



Handläggande organ	Fastställt	Utgåva	Sida
<b>SVENSK MATERIAL- &amp; MEKANSTANDARD, SMS</b>	1998-08-21	1	1 (1+28)

© INNEHÅLLET I SVENSK STANDARD ÄR UPPHOVSRÄTTSLIGT SKYDDAT. SIS HAR COPYRIGHT PÅ SVENSK STANDARD. EFTERTRYCK UTAN TILLSTÅND ÄR FÖRBUDET.

## Mechanical vibration and shock – Guidance on safety aspects of tests and experiments with people – Part 1: Exposure to whole-body mechanical vibration and repeated shock (ISO 13090-1:1998)

The European Standard EN ISO 13090-1:1998 has the status of a Swedish Standard. This document contains the official English version of EN ISO 13090-1:1998.

Swedish Standards corresponding to documents referred to in this Standard are listed in "Catalogue of Swedish Standards", issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

## Vibration och stöt – Vägledning om säkerhetsaspekter för prov- ningar och experiment med män- niskor – Del 1: Exponering för me- kaniska helkroppsvibrationer och upprepad stöt (ISO 13090-1:1998)

Europastandarden EN ISO 13090-1:1998 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 13090-1:1998.

Motsvarigheten och aktualiteten i svensk standard till de publikationer som omnämns i denna standard framgår av "Katalog över svensk standard", som ges ut av SIS. I katalogen redovisas internationella och europeiska standarder som fastställts som svenska standarder och övriga gällande svenska standarder.

ICS 13.160



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 13090-1**

June 1998

ICS 13.160

Descriptors: vibration, mechanical shock, humans, experimentation, tests, vibration tests, hazards, safety, general conditions.

English version

**Mechanical vibration and shock – Guidance on safety aspects of tests and experiments with people – Part 1: Exposure to whole-body mechanical vibration and repeated shock (ISO 13090-1:1998)**

Vibrations et chocs mécaniques – Lignes directrices concernant les aspects de sécurité des essais et des expérimentations réalisés sur des sujets humains – Partie 1: Exposition de l'ensemble du corps aux vibrations mécaniques et aux chocs répétés (ISO 13090-1:1998)

Mechanische Schwingungen und Stöße – Leitfaden zur Sicherheit von Prüfungen und Versuchen mit Menschen – Teil 1: Einwirkung von mechanischen Ganzkörper-Schwingungen und wiederholten Stößen (ISO 13090-1:1998)

This European Standard was approved by CEN on 14 May 1998. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

**CEN**

European Committee for Standardization  
Comité Européen de Normalisation  
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 BRUSSELS

**Contents**

	Page
Foreword .....	3
Introduction .....	4
1 Scope .....	5
2 Normative references .....	5
3 Definitions .....	6
4 Hazard of mechanical vibration and repeated shock experiments on human test subjects .....	6
5 Classifying experiments according to severity of vibration exposure .....	8
6 Practice for laboratory tests and experiments .....	9
7 Selection of human test subjects .....	12

**Annexes**

A (informative) Severity of exposure .....	13
B (informative) Example of consent form for a human test subject in mechanical vibration and repeated shock experiments .....	15
C (informative) Medical contra-indications to participation in experiments involving whole-body mechanical vibration and repeated shock .....	16
D (informative) Principles pertaining to the use of human subjects .....	18
E (informative) Design of equipment .....	20
F (informative) Guidelines for the preparation of an experimental or test protocol for submission to an Ethical Committee .....	24
G (informative) Bibliography .....	27
ZA (normative) Normative references to international publications with their relevant European publications .....	28

## **Foreword**

The text of the International Standard ISO 13090-1:1998 has been prepared by Technical Committee ISO/TC 108 "Mechanical vibration and shock" in collaboration with Technical Committee CEN/TC 231 "Mechanical vibration and shock", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 1998, and conflicting national standards shall be withdrawn at the latest by December 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

### **Endorsement notice**

The text of the International Standard ISO 13090-1:1998 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

## Introduction

People may be exposed to mechanical vibration and repeated shock intentionally in the course of experiments to determine their response to such environments and in the course of experiments or tests performed for other purposes. It is widely accepted that exposure to mechanical vibration and repeated shock of sufficient magnitude can cause injury or impair health.

In this part of ISO 13090, guidance is provided on the safety aspects of equipment or procedures which are particular to experiments involving mechanical vibration and repeated shock and which affect the safety of those involved.

The purpose of this part of ISO 13090 is to reduce the chance of the subjects, or those monitoring or conducting the experiments, being exposed to undue risk of injury or impaired health arising from such exposure, or of injury attributable to the malfunction or poor operation of the equipment used to generate the mechanical vibration and repeated shock. Guidance on the design of equipment is included in annex E.

In accordance with accepted practice for experiments in which human subjects are involved, the experimenter should obtain approval from an independent Ethical Committee, or "Human Use Committee", giving details of the planned experiment together with a written justification. Some guidelines are included in annex F.

This part of ISO 13090 represents the best international consensus at this time and may be subject to change in the light of future developments in scientific knowledge and experience.

# Mechanical vibration and shock — Guidance on safety aspects of tests and experiments with people —

## Part 1: Exposure to whole-body mechanical vibration and repeated shock

### 1 Scope

This part of ISO 13090 provides guidance on the safety aspects of the design of equipment and the conduct of tests and experiments in the laboratory in which human subjects<sup>1)</sup> are exposed to mechanical vibration and repeated shock.

This part of ISO 13090 is concerned with tests and experiments in which subjects are exposed to whole-body mechanical vibration and repeated shock, as described in ISO 2631-1. Local vibration is not within the scope of this part of ISO 13090, but some of the general procedures may be applicable.

The experiments to which this part of ISO 13090 is applicable include those performed to determine the response of subjects to mechanical vibration and repeated shock stimuli. They also include those experiments in which mechanical vibration and repeated shock are part of the environment in which other investigations are performed, and to experiments or tests to compare the attributes of equipment intended to alleviate the effects of mechanical vibration and repeated shock on the user (e.g. testing of seat suspensions, seat cushions and other attenuating devices, including tests according to ISO 10326-1).

NOTE Measures in addition to those described in this part of ISO 13090 may be necessary in those countries which have relevant national requirements.

### 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 13090. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 13090 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2041:1990, *Vibration and shock — Vocabulary*.

ISO 2631-1:1997, *Mechanical vibration and shock — Evaluation of human exposure to whole-body vibration — Part 1: General requirements*.

ISO 5805:1997, *Mechanical vibration and shock — Human exposure — Vocabulary*.

ISO 10326-1:1992, *Mechanical vibration — Laboratory method for evaluating vehicle seat vibration — Part 1: Basic requirements*.

---

1) Hereinafter referred to as "the subject" or "subjects".

### 3 Definitions

For the purposes of this part of ISO 13090, the definitions given in ISO 2041 and ISO 5805 apply.

## 4 Hazards of mechanical vibration and repeated shock experiments on human test subjects

### 4.1 General

Those who engage in experiments which involve exposing subjects to mechanical vibration and repeated shock, and those who supply equipment for such experiments, should address three types of hazard specific to such experiments, in addition to the general responsibility for safety, as follows:

- a) the inherent hazard that exposure to the mechanical vibration or repeated shock which the experiment is intended to reproduce may lead to injury or ill-health, either immediately or at some time in the future (see 4.2);
- b) the extraneous hazard that malfunction or inadvertent operation of the equipment used to generate the mechanical vibration or repeated shock may cause the subject to be exposed unintentionally to motions so severe as to cause injury or ill-health;
- c) the hazard of injury to the subject, the experimenter, or others in the vicinity arising from any of the following:
  - 1) the relative motion between the vibration equipment and its surroundings,
  - 2) mechanical, electrical or other failures,
  - 3) falling.

### 4.2 Inherent hazards in mechanical vibration and repeated shock experiments

#### 4.2.1 General

The inherent hazard that exposure of a subject to mechanical vibration or repeated shock may lead to injury or ill-health depends on the following two possible causes:

- a) use of mechanical vibration or repeated shock that is too severe in terms of magnitude or duration, see 4.2.2;
- b) failure to exclude from the test a subject who is medically unfit or otherwise particularly sensitive to mechanical vibration or shock.

NOTE Precautions to be taken with subjects are given in clause 7 and annex D.

#### 4.2.2 Severity of mechanical vibration or shock stimulus

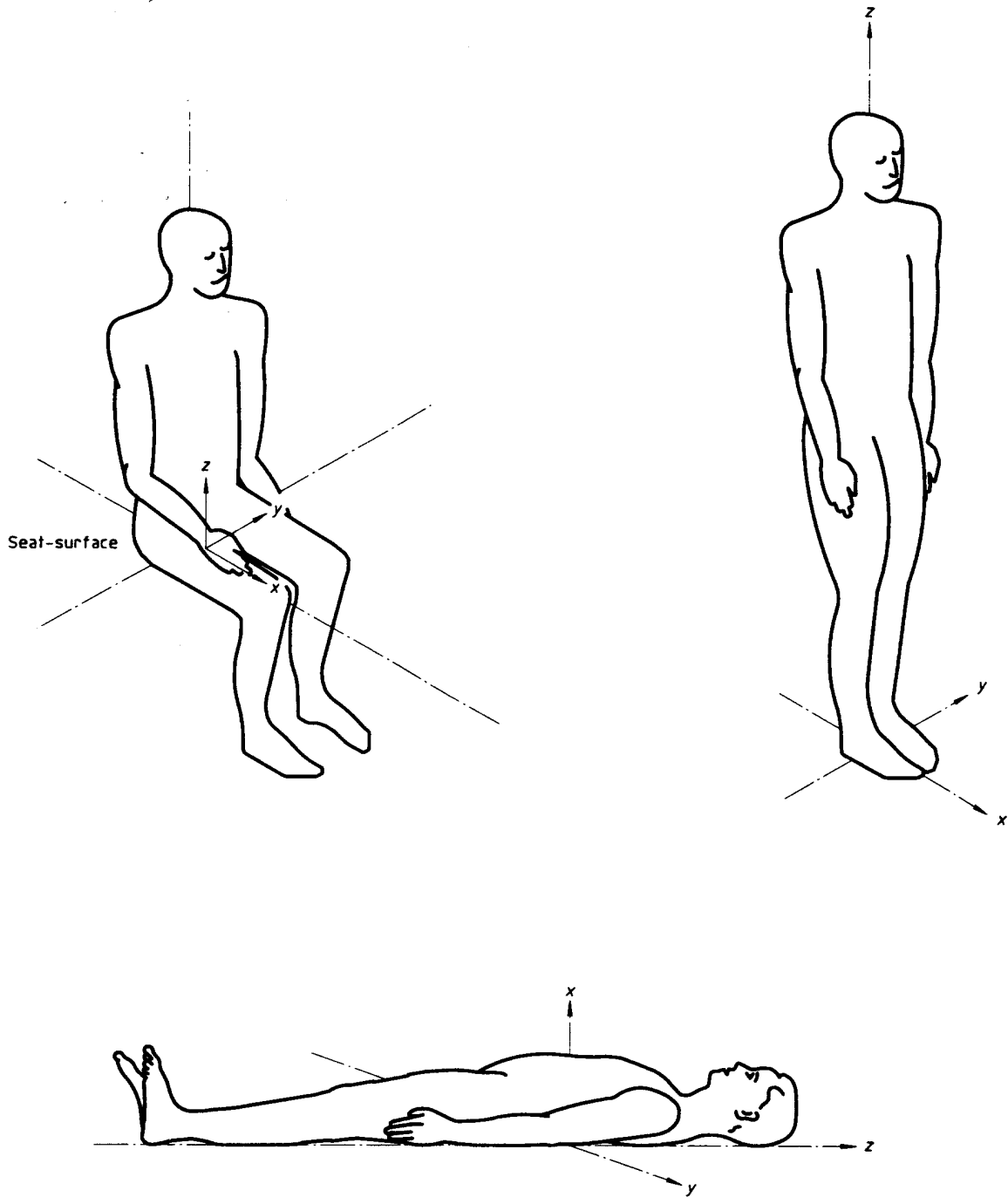
The effects on subjects of mechanical vibration and repeated shock depend on the magnitude, frequency content, direction of action and duration of the stimuli, all of which should be included in assessing the severity.

In all cases, the mechanical vibration is to be measured at the interface of the subject with the vibrating surface. Vibration may be characterized as deterministic (including periodic) or random and, for the purposes of this part of ISO 13090, vibration is restricted to frequencies between 0,5 Hz and 80 Hz. Repeated shocks may be applied with or without the presence of vibration, with various characteristics.

Mechanical vibration and repeated shock should be characterized from measurements of acceleration in three mutually perpendicular axes (see figure 1).

R.m.s. values of acceleration should be obtained using frequency weightings according to ISO 2631-1. The r.m.s. value should be determined using linear integration over the full period of exposure.





**Figure 1 — Basicentric axes of the human body**

### **4.3 Extraneous hazards in mechanical vibration and repeated shock experiments**

Many vibrating devices used in experiments have a large quantity of available or stored energy. An inherent problem in the design of vibration systems is that the subject may be exposed to unexpected or frightening transients or, at worst, to potentially dangerous magnitudes of mechanical vibration or shock as a result of an equipment malfunction.

Equipment design should be such that, in the event of malfunction or emergency stop procedures, the subject should not be exposed to accelerations of hazardous magnitude or duration. Equipment should be designed so that no failure could result in magnitudes of mechanical vibration or shock producing accelerations in excess of an acceptable short-term magnitude, unless the experiment is designed to study the effects of higher magnitudes. For such experiments, the magnitude during failure conditions should be only slightly in excess of those being studied.

The equipment should be tested under simulated fault conditions (e.g. as suggested in annex E), to ensure so far as is reasonably practicable that the short-term acceleration does not exceed an acceptable magnitude.

### **4.4 Physical contact with moving parts**

#### **4.4.1 General**

Mechanical vibration and repeated shock experiments present the following three particular physical hazards:

- a) the experimenter or another person in the vicinity of the equipment may receive a blow through inadvertent contact with the moving parts;
- b) the subject on a moving part may receive a blow through inadvertent contact with a fixed object;
- c) anyone on the equipment or in the vicinity may be at risk from pinching or shearing between fixed and moving parts.

#### **4.4.2 Restraint of subjects**

In experiments where subjects are restrained, special care should be taken to ensure that during normal operation or malfunction the restraint itself does not present a hazard.

## **5 Classifying experiments according to severity of vibration exposure**

### **5.1 General**

The recommendations in this part of ISO 13090 provide for two categories of experiment which are differentiated, according to the degree of risk, as to whether or not a physician or medical doctor should be in attendance or on call. The decision is based on an assessment of the degree of severity of mechanical vibration or repeated shock to which the subjects are to be exposed.

An independent Ethical Committee (see annex F) shall be required to review any proposed experiment involving the exposure of human subject to vibration. This committee shall decide whether an experiment carries "greater than minimal risk", and what is required by way of medical supervision.

### **5.2 Experiments involving minimal risk**

Ethical Committees may not require that a physician or medical doctor be in attendance or on call for tests or experiments in which the subjects are exposed to magnitudes of mechanical vibration or repeated shock comparable to those found in common forms of transportation and in any but the most severe of civilian working environments (see annex A).

### **5.3 Experiments involving some inherent risk**

For experiments in which any subject is exposed to mechanical vibration or repeated shock in excess of that which would be consistent with the safe exposure of workers (see annex A) a physician or medical doctor should be in attendance or on call (see 6.2.4). Prior advice should also be sought from a relevant medical specialist on the inherent risk of the experiment and on the criteria for the selection of subjects (see clause 7).

It is recognized that for certain tests or experiments involving the exposure of subjects to vibrations which simulate real work conditions, the above criterion may require the continuous attendance of a physician or medical doctor when this would be neither expected, nor practicable in the work conditions themselves. In such cases, the advice of the Ethical Committee should be sought as to whether or not the presence of the physician or medical doctor is warranted.

## **6 Practice for laboratory tests and experiments**

### **6.1 General**

The risk of injury in experiments involving human test subjects can be reduced by observing good practices. These include the selection and training of personnel, adherence to well-defined procedures, and the discipline of maintaining adequate records.

### **6.2 Manning**

For any experiments in which a subject is on apparatus capable of causing mechanical vibration or shock stimulus, there should be an operator at the control panel for that apparatus who has a clear view of, or otherwise maintains contact with, both the subject and the apparatus. In some circumstances it may be desirable for a second person to be present as an observer.

For experiments involving greater than minimal risk, i.e. in which the subjects are exposed to mechanical vibration and repeated shock whose severity exceeds that which is consistent with the safe exposure of workers (see annex A), the Ethical Committee may require that a physician or medical doctor be in attendance (see 5.3).

At the time of any test or experiment, there should be, within the laboratory or in close proximity to it, a person trained in first aid, and a means of communicating with the local emergency services.

#### **6.2.1 Experimenter**

In any test or experiment, one of those present should be designated as the person responsible for the test or experiment and be recognized as such by all concerned.

#### **6.2.2 Operator**

It is imperative that the operator has received training in operation of the equipment either from the manufacturer or from a responsible person experienced in the use of the equipment. The main need is for experience and proficiency in running the equipment, but the operator should also be fully conversant with emergency procedures. The operator should be backed by an adequate maintenance staff.

#### **6.2.3 Observer**

The observer should have a good understanding of the test or experiment being conducted and be familiar with emergency procedures for the equipment.