BioScan
See life in real-time

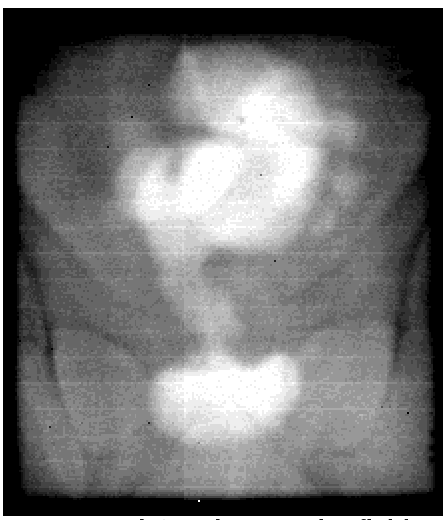
Since 1990 the activities of BioScan Switzerland focus on biomedical X-ray imaging and non destructive testing (NDT). BioScan designs, manufactures and commercializes really new products using cutting-edge technology.

FDA 510(k) **Clearance K013897**	**IRIS**	CE 0120

THE FIRST REAL-TIME DYNAMIC IMAGING SYSTEM EVER MARKETED FOR RADIOTHERAPY. TRUE MONITORING DEVICE OF THE PATIENT'S POSITION AND ORGAN MOTION DURING THE TREATMENT.

1. Portal Imaging with IRIS (Interactive Radiotherapy Imaging System).

BioScan's X-ray detection system **IRIS** can be used for real-time imaging during treatment in radio-oncology. This patented method is used to obtain better image quality at the high energies (up to 30 MeV) used in radio-oncology.



Rectum (18 MV) – Anterior field

With its two-dimensional fine granularity, IRIS makes possible real-time measurement of X-ray beams and on-line mapping of the local doses received. Due to fast signal digitization on the early stage, its operation is essentially digital, which ensures fast real-time processing of the images of the irradiated object. Thus, it makes possible direct control of the X-ray source and collimators to steer the beam precisely onto the treatment site.

IRIS - its advantages

IRIS gives real-time high quality images with very visible characteristic anatomic structures at a rate of 3 to 10 images per second. As a result, immediate position readjustments are possible. Treatment site localization can be further improved by using contrast liquids or metallic markers. This could be especially helpful in irradiation of small volumes without characteristic anatomical structures.

2. Overview of traditional technologies

a) Port films

Port films have served for decades as the only verification system for checking the reproducibility of the simulation-to-treatment geometry. The ability to detect and correct systematic and random set-up errors by using port films is limited for the following reasons :

- films are taken before the treatment session and may not reflect the "real" situation,
- films are not immediately available, and corrections are made on a "next session" basis (interfraction corrections),
- weak definition and poor image quality for high-energy beams and small treatment volumes.

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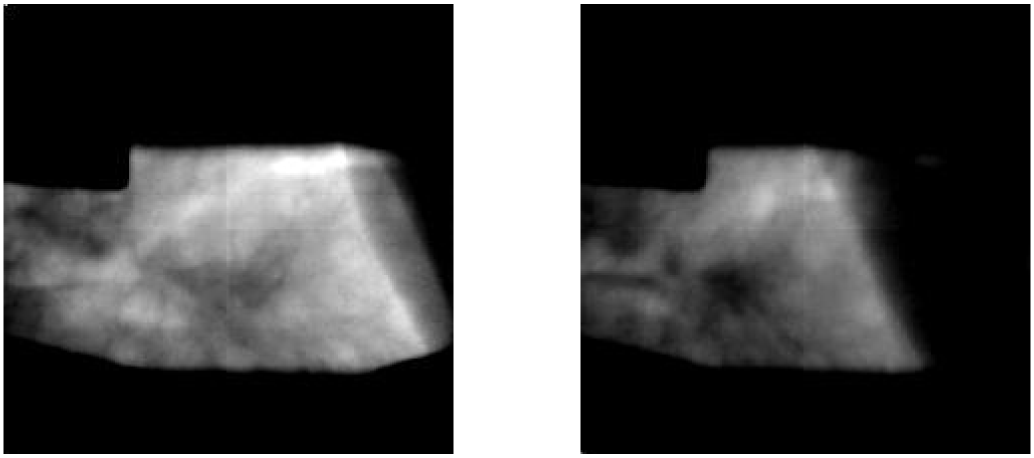
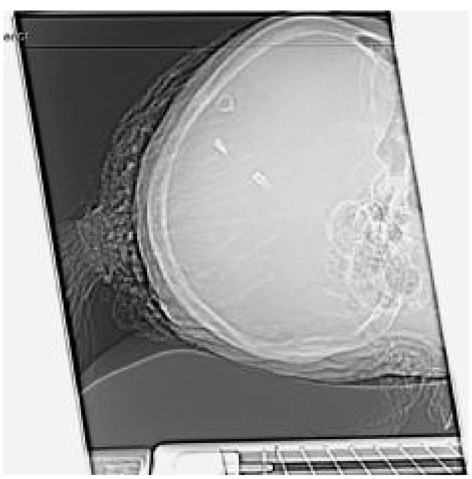


Oesophagus (18 MV) - Lateral field
These two images show the shifting of the organs
due to the breathing (about 3.3 cm).

b) EPIDS

In the last decade, on-line visual monitoring systems have been developed, called « electronic portal imaging devices » (EPIDs). Compared to port films, EPIDs have the following advantages:

- real time imaging of the treatment field, giving a possibility of dynamic monitoring (fluoroscopy-like),
- quantification of patient movements during irradiation,
- automatic adjustements of beam or patient position, based on a simulator image or a reconstructed reference image ("gold standard"),
- dosimetric mapping of the exit beam using transmission images, which can be applied for *in vivo* dose measurements, for design of tissue compensators and for verification of flux in intensity-modulated beams with dynamic multileaf collimators.

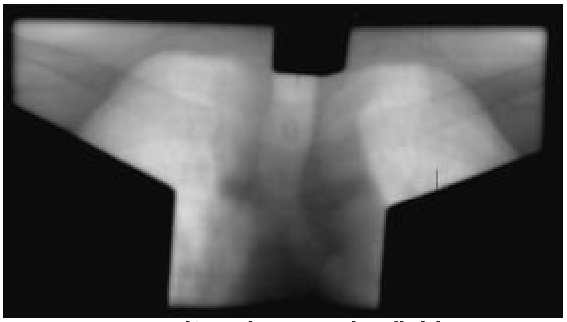


Head (6 MV)

However, currently-available EPIDs, based mainly on liquid ionization chambers or fluorescent screens viewed by CCD's through an optical system, give poor definition of structures and image quality, similar to that of port films. Furthermore, the image acquisition time (4-5 seconds) together with the time needed to process and analyze the images, is so long that it makes practically impossible any field adjustments (intrafraction corrections) before the end of the treatment session.

3. Medical Challenges

According to World Health Organization statistics, more than 9 million new cases of cancer are diagnosed each year worldwide, and more than 6 million deaths occur every year due to cancer. Cancer kills approximately 15,000 people per year in Switzerland. It is the second most frequent cause of death after cardiovascular diseases. These figures are increasing due to the ageing of the population.



ENT (6 MV) – Anterior field
New sensitive surface : 41 cm x 41 cm

There are five types of cancer therapy that are most commonly used :

1. surgery,
2. radiotherapy,
3. chemotherapy,
4. immunotherapy, and especially,
5. combinations of these four therapies.

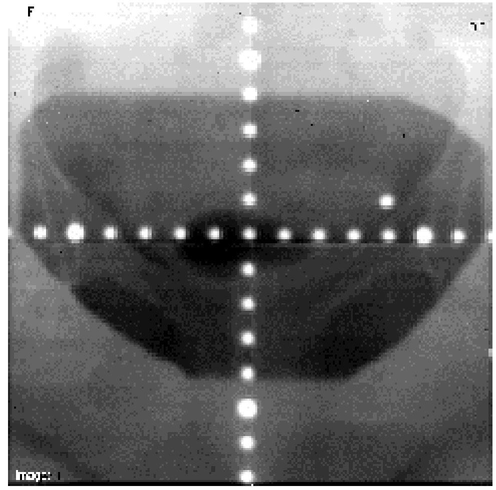
Oncological radiotherapy is one of the most efficient new methods. When combined with surgery it ensures an 80 % success rate.

Prostate - Lateral field
Double-exposure IRIS image
at 6 MV with 2 MU.

However, it has drawbacks due to damage to healthy tissues surrounding the tumor. Cancer experts stress the need to improve the precision in delimiting the zones being irradiated by means of visualization an better localization of the treatment site. Such an improvement will have direct and immediate consequences on the survival rate of patients. In other words, to protect the surrounding healthy tissues, one has to monitor continuously in real-time the delivered dose and maintain precise beam focusing on the tumor.

Any improvement in precision is based on simultaneous optimization of the target conformation and a reduction of irradiated volume.

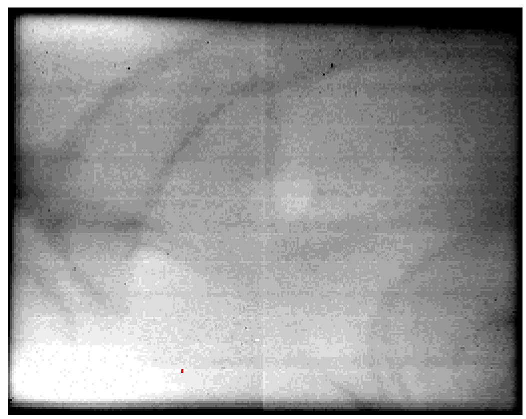
A direct consequence of the reduction of irradiated volume is an increased tolerance to radiation. As tolerance increases, a higher treatment dose may be given for the same damage of normal tissue. A higher dose delivered to the target is expected to provide a higher probability of tumor control. Precision in radiotherapy is limited, however, by movement of the patient during the treatment. Immobilization devices have improved the reproducibility of the daily patient set-up. Random movements have also been observed in tumor-bearing organs such as the prostate or the bladder.



Bladder - Lateral field
Double-exposure IRIS image
at 6 MV with 2 MU

4. Technical Data

IRIS uses a large area pixel matrix based on solid state amorphous silicon technology. The detection matrix works as a complete electronic camera. It is much smaller and lighter than a conventional optical CCD camera with an image intensifier. Since this detector tolerates X-rays it can be placed directly in the beam.



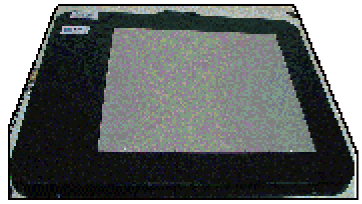
Rectum (18 MV) – Lateral field

Main features of IRIS :

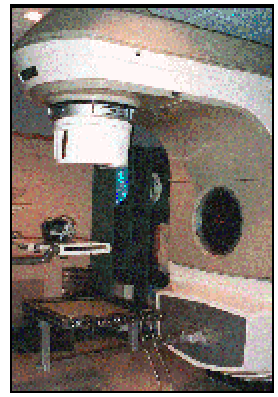
- **Energy range up to 30 MeV,**
- **High dose rate operation (up to 400 MU/min),**
- **Dynamic visualization,**
- **Frame rate : up to 10 frames per second,**
- **ADC resolution : 16 bits (65536 gray levels),**
- **Compact design,**
- **Radiation hardness.**

Control room

Model IRIS-20



Model IRIS-41



Treatment room

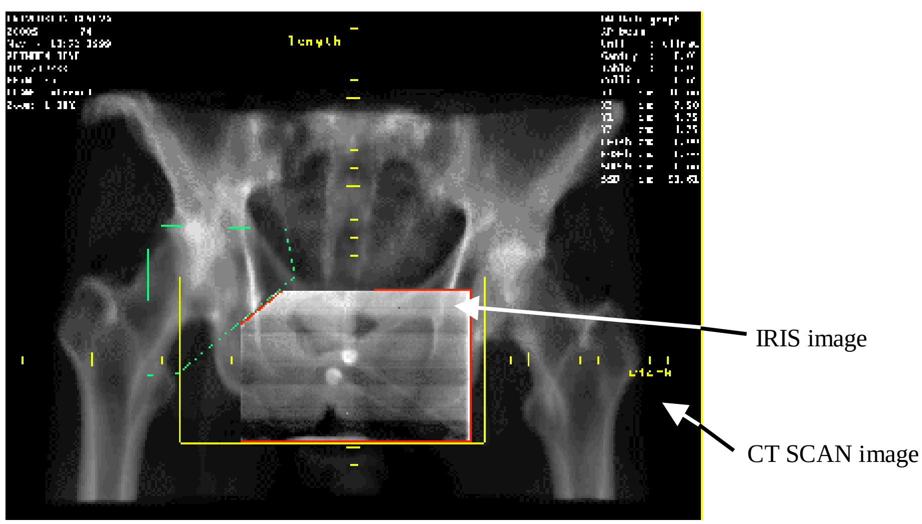
Product range :

	IRIS-20	IRIS-41
Sensitive area	20 cm x 20 cm	41 cm x 41 cm
Pixel size	750 µm x 750 µm	400 µm x 400 µm
Resolution	128 x 128 pixels	1024 x 1024 pixels
Weight	7 kg	23 kg

- Personal computer : Midi tower size,
- Monitor : 17" to 21" size,
- Maximal detector-computer distance : 100 m.

Computer configuration :

Personal computer with an Intel Pentium IV, PCI system interface, RF noise protected housing, 1024 MB RAM, 120 GB hard disk, 128 MB video memory, CDRW, keyboard, mouse, Windows™ operating system.



Reference image (obtained with a CT-Scan Picker) with overlapping dynamic images obtained with IRIS during the treatment.

5. Dedicated Image Processing Software : IRIS-View

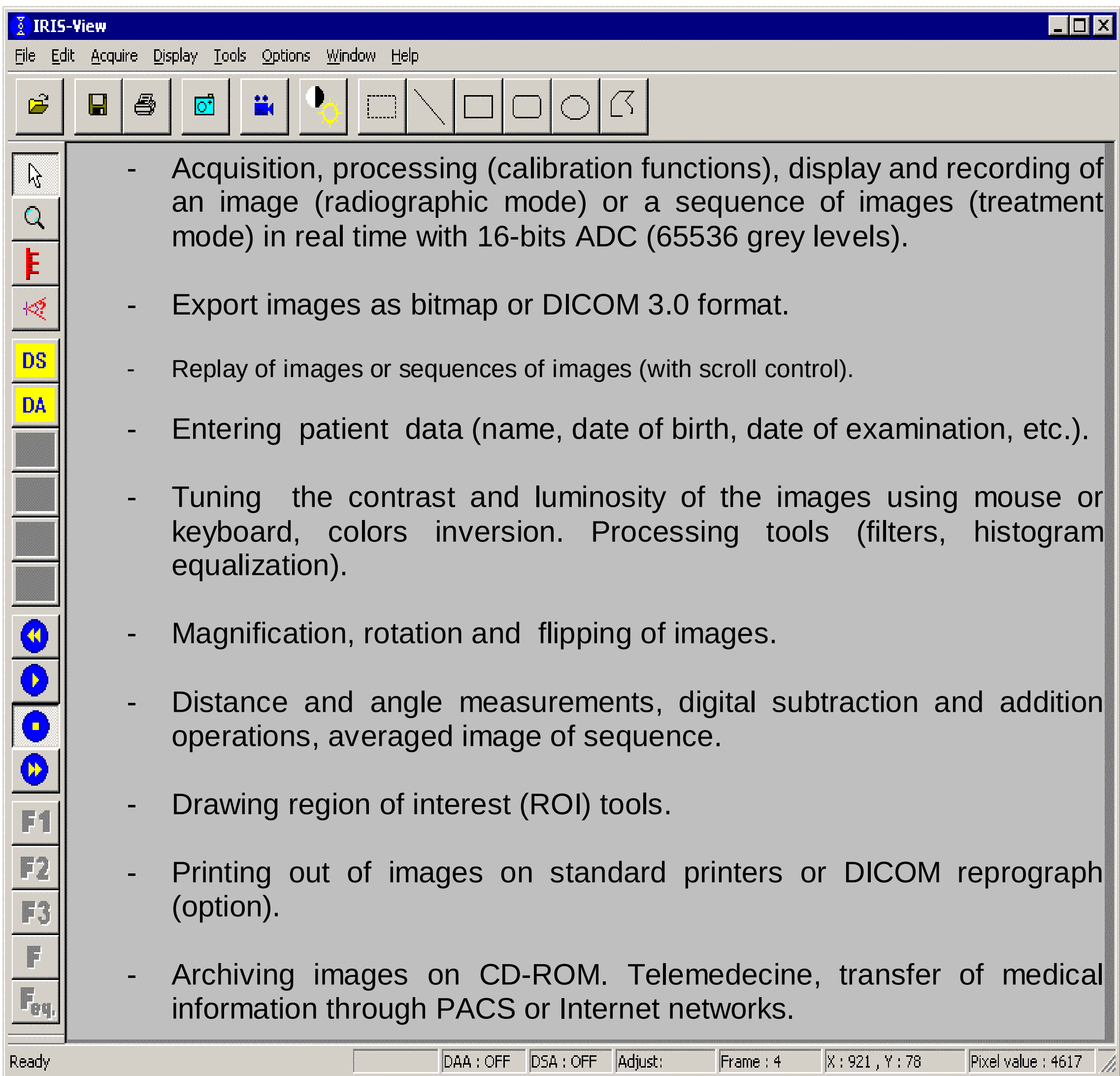
IRIS-View is the software used for image acquisition and treatment. It is specially conceived to take images, display and analyze them using IRIS systems in a clinical environment.

It is very easy to use and is first devoted to radio-oncologists and radiotherapy technicians.

IRIS-View runs on a PC under Windows™ operating system. A dedicated frame grabber is used for data acquisition and I/O control of the detector.

Data is digitized with a 16-bit resolution (65536 grey levels). The input / output card uses a PCI bus for functions related to detector control and direct transfer of images in the PC memory. DMA (Direct Memory Access) ensures image acquisition without using central memory of the PC. Thus, it is available for other control functions or image processing during data transfer, for instance - applying gain and offset corrections on-line.

IRIS-View allows the following main functions :



- Acquisition, processing (calibration functions), display and recording of an image (radiographic mode) or a sequence of images (treatment mode) in real time with 16-bits ADC (65536 grey levels).
- Export images as bitmap or DICOM 3.0 format.
- Replay of images or sequences of images (with scroll control).
- Entering patient data (name, date of birth, date of examination, etc.).
- Tuning the contrast and luminosity of the images using mouse or keyboard, colors inversion. Processing tools (filters, histogram equalization).
- Magnification, rotation and flipping of images.
- Distance and angle measurements, digital subtraction and addition operations, averaged image of sequence.
- Drawing region of interest (ROI) tools.
- Printing out of images on standard printers or DICOM reprograph (option).
- Archiving images on CD-ROM. Telemedecine, transfer of medical information through PACS or Internet networks.