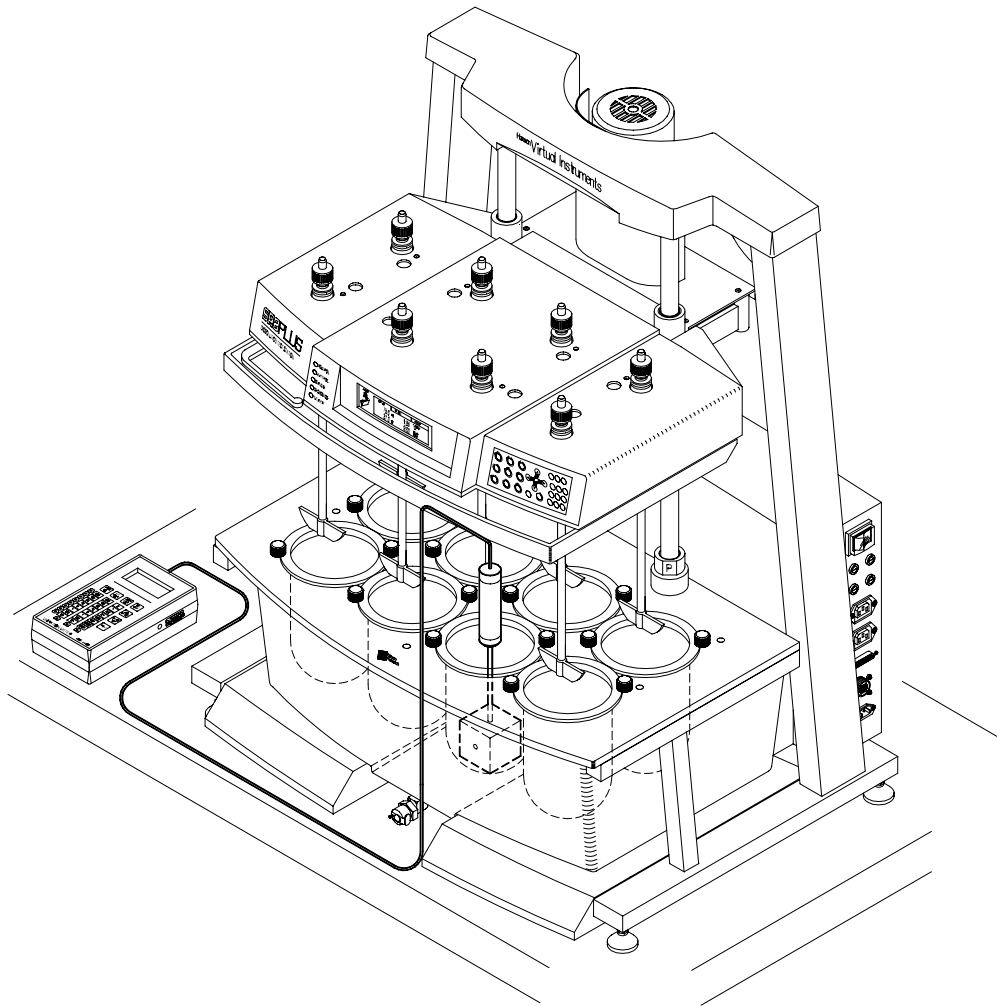


Vibration Meter Operation Manual 65-233-209

REV. A
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Introduction

Vibration is one of the more common input variables producing unwanted variation in dissolution data. The U.S. Pharmacopoeia, 711 Dissolution states: “No part of the assembly, including the environment in which the assembly is placed, contributes significant motion, agitation, or vibration beyond that due to the smoothly rotating stirring element”. The term significant requires further definition in order to establish useful vibration limits. The limits specified in this manual are based on values suggested in the Handbook of Dissolution Testing, 2nd edition, Copyright 1991 by William A. Hanson. The most satisfactory method of monitoring vibration requires the use of a vibration meter. The Hanson vibration meter measures true vibration in terms of displacement, velocity and acceleration. A special probe adapter facilitates vibration measurements in several key locations on the dissolution test station. The meter is also useful in identifying external sources of vibration when vibration measured at the dissolution test station is excessive. Included in this manual is a Vibration Measurement Record which may be copied and used to establish a permanent record of actual measurements. The meter and probe are supplied in a convenient storage case designed to protect the instrument and maintain calibration.

Meter set-up (see fig. 1)

Turn the Vibration Meter On.
Set the meter mode to displacement by pressing the “DISP” function button on the instrument. Set the range button to the 0.001inches position by pressing the down(▼) range button. With this range setting, the upper full-scale (10) reading equals 0.001inches displacement.

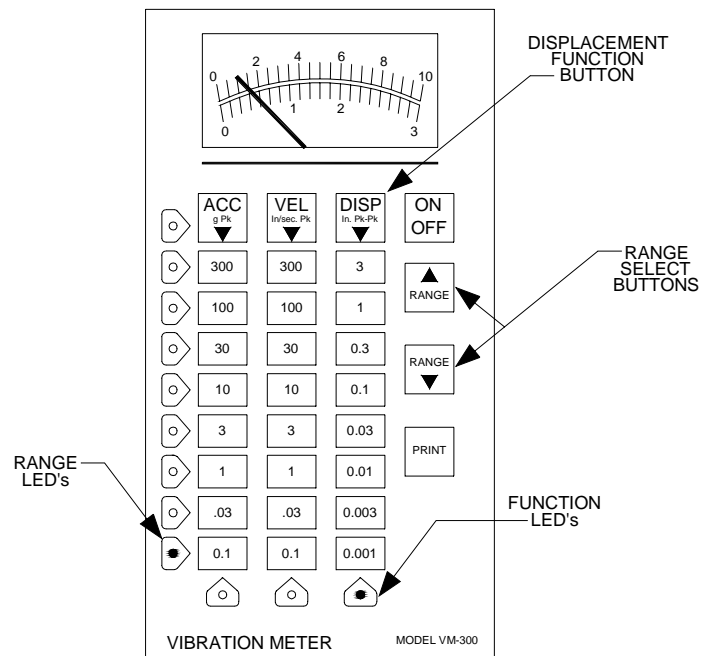


Figure 1

Pre vibration test check out

1. Verify that the dissolution instrument is in an aligned condition (ref 65-233-102 Alignment Kit Manual).
2. Inspect the structural integrity of the work bench to be sure it does not rock and that it provides a sound support for the dissolution station.
3. Check to be sure all four mounting feet on the dissolution station are contacting the workbench and that the station does not rock.
4. Check the workbench and immediate area for laboratory items which may be transmitting excessive vibration to the dissolution tester.

Checking vibration at dissolution work bench

Turn power to the Dissolution instrument off. Locate the probe on the workbench adjacent to the dissolution water bath with the probe oriented in the vertical position (see fig. 2). Turn the meter on and record the vibration reading on the Vibration Measurement Record Sheet. Vibration at the workbench is recorded for reference only.

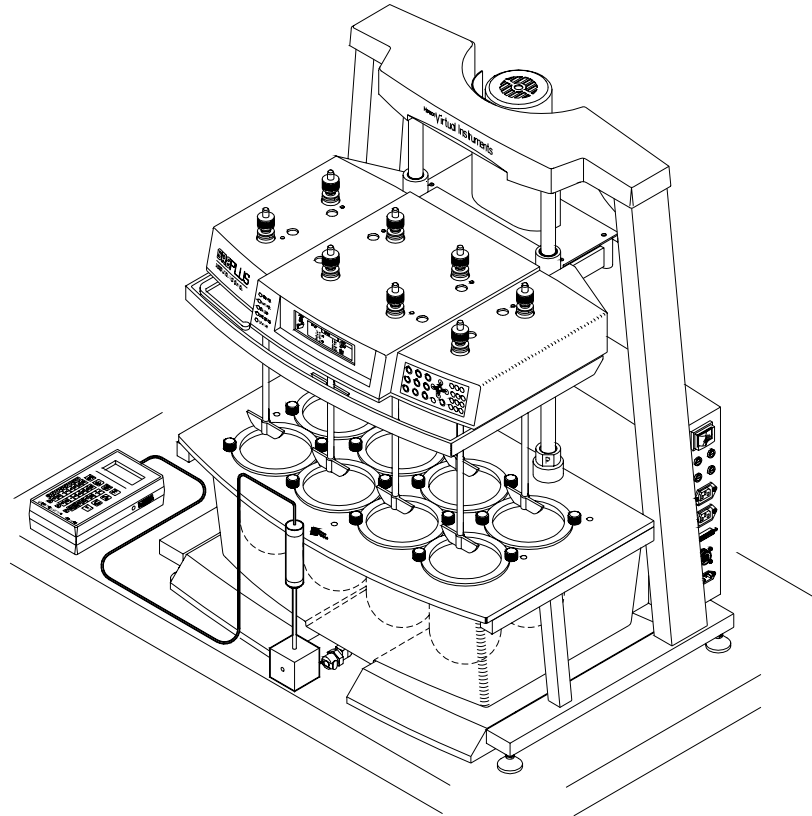


Fig. 2

Checking vibration at the dissolution instrument baseplate

CAUTION! Prior to turning on power to the dissolution control, make sure the vibration meter's probe cable is not close to paddle or basket shafts and will not interfere with or wind up on rotating shafts.

Place the probe in the vertical position on the baseplate as shown (see fig. 3). With paddle or basket shafts in place, set speed to 100 rpm. Turn the dissolution instrument's control on and make sure the bath circulator is running and the shafts are rotating. Turn the meter on and record the vibration reading on the Vibration Measurement Record Sheet. Vibration at the baseplate is recorded for reference only.

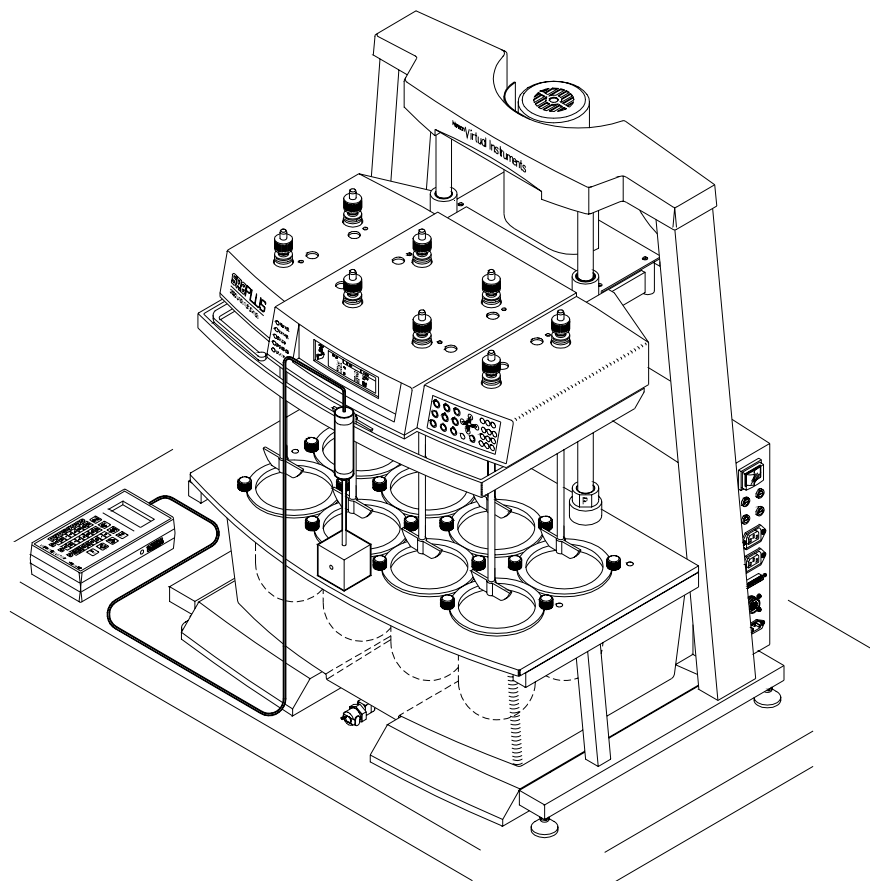


Fig. 3

Checking vibration at the dissolution vessel:

CAUTION! Prior to turning on power to the dissolution control, make sure the vibration meter's probe cable is not close to paddle or basket shafts and will not interfere with or wind up on rotating shafts.

Remove paddle from vessel position to be tested and empty contents of vessel. Place the probe adapter in the vessel so that four corners of the square adapter are resting on the curvature of the vessel bottom (see fig. 4). All shafts should be in place except for the test position. Turn the dissolution instrument's control on and make sure the bath circulator is running and the shafts are rotating. Set paddle or shaft speed to 100 rpm. Turn the vibration meter on and record reading on the Vibration Measurement Record Sheet. The maximum allowable vibration is 0.0001 inches.

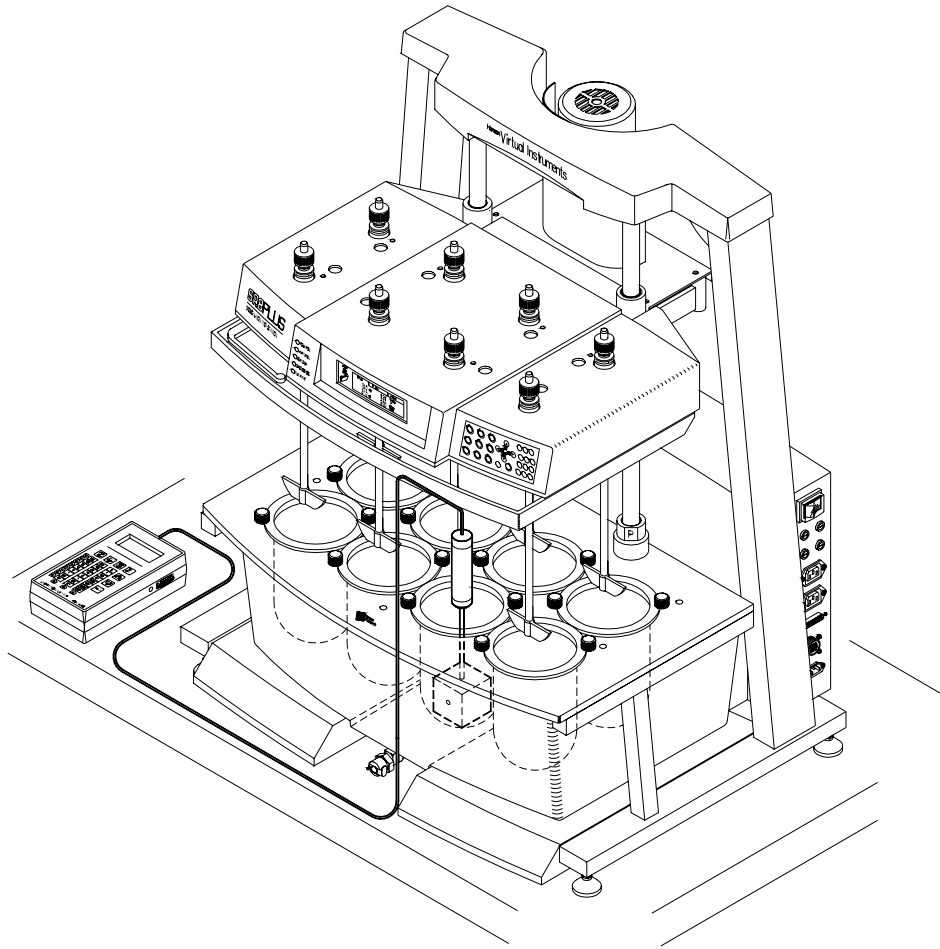


Fig. 4

Calibration of the Vibration Meter

The vibration meter is calibrated at the factory and packaged in a protective case to maintain calibration. After each use the instrument should be immediately returned to the protective case for storage. It is recommended that the complete kit be returned to Hanson Research Corporation every twenty four months for recalibration and certification. The protective case has a calibration tag on the outside which indicates the last calibration date and the next required calibration date.

Please contact Hanson Research Corporation at (800) 821-8165 to make arrangements to return the instrument for calibration.

Vibration Measurement Record

Displacement, Mils

| Inspector | Date | Work bench (reference) | Baseplate (reference) | Vessel 0.0001 in. max. |
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