (N)			Monitored pressure (N)		
Cell 1	Cell 2	Cell 3	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 4	Cell 5	Cell 6

When the preset pressure limit is exceeded, a "click" noise from a relay is heard.

Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6

2. Torque

Applied torque (Ncm)			Monitored torque (Ncm)			Applied torque (Ncm)			Monitored torque (Ncm)		
Cell 1	Cell 2	Cell 3	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 4	Cell 5	Cell 6

	Tested by:	Approved by:
Date:		