Scican Ltd. 1440 Don Mills Road, Toronto, Ontario, Canada. M3B 3P9

Product Advice Sheet – SD-424

HYDR*IM* Washer Disinfectors - Recommended (minimum) Testing Requirements*

The HYDR*IM* range of washer-disinfectors' intended purpose is for the cleaning and thermal disinfection of re-usable medical devices, in a single operating cycle.

All HYDR*IM* units have been subject to Type Testing as required by standard EN ISO 15883-1 (Note: current standard applies) and the relevant subsequent parts specific to the intended purpose of the unit. Works (factory) Testing is part of the final inspection.

*All HYDR*IM* units have been designed to be self monitoring, and should continue to perform on an ongoing basis in accordance with the specifications outlined in the standard; however, SciCan recommends that a regimen of periodic testing is carried out at specific intervals to ensure the ongoing performance of the machine continues to be as intended.

IMPORTANT NOTES:

- **This document outlines the minimum requirements to ensure that the equipment performs to specification. Refer also to the national and local regulations and requirements of your regulatory agency. Please consult your local dealer or your medical authorities for details.**
- **Installation, commissioning, repair, annual servicing and re-validation MUST be undertaken by SciCan approved technicians. Failure to properly maintain this equipment may invalidate the results of the following testing regimen.**

The recommended periodic testing requirements are as follows:

- **Commissioning/Installation testing**
  - Undertaken by - **SciCan approved installation/service/test engineer**.
    - Installation qualification, operational and performance tests in accordance with the relevant **HYDR*IM* Washer Disinfector Installation Manual and Preventative Maintenance Schedule** document included with the unit.
    - User training in accordance with the above.
- **Daily tests and checks**.
  - Undertaken by - **the User.**
    - door lock check

- wash arm rotation check (turning and potential blockage of nozzles)
- door seal check
- load carrier check
- check and clean chamber filters (screens)
- check load before releasing load - visual examination (inspection under magnification, when appropriate) of each load for residual soil

- **Weekly tests and checks**.

  - Undertaken by - **the User.**

    - Daily checks, plus:
    - Residual protein testing
      - SciCan recommends the Browne Ninhydrin Protein Detection Kit.)

      *Note: There are a number of commercially available tests on the market which **may** be similar. If these tests are chosen, then we would advise the nearest to Ninhydrin equivalence wherever possible.*

- **Monthly tests and checks**.

  - Undertaken by - **the User.**

    - Daily and weekly checks, and
    - Residual soil testing with surrogate device.
    - SciCan has tested and approved the following surrogate soil test devices
      - Browne STF Load Check system
      - Simicon RI Cleaning Indicators
      - SteriTec Wash Check

      *Note: There are a number of commercially available tests on the market which **may** be similar but have not been tested by SciCan. If these tests are chosen, then we would advise that you consult with your HYDRIM dealer or local authority to establish suitability prior to use.*

  (See Annex A of this document for advice on using the surrogate device in your HYDRIM WD)

- **Annual tests, checks and re-validation**.

  - Undertaken by - **SciCan approved installation/service/test engineer**.

    - **IMPORTANT NOTE –** A full annual service should be undertaken before re-validation in accordance with relevant **HYDR*IM* Washer Disinfector Installation Manual and Preventative Maintenance Schedule** document included with the unit.
    - Re-validation testing will include,
      - Automatic control test/ Full cycle profile thermometric check of time and temperature, (see annex B of this document)
      - Chemical dosing test, where appropriate (see Annex C of this document)

- Cleaning Efficacy Test – revalidation test with appropriate test soil. (See annex D of this document)
- Ninhydrin Residual Protein Test. (See annex E of this document)
- Load Dryness Test. (See annex F of this document)

Annex A – The use of cleaning efficacy test surrogate devices in HYDR*IM* washer disinfectors

This test is designed to demonstrate the satisfactory performance of the abilities of the machine to remove gross soil from contaminated instruments.

All HYDR*IM* units have been subject to Type Testing and Works (factory) Testing as required by standard EN ISO 15883-1 (Note: current standard applies). This includes the use of a wide range of commercially available surrogate devices for use by the user of the washer-disinfector (WD) which emulate the removal of gross soil from medical devices. (Note that some may also emulate the removal of proteins).

Although in general terms all these devices are designed to work in the same way, they may vary in type and brand depending on the region/country where the WD is located.

SciCan has tested a number of devices (listed in the test schedule above). Other devices may be used but should conform to the requirements below.

Test device requirements.

All HYDR*IM* units have been designed to comply with the requirements of EN ISO 15883.

Part 5 of this standard specifies a number of ‘test soils’ which are used in various countries for replicating the likely contaminants that may be deposited on surgical devices when used in surgical procedures.

When selecting a surrogate (user) test it is recommended that the test is one that replicates wherever possible the test soil in the region where the WD is located.

Test availability.

These tests should be readily available from many local steriliser and WD supply houses. If one cannot be found in your region, **please contact the dealer who supplied your HYDR*IM* unit.**

Using the device.

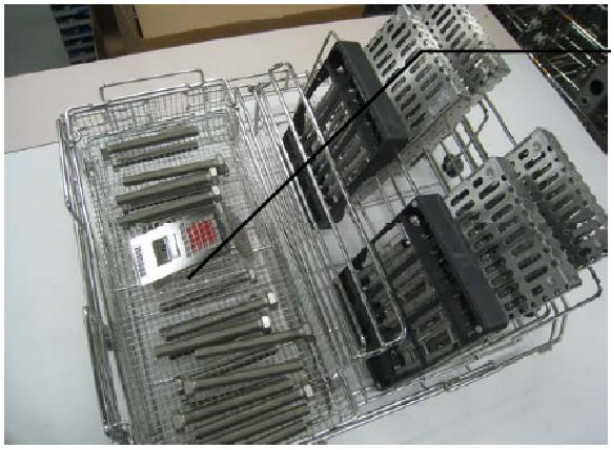
Follow the manufacturer’s instructions with regard to loading the wash efficacy indicator into any holding device, place the device in an open basket near the centre of the load carrier and surround the device with a normal (typical) load. **Do not cover the device with the remainder of the load.**

Run a **P2 Regular Wash** cycle unless specified by the device manufacturer.

Typical test device placement illustrations

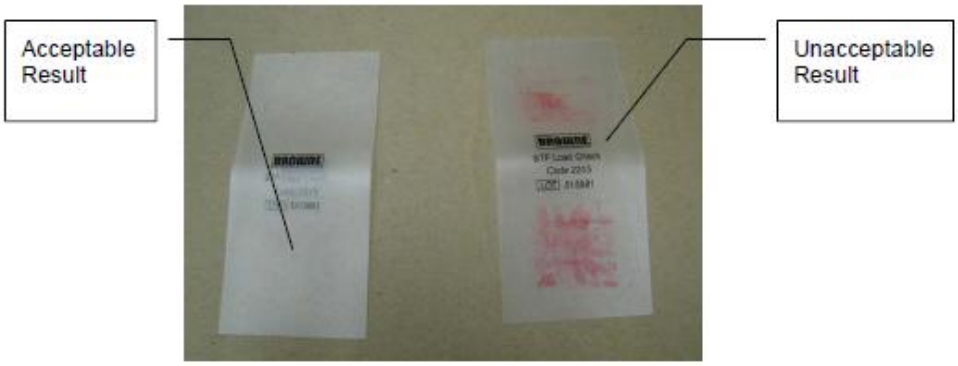
Notes:

- Loads shown are for reference only
- Load furniture may vary from that shown
- Browne STF Load Check system used in these illustrations for visual reference only



Pass/Fail criteria.

These criteria should be specified by the manufacturer of the device. **(Normal pass criteria is a test strip clean of any simulated soil)**



Please note: Indicators that have been exposed to ambient air for an extended period of time may have dried-on test soil and may produce a false negative (fail) test result. Ideally, once a package has been opened, indicators should be stored in a re-sealable plastic bag.

Annex B – Automatic Control Test/Full Cycle Profile thermometric check.

General

- This test is designed to demonstrate that the operating cycle functions correctly and the values of the cycle variables indicated by the WD and recorded by any instruments fitted to the WD, compare to values obtained from independent recording devices calibrated to National or International standards and the original specification of the unit.

- The temperature sensor(s) for thermometric testing (depending on test equipment used) shall be connected to the chamber during this test. One sensor MUST be placed adjacent to the control/validation sensor in the unit so that if appropriate, the calibration may be checked during periods of stable temperature.

Equipment Requirements

- **Minimum** requirements – calibrated independent temperature reference device (digital thermometer) with at least 1 (one) matched thermocouple.
- **Recommended** requirements - calibrated independent temperature/time reference device (data logger) with at least 3 (three) matched thermocouples or RFID wireless recording devices.

Procedure

- Attach the independent reference device to the unit as appropriate. A thermocouple entry port is provided on all HYDR*/M* units to enable thermocouples to be inserted into the chamber without the need to compromise the door seal. The top panel of the machine must be removed to access the port.

- Depending on the test equipment being used (see above) the thermocouples/loggers should be located in priority order throughout the machine.

    - If using the minimum single thermocouple this MUST be located adjacent to the control/validation duplex thermocouple, located in the sump under the coarse filter.
    - If using 3 thermocouples/loggers, one must be placed as above and two in the load. It is recommended that the two load thermocouples/loggers are placed diagonally opposed to each other in the corner of the load. This represents the coldest parts of the load.
    - If more than 3 thermocouples/loggers are being used then the preferred locations in order of priority should be as follows:
        - Load extremities.
        - Load centres.
        - Chamber corners*
        - Chamber walls*

* Note: this is only appropriate where thermocouples/loggers can be fixed to vertical surfaces.

- Place the test load appropriate to the model of WD in the load carrier(s) normally used by the operator. **Note:** Ideally the load requirements should be specified and documented by the user of the device and a pre-defined 'worst case' load of actual instruments appropriate to the intended purpose of the unit and its accessories should be agreed upon prior to testing. (Notes on recommended load types can be found in Annex G of this document.)

- However, if this is not possible, the load shall consist of a mass of stainless steel bolts evenly distributed, in wire baskets, throughout the usable chamber space to the recommended quantity considered by SciCan to be representative to the chamber size of the unit being tested*. The bolts should be austenitic stainless steel grade, M12 x 100 mm long with hexagon heads. They should be cleaned, degreased and dried before use.

  * Recommended load is 24 bolts for 50/60 litre units (single level load carrier) and 48 bolts for 110 litre units (double level load carrier).

Example of bolt loading in 110 litre unit (double level load carrier shown).

- Close the door of the unit.

- Ensure there is sufficient process chemical to complete the test.

- Where multiple cycles are displayed on the WD screen, select the operating cycle to be tested based on the cycle which is used in normal operation. For validating thermal disinfection, the appropriate disinfection program MUST be selected.

- Start the appropriate cycle.

- If the WD does not have a recording device (e.g. printer), and/or the reference device does not have data recording capabilities, (e.g. simple digital thermometer) observe

and note manually the elapsed time, indicated chamber temperature(s) from the machine display and the indicated chamber temperature(s) from the reference device display at all significant points of the operating cycle, for example the beginning and ending of each stage or sub-stage, and the maximum values during the holding time.

- Record any manual readings.

- Where recording devices and data logging devices are being used, printouts/displays of the cycle will be required for analysis on completion of the cycle.

Results

The test shall be considered satisfactory if the following characteristics are observed:

- During the whole of the operational cycle all the recorded values of the cycle variables are within the maximum and minimum process limits specified for the relevant HYDR*IM* unit.
- At significant points in the cycle, the reading from the WD display, reference device display (or plot if using a data logger) and recording device (if fitted) are within ± 2ºC at their comparative time intervals.
- The time for which the disinfection temperature was maintained was not less than the specified time for the cycle being tested.
- The door(s) cannot be opened until the cycle is complete
- The person conducting the test does not observe any mechanical or other anomaly.

As all HYDR*IM* WD units are microprocessor controlled and self validating this test should only need to be conducted once per re-validation. In the event of the unit failing to reproduce the results above, and only after corrective action is taken to restore the unit to factory specifications, further tests should be conducted three times to ensure consistent results.

- In this event, it should be noted that the variation in temperature at the same points in the three test cycles should differ by no more than 4ºC

Notes:

- On HYDR*IM* G4 type units, the factory (works) test cycles will be recorded on the unit's internal memory card (which may be referenced on the works test certificate) and may be used as a basis for comparison during revalidation if appropriate.
- These cycles will generally be the first cycles recorded by the unit and may be retrieved in a number of ways (for cycle master reference purposes) if required:
    - When the USB device is first inserted into the data logger during installation, any cycle data stored on the internal memory card should be automatically downloaded (ONCE ONLY) to the USB device. These cycles MAY either still be on the USB device or it may have been transferred to the customer's storage media (computer etc). The entire archive can be copied onto a new USB via the following button sequence:

NOTE: Depending on how many files are stored on the memory card, this could take a couple of hours

- If the HYDR*IM* G4 unit is connected to a local area network, cycle data may be retrieved from the unit's web portal archive through any computer or smart device connected to the same network.
- If the HYDR*IM* unit is not connected to a local area network, a hard wired connection via ethernet cable directly to a laptop can also be used to access the unit's web portal archive.

Annex C – Chemical dosing test

General

The HYDR*IM* detergent dosing system consists of either (i) a peristaltic pump plus flow switch (non G4 units) or (ii) a bellows pump (G4 units). For proper operation, the pump flow has to be adjusted/ checked at initial factory setup and at regular maintenance intervals.

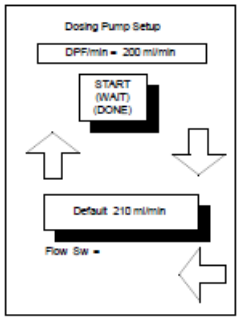
Note that this test can only be performed on certain Hydrim derivatives as listed below:

Unit type	Test available	Notes
HYDR*IM* C51wd	No	
HYDR*IM* M2 – software lower than R320	No	See M2 service manual
HYDR*IM* M2 – software R320 or higher	Yes	
HYDR*IM* C61wd G4	Yes	
HYDR*IM* M2 G4	Yes	

<u>Procedure for M2 (non G4) units (software R320 or higher)</u>

- For this operation a small bottle (around 40ml) and a measuring tube (minimum 40ml) are required.

- To start the procedure, go to the Dosing Pump Setup screen located in the Technician menu under the sub menu Diagnostic Tools (2),



- Ensure that there is sufficient process chemical available in the unit to perform this test.

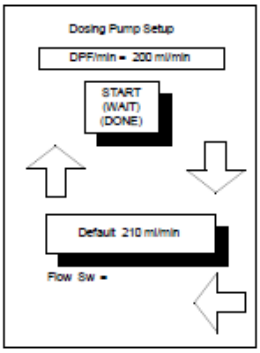
Before pressing the Start button please read the following instructions:

- By pressing the Start button the dosing pump is activated and the message **WAIT** is displayed.
- When the flow switch turns **ON** (Flow Sw = 1) the dosing pump will run for an additional 10 seconds and the message **DONE** is displayed shortly afterwards.
- Run this sequence once to ensure that the internal dosing system is primed (flow switch, internal tubing).
- Once this is completed, prepare to collect the detergent delivered to the washing chamber with the small bottle, see picture below, and press the START button.

- The dosing pump will activate again for 10 seconds (assuming that the flow switch is primed with detergent as specified above).
- When the detergent delivery ends, transfer the liquid collected from the small bottle into the measuring tube and read the volume = D [ml].
- Now multiply volume D by 6 to find the Dosing Pump Flow (DPF) in ml/min.
- For example for D = 35ml => Dosing Pump Flow = 35 x 6 = 210 ml/min
- **The DPF/min value should be as follows:**

Unit type	DPF range
HYDR*IM* M2 – software R320 or higher	190 - 242

- If the number is outside of these values, exit the Dosing Pump Setup and check that the dosing pump is running correctly, repeat the procedure above, and if the DPF value is still outside of the specified range, replace dosing tubing and/or pump.



- When the DPF value is acceptable, use Up or Down arrow to change DPF/min value to the new calculated value.
- Exit the Dosing Pump Setup screen by pressing the left arrow.
- This ends the Dosing Pump Flow check/adjustment process.

As all HYDR*IM* WD units are microprocessor controlled and self validating this test should only need to be conducted once per re-validation. In the event of the unit failing to reproduce the results above, and only after corrective action is taken to restore the unit to factory specifications, further tests should be conducted three times to ensure consistent results.

- In this event, the volumes of the dispensed liquids during each of the 3 tests should be within ± 5% by volume.

Test Acceptance criteria.

- The DPF value is within the acceptable range.

Procedure for C61wd G4 and M2 G4 units

This procedure requires the following items:

- 1x Dosing Pump Test Adapter (01-113909S)
- 1x 100mL Graduated Cylinder

- Turn unit ON and go to Technician menu. Go to **Dosing System** Screen located in **Technician Menu / Diagnostic Tools /Component Test**.

- For **M2 G4**: Remove upper trolley from the unit. **For C61wd:** Remove trolley from the unit.

- Insert dosing pump test adapter on the opening of the chamber intake fitting. If necessary hold in place with light pressure (Figure 1).

- Press **ON** button on display to start bellows dosing pump. Collect the chemical coming out from the chamber intake fitting into a graduated cylinder. A countdown will appear on screen to indicate progress. (Figure 2)

- Press **OFF** button on display after the countdown is finished. The dosing valve (M2 G4) or dosing fill pump (C61wd G4) will activate to refill the dosing reservoirs as indicated by a buzzing noise. **Any further testing should not be undertaken while this process is taking place.**

- Read the chemical volume inside the cylinder. The volume collected should be:

Unit type	Chemical volume
HYDR*IM* C61wd G4	**41.0 – 45.4 ml**
HYDR*IM* M2 G4	**91.2 – 100.8 ml**

- If the chemical volume is outside these ranges, check all the tubing for proper connections and kinking. Repeat the test. Replace bellows dosing pump if value is still outside the range.

- **Empty the cylinder and repeat above procedure. The chemical volume should be within the same range.**

In the event of the unit failing to produce the results above, and only after corrective action is taken to restore the unit to factory specifications, further tests should be conducted three times to ensure consistent results.

Figure 1: Dosing Pump Test Setup

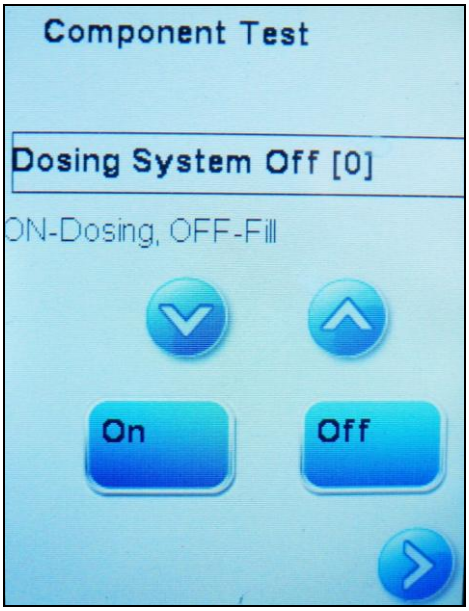


Figure 2: Screen Display

Annex D – Cleaning Efficacy testing.

General

This test is designed to demonstrate the satisfactory performance of the abilities of the machine to remove gross soil from contaminated instruments.

For this test, an approved test soil should be used which should be based on the applicable regional annex of **EN ISO 15883-5** (latest edition applies).

Note that there are a number of approved test soils which are specified for different regions and it is recommended that the appropriate test soil is used for this test.

IMPORTANT NOTE:

The test soils recommended in EN ISO 15883-5 are laboratory prepared. However, in many regions, a dehydrated test soil (with National standards equivalence) may be available and is recommended on the basis that it has a much longer shelf life than laboratory produced blood based products.

If in doubt, please call the dealer who supplied the unit for advice and guidance.

Equipment requirements, procedure for testing and interpretation of results.

This will vary depending on the test soil being used. Reference should be made to EN ISO 15883-5 for the method, equipment and results appropriate to the chosen test soil.

Note:
If the unit you are testing does NOT have a separate wash TEST cycle, then the operating cycle chosen must be stopped before the final rinse portion. i.e. the cycle should consist of Pre-wash, Wash and Intermediate rinse(s) (if appropriate) only.

All standard cycles on each HYDR*IM* unit derivative will have the same Pre-wash, Wash and Intermediate rinse parameters so any of the wash cycles can be selected for this test (P2 Regular Wash, P3 Heavy Duty Wash & Disinfect or P4 Custom, when appropriate).

If in doubt, please call the dealer who supplied the unit for advice and guidance.

Test loads.

Select the test load appropriate to the type of WD in the load carrier(s) normally used by the operator. **Note:** Ideally the load requirements should be specified by the user of the device and a pre-defined ‘worst case’ load of actual instruments appropriate to the intended purpose of the unit and its accessories should be agreed upon prior to testing. (Notes on recommended load types can be found in Annex G of this document.)

However, if this is not possible, the load shall consist of a mass of stainless steel bolts evenly distributed, in wire baskets, throughout the usable chamber space to the recommended quantity considered by Scican to be representative to the chamber size of the unit being tested*. The bolts should be austenitic stainless steel grade, M12 x 100 mm long with hexagon heads. They should be cleaned, degreased and dried before use.

* Recommended load is 24 bolts for 50/60 litre units (single level load carrier) and 48 bolts for 110 litre units (double level load carrier).

Procedure

- Select 12 (twelve) items of the load to be contaminated. If actual instruments are being used, then select 3 (three) of 4 (four) types that are considered to be the biggest challenge to the machine.

- Using protective gloves, prepare laboratory or dehydrated test soil in accordance with the manufacturers instructions. Sufficient soil should be prepared to fully coat the 12 (twelve) selected items.

- Place test soil in tray.

- Apply the soil to the test pieces by fully immersing solid items in the soil or, for larger and hollow items, apply an even coat of soil using the paint brush.

- Allow excess soil to drain from the items and allow them to dry at room temperature (15 °C to 25 °C) for not less than 30 min and not more than 2 h.

- Fully load the WD with the chosen load and evenly distribute the inoculated load items in the load ensuring that some are on the extremities of the carriers.

- Run a normal operating cycle (or wash test cycle if available).

- At the appropriate point in the cycle, stop the unit and remove the load items from the WD and subject them to careful visual examination for residual soil.

- For the cleaning process to be regarded as satisfactory there shall be no visible residual soil present on the load.

- **NOTE:** This test needs to be satisfactory before any residual protein testing is undertaken.

Annex E – Ninhydrin test for residual protein.

General

- Much of the contamination which occurs on reusable medical devices is, in whole or part, proteinaceous in nature. The method described below provides a pass/fail test with a high level of sensitivity for proteins and amino acids.

- For this test the Browne Ninhydrin Protein Detection Kit is recommended as it is compatible with the requirements of EN ISO 15883-1 (Note: current standard applies)

- Instruments (or surrogate items) used in this test should be ones that have been recently processed in the WD and known to be visibly clean – (see Annex D).

Equipment and materials requirements.

- Cotton swabs (with plastic handles)
- 2 % ninhydrin in 70 % isopropanol
- Sterile distilled water
- Oven (110 °C)

Procedure

- Moisten the swab with sterile distilled water and use it to swab the surface of the instrument(s) to be tested.

- Ensure that the area to be swabbed is not less than 5 cm^2 and not more than 50 cm^2.

- After swabbing the instrument, examine the swab. Any discolouration indicates that the instrument was not clean and there is no need to proceed further at this point.

- If acceptable, place a drop (approximately 0.05 ml) of the ninhydrin reagent on the swab and allow to air dry for approximately 5 min.

- If a purple coloration develops, residual protein/amino acids have been detected and no further action is needed at this point.

- If no colour has developed, transfer the swab to the oven and heat at 100°C to 110°C for 30 min and re-examine the swab for purple colouration.

- Run a positive and negative control for each series of tests carried out.

Acceptance criteria

- There shall be no discoloration of the swab prior to the application of the ninhydrin reagent.
- There shall be no visible purple discoloration of the swab after application of the ninhydrin reagent before **or** after heating at 100-110°C for 30 mins in oven.

Annex F – Load Dryness Test.

General

- The following test shall be carried out when the operating cycle includes a drying stage.

- This test may be undertaken as an extension of the Automatic control/Full cycle profile thermometric check if the cycle selected has a drying cycle following on from thermal disinfection. Data recorded during the drying phase should be ignored for the purposes of the thermometric tests.

Equipment and materials requirements.

- Coloured (e.g. blue or green) crepe paper.

Procedure

- If this test is not an extension of the thermometric full cycle profile test then proceed as follows:

- Select the test load appropriate to the type of WD in the load carrier(s) normally used by the operator. **Note:** Ideally the load requirements should be specified by the user of the device and a pre-defined 'worst case' load of actual instruments appropriate to the intended purpose of the unit and its accessories should be agreed upon prior to testing. (Notes on recommended load types can be found in Annex G of this document.)

- However, if this is not possible, the load shall consist of a mass of stainless steel bolts evenly distributed, in wire baskets, throughout the usable chamber space to the recommended quantity considered by Scican to be representative to the chamber size of the unit being tested*. The bolts should be austenitic stainless steel grade, M12 x 100 mm long with hexagon heads. They should be cleaned, degreased and dried before use.

  * Recommended load is 24 bolts for 50/60 litre units (single level load carrier) and 48 bolts for 110 litre units (double level load carrier).

- Carry out a normal operating cycle from a cold start, i.e. the WD shall not have been used within the previous hour.

- Within 5 min of the end of the operating cycle, place a sheet of coloured (e.g. blue or green) crepe paper on a flat surface and place the load on it.

- When removing the load from the WD, and as the individual load items are placed onto the crepe paper, observe and record any water being discharged.

- Examine the crepe paper for dampness shown by dark spots on the paper which shall be regarded as evidence of residual water.

- Items with lumens should also be visually examined for internal retained moisture.

Results

- Report whether or not any residual water was found**.**
- If water was found, possible causes could be:
    - Blocking of the exhaust
        - Front of the unit must be clear
        - Duct inside the chamber must be clear
    - HEPA Filter has been exhausted
    - Malfunctioning blower
- Refer to the service manual for instructions on servicing/replacing parts.

Annex G – Recommended load configurations.

General considerations when choosing a load for validating HYDR*IM* units:

There are various different loads that can be used to validate HYDR*IM* WD units both for cleaning efficacy testing and thermometric testing of the thermal disinfection cycle.

It is important when considering a validation load to familiarize yourself with any local, national or international guidelines that may take precedence when validating.

If there are no specific overriding guidelines in force, SciCan recommends using one of the following:

1. Select a validation load using the load carrier(s) and instruments normally used by the operator. The load requirements should be specified and documented by the user of the device and a pre-defined 'worst case' load of actual instruments appropriate to the intended purpose of the unit and its accessories should be agreed upon prior to testing.

2. Use a 'surrogate' load, again using the load carrier(s) normally used by the operator. A typical surrogate load can consist of a mass of stainless steel bolts evenly distributed throughout the loading space to the maximum mass specified for the WD. The bolts should be austenitic stainless steel grade, M12 x 100 mm long with hexagon heads. They should be cleaned, degreased and dried before use.

3. A test load in accordance with the national requirement listed in the appropriate annex of EN ISO 15883-5 (Note: current standard applies).

4. A load in accordance with SciCan type test loads.

Notes:

- In some cases, specified loads in the various sections of 3 above may be fixed and not truly reflect the use of the WD being validated.
- SciCan type test loads are also very specific and are designed to comply with the requirements of EN ISO 15883-5 (Note: current standard applies) and also the 'worst case scenario' loads.
- **For this reason, SciCan recommends wherever possible to use loading as in 1 or 2 above as they are likely to be more representative of typical general user requirements.** The specific tests in this document reflect this advice.

General load information.

The intended purpose of the HYDR*IM* range of washer disinfectors is as a general instrument thermal WD, predominantly aimed at the general dental market. There will therefore be many combinations of instruments that can be processed in the HYDR*IM* unit depending on:

- Size of practice
- Types of procedures undertaken at any one time
- Specialisation of practice
- Instrument management protocols

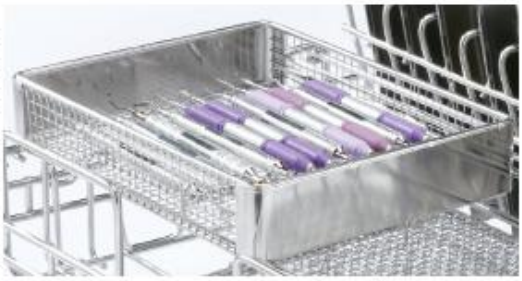
It is difficult therefore to show all the possible combinations available, so below we have given examples of the most common typical basket loadings, the recommended loading of general instruments, and the worst case loading the unit has been type tested and validated for.

Basket loading: (Note: Baskets shown are typical for illustration purposes only and may vary dimensionally depending on unit size/derivative.)

Solid straight and hinged instruments

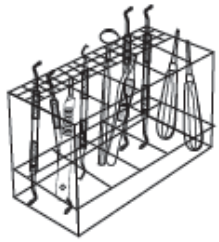
For example: scalpels, scissors, curettes, excavators, pluggers, etc.

Solid straight instruments

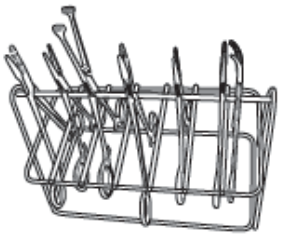


For example: pliers, knives, explorers, scalers, etc.

Example 3 – hinged instruments, solid instruments and open hollow instruments

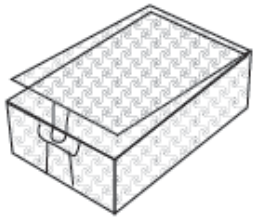


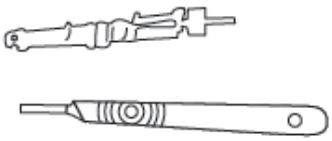
For example:
Scalers, curettes, dental elevators, single part mirrors, suction tubes etc.



For example: Tissue forceps and scissors.

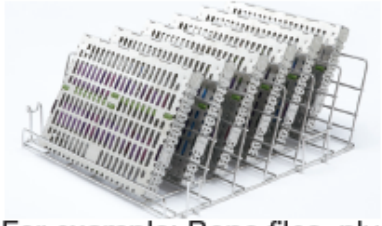
Small and disassembled instructions

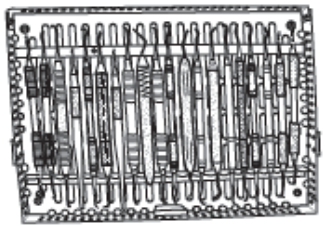




For example: Two piece mirrors, scalpel knife handles, etc.

Instrument sets in cassettes – full load





For example: Bone files, pluggers, curettes, excavators, etc.

Validated load configurations - Type Test Loads:

As part of the requirements of EN ISO 15883 all HYDR*IM* units have been type tested for cleaning efficacy and thermal disinfection. The load configurations used for validating the machine were the recommended standard optimal loading for instruments not in containers and the recommended maximum instrument loading – instruments and cassettes as discussed above.

All HYDR*IM* units are validated in the factory using the following configurations (**instruments where shown are for visual reference only and do not represent actual type test loads**):

1. Recommended standard optimal loading for instruments not in containers (cassettes).

For a full load of general surgical instruments the recommended basket configuration is:

50/60 litre single level units

- 2 x 01-107241 – STAT*IM* 5000 Baskets

110 litre double level units

- 4 x 01-108232 – Long Basket

2. Recommended maximum instrument loading - instruments in cassettes.

For a full load of general surgical instruments contained in cassettes the recommended configuration is:

50/60 litre single level units

C51wd models

C61wd G4 models

- **C51wd -** 1 x 01-109153 4 cassette rack + 4 x SYS-TM4B instrument cassettes.
- **C61wd G4 -** 1 x 01-113251 6 cassette rack + 6 x SYS-TM4B instrument cassettes.

110 litre double level units (all models)

- Top – 1 x 01-109963S – Cassette rack, full size + 5 x SYS-TM4B instrument cassettes.
- Bottom – 1 x 01-109963S – Cassette rack, full size + 5 x SYS-TM4B instrument cassettes.