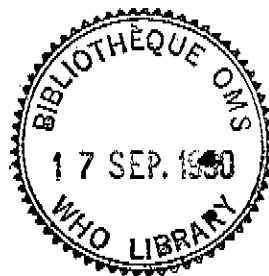


WORLD ORAL CARE MATERIALS

# Basic Guidance for Oral Health Care Settings

## Part 1

- Oral Care Settings for  
Community Oral Health and  
First Referral Level Care
- Requirements for Equipment



*Prepared by*  
**The Expert Group on Equipment and  
Materials for Oral Care (EGEMOC)**  
*for*



The Oral Health Programme  
**World Health Organization**



BASIC GUIDANCE FOR ORAL CARE SETTINGS

prepared by

The Expert Group on Equipment and Materials for Oral Care (EGEMOC)

for

THE ORAL HEALTH PROGRAMME, WORLD HEALTH ORGANIZATION

Contents

	<u>Page</u>
I. INTRODUCTION .....	2
The Expert Group on Equipment and Materials for Oral Care	2
Purpose of this Document .....	3
II. SETTINGS FOR ORAL CARE .....	5
Classification of Oral Health Care Settings .....	5
The Preferred Work Position .....	7
III. COMMUNITY ORAL HEALTH CARE EQUIPMENT .....	8
IV. FIRST REFERRAL LEVEL ORAL CARE EQUIPMENT .....	10
1. Operator's Support .....	12
2. Patient support .....	13
3. Lighting for intra-oral work .....	15
4. Operator's powered (dynamic) instruments .....	16
5. Operator's work surface .....	18
6. Operator's handwash facility .....	18
7. Assistant's support .....	19
8. Assistant-controlled instruments .....	20
9. Assistant's work surface .....	21
10. Storage for devices and materials .....	21
11. Assistant's handwash facility .....	21
12. Control systems and junction boxes .....	22
13. Preparation and sterilization area .....	22
V. ACKNOWLEDGEMENTS .....	23
ANNEX .....	24

This document is not a formal publication of the World Health Organization (WHO), and all rights are reserved by the Organization. The document may, however, be freely reviewed, abstracted, reproduced and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes.

The views expressed in documents by named authors are solely the responsibility of those authors.

Ce document n'est pas une publication officielle de l'Organisation mondiale de la Santé (OMS) et tous les droits y afférents sont réservés par l'Organisation. S'il peut être commenté, résumé, reproduit ou traduit, partiellement ou en totalité, il ne saurait cependant l'être pour la vente ou à des fins commerciales.

Les opinions exprimées dans les documents par des auteurs cités nommément n'engagent que lesdits auteurs.

## I. INTRODUCTION

The provision of oral health services is costly. However, analysis of oral health care needs and the identification of the work skills required, allows for logical design of equipment and work places that will directly reduce costs, improve application of skills and increase productivity. Equipment presently produced in industrialized countries is often unsuitable for use in developing countries because of high cost, unsatisfactory performance in the prevailing environmental conditions and problems related to maintenance and repair.

### The Expert Group on Equipment and Materials for Oral Care

Recognizing this situation, an Expert Group on Equipment and Materials for Oral Care (EGEMOC) was established by the Director-General in 1986 to address these problems. The responsibilities of the Group cover the following:

- to advise on how new developments in education, care systems and technology affect design and use of oral care facilities, equipment and materials;
- to provide countries with information on essential products for oral care;
- to promote the design, development, manufacture and use of appropriate equipment so that essential oral care can be extended to all populations;
- to collaborate with the FDI, ISO, dental manufacturers, dental educators and the dental profession in ensuring that consideration of health aspects of standards for oral care equipment are adequate.

Members of the Group are:

Professor G. Beagrie; Ms S. Kawaguchi; Professor E. Kirk;  
Dr P. Laplaud; Chairman, Dr J. Stanford.

WHO secretariat:

Mrs J. Sardo Infirri; Dr D. Barmes, Oral Health Programme Manager  
(ex-officio).

The Group combines expertise in education and training, in clinical practice, public health administration, standards development, health services research and design of clinical and training facilities.

The programme of work includes research leading to the preparation of documentation on:

- logic of performance and ergonomometry for design of facilities and for equipment, instruments and materials for oral care;
- logic for specification;
- principles of functional classification of hand instruments for oral care to relate to the design of equipment and facilities;
- recommendations of specifications for hand instruments suitable for use by the seated operator in optimal control posture, and for the supine patient;
- guidelines for purchase, storage and use of materials and medicaments for oral care;
- an information base using significant classifications for management and inter-centre communications;
- development of evaluation procedures and tests to determine suitable performance indicators for equipment, materials and instruments in order that the conformity of individual products to guidelines or specifications recommended by EGEMOC may be assessed.

As part of the collaboration with FDI and ISO, the World Health Organization is concerned with providing input on the health aspects of international standards. The work of EGEMOC should not be seen as providing alternative or conflicting specifications or standards, but rather, seeks to collaborate in areas of mutual responsibility.

#### Purpose of this Document

The complete document will provide guidance and recommendations for minimum requirements for equipment, hand instruments and materials and medicaments for oral health and care. Section I details requirements for equipment for community \* and first referral level \*\* care. Sections II on instruments and III on materials and medicaments will be prepared during the course of 1990 and 1991.

---

\* Community level care includes examination, prevention, surface care and relief of pain.

\*\* First referral care includes examination and diagnosis, prevention and control procedures, restorative care, extractions and denture repair: it may also include anterior root canal fillings and simple prosthetics.

Facilities, equipment and instruments must meet well-defined requirements, for both training and work procedures. This document indicates preferences for which WHO invites responses and the co-operation of manufacturers and other interested parties. There are also areas identified where new development is still required. It is hoped, that the guidelines established by WHO on the advice of EGEMOC will be of assistance to those interested in the search for improved oral health care.

For the purpose of clarity, the terminology used in this document will comply, in so far as possible, with the FDI/ISO and WHO accepted standards.

## II. SETTINGS FOR ORAL CARE

In the past, designers have focused on the development of highly-adaptable equipment for a wide variety of possible uses. The WHO Technical Report Series No.750 - Alternative Systems of Oral Care Delivery - recognizes the importance of design in planning the workplace. It is fundamental that the objectives and requirements of an oral care service be defined before facilities are built and/or equipped, so that the setting and equipment is supportive of the work envisaged. Where personnel depend on equipment \* for work, efficacy is jeopardized unless the equipment is effective, safe, economic and reliable. Using this premise, prescriptive design requires a clear definition of need before a facility is constructed. The potential to reduce capital costs arises from the elimination of any equipment items beyond those necessary for efficiency; and avoiding duplication of systems and instruments.

### Classification of Oral Health Care Settings

Table I provides a classification of oral health care settings and equipment, to help define objectives and requirements for any specific service. From the specifications of need, the types of activities and the relationships and contacts between care providers and patients, equipment design and its placement can then be defined.

Equipment is needed for the following types of activities:- communication and consultation, which encompasses reception, interview, and demonstration; manipulative oral procedures, as outlined in Table I; instrument preparation, sterilization and storage; data processing and management of records, mainly required at referral level; technical laboratory, also at referral level; and finally, general facilities for study, evaluation, services and waste disposal, again mainly at referral level.

Certain principles relating to contact and interaction between the people involved, be they patient, care provider or auxiliary, apply to the design and equipping of all care settings. These principles are important and should be adhered to, since they enhance attainment of objectives and increase satisfaction in the work environment. These principles concern both communication and interpersonal inter-reactions, as well as the effectiveness and safety of care procedures. In other words, settings and equipment should be designed to maximize self-awareness, self-positioning, and indicate direction and responsibility. Thus by design, all care facilities, whether for community or referral level care, should provide an environment that is immediately understood and thus correctly used by operators, assistants and patients. For example:

- (i) Communication is enhanced when design allows the receptionist and entering patients to be immediately visible to each other.
- (ii) Care areas should not only be non-threatening, but should encourage patients to cooperate in treatment and thus contribute to optimal use of the facility.

---

\* Oral care equipment is defined as "machines, apparatus, and accessories thereto, especially manufactured or presented for the use of authorized persons in the practice of dentistry or its associated procedures". ISO Standard 1942 section 4.

TABLE 1  
ORAL CARE SETTINGS AND EQUIPMENT

WHO terminology	EGEMOC terminology for training and oral care	Type of setting and equipment	Oral status and * Intervention index codes (OSI)
Epidemiology	Examination	Support for patient, operator and recorder	0
Community health care (oral)	Prevention and surface care	Patient and operator support, preparation and storage	0, 1, 2
First referral level oral care centre (dental clinic)	First referral level	Patient, operator and assistant support, waiting and communication areas, services - water, air, electricity, preparation and storage	5, 6, 7, 9, (limited)
Final referral level oral care centre (dental or hospital clinic)	Final referral level care	Patient, operator and assistant support, waiting and communication areas, services - water, air, electricity, preparation and storage, diagnostic and laboratory.	3, 4, 5, 6, 7, 8, 9

NB: Primary Health Care includes both community and first referral level care.

\* The OSI code numbers indicate, for each care level, the interventions most usually performed: however, it should be noted that there may be other procedures provided at both community and first referral levels.

The Preferred Work Position

Three (3) major principles define the preferred work position of an operator involved in any form of intra-oral work. These are:

1. For optimum control of fine manipulative tasks an operator requires to be seated, working in the midline of the body, and level with his or her heart. The only practical and effective way to meet these requirements is to treat the patient in a supine position.
2. The maintenance of the preferred work position requires specific posture, position and spacial relationships between patient, operator and assistant.
3. The preferred work point for intra-oral care becomes "reference" for the arrangement of the rest of the setting i.e. equipment and furniture.

In order to adhere to these principles, the place in which intra-oral work is done must provide for:

- a) an operator seated at his or her preferred height, with unimpeded access to a supine patient;
- b) a patient comfortably supported in a stable supine position;
- c) the ability to bring the mouth of the patient to the operator's preferred working position;
- d) a seated assistant with unimpeded access to the patient's left-hand side without compromising the operator's working positions and/or postures;
- e) the operator to have access to instruments within the forearm extension range;
- f) the assistant to have access to instruments, materials and work surface within the forearm extension range;
- g) the operator, assistant and patient to have unimpeded access to the clinical area without movement of equipment, or crossing of service lines;
- h) a work surface that is accessible to both assistant and operator;
- i) the ability to change the facility from an assisted to a solo-operating mode easily.

### III. COMMUNITY ORAL HEALTH CARE

The WHO strategy of Health for All by the Year 2000 is based on the concept of Primary Health Care. This means the use of practical, scientifically sound, socially and economically acceptable methods and technology in all communities, to provide essential health care through the active participation of members of the community.

For both community and referral level oral care, the major principles defining the preferred work position and the design of equipment given in Chapter II apply. The main difference between settings for community and first referral level care, is the potential for the participation of the community in construction of the equipment in community care settings; whilst for referral level care settings, the need for added sophistication requires the input of dental manufacturing expertise.

A model for Primary Oral Health Care was tested in Thailand \*. This model was based on the provision of basic oral health care in the community, with referral care available in clinics situated in district or provincial towns. It provided a preventive and education programme of health promotion with wide coverage, to develop and identify "self-care" responsibility within the community as the major catalyst for change. The community participated in decision making about their oral health and care. Thus it was involved in selection of primary health care workers and in defining the range of care to be provided, as well as priorities of access to treatment at referral level. The villagers also constructed bamboo beds for patient support and bamboo stools for the oral care operators.

#### Requirements for Oral Care in the Community

For community oral care, the following equipment is needed:

1. A stable surface for patients to lie on, any stable flat surface that is sufficiently large and of a convenient height can be used, e.g. a medical examination couch, bench, or table, or a purpose built structure, provided a suitable headrest can be attached. The general specifications are:
  - width 40 cms + accessory support for upper arms;
  - length 165 cms;
  - height between 55 and 70 cms (this may vary according to the average height of the population);
  - to support 135 kg weight.
2. A small head rest that allows comfortable and stable orientation of the patient's head, both laterally and sagittally, without restricting the movements of the operator.
3. A stool for the operator - preferably 3 legged with a simple height adjustment mechanism through a range of 10 cms.

\* Alternative Systems for Oral Care Delivery: World Health Organization Technical Report Series No. 750, 1987, Geneva

4. Work surfaces - either attached to the patient support or free standing, providing support for:

- instruments, materials and medicaments;
- dishes for washing and disinfection;
- hand washing bowl, cleaning solution and towel;
- recording information.

5. A light, where sunlight is insufficient and where services permit.

#### IV. FIRST REFERRAL LEVEL ORAL CARE EQUIPMENT

WHO policy is to ensure that oral health care is widely available in the community, integrated with general health care and making maximum use of auxiliary and primary health care personnel as appropriate.

Referral care is an essential part of primary health care. However, the provision of first referral level oral care in most communities in developing countries, has not been seen as economically or logistically feasible. This is mainly due to high costs of equipping facilities and of maintaining the equipment in working order.

Siting of referral care centres must reconcile several, sometimes opposing, factors:

- ease of access for the population
- minimum travel for providers and
- the establishment of appropriate management systems.

Wherever available personnel and resources permit, and oral disease levels indicate the need, facilities with several operatories are first choice. Such facilities can be staffed, managed and maintained more effectively and economically than a single, isolated operatory.

For referral level care settings, there are specific requirements for space for equipment; there is also need to provide adequately for equipment to be able to function in the prevailing climatic and environmental conditions.

##### Space requirements

- Each oral care operatory requires a minimum space of 3.3 m x 2.1 m, to which space for circulation and support services must be added (see Figure 1).

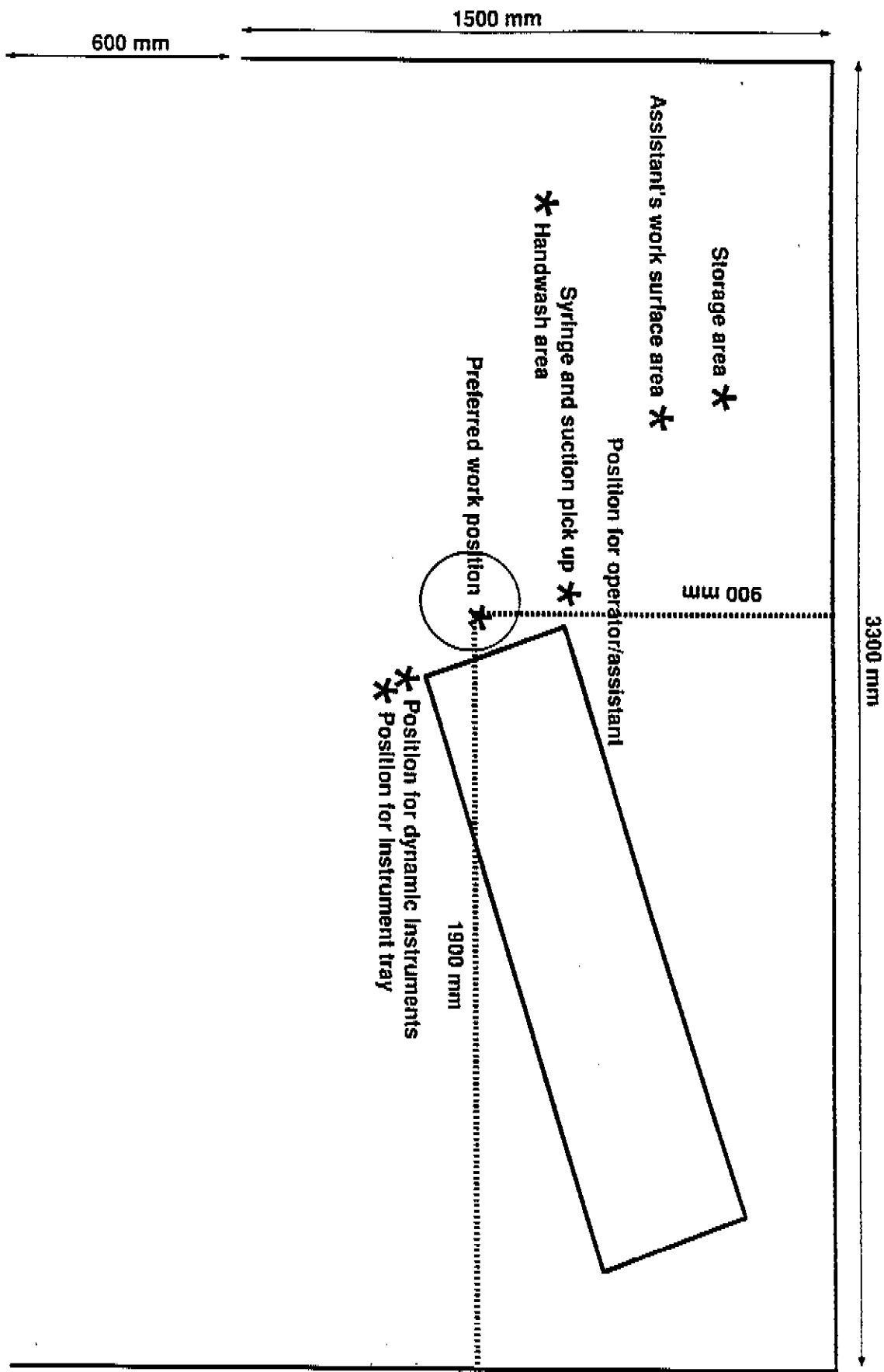
##### Environmental and climatic conditions

- Equipment should be designed to function without air conditioning; thus, dust and moisture filters that are easily cleaned and replaced are needed.
- A water filter and demineralizing unit is required.
- Voltage surge protection, trip switches and electric current stabilizers are essential.
- Oil free pressurized air is needed.

##### Servicing

- All items in the operatory should be easily maintained by the operator, and able to be repaired by personnel with limited workshop skills.

Figure 1.



As indicated in Chapter II the principle of the preferred work position dictates the design and arrangement of equipment for referral level care. The following sections of the report provide health planners and manufacturers with the specifications and desirable characteristics of the various parts of equipment for referral care clinics.

Each item is considered in terms of efficiency, safety, (structural, mechanical, and biological) and other needs.

In the fulfillment of these requirements it is expected that manufacturers will be able to provide a wide variety of products which will comply with the specifications, and will also range in cost.

## 1. OPERATOR'S SUPPORT

### **Efficacy**

- a stable support of such a height that the operator can be seated with his/her thighs parallel to the floor;
- height adjustments to meet the requirements of 95% of the population;
- different height settings are needed for the operator and assistant;

### **Safety**

#### Structural:

- recommended to be locally produced in any material that meets structural requirements;
- height adjustment cylinders may be needed;

#### Mechanical:

- adjustment controls placed so they cannot be accidentally activated;
- a total load of 135 kg can be supported;
- all movements to be capable of smooth regulation by the operator;
- foot-operated adjustment systems are preferred to avoid contamination;
- bursting pressure and release; (see notes under patient support requirements);

#### Biological:

- all surfaces, but particularly the seats, to be smooth and non-retentive and to withstand repeated cleaning with cold sterilizing solutions;

## Reliability

### Warranty:

- to be stated: minimum of one year, preferably two years, on parts from date of installation;

### Maintenance:

- designed so that a simple replacement of the cylinder is easy;
- seat recoverable, other components replaceable;

### Usage:

- life expectancy for all parts of at least 10 years from the date of installation;

### Spare parts stock:

- to be available from supplier and manufacturer for at least 10 years from the date of cessation of manufacture of the product;

### Description:

- identification of a permanent nature naming the manufacturer, serial number model number, and electrical rating to be provided;

### Documentation:

- clear instructions to be provided on operation, cleaning and maintenance;

## 2. PATIENT SUPPORT

### Efficacy

- of sufficient length, width and strength to provide stable support for a supine patient;
- a limited range of height adjustment;
- a small headrest that provides a firm and stable support with sufficient vertical adjustability to accommodate the various dimensions of populations and allows comfortable self-positioning and orientation of the head, both laterally and vertically for the provision of oral care in optimal work conditions; it would appear, taking the horizontal plane of the patient support as the reference, that a head support adjustment of 5 cm downwards and 10 cm upwards accommodates most people;

## Safety

### Structural:

- ISO standard 6875:1990, for dental chairs, requires that 135 kg plus the additional mass of equipment mounted on the patient support, as specified by the manufacturers, be supported;

### Mechanical:

- moving parts that could injure the patient or performer must be covered by a guard;
- controls must not be susceptible to accidental activation;
- where hydraulic systems are used, a foot activated adjustment mechanism should also be available; the bursting pressure must exceed maximum working pressure, and pressure relief systems must be fitted;

### Electrical:

- ISO 6875:1988 sections 5.1 and 5.2 and IEC 601.1:1988 standards apply; the principle requirements are:
  - to be enclosed for protection of patients and operator;
  - requirements on leakage current, dielectric strength and grounding impedance to be met;
  - the indicator light, where applicable, to be clearly visible;

### Biological:

- all exterior surfaces must be capable of withstanding frequent cleaning, without deterioration;
- materials to be non-retentive;
- provision for a removable/disposable cover for the headrest;

## Reliability

### Warranty:

- to be stated; minimum of 12 months, preferably two years, from date of installation;

### Spare parts stock:

- to be available from supplier and manufacturer for at least 10 years from the date of cessation of manufacture of the product;

### Usage:

- life expectancy for all parts of at least 10 years from date of installation;

Installation:

- a full illustrated description of installation procedures to be supplied; enumerating the manufacturers and buyers responsibilities;

Description:

- identification of a permanent nature naming the manufacturer, serial number model number, and electrical rating to be provided;

Documentation:

- to include installation manuals, complete operating and maintenance instructions and wiring and plumbing diagrams.
- sufficient information should be given to allow engineers to evaluate the type of construction, control system and necessary services;

3. LIGHTING FOR INTRA-ORAL WORK

**Efficacy**

- to give light nearly coincident with the operator's sight line;
- to be capable of being directed with a focused beam at the oral cavity;
- it would appear that an illumination range of a minimum of 8,000 lux and a maximum of 18,000 lux is desirable;
- in the interest of reducing contamination, the light(s) should be fixed or adjustable without using hand contact;
- not to impede access of the operator, assistant or patient;

**Safety**

- IEC 601.1:1988 standards apply, and ISO Draft Proposal 9680.3.1989 under discussion; the principal requirements are:
  - to be enclosed sufficient to protect patient and oral care personnel;
  - ultra-violet spectrum to be restricted;
  - the temperature of surfaces of the lamp housing shall not cause injury when touched during operation;

**Reliability**

Warranty:

- to be stated separately for bulbs and appliances;

Spare parts stock:

- to be available from the supplier and manufacturer for at least 10 years from the cessation of manufacture;

Usage:

- life expectancy, except for bulbs, to be at least 10 years from the date of installation;

Installation:

- a document on installation be provided enumerating the manufacturers and buyers responsibilities;

Description:

- identification of a permanent nature naming the manufacturer, serial and model numbers and the electrical rating to be provided;

Documentation:

- an illustrated document to allow users to arrange intra-oral illumination to the best advantage of the operator without discomfort for the patient;
- sufficient information should be given to allow engineers to evaluate the type of construction, control system and necessary services;

Bulb life:

- to be stated; rated at 12 or 24V and regulated to 9.5 or 17.5V, with heat emission control, as standard.

4. OPERATOR'S POWERED (DYNAMIC) INSTRUMENTS

Efficacy

- to be grouped, positioned and oriented for easy pick-up and replacement, to be operational without regripping the instrument;
- to be within the forearm extension range;
- to be below the level of the operating point;
- placement should not interfere with patient, operator or assistant;
- must not impede manual or visual control (weight, drag and sight lines)

Requirements of a clinic setting place them to the operator's right side, but they should be capable of modification for use by left-handed operators.

The following functional requirements must be met:

High speed instrument:

- friction - grip
- bur speed, free-running >250,000 rpm
- effective water air spray
- quick disconnections fittings compatible within the setting

Low speed instrument:

- bur speed, it would seem that free running bur speeds between 2,000 - 15,000 rpm meet the basic requirements for these systems to provide high torque at low speed;

Scaling device:

- sonic or mechanical;

Triple syringe:

- heated water at latitudes greater than 45° unless ambient temperatures are controlled;
- water retraction is unacceptable;
- exchangeability by uniform connectors;

Foot Controls: (other controls are considered in Section 13)

- modern dentistry requires use of a foot control to activate the dynamic instruments;
- the foot control should meet ergonomic requirements of the operator, should not disturb the working posture, nor interfere with access of patients or oral health care personnel;
- if the set of dynamic instruments is not mounted on the patient-support, special attention must be given to make sure that the above requirements re interference to the operator, and access of patients are observed;

**Safety**

Biological:

- any surface liable to be contaminated by hand or intra-oral contact to be disposable, sterilizable, or designed for barrier isolation;

Mechanical:

- no part of the equipment shall cross the patient or interfere with the operator's posture, access of the patient or other personnel;

- pressure and bursting regulations apply;

Electrical:

- ISO and IEC standards shall apply;

General:

- ISO IEC 601 shall apply to instrument holders;

**Reliability**

Warranty:

- to be stated; a minimum of 12 months, preferably two years, from the date of installation;

Spare parts stock:

- an illustrated catalogue of all spares with "exploded" diagrams
- a statement that dealer/manufacture stocks will be maintained for a minimum of 10 years from date of cessation of manufacture;

Installation:

- a document on installation enumerating manufacturer/buyer responsibilities;

Documentation:

- an illustrated document to allow users to identify performance and surface characteristics and ranges of movement or option for position;
- sufficient information should be given to allow engineers to evaluate the type of construction and control systems, and necessary services.

5. OPERATOR'S WORK SURFACE

**Efficacy**

- a small work surface primarily for instrument support is required at the operator's right-hand side;
- it must not compromise the operator's performance or access, patient's access nor instrument exchange;
- if fixed, it shall be attached to the patient's support; it may be free-standing or mobile.

6. OPERATOR'S HANDWASH FACILITY

**Efficacy**

- the flow of water and cleansing agents should be foot controlled;

- immediate access to the handwash facility should be easy for both operator and assistants.

## 7. ASSISTANT'S SUPPORT

### **Efficacy**

- a stable stool of such a height that the operator can be seated with his/her thighs parallel to the floor;
- where operator and assistant are of equal height, the assistant's support to be approximately 20 cm higher;
- a footrest is required;
- the range of vertical adjustments to meet the requirements of 95% of the population;

### **Safety**

#### Structural:

- recommended to be locally produced in any material that meets structural requirements;
- height adjustment cylinders are needed;

#### Mechanical:

- adjustment controls placed so they cannot be accidentally activated;
- the ISO standards require a total load of 135 kg to be supported;
- all movements to be capable of smooth regulation by the performer;
- foot-operated adjustment systems are preferred to avoid contamination;
- bursting pressure and release; (see notes under patient support requirements);

#### Biological:

- the surfaces, particularly the seat, to be smooth and non-retentive and to withstand repeated cleaning with cold sterilizing solution;

### **Reliability**

#### Warranty:

- minimum of one year on parts from date of installation (to be stated);

Maintenance:

- designed so that a simple replacement of the cylinder is easy;
- seat recoverable, other components replaceable;

Usage:

- life expectancy for all parts of at least 10 years from date of installation;

Spare parts stock:

- seat recoverable, other components replaceable;

Description:

- identification of a permanent nature naming the manufacturer, serial number model number, and electrical rating to be provided;

Documentation:

- to include complete operating and maintenance instructions.

8. ASSISTANT-CONTROLLED INSTRUMENTS

Efficacy

- high volume low pressure evacuation (HVE);
- access to operator's triple syringe;
- the instruments to be accessible to the operator's left hand by limited forearm movement;
- both instruments to be located in acceptable positions for an assistant working from the 4 o'clock position, who should also have direct access to a work surface for the preparation of materials;

Requirements for HIGH VOLUME EVACUATION (HVE) \*

- a swivel connector between the holder and the nozzle;
- a manually operated on/off valve at the hand-held part of the evacuation tube;
- requirements of the holder and nozzle of the HVE are:
  - a) a soft, bevelled tip
  - b) the ability of the HVE tip to be easily located in the following positions: right and left, buccal, sublingual and retromolar pad regions;

---

\* A standard for (HVE) should be developed and incorporated.

- c) either the patient or the assistant should be able to hold the instrument in an appropriate position;
- the tubing must be resistant to all cold sterilizing solutions;
- a vacuum separator that is easily cleaned and self-emptying with an easily accessible, cleanable, replaceable filter, to be set in the line;

#### Safety

##### Structural:

- the tubing not to collapse under working pressures and conditions;
- the tubing to be anchored to both the holder and the "unit";

##### Biological:

- the mouth-piece should withstand frequent sterilization without distortion;
- the solids trap filter to be cleanable;
- instructions on all procedures to be followed to prevent the risk of cross contamination should be available;
- servicing of solids trap filter to be specified;

#### Reliability

##### Warranty:

- a minimum of 1 year, preferably 2 years, on parts, from date of installation;
- spares to be available for 10 years from cessation of manufacture;

#### 9. ASSISTANT'S WORK SURFACE

A stable work surface to be provided which is compatible with the solo operating mode. It should be easily accessible from both working positions. Construction of the work surface must recognize current requirements of microbiological and materials (e.g. mercury) hygiene.

#### 10. STORAGE

Is to be provided.

#### 11. ASSISTANT'S HANDWASH FACILITY

Common facilities should be provided for operator and assistant.

## 12. CONTROL SYSTEMS AND JUNCTION BOXES

### Efficacy

- air control systems are currently favoured on the grounds of simplicity, cost and ease of maintenance;
- control system(s) should be of small bulk and weight;
- requirements for junctions and services to be specified

### Safety

- there should be one master switch to shut down AIR, WATER and POWER simultaneously;
- water (valve) to be regulated and filtered;
- air valve to regulate and filter with condensation trap to external tap;
- both air and water to have "quick disconnection" fittings of different size;
- internal voltages to be of 12 or 24 volts;
- there should be a control system to protect powered equipment from external voltage surges and variation.

## 13. PREPARATION AND STERILIZATION AREA

An area separate from, but convenient to, the clinical work stations is needed. Appropriate work spaces including working surfaces, sinks and water faucets, waste item disposal units, and storage space are needed for the following procedures:

- cleaning
- disinfection
- sterilization
- storage of cleaning and disinfection products

A separate area with shelves for storage of sterile sets of instruments is also required.

#### V. ACKNOWLEDGEMENTS

The contributions made by the following companies to the development of this document are gratefully acknowledged.

A-Dec International Inc  
Ash/Dentsply  
Dentalwerk Buermoos Ges.m.b.H.  
Fabbrica Apparechi Odontoiatrici (FAO)  
J. Morita Corporation  
Kaltenback and Voigt GmbH & Co (KaVo)  
Medic Corporation Inc  
Officine Meccaniche Specializzate SpA (OMS)  
Ritter AG  
Siemens AG

**RULES FOR PRESENTATION OF  
ORAL CARE PRODUCTS TO WHO FOR ASSESSMENT**

- A. Submit a request for assessment and then follow the WHO instructions for submission of a product to the WHO Collaborating Centre designated to perform the tests (available from ORH, WHO, Geneva).
- B. Provide three copies of all informative and descriptive material, directions for use, cautions and relevant material. The documentation should contain the following:
1. Name and use of item;
  2. Number of patent(s) relating to product;
  3. Composition, physical, and chemical properties of dental materials. Submit data to show compliance with ISO, IEC or national standards, if applicable;
  4. Material used in construction and method of operation of a dental instrument or piece of equipment;
  5. Evidence of safety and usefulness of product, noting:
    - a) evidence of safety and usefulness of the product may be in the form of published reports or unpublished information, obtained from appropriate scientific studies using biological and clinical observations;
    - b) evidence should be both sufficient in quantity and adequate in quality to permit sound conclusions. This requirement is especially important because most clinical studies involve subjective interpretations on the part of both the observer and the patient;
    - c) a sufficient quantity of data should be provided, not only should the number of observations in a single study be adequate, but reports of additional investigations by independent groups are usually required;
    - d) evidence that is adequate in quality is necessary in a study to use controls or comparison products under the same conditions of use as the test products. Double-blind studies are desirable whenever possible;
  6. A description of quality control processes routinely performed on the subject product;
  7. Names of owners, officers of the firm, or other individuals authorized to furnish information;

8. Names and qualifications of scientific personnel responsible for formulation and testing of item or product;
  9. All other information required by the Guidelines for a specific product as recommended by EGEMOC.
- C. No use of the WHO name shall be made in advertising and promotional material for the product without the express permission of the World Health Organization.

A typical arrangement for a presentation to WHO follows. It should be used as a guide in preparing and structuring the documentation. A summary report of no more than five pages in length, covering all information on safety and efficacy of the material or device should be included. Each presentation must also be indexed.

ARRANGEMENT OF PRESENTATION TO WHO

Cover

1. Name and address of applicant.
2. Name and use of products.
3. Number of patent(s) relating to product.
4. Name of owners, officers of the firm, or others who are authorized to furnish information and represent the firm to EGEMOC.
5. Names and qualifications of scientific personnel responsible for formulation and testing of item or product.

Layout of text required

1. Table of contents of entire presentation.\*
2. Comprehensive summary of all information on safety and effectiveness of material, instrument or equipment.\*
3. Statement of composition, properties, or components.\*
  - Complete listing of the composition, physical and chemical properties of a dental material.
  - Materials used in construction and principles of operation of a dental instrument or piece of equipment.
4. In vitro evaluations.\*+
5. Biological evaluations in accordance with ISO TR 7405, if applicable.\*+
6. Clinical evaluations.\*+
7. Instructions on labelling, packaging, operating and installation.\*+
8. Promotional material.\*
9. Description of quality control processes.\*
10. Comprehensive bibliography.\*
11. Copies of most significant articles.\*
12. Appendices-evaluation forms, individual case histories, detailed descriptions of test evaluation methods.\*

\* Indicated tabs (flag)

+ Extended details of in vitro, biological, and clinical studies should be included in the appendix to the presentation.

- - -